

Year ended March 31, 2022

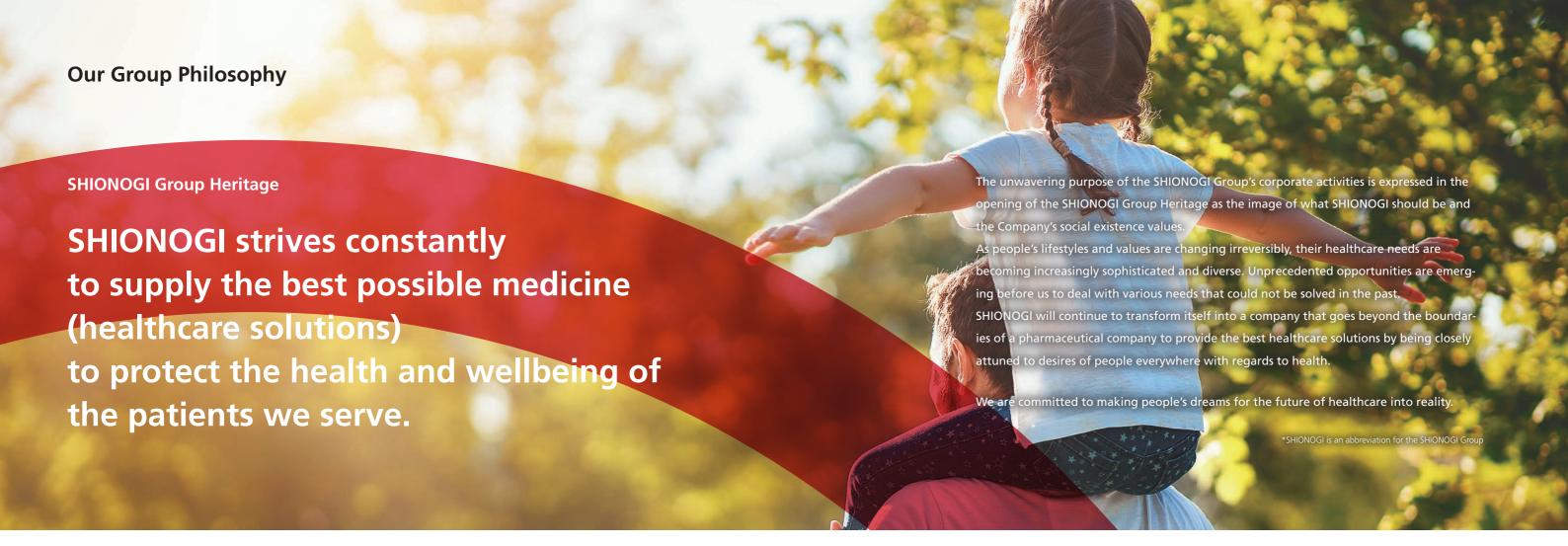


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Capability and Vision, unified.

Shionogi & Co.,Ltd.



#### **SHIONOGI Group Vision**

### **Building Innovation Platforms to Shape the Future of Healthcare**

SHIONOGI is transforming itself from a drug discovery-based pharmaceutical company to a HaaS\* company in order to pursue the health that people truly desire and to deliver unprecedented new value to society.

\*Healthcare as a Service: Provide a range of healthcare services in line with customer needs, rather than only providing pharmaceuticals.

#### Our Philosophy

The Company Policy of Shionogi Shionogi's Purpose Shionogi strives constantly to supply the best possible medicine to protect the health and wellbeing of the patients we serve. For this purpose, Shionogi will need to Pursue the search for even better medicines Produce even better medicines. Promote awareness of these better medicines to more people so that more **Building Innovation Platforms** people will be able to use these medicines. SHIONOGI Group to Shape the Future of Research, produce, and promote in an even more economical manner. Healthcare For this purpose, Shionogi will need to Strive ceaselessly day after day to improve their skills. Strive ceaselessly day after day to improve as human beings Re trustworthy Be bold As a result, Shionogi people will • Be dauntless in spirit Find even greater satisfaction in their daily work and in their daily lives. • Build greatness out of diversity Find even greater improvement in the quality of their lives. Find even greater prosperity in their lives. Established in 1957

## SHIONOGI is uniting globally to take a new step forward in transforming itself into a HaaS company

## Capability and Vision, unified.



#### Our minds on the new group brand

The "FUNDOH" weight mark which stands "accuracy", "honesty", and "trust" has been a longtime Group Brand Symbol of Shionogi & Co., Ltd and its group companies.

Reflecting SHIONOGI's intention to transform to a global HaaS company, we have refined the Group Brand Symbol and logotype design and evolved it into an identity that embodies the new SHIONOGI.

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#### Forward-looking statements

This report contains forward-looking statements. These statements are based on expectations in light of the information currently available, assumptions that are subject to risks, and uncertainties which could cause actual results to differ materially from these statements. Risks and uncertainties include general domestic and international economic conditions, such as general industry and market conditions, and changes of interest rates and currency exchange rates. These risks and uncertainties particularly apply to forward-looking statements concerning existing products and those under development. Product risks and uncertainties include, but are not limited to: completion and discontinuation of clinical trials; obtaining regulatory approvals; claims and concerns about product safety and efficacy; technological advances; adverse outcome of important litigation; domestic and foreign healthcare reforms; and changes of laws and regulations.

For existing products, there are also manufacturing and marketing risks, which include, but are not limited to, inability to build manufacturing capacity to meet demand, unavailability of raw materials, and competition with other companies' products. The Company disclaims any intention or obligation to update or revise any forward-looking statements whether as a result of new information, future events, or otherwise. This report contains information on pharmaceuticals (including compounds under development), but this information is not intended to make any representations or advertisements regarding the efficacy of these pharmaceuticals nor provide medical advice of any kind.

#### ■ External evaluation

#### ESG index







FTSE Blossom Japan Sector







2022 CONSTITUENT MSCI JAPAN ESG SELECT LEADERS INDEX

2022 CONSTITUENT MSCI JAPAN



External recognition related to IR and sustainability





### Other

Selected by domestic equity managers at the Government Pension Investment Fund as having an "Excellent Integrated Report" (second consecutive year)

#### ■ Commitment to society



WE SUPPORT SHIONOGI has endorsed and supported the United Nations Global Compact. See our website for more information https://www.shionogi.com/global/en/sustainability/ungc.html

#### ■ Editorial Policy

In order for stakeholders\*1 better understand SHIONOGI's corporate value, we conduct integrated reporting based on integrated thinking.

#### ■ Period covered

Results for fiscal 2021 (April 1, 2021 to March 31, 2022). Some of the activities after the same period are included

#### ■ Target organizations

This report covers 53 Group companies (the Company, 48 consolidated subsidiaries, 3 affiliated companies, and 1 jointly controlled entity). The scope of our environmental activities covers all of Shionogi & Co., Ltd business sites and major domestic group companies. For some indicators, major overseas group companies are also included in the scope of coverage.

#### ■ Reference Guidelines

IIRC\*2 "International Integrated Reporting Framework," "GRI (Global Reporting Initiative) Sustainability Reporting Standards," "ISO 26000," Ministry of the Environment "Environmental Reporting Guidelines 2018," and Ministry of Economy, Trade and Industry "Guidance for Collaborative Value Creation"

\*2 IIRC was reorganized as the Value Reporting Foundation (VRF) in June 2021. VRF was integrated into the ISSB of the IFRS Foundation in August 2022.

#### ■ Disclosure and engagement

#### Financial information

https://www.shionogi.com/global/en/investors/ir-library.html

#### Securities report (JP)

https://www.shionogi.com/jp/ja/investors/ir-library/ securities-report.html

#### Non-financial information

#### Sustainability

https://www.shionogi.com/global/en/sustainability.html

https://www.shionogi.com/global/en/company/policies.html

Basic Views and Guidelines on Corporate Governance https://www.shionogi.com/global/en/company/cg/basic.html

#### **Environmental Initiatives**

https://www.shionogi.com/global/en/sustainability/environment. html

Shareholders and investors SHIONOGI's stakeholders

Employees Society Customers

2 Shionogi & Co., Ltd. Integrated Report 2022 Shionogi & Co., Ltd. Integrated Report 2022 3 Special Feature

# COVID-19 Initiative Results and Learning

# Results

#### Commitment to fighting COVID-19

Pre-symptomatic phase/detection



- Provide wastewater epidemiological surveillance service by establishing AdvanSentinel Inc.
- Launch of mutational analysis service

## Diagnostic drugs

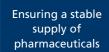


- Sales of antigen test kit products
- Sales of SARS-CoV-2 antigen test kit products for assisting in predicting exacerbation
- Sales of Th2 chemokine TARC kit for assisting in predicting exacerbation
- Online sales of PCR testing services for COVID-19 (SARS-CoV-2)





Research and development of pharmaceuticals to prevent severe disease





- Inventory management in cooperation with raw material suppliers and procurement contractors
- Thorough-going employee health management and measures to prevent the spread of infections

## Business continuity initiatives



- Respond in line with our business continuity plan (BCP)
- Introduced systems in response to new workstyles, such as telework and staggered work hours

## Prophylactic vaccines



- Research and development of a recombinant protein vaccine
- Research and development of a nasal vaccine
- Research and development of a universal antigen vaccine





• Research and development of antiviral drugs





• Support to health centers in Tokyo and Osaka prefectures

# Providing disease information





• Providing information via websites

#### Cooperation/alliances with international societies



• Described our programs in a video submission to the UN's #Uniting Business to Respond to COVID-19 campaign

#### Initiatives for total care

As a leading company in infectious diseases, it is SHIONOGI's mission to combat the threat of COVID-19, which is having a significant impact on the lives, livelihoods, and economies of people worldwide. SHIONOGI has been working with public institutions, academia, and our partner companies to help bring COVID-19 to an early end through research, development, and provision of a wide range of medical solutions from a total care perspective, including detection (epidemic forecasting), prevention, diagnosis, treatment, and exacerbation suppression. In particular, the development of oral therapeutics that are effective, safe, and convenient is highly anticipated worldwide as we learn to live with COVID-19. Based on the results of the Phase 3 clinical trial of S-217622 (ensitrelvir), we will accelerate our efforts to commercialize the drug in

Japan and globally. In addition, we have made progress in several late-stage clinical trials for prophylactic vaccines, including comparative studies with existing vaccines, aiming for both initial immunity and booster immunity. We plan to file for approval as soon as the necessary data and production framework are prepared. Furthermore, in efforts related to epidemic forecasting, we have taken a major step toward social implementation of wastewater monitoring by establishing Advan-Sentinel Inc. with Shimadzu Corporation. In addition to this, we were able to start providing diagnostic drugs and kits that predict not only the presence of infection, but also individuals at risk of severe exacerbation. A Phase 2 clinical trial is in progress at our partner company for the development of a drug candidate for exacerbation suppression.

#### Things we were able to do because we are SHIONOGI

As a drug discovery-based pharmaceutical company boasting an internally-discovered pipeline ratio of 73% (as of March 2022), SHIONOGI places the highest priority on solving the problems of patients and society in its daily drug discovery activities. Small-molecule drug discovery in particular is one of our long-cultivated strengths. For example, information on the anti-HIV drug *Tivicay* was utilized in the chemical structure conversion of the influenza antiviral drug *Xofluza*, and great use was made of the knowledge gained from the discovery of *Xofluza* in the new COVID-19 therapeutic drug S-217622. Furthermore, the basic skeleton of S-217622 also utilizes the structure of S-600918, which is being developed for the treatment of chronic cough. SHIONOGI's accumulated experience

in antiviral research and small-molecule drug discovery has made it possible to create promising compounds with such amazing speed. In the evaluation of the drug efficacy of compounds, we have a library of bacteria and viruses that we have accumulated over the years, and we have a system in place that allows us to efficiently utilize this library in combination with our library of compounds. In addition, SHIONOGI's strength lies in its broad base of researchers who handle viruses in our Biosafety Level 3 (BSL-3, a Japanese standard) laboratories which only trained personnel are allowed to work with. We believe that these are the factors that enabled us to push through the challenge of COVID-19 with such promptitude.

#### Helping to restore the safety and well-being of society

We believe that helping to restore the safety and well-being of society through the early termination of the pandemic is our true contribution to the SDGs. If we gain favorable results from the Phase 3 clinical trial of S-217622, a therapeutic agent that enables early treatment of COVID-19 patients,

including those who are not at risk of severe exacerbation, we believe that this will contribute to the restoration of a society where people can live with peace of mind. Shionogi is making concerted efforts to achieve this goal.



Shionogi & Co., Ltd. Integrated Report 2022

# How

As a leading company in infectious diseases, SHIONOGI is working with public institutions, academia, and our partner companies to develop therapeutic agents for COVID-19. We are building a distribution system so that we can deliver these therapeutic drugs to patients as soon as possible, progressing from drug discovery to clinical research to filing for approval at an unprecedented speed, as we adapt to constantly changing circumstances.



**Takafumi Sato** Vice President, Laboratory for Drug Discovery and Disease Research (At the time: Research Project Manager, Pharmaceutical Research Division)

## Aware of the risks, taking up the challenge of "clinical trials within six months"

The research project manager guides the selection and evaluation of candidate compounds for development based on the lead compound (the predecessor compound of development candidates) found in the research theme and the drug discovery logic (evaluation methods, etc.). The COVID-19 project required a different level of speed. We were being asked to expedite the process of drug discovery, which normally takes three to five years, so that, through resource investment, we could begin clinical trials within six months. We could not possibly fulfill the deadline using our conventional step-by-step approach. We had to decide on taking the risk to manufacture the necessary drugs in order to quickly advance compounds that met certain criteria in the exploratory compound evaluation to the nonclinical pivotal studies conducted in compliance with the regulatory standards. The series of difficult stages proceeding the decision for clinical development cannot be described here in full. However, we were able to achieve early creation of S-217622 thanks to close strategic coordination between the President, division head, and project members under a general policy of "narrowing down actions to the minimum necessary and proceeding with risk-taking"; thanks to the laboratory's concerted efforts based on our strengths in small-molecule and infectious disease drug discovery; and thanks to the cooperation of our external business partners who readily agreed to my reckless request to "bring all Japanese companies together" in response to the national crisis of COVID-19.



Masato Gomi Formulation R&D Laboratory

## Delivering easy-to-administer formulations to patients as quickly as possible

We took on the challenge of developing drug formulations at an unprecedented speed while adapting to the fast-moving changes in the development situation within a short period of time. We are designing a multi-dose formulation that can handle a wide range of clinical doses and a manufacturing process that enables seamless vertical start-up of commercial production, as well as planning a regulatory strategy to establish a maximum duration of use in a short period of time. Through these we were able to complete the application for manufacturing and marketing approval and begin commercial production (establishing a supply system for one million people in FY2021) within just ten months from the start of formulation development. We also made bold efforts to reduce the size of tablets in order to provide a high value-added formulation with an advantage over leading competitors' products. This process was not always a walk in the park, but the whole team worked together to overcome these challenges and quickly devise ways to improve the situation. This allows us to complete our mission of delivering therapeutic drugs to patients as soon as possible. Our next mission is to provide this formulation globally and help patients in need all over the world.



Yuko Tsuge Development Project Leader Clinical Research Department

## "All SHIONOGI" to take on a global mission

The Research Division staked its reputation as an infectious disease company on S-217622, a development compound to formulate entered the clinical stage in July 2021. At this point, there was no oral COVID-19 treatment in practical use, and there was a need for an innovative oral therapeutic that could be easily prescribed to a wide range of patients in order to control this unprecedented pandemic. From here, the fight began for the development project to deliver S-217622 to patients in Japan and around the world as quickly as possible. The development of S-217622 is a social responsibility, and the "All SHIONOGI" team, transcending organizational boundaries, aimed to obtain approval as quickly as possible. Through daily discussions with project members and management, I felt a sense of company-wide unity and the powerful impetus that comes with it. As a result of everyone's continuous efforts to do their best, we were able to file for approval within a short period of about seven months from the start of Phase 1 clinical trial. We will continue the ongoing clinical trials to completion without any relaxation of efforts, aiming to obtain official approval.



Yasuhiro Makino Regulatoryl Affairs Department

## The challenge of filing for approval at an unprecedented speed

Our mission is to deliver S-217622 to society, healthcare professionals, and patients as soon as possible in response to the emergency of the COVID-19 pandemic. Although we are working to deliver the product as quickly as possible, we still have to ensure its safety and efficacy as we do with all other pharmaceuticals to date. In the pre-application state, it was crucial that we were able to seek solutions to various issues related to screenings and investigations and carry them out. It was also necessary to take prompt action to resolve issues from an early stage through close communication with the authorities. SHIONOGI began submitting relevant materials to the authorities in October 2021, filed for approval in February 2022 using the conditional approval system, and switched to the emergency approval system in May 2022. Based on the progress of the Phase 3 trial, the matter was continued for further discussion, but we will continue to work with the authorities to deliver the therapeutic drug as soon as possible.



Yudai Iwaki Shionogi Pharma Co., Ltd. echnology Development Division

## Pursuing quality along with speed

This COVID-19 project needed to be handled at a speed that would have been unthinkable in the past, as the commercial manufacturing system was to be established and ready for initial manufacturing in four months, before the results of the Phase 1 clinical trial would be available. While various matters such as formulation dosage, packaging capacity, and product name had not yet been decided, we shared and discussed numerous issues across the organization and proceeded with speedy decision-making and implementation in order to clear the extremely high hurdle of establishing an appropriate manufacturing system that complies with Good Manufacturing Practice (GMP). In addition, SHIONOGI Pharma was able to establish a commercial manufacturing system in the fastest possible timeframe by "Be bold" — developing efficient validation strategies to assure the quality of pharmaceutical products based on scientific evidence — while leveraging its accumulated experience and technology, and by making a concerted company-wide effort.



Nobuaki Tanaka New Product Planning Department

## In order to deliver to patients promptly and reliably

As the commercial team, we united under the shared mission of the research and development project teams to deliver S-217622 to patients as soon as possible, and collaborated in building a distribution system. We were required to finish as quickly as possible while responding flexibly to the ever-changing social environment and needs, such as the transition to the Omicron variant and the emergence of oral therapeutics. By making full use of our experience and know-how in building prescription registration systems for Vyvanse and OxyContin, we were able to build such a system (which is required post-approval) that meets all the necessary conditions in just three months from the start of the project. We are still working to build a system that will enable us to start providing S-217622 as quickly as possible by mobilizing the power of our team and responding to each of these ever-changing circumstances by adding the necessary support and expanded functions.

# COVID-19 Initiative Results and Learning

# Learning from here

Since the outbreak of the pandemic in 2020, SHIONOGI has given top priority to the development of various solutions to achieve total care for COVID-19, while also making bold resource shifts. In the area of therapeutic drugs, SHIONOGI has promoted the establishment of R&D and production systems at an exceptional speed, and filed for manufacture and sales approval in Japan just about seven months after the start of clinical trials in July 2021. And we have learned a lot from our experience in this exceptional environment.

#### What SHIONOGI has learned

#### Importance of the ability to innovate

The COVID-19 pandemic instantly shattered preconceptions about the pharmaceutical business, where it is said to take 10 to 15 years before a new drug is launched. Without this experience, we could not have developed the risk-taking and speed-oriented way of proceeding in an emergency and the decision-making and judgment skills necessary to determine the effectiveness and safety aspects of a project. We have already begun to replace some of our Standard Operating Procedures (SOPs) for normal times with these emergency R&D procedures and have begun to deploy them in initiatives other than COVID-19. In addition, there are currently only two pharmaceutical companies in the world that have launched oral therapeutics that have been proven effective and safe, and that can be taken easily, and we are the closest to becoming the third company to do so. We were also able to reaffirm that SHIONOGI has the capability to create drugs at a high level, as it is taking on the challenge of developing drugs that can be used by a wider range of patients than the two preceding drugs. It was also an opportunity to recognize once again that SHIONOGI cannot continue to demonstrate its value to society unless it transforms its desire to solve the world's problems into "the power of monozukuri (product creation)" and continues to innovate.

#### Determination to deliver globally with our own hands

In the development of our COVID-19 treatment, we have to ask ourselves why there was such a large difference in the timing of our market launch compared to the two companies that preceded us, despite the fact that there was only a few months difference in the time it took to create the compound that would form the base of the drug. Various causes have been identified, such as differences in the countries where development took place and differences in the prevalent strains at the time of clinical trials. One possible cause raised is a "lack of commitment to global development". Until now, SHIONOGI has relied on its business partners for much of its global expansion, despite creating drugs that have attracted worldwide attention, such as dolutegravir-related products and Xofluza. An over-emphasis on entrusting global matters to our partners can limit the options for finding the fastest, most optimal solution. We at SHIONOGI are confident in the drugs we create, and are committed to delivering them on a

global scale by negotiating with governments and regulatory authorities in various countries. And we will continue to contribute to global health by clearly defining where we will put in the hard work and where we will entrust it to our partners.

## Pursuing a sustainable infectious disease business

This pandemic has given us an opportunity to clarify the reasons why SHIONOGI has been able to continue its infectious disease business to date and the challenges we must confront in order to sustainably continue our infectious disease business in the future. One of the reasons why we have been able to sustain our infectious disease business to date is that we have been dealing with drugs for chronic infectious diseases, such as HIV. Unlike acute infectious diseases, chronic infectious diseases require continuous treatment over a long period of time, and thus can be expected to provide a stable revenue stream. On the other hand, acute infectious diseases, such as seasonal influenza, are an extremely difficult business, as revenues are largely dependent on the presence or absence of epidemics, and even if an innovative new drug is launched, revenues can be significantly lower than expected for three consecutive fiscal years, as with Xofluza. As the world has reaffirmed during the recent pandemic, this business is indispensable for social and economic stability. Therefore, as a leading company in infectious diseases, we must urgently establish new business models in this area in order to continue in efforts to "protect people worldwide from the threat of infectious diseases", which we have identified as a key material issue.

#### ■ SHIONOGI's Goals for FY2022 and Beyond

#### Learning in the exceptional environment of a pandemic

- Significant resource shifts and process changes drove R&D and production at a new and amazing speed
- Recommendations for policy changes through the pharmaceutical industry

FY2022 and Beyond Establishment of a sustainable infectious disease busi-

- · World-class drug discovery capability with speed, advanced decision-making, and effective resource allocation honed during the COVID-19 situation
- Further strengthening of the vaccine business
- Global expansion of the infectious disease business

Leveraging the experience of the pandemic, continue pushing forward to achieve our goals without changing gears

#### Difficulties in the Infectious Disease Business

When we look at the global acute infectious disease market, we see cases of successful drug development that fail to pay back their investment and are subsequently bankrupt or acquired because not only is the market less predictable than in other disease areas, but also more powerful drugs are used only when other drugs are not effective in terms of proper use to prevent the development of new resistant bacteria or viruses. Even major pharmaceutical companies are withdrawing from this market one after another, citing inability to

recoup their huge R&D costs and maintenance costs for manufacturing facilities. If this situation continues, the number of specialized personnel conducting research in the area of infectious diseases, where investment is scarce, will also decrease, and the market will become less and less dynamic — a vicious circle that will keep expanding. Although dealing with infectious diseases is an indispensable initiative for society, it is an extremely challenging business model for pharmaceutical companies.

#### ■ The Collapsed Acute Infectious Disease Market

Society's needs Enormous R&D costs Maintenance costs for manufacturing facilities



Difficult epidemic forecasting Appropriate use Promotion of switching to GE products

Unable to recoup investment and form a healthy pipeline

#### Big Pharma exits antimicrobial market

- AstraZeneca sold its small-molecule antimicrobial business to Pfizer (2016)
- Sanofi transferred its infectious disease division and 100 employees to Evotec (2018) Novartis withdrew from antimicrobial research (2018)

## Bankruptcies and acquisitions of small companies

- Achaogen filed for bankruptcy within a year of plazomicin approval in July 2018 (April 2019)
- Melinta Therapeutics filed for bankruptcy (December 2019)

Revenue

• La Jolla Pharmaceutical acquired Tetraphase Pharmaceuticals following approval of eravacycline in August 2018 (July 2020)

### Building an Infectious Disease Business Model and Transforming to a HaaS Company

In order to build a sustainable infectious disease business model, SHIONOGI intends to combine efforts in chronic infectious diseases and vaccines, for which a healthy pipeline can be formed through stable earnings, and acute infectious diseases, for which profitability is difficult to predict but essential, to create an infectious disease business that is sustainable in its totality. The key issue for making this business model work is still how to manage the acute infectious disease business, but this is not a problem that can be solved by one company alone. The COVID-19 situation has triggered, especially among G7 countries, a renewed awareness of the importance of strengthening preparedness for global health threats, such as antimicrobial resistance (AMR), and has accelerated discussions on how to resolve this issue as an international community. In Japan, society as a whole is beginning to accelerate its efforts to strengthen preparedness. For example, the proposal for the formulation of the "Basic Policy for 2022" includes the early

establishment of an incentive system to ensure sustainable innovation in antimicrobial drug research and development. In addition to the pull incentives represented by the subscription model and stockpiling, we believe that enhancing mechanisms to promote pipeline formation through push incentives, which are support to promote research and development, will help maintain stability in the infectious disease market and, as a result, enhance preparedness for new pandemics. Of course, companies that receive incentives must always be prepared to make their maximum contribution in the event of an emergency, including the drugs they provide and the human resources to respond. It is essential that not only companies but also society as a whole have a system to continuously tackle infectious diseases. We aim to become a company that can grow sustainably with society by establishing a platform that can provide total care for infectious diseases to prevent a repeat of pandemics or otherwise minimize their damage.

#### ■ Toward Building a Sustainable Infectious Disease Business

Promotion of R&D Human resource development (Push incentives) BARDA, CARB-X, GARDP, CEPI, etc.

Profit structure that is not affected by epidemics (Pull incentives) Stockpiling, subscription-based reimbursement

Strengthening and maintaining the supply chain

**Current Infectious Disease Business** 

Sustainable infectious disease business

Continued society-wide commitment to infectious



Aiming to transform ourselves into a HaaS company, we will not slow down as we continue the full-throttle drive toward the realization of transformation centered on infectious diseases

### Looking back on our business in fiscal 2021

First of all, I would like to express my deepest condolences to those who lost their lives due to COVID-19, which continues to infect people around the world, and my sincere wishes for the speedy recovery of all those who have been affected and those who are suffering from the aftereffects of the disease. I would also like to express my deepest respect to the many people, including medical personnel, who have been working hard to provide patient care, prevent the spread of infection, and maintain the medical system in the face of recurring outbreaks.

SHIONOGI has contributed to the development of healthcare based on its Company Policy (SHIONOGI Group Heritage) of "constantly supplying the best possible medicine (healthcare solutions) to protect the health and wellbeing of the patients we serve". In fiscal 2021, we continued to respond to the urgent demands of society by making Group-wide efforts to deliver COVID-19 solutions to all people in Japan and around the world. At this point in time, we have not been able to fully meet the expectations of society and our shareholders by actually providing a therapeutic drug or vaccine. We take this situation very seriously. On the other hand, it is also true that we have evolved as a company by investing a great deal of management resources, learning from the risks we have taken, and changing various processes.

First, for the therapeutic drug S-217622 (ensitrelvir), we started nonclinical studies in May 2021 and clinical trials in July of the same year. Just seven months later, in February 2022, we filed an application for approval in Japan, having results up to the Phase 2b trials. Of course, this was a provisional application, so to speak, for review under the conditional approval system (currently the newly introduced emergency approval system) in consideration of the urgency of the situation. We accelerated the Phase 3 study during this review period, and by July 2022 we had enrolled a total of more than 2,900 patients in the Phase 2/3 study. While it is said that it usually takes 9 to 17 years for the research and development of a new drug, we were able to advance the project, including preparations for commercial production, at an unprecedented speed of approximately two years from the start of drug discovery research for the target 3CL protease to the completion of registration for Phase 3 trials. We are proud of this great accomplishment. During the course of the project, we faced some difficulties when the fifth wave of infections had settled and the number of infected patients had dropped to almost zero, and in the sixth wave when medical institutions were too overwhelmed to conduct clinical trials, but we worked hard to obtain cooperation from medical institutions and local governments to accelerate the accumulation of cases with the help from other industries that have strengths in online services. The achievements of launching Japan's first clinical trials in hotels and at home have become valuable assets for SHIONOGI, which will continue to take on the threat of infectious diseases in the future.

As for S-268019, a prophylactic vaccine, it was a year in which we appropriately dealt with many difficulties and changes in the environment and accumulated capabilities. As mRNA vaccines have become widely available globally and it has become difficult to verify their efficacy in prevention of disease onset conventionally using large-scale clinical trials, we have repeatedly exchanged opinions with relevant ministries and regulatory authorities in order to have the need for an alternative evaluation method communicated from Japan. As a result, in September 2021, the International Coalition of Medicines Regulatory Authorities (ICMRA) announced its policy to use neutralizing antibody titers after vaccination as an alternative indicator of efficacy in preventing disease onset. We believe that this was an important achievement of public and private sectors in collaboration, linking to the potential of a vaccine produced in Japan. In parallel, we were able to discuss cooperation in conducting large-scale clinical trials with Vietnam and other Asian countries, which was another major step toward preparing for the next pandemic. Meanwhile, SHIONOGI made the decision in July 2021 to switch out the formulation it had been evaluating. The switch was made in anticipation of greater emphasis being placed on neutralizing antibody titers as the aforementioned alternative indicator. There were heated debates in the same vector among the respective value chains on how to make up for the development delays that would occur while striking a balance between efficacy and safety. I feel that SHIONOGI has grown

#### Message from the CEO

as a company in the way it has responded to these issues and advanced to this point. The later the vaccine is developed, the more tests are required before filing for approval in Japan, such as additional inoculation tests and more case studies of children and the elderly, but we are currently obtaining favorable results in several final tests. Although we are still working on scaling up production, we have been able to move forward to the point where we are just one step away from filing for approval. Although this is the first time SHIONOGI has developed a vaccine, we are determined to make it a success so that we can make it into a core business in the medium- to long-term, and expand into dealing with mutant strains and other diseases, and expand into new technologies such as nasal vaccines.

In June 2021, the wastewater epidemiology surveillance service to monitor the prevalence of infection and the emergence of mutant strains launched, and in early 2022, a joint venture with Shimadzu Corporation for the purpose of sewage monitoring and other public health risk assessments called AdvanSentinel was launched and is off to a good start toward establishing itself as social infrastructure.

Through these activities, we have reaffirmed that the desire to solve the issues of people and society and to deliver solutions at any cost, are what nurtures people and organizations, and produces innovations that are globally competitive.

SHIONOGI will continue to reflect the efforts, experience, and innovations we have accumulated over the past two years in our vaccines, treatments, and other solutions, and will continue to make it our top priority to deliver them as soon as possible.

Although we had the highest amount of R&D expenditure in the history of SHIONOGI due to intensive investment in the development of COVID-19 drugs and vaccines, revenue and profit exceeded our targets and we were able to increase both figures for the first time in three years. I believe that we were able to fulfill our responsibilities to a certain extent in that we achieved our earnings forecast despite aggressive R&D investments. On the other hand, there were some exceptional factors that contributed to our performance, such as the one-time income from the settlement of the dolutegravir patent infringement lawsuit, and we continue to face challenges in terms of growth through expansion of our so-called base businesses, i.e., domestic and overseas businesses over which we have control. We will invest resources in COVID-19related products and other growth drivers, and make strenuous efforts to continue and expand the trend of increased sales and profits toward the goals set forth in our medium-term business plan "Shionogi Transformation Strategy 2030 (STS2030)."

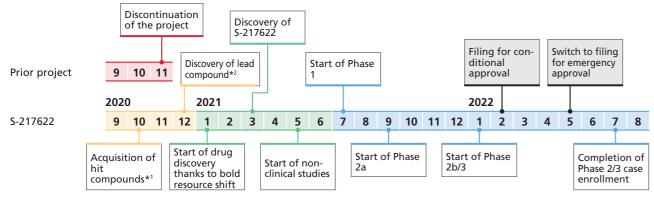
## **Lessons learned from the COVID-19 pandemic and future trends**

#### Becoming a company that begins with "the issues"

In recent years, the social environment and the needs of stakeholders have diversified and changed at a very rapid pace, and the COVID-19 pandemic has greatly accelerated this trend. Even taking the example of expectations for thera-

peutic drugs, as vaccines uptake becomes more widely spread, needs are shifting from patients with severe disease to those with mild disease, and from patients with risk factors for severe disease to a wide range of patients with or without risk factors. One of the reasons for the sluggish performance of new products, which I recognize as one of the negative

#### COVID-19 Treatment R&D Timeline



<sup>\*1</sup> Hit compound:

points to reflect upon in SHIONOGI's previous medium-term business plan, was the plan's so-called "product-out" approach. IT was based on the assumption that customers would opt for small-molecule drugs with superior efficacy and safety at relatively low prices. However, it is clear that this approach is no longer applicable to pharmaceuticals, which are protected by patents for a limited period of time. In order to continue to provide products and services that are chosen by our stakeholders going forward, we must stay close to the needs of our customers and society, anticipate and incorporate into our business activities, not only the needs that exist today, but also the healthcare needs of 10 to 20 years from now. This way, we can continue to provide new value to our customers and society to satisfy those needs. To this end, in addition to the above-mentioned mindset of "the desire to respond to issues," there is an urgent need to develop an organization and employees who are eager to acquire new perspectives to identify the essence of these issues and the capability to lead to solutions. We are in the process of reviewing our system for strengthening human resources.

#### Discerning what must not change and what must continue to change

This pandemic has truly brought us so many changes. Some of those changes were things that needed to change for the future that suddenly appeared before us, and others that were a temporary adjustment but will come back, albeit in a slightly different form. It is important to differentiate what is part of the new normal and what are the values that cannot and shall not be changed. For example, the COVID-19 pandemic led to a review of processes, and the speed of pharmaceutical R&D, which accelerated guickly, is already becoming the global standard as an irreversible change. In this emergency situation, SHIONOGI has also been advancing R&D at a speed that exceeds previous concepts. Now the test will be

how we can apply the lessons learned and experiences gained during the pandemic to other items and projects and raise our work methods to the new global standard. I keenly recognize that we have entered an era in which companies will be eliminated unless they continue to take risks and evolve without fearing change, while remaining constantly aware of the scientific ability to create new value and of patient safety — two things which must not change — and deliver them to the world as quickly as possible.

#### Sophistication of decision-making

Speedy and sophisticated decision-making is required in order to respond quickly to changes in the environment and societal needs, provide new value to customers and society through business activities, and achieve sustainable growth. In 2020, SHIONOGI introduced a system (SHIONOGI new Approval Management System 2020: SAMS) to enhance the sophistication of decision-making, and established a system that records the work processes of "who, what, when, where, and how decisions are made," making them completely transparent, and enables tracing of the execution of measures decided upon. In addition to continuing to strengthen management, which is the key to this transparent process, we are also comparing ourselves and our operations with those of the world's most advanced companies to increase transparency and traceability as we work to transform ourselves into a globally competitive company.

From fiscal 2022 onward, we will accelerate our efforts to become a HaaS company through the implementation of STS2030, a strategy to achieve the SHIONOGI Group Vision of "building innovation platforms to shape the future of healthcare." In fiscal 2022, we will contribute to the early end of the pandemic by providing COVID-19 therapeutic drugs and prophylactic vaccines, while steadily advancing toward the realization of the SHIONOGI Group Vision.

## Our medium- to long-term growth strategy

As the COVID-19 pandemic drags on, the world "order" continues to change dramatically with the China-U.S. trade war, the worsening situation in the Middle East, and Russia's invasion of Ukraine. Each of these regions is searching for how they will characterize themselves going forward, i.e., how they will "grow" qualitatively and quantitatively. And these changes in the world will continue to occur. On top of that, we must always be trying to envision SHIONOGI's next stage of development, predicting what it will look like 10 to 20 years from now.

These changes in the external environment have reminded us that our focus areas of infectious diseases and psychoneurological diseases are disease areas that humanity must consider in times of emergency, even more so than in ordinary times. That there is a great need for drugs against infectious diseases goes without saying, but many people are also suffering from psychoneurological diseases due to COVID-19 and the worsening global situation. These diseases, however, have virtually no fundamental solution and there are many unmet needs remaining. Furthermore, I believe that vaccines as preventive medicine will continue to grow as a necessary healthcare solution for society going forward, in that they are often targeted to healthy people, whereas curative medicines are targeted to people with diseases. In addition, I believe that our participation in remote/online medical care (provided by Stream-I, Inc, a joint venture with M3, Inc.) and our joint ven-

An active compound found in a compound library screening test.

A compound which becomes more activated than hit compound by in vivo evaluation or other means. It is the basis for further improvement of activity, solubility, stability, pharmacokinetics, safety, etc. through chemical synthesis

#### Message from the CEO



ture with the Ping An Group, scoping China and Southeast Asia, will be extremely important strategies or growth drivers for SHIONOGI in the future.

Although the pandemic has greatly accelerated social changes, I am proud that the premise of STS2030 is a strategy that anticipates these global changes to some extent and is consistent with our direction. I am confident that by following the SHIONOGI Group Vision and STS2030 and working toward becoming a HaaS company, we will be able to flexibly respond to these major changes in the environment. As a result of our bold response to the changes brought about by COVID-19, the path toward the SHIONOGI Group Vision is becoming clearer, and we are now considering updating our plan with a view to evolving onward to the next step under STS2030.

#### Building an infectious disease business model

Despite how obvious the reasons were for the withdrawal of many pharmaceutical companies from the field of infectious diseases, the measures taken were mainly push incentives focused on the discoveries of new drugs, and there was insufficient understanding of the issues surrounding the infectious disease business and insufficient measures to address them. While this is not a problem that can be solved solely through

the efforts of individual companies, it is essential for SHIONOGI to build a sustainable business model in order to continue contributing to this field. Although I speak of "infectious diseases", to be precise our efforts to date have been focused on treatment. However, we cannot truly solve social issues from the perspective of protecting people from the threat of infectious diseases and protecting society from the ravages of pandemics, as well as preparing for the next threat, unless we consider the total picture of infectious diseases, from detection (epidemic forecasting) to prevention, diagnosis, treatment, and exacerbation suppression.

#### The three pillars of chronic, acute, and vaccines

In order to build a sustainable business in the area of infectious diseases, which is known to have low profitability, we will continue to work with a clear awareness of the three pillars of our business: chronic, acute, and vaccine. We are confident that we can build a sustainable business by dividing our portfolio into these three pillars, even in the low-profitability infectious disease business. To achieve this, it is important to secure stable revenues from chronic infectious diseases such as HIV infection and from vaccines, while at the same time, for acute infectious diseases such as COVID-19, influenza, and AMR, to balance pull incentives, represented by subscription-type reimbursement models and stockpiling, with push incentives that support the promotion of R&D. By doing so, we believe we can build an infectious disease business that is sustainable in its totality by creating a model that can be sustained as a business even if there are some fluctuations in

## Global development of the infectious disease business

Until now, global development of dolutegravir and Xofluza was led by our partners. From now on, we have established a policy that we will take on as much as possible of the role that has been played by our partners, including negotiations with governments in various countries, and that we will deliver SHIONOGI's products to emerging countries on our own. Of course, there is no change in our direction insofar as collaborating with external partners to leverage each other's strengths on activities that are inefficient or impossible for us to do on our own. At this point, it is difficult for SHIONOGI to provide cefiderocol to low- and middle-income countries on its own, so we have chosen to collaborate with GARDP and CHAI while contributing to global health through our own hard work. On the other hand, the experience of COVID-19 has expanded the scope of what SHIONOGI can handle on its own, and we will work to maximize value, including the returns we can obtain, by doing what we can on our own as much as possible.

# Realization of the HaaS model in areas such as psychoneurological diseases

In the area of psychoneurological diseases, including pain, which is another area of focus, we are also aiming to provide services that go beyond pharmaceuticals by focusing on the needs of patients and society.

Psychoneurological diseases are considered areas of high unmet medical need, despite the fact that, a variety of treatment options are available due to the difficulty in identifying the cause of illness. Because symptoms vary from patient to patient, uniform treatment cannot provide maximum benefit. There is a need to establish techniques and methods that enable objective and early diagnosis even in cases of complex complications of various diseases, and to aim at providing individualized and optimal treatment and services according to disease background and symptoms. Dementia, for example, impairs cognitive functions such as memory, learning, language, and judgment, which not only reduces the quality of

life (QOL) of the patients themselves, but also leads to physical, mental, and financial burdens for caregivers, and has a tremendous impact on society. However, satisfaction with existing treatment methods is low, and there is longstanding demand for new treatment methods. In addition to working on the development of therapeutic drugs, SHIONOGI and its partners have begun joint research to see if dementia care can be realized by stimulating the natural senses in a way that is integrated into daily life, using, for example, sound, which has the potential to enhance specific rhythmic activity in the brain (gamma waves), with the aim of improving cognitive function.

In addition, we are working with partner companies and academia to develop solutions that go beyond pharmaceuticals, such as apps for ADHD, sleep treatment, and brain wave measurement, and we hope to help build a society in which everyone can live a vibrant, authentic life by expanding healthcare services and contributing to the improvement of the social environment.

#### Toward the realization of our business model

## Organizational evolution and human resource development

As our business model becomes clearer and what we want to achieve becomes more defined, the capabilities and mindset that SHIONOGI should possess in this global competition are also coming into view. While it is of course necessary to develop new capabilities to meet changing needs, the most important thing for SHIONOGI in the future is to continue to

enhance its strengths and expertise in order to compete on a global scale, and this applies to the organization and to each and every employee in the Group. While mutually questioning whether we are disciplined enough on a daily basis to be globally competitive, we will continue to refine our strengths and work on the evolution of our organization and the development of our human resources to become a hub of cocreation that other companies and different industries will choose to partner with.

#### To all our stakeholders

On July 1, 2022, SHIONOGI announced the establishment of a new group brand and a new group brand mark. The purpose of this rebranding is to demonstrate both internally and externally the company's commitment to pursue innovation, shape the future of healthcare, and sustainably grow while helping to meet the healthcare needs of society on a global scale. The new brand symbol contains the two conceptions: that which must not change, i.e., that which must be protected, and that which must continue to change, to evolve. Change is accompanied by pain and resistance, but the entire SHIONOGI Group shares this belief that we must shed our

skin and be reborn anew, while absolutely preserving what is important to us, and enjoying the transformation process. As mentioned above, we have decided to take this opportunity to personally deliver SHIONOGI's products and services to emerging countries as well. This may not be an easy task, but we will continue to take on the challenge of change so that SHIONOGI can truly provide value on a global scale and be recognized by stakeholders around the world as a company that will be needed in the future. We look forward to your continued guidance and support.

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## **Our History**

Both the world and SHIONOGI have changed significantly over time, but we have not forgotten our founding spirit, and our head office is still located where we were founded, in Osaka's Doshomachi. Here, we describe how SHIONOGI has grown in response to the changes that have taken place over the past century and a half.

1910

## 1878

#### Founded

On March 17, 1878, his 24th birthday, Gisaburo Shiono, Sr., who learned about the drug wholesaling business from his father, Kichibe, strikes out on his own and estab-

lishes a drug wholesaling business named Shiono Gisaburo Shoten at 12, Doshomachi 3-chom in Osaka.



#### From Japanese and Chinese medicines to Western medicines

At that time, Western medicines were available through foreign trading houses in Yokohama and Kobe, but they were expensive because drug wholesalers who were not familiar with trading bought the medicines at whatever price the foreign traders asked for. Gisaburo soon added people experienced in trading and fluent in English and imported medicines directly so that even the common people would be able to buy them at a reasonable price.

#### Registered the corporate emblem FUNDOH

Reliability and trust are necessary qualities for corporate management. Since our founding as Shiono Gisaburo Shoten, we have regarded reliability and trust as our most valuable "capital." SHIONOGI's Group brand symbol is derived from the fundoh, which is the balance weight tradition ally used to weigh medicine on a scale. The FUNDOH also symbolizes "accuracy," "honesty," and "trust," meaning that we always pursue



the Edo era



Group brand symbol

#### Constructed the Shiono Seiyakusho manufacturing plant

A new pharmaceutical manufacturing plant, called Shiono Seiyakusho, was built in Nishinari- gun, Osaka (the present-day Fukushima-ku, Osaka) to formally launch the business of manufacturing new drugs. This gave Shionogi a pharmaceutical division in both name and reality and was also the moment that SHIONOGI embarked on a new path as a drug manufacturer. Gisaburo's second son and director of the plant, Chojiro, wanted to get the company through tough operating conditions, so he invited Heizaburo Kondo, a doctor of pharmacology who had just returned from studying in Germany, to serve as

#### 1943

## Renamed the Company Shionogi Seiyaku K.K. (now Shionogi &

In 1919, Shiono Gisaburo Shoten, the drug wholesaler led by Gisaburo's eldest son, Shotaro, and Shiono Seivakusho K.K., the pharmaceutical business led by his second son, Chojiro, were merged in order to further expand the company. The new company was named Shionogi Shoten Co., Ltd. In 1943, the name was changed again, to Shionogi Seiyaku K.K. (the present Shionogi & Co., Ltd. in English) to demonstrate that the company would focus on the drug manufacturing business

#### SHIONOGI's Company Policy (now SHIONOGI Group Heritage) established

Since our founding, SHIONOGI has survived the changing times and developed our own philosophy and thinking, Our Company Policy, which is our eternal goal, has enabled us to move forward without losing sight of our basic direction as a pharmaceutical company, which is "to serve people's health.

## 1983

## Construction of the Kanegasaki

The Kanegasaki Plant was built in the town of Kanegasaki, Isawa-gun, Iwate Prefecture where a large factory site was secured as one of our key factories, based on a long-term plan for the future expansion of our pharmaceutical manufacturing



Kanegasaki Plant

#### 1998

#### Establishment of the Shionogi Code of Conduct

The Shionogi Code of Conduct was established to complement the SHIONOGI Group Heritage as a criterion for behavior as the company went global and developed into a global corporation. The Company Policy describes our business purpose, while the Code of Conduct sets forth the type of conduct that SHIONOGI should practice as a member of society and as a pharmaceutical company.

#### 2020

#### Revising our management philosophy

To continue growing as the external environment and values evolve, we need to reflect society's and customers needs in our targeted Vision and in the Values that are essential to achieving this Vision, and to have the flexibility to take action. We therefore established a new Vision and Values for our Company Policy, which is the foundation we call Heritage that serves as the basis for all of our activities.

#### Launch of a new brand

SHIONOGI has declared to the outside world that the entire SHIONOGI Group will work together to vigorously promote business transformation and develop a new brand with the aim of gaining wider recognition and appreciation for SHIONOGI's activities among stakeholders in Japan and overseas. The corporate emblem, the FUNDOH, has also been renewed, reaffirming our commitment to embodying Heritage.

# Salvarsan

Chronology

#### SHIONOGI's first step in fighting infectious diseases

In the early 1900s, syphilis was a serious infectious disease for which no cure existed. We started importing Salvarsan in 1911, two years after it was developed overseas in 1909, and this was a major step in the treatment of patients suffering from syphilis

#### Sinomin

#### Our first in-house developed drug that made a global contribution

In the 1950s, infectious diseases like tuberculosis and pneumonia ranked among the most common causes of death. We therefore began R&D into infectious diseases, having made the management decision to become fully involved in the major social issue of infectious disease. Sinomin, a sulfonamide we launched in 1959, was out-licensed to Roche of Switzerland, and it has been instrumental in treating infectious diseases throughout the world. Even now, more than 60 years since its launch, it continues to contribute to people's health as Baktar, a combination with trimethoprim.

#### Tivicay

#### Contribution to HIV treatment

In 1988, we founded our Institute for Medical Science and began researching HIV and other antiviral medicines. After many failures, we launched the HIV drug Tivicay in 2014. Tivicay possesses superior effectiveness and safety, and it is an HIV integrase inhibitor for which it is difficult to develop resistance. We are there fore making a major contribution to treating people around the world so that they can live with HIV and have a better quality of life.

#### Xofluza

#### An influenza antiviral drug with a new mechanism of action

We launched the influenza antiviral drug Xofluza in 2018. By combining the power of our value chain and alliances and utilizing the SAKIGAKE designation system, we were able to obtain approval in Japan and launch the drug with the short time period of about three years from the start of Phase 1 clinical trials. This drug is both effective and convenient, and it is helping influenza patients and their families, as well as the healthcare community.

#### The trump card in antimicrobial infectious disease treatment

In 2020, we launched the multi-drug resistant antibiotic Fetroja in the U.S. This drug could become the trump card for saving patients whose lives have been endan gered due to the lack of treatment options. We are providing cefiderocol to many countries and regions, including low- and middle-income countries, through alliances and other means by employing Managed Access Programs (MAPs), thus contributing to the treatment of patients.

#### Cabenuva, Apretude

#### Contributing to improving the quality of life of people living with HIV

In 2020, Cabenuva (cabotegravir + rilpivirine), a long-acting HIV drug, and, in 2021, Apretude (cabotegravir), a long-acting HIV prophylactic drug, were launched. The launch of these drugs has made it possible to treat and prevent HIV, which hitherto required daily doses of drugs, with a once-every-two-month injection, contributes to improving the quality of life of people living with HIV.





1912 The new cardiac drug Digitamin

1910





## 1990 1997 The cephem antibiotic Flomox

## 2000 2010 2003 The cancer pain analgesic OxyContin 2005 Cymbalta The hyperlipidemia treatment Crestor The carbapenem antibiotic Finibax



The hypertension treatment Irbetan The acne vulgaris treatment Differin The idiopathic pulmonary fibrosis treatment *Pirespa* 

#### 2010 The influenza antiviral drug Rapiacta The antidepressant drug

The injectable cancer pair analgesic OxiFast

The hypertension treatment Aimix 2013

The hypertension treat-2014 The anti-HIV

drug Tivicay Tivicav

## 2015

The anti-HIV drug *Triumeq* The allergen immunotherapy Actair

The thrombocytopenia treatment Mulpleta

#### 2016 The hypercholesterolemia treatment Crestor OD

tablets 2017 The cancer pain treatment

Methapain The attention-deficit/ hyperactivity disorder (ADHD) treatment Intuniv Symproic The chronic cancer pain treatment OxyContin TR tablets 2018 The influenza antiviral

The opioid-induced consti-

nation treatment

drug Xofluza

Xofluza

2019

The attention-deficit/

hyperactivity disorder

(ADHD) treatment Vyvanse

# Fetroja (cefiderocol)

2020

2020

A multidrug-resistant Gram-negative bacterial infec-

tion treatment Fetroia

(cefiderocol)

The long-acting anti-HIV drug Cabenuva (cabotegravir +

The IgG/IgM antibody test kit for COVID-19 (research reagent)

The long-acting HIV prophylactic drug Apretude (cabotegravir)

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### **Value Creation Process**

# **Building Innovation Platforms to Shape the Future of Healthcare**

SHIONOGI strives constantly to supply the best possible **SOlutions** to protect the health and wellbeing of the patients we serve.

#### Material issues addressed by SHIONOGI p.26-27

- Material issues to create new value for customers and society
- Material issues to realize a sustainable society and support SHIONOGI's growth

#### Implementation of

#### Inputs (FY2021)

#### ■ Human capital

- Penetration of our philosophy 86%
- Education & training expenses ¥107 million
- SCD\*1 (now SBP)\*2 education & training expenses + divisional education and training expenses
- \*1 Shionogi Career Development Center Co., Ltd.
- \*2 Shionogi Business Partner Co., Ltd
- · Human resources development programs
- Implementation of all manager improvement programs
- IT human resources development
- Pool of human resources for future management
- Number of Associate Corporate Officers (cumulative over the past two years) 20 persons
- Work-life balance framework
- Start applying the Super Flex System

SHIONOGI's **Business Model** 

- Introduction of the side work system - Introduction of a voluntary three-day weekends
- · Studied or worked overseas 12 persons

Research

Marketing

#### ■ Intellectual and manufactured capital

- · SHIONOGI's unique expertise and technology for R&D
- Library of bacterial strains, compound libraries
- Small-molecule drug discovery engine - SHIONOGI's proprietary expertise and technology for vaccine R&D (BEVS)
- R&D expenses ¥73.0 billion
- Capital investment ¥27.3 billion (IT investment, plant and equipment investment,
- R&D laboratories (Kanzakigawa, Kuise)
- Group Company facilities
- Expertise, technology, and facilities for antimicrobial and medical narcotic drug manufacturing
- Vaccine manufacturing facility
- Facilities with continuous manufacturing
- High-potency manufacturing facility

HIONOGI's strengths cultivated

**Innovation skills** 

Alliances and collaborations Expertise in infectious diseases Human resources

### ■ Social and relationship capital

- Diverse partnerships (15 new partnerships in FY2021, 21 STS2030 partnerships cumulatively)
- · Assistance based on the expectations of national & local governments and society
- Brand strength

#### Financial capital

- Total capital ¥1,150.6 billion
- Equity attributable to owners of parent ¥975.7 billion
- STS2030 Phase1 ¥500 billion to be
- Cash and cash equivalents ¥254.4 billion (rating information: AA-)

#### Natural capital

Develop-

Manufac-

turing

- Total energy consumption 333,548MWh
- Water consumption 1,366 thousand m<sup>3</sup>

## Outcomes (as of March 31, 2022)

Issues and needs

- Human capital p.50-53, 97
- Practice of our philosophy 73%
- · Achievement of work-life balance
- Percent of men taking childcare leave 51.4% (up 10.3%pt YoY)
- Decrease in employees working shorter hours for childcare, increase in full-time employees Total number of employees working shorter hours for childcare: 113% of the previous year's total, 61% compared to before the revision of scheduled working hours
- Number of appointments to executive officers from the human resources pool (Associate Corporate Officers) (cumulative number of new appointment over 2 yrs.) 4 persons
- Percent of female managers 12.4% (up 0.9%pt YoY)
- · Human capital utilization
- Applicants for the side work program 59 persons
- Employees who completed IT-related training 44

#### ■ Intellectual and manufactured capital p.40-47

- Accumulated specialized knowledge and technologies in R&D, manufacturing, distribution, marketing and guaranteed reliability of pharmaceutical products R&D speed comparable to other mega pharma
- Internally-discovered pipeline ratio 73% (as of March 31, 2022)
- COVID-19 prophylactic vaccine production facility

companies

 COVID-19 therapeutic drug production facility

#### ■ Social and relationship capital p.28-29, 48-49, 54-57, 62-65, 97

- Number of countries where dolutegraving (including the Medicine Patent Pool) was offered: More than 140 countries
- Number of countries where cefiderocol can be offered: 135 countries
- Total website visitors: 9.19 million users
  - \* Excluding websites for healthcare professionals

## ■ Financial capital

motivated and can grow

p.30-31, 36-39, 90-96

suppliers 86% completed)

• Profit before tax ¥126.3 billion

**Impact** 

**Stakeholders** 

ers and

- · Annual TSR: 28.4% for the past yr., 6.9% for the past 5 yrs.
- ROE 12.5%
- Natural capital p.70-71, 97-99
- Effluent management of antimicrobial agents in wastewater (audits of SHIONOGI production sites and relevant
- Greenhouse gas (GHG) emissions (Scopes 1 + 2) Vs. FY2019 2.4% increase
- · Controls on water consumption Vs. FY2020 Increased by 149 thousand m<sup>3</sup>

#### **Outputs**

Fetroja (cefiderocol) for the infections

Xofluza influenza antiviral

Tivicay anti-HIV drug

Wastewater epidemiology service (AdvanSentinel)

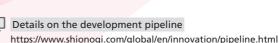




Details on the development pipeline

treatment of multidrug-resistant Gram-negative bacterial







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## Transformation into a HaaS company

SHIONOGI aims to continue to grow sustainably with society by addressing the needs of patients and the world, and by continuously creating innovations that solve a wide range of healthcare issues. We are committed to transforming ourselves into a HaaS company that provides value beyond the traditional framework of treatment, and are working uncompromisingly every day to deliver cutting-edge healthcare solutions created through innovation to as many people as possible as quickly as possible.

## **SHIONOGI Today**

SHIONOGI's Business Model



## **Transformation**

**Medium-Term Busi**ness Plan STS2030

p.34-49

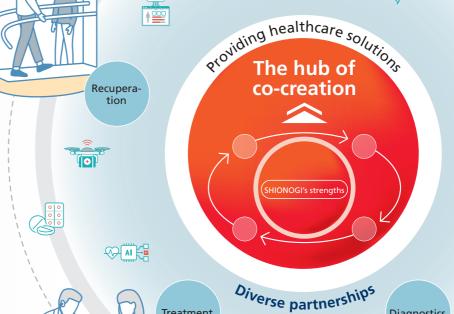
**R&D Strategy** 

**Top-line Strategy** 

Management Foundation Strategy







While we have an abundance of various information to make use of, the needs in the healthcare field are becoming increasingly sophisticated and diverse. We are on the verge of transforming into a society where people choose their own solutions to protect, promote, and heal their own health. SHIONOGI will thoroughly refine its accumulated strengths to become the partner of choice for a wide variety of companies, breaking through stereotypes to meet the needs of people and society. We are going to transform ourselves into a HaaS company that opens a new era of healthcare as the hub of co-creation.









# Medicines and beyond, the healthcare SHIONOGI wants to achieve

In response to the changing environment, the SHIONOGI Group Heritage to "constantly supply the best possible medicine to protect the health and wellbeing of the patients we serve" expands the interpretation of "medicine" to healthcare solutions.

Vice President, New Business Promotion Department

#### Hiroyuki Kobayashi

From globalization, remarkable technological advances in various fields, unexpected outbreaks of infectious diseases, military conflicts and geopolitical clashes, to world affairs and people's lives, the world is rapidly changing and becoming more complex. The healthcare field must also evolve in response to this situation. One example of such evolution is the development of new areas other than conventional diagnosis and treatment, such as the detection and prediction of infectious disease outbreaks and initial symptoms. We believe that the creation of such new businesses is one aspect of "delivering value by providing healthcare as a service (HaaS)" as stated in STS2030.

The mission of the New Business Promotion Department is to create HaaS in order to contribute to society, and to create a mechanism for HaaS creation. AdvanSentinel, which was established in January 2022, is already working on a wastewater surveillance demonstration in collaboration with relevant ministries and local governments as a measure to combat pandemics. In August of the same year, Yui Connection was established with the aim of realizing a society in which people can live their lives to the fullest. This start-up launched a service that visualizes the needs of students at elementary and junior high schools and provides teachers with education plans appropriate for each student.

Going forward, SHIONOGI will continue to contribute to society by creating new sustainable healthcare services, particularly in infectious and psychoneurological diseases, which SHIONOGI has identified as its core therapeutic areas.







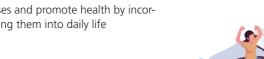
- Preventative vaccines
- Disease awareness

Solutions to be applied on a daily or timely basis according to disease characteristics and risk of developing the disease

- Wastewater epidemiology
  - services Disease awareness
  - OTC drugs
  - Supplements/health foods

Solutions that reduce the risk of future diseases and promote health by incorporating them into daily life

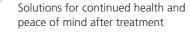






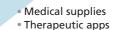






Recuperation





- Sensory stimulation
- OTC drugs

Solutions to realize individualized and optimal treatment that is not limited to drug therapy alone





- Al diagnostic support
- Diagnostic apps
- Diagnosis using brain waves

Solutions leading to early treatment and prevention by guickly and accurately detecting current diseases and their predictive signs









Patient journey

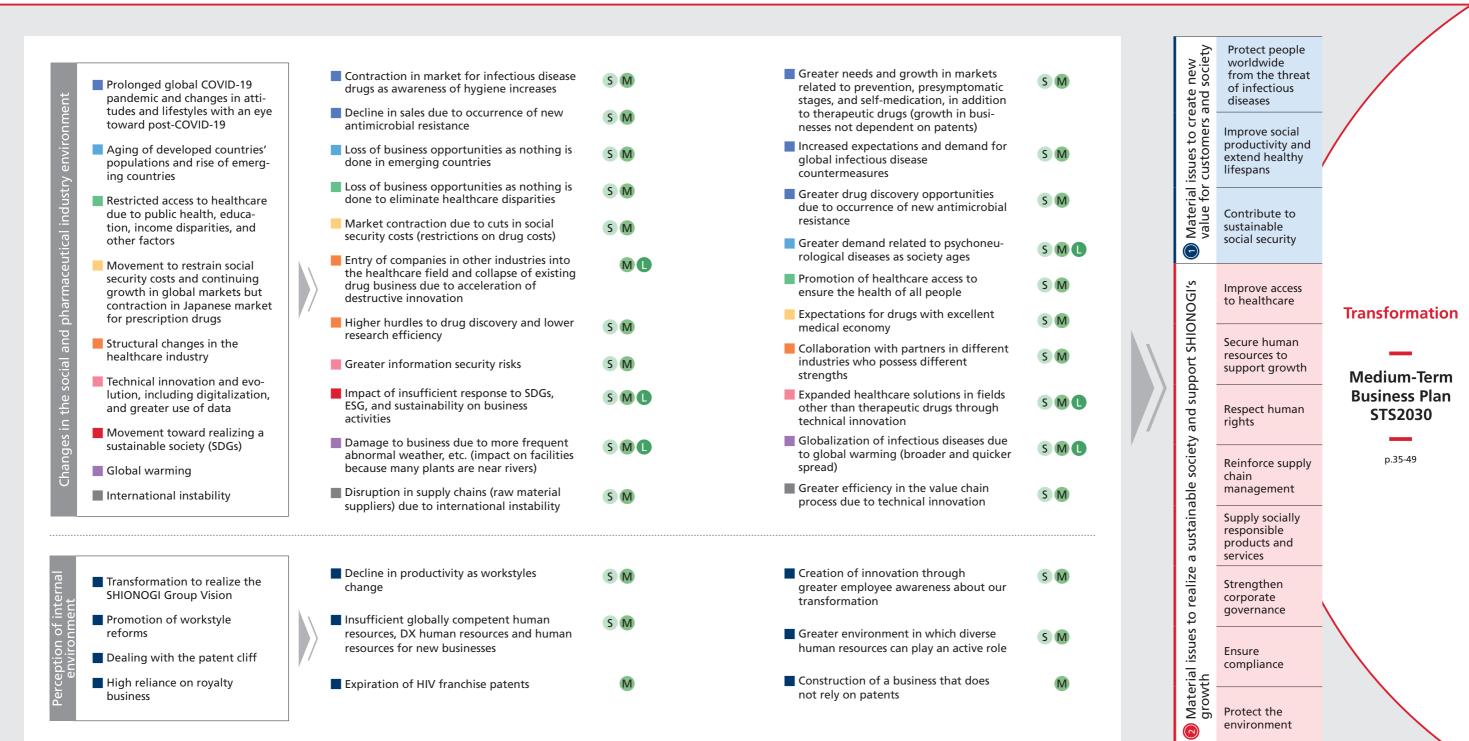
## **Risks and Opportunities**

In identifying our material issues (materiality), we analyzed and assessed the risks and opportunities for SHIONOGI from internal and external environmental changes. Going forward, as we pursue these initiatives, we will continuously evaluate our risks and opportunities and reflect them in SHIONOGI's initiatives with respect to our material issues (materiality).

Risks



**Opportunities** 



Shionogi & Co., Ltd. Integrated Report 2022

## **SHIONOGI's Material Issues**

Through its business activities and in response to healthcare needs and social issues, SHIONOGI is growing as a company that society needs and aims to share outcomes with our stakeholders. SHIONOGI is therefore identifying material issues (materiality) that we will prioritize in the light of our current situation and needs, as well as our business risks and opportunities.

## ■ Materiality Map Very high Material issues to create new value for customers and society Material issues to realize a sustainable society and support SHIONOGI's growth High Relevance to SHIONOGI's business Very high

	Material issues	Major initiatives	Main associated indicators	SDGs we contribute particularly
ers		Provide products and services for acute infectious diseases	Number of acute infectious disease-related pipelines     Number of serious infectious disease-related pipelines	
TOM	Protect people worldwide from the threat of infectious diseases	Provide products and services for chronic infectious diseases	Number of HIV-related product pipelines     Contribution to improvement of QOL with cabotegravir	
s cns	p.54-57	Build a vaccine business	Provide COVID-19 vaccine     Establish vaccine production facilities	3 GOOD HEALTH AND WELL-BEING
new value for customers and society	Improve social productivity and	• Discover products and services for disease areas with high unmet medical needs	<ul> <li>Number of psychoneurological diseases-related pipelines</li> <li>Number of oncology-related pipelines</li> <li>Number of pain-related pipelines</li> </ul>	<i>-</i> ₩•
and soc	extend healthy lifespans p.58-59	<ul> <li>Raise awareness of the characteristics of the disease and the problems faced by those affected by the disease to promote social understanding</li> </ul>	Number of educational activities conducted using webinars     Number of support services provided in the area of developmental disorders	
a	Contribute to sustainable social	Extend healthy lifespans by providing new treatment options	Percentage of products and services provided per modality	_
	security p.60-61	Promote self-medication	Numbre and sales results of OTC drugs	
		Develop innovative therapies	Global Development Products	8 DECENT WORK AND ECONOMIC GROWTH
		Promotion of proper use	Amount of information supplied for proper use and disease awareness	
ָ ה ה	Improve access to healthcare	Create an environment of improved access	<ul> <li>Signed agreement for access to cefiderocol</li> <li>Number of countries where ViiV offers dolutegravir and cabotegravir globally</li> <li>Number of countries adopting subscription-type reimbursement model</li> </ul>	
	p.62-65	Strengthen health care systems	Programs to strengthen healthcare infrastructure in developing countries     Mother to Mother SHIONOGI Project	
		Secure diverse human resources	Provide the human resources that each organization needs     Number of internal recruits     Number of mid-career hires	9 NOUSTRY, INNOVATION AND INFRASTRUCTURE
and suppo	Secure human resources to support growth p.50-53	Nurture human resources who possess exceptional strengths	<ul> <li>Manager training hours and costs</li> <li>Percentage of employees using assistance programs for self-investment</li> <li>Human resource pool for future management</li> <li>Number of IT/digital personnel trained</li> <li>Number of people applying for side work</li> </ul>	
ברץ מו		Foster an environment and culture in which everyone can work comfortably	Percent of female managers     Percent taking childcare leave	
) )		Health care and occupational safety and health	Improve health literacy     Health checkup reception rate     Percent of employees who smoke     Severity rate     Frequency rate	2
) ) ) )	Respect human rights p.69	Address human rights issues	Conduct human rights impact assessments     Evaluations of effectiveness by external experts	12 RESPONSIBLE CONSUMPTION AND PRODUCTION
	Reinforce supply chain	Develop policies and codes of conduct	Develop policies and provide training for Group employees in Japan	CO
i	management p.68	Evaluate sustainability of suppliers	Percentage of total suppliers evaluated	
. פפודע	Supply socially responsible products and services	Stably supply products and services	<ul> <li>Monitor and improve procurement management indicators and delivery indicators set by SHIONOGI</li> <li>Conduct regular/non-regular discussions with suppliers to ensure stable procurement</li> <li>Periodic evaluation of contract manufacturers and support for establishing business continuity plans (BCP)</li> </ul>	_
2	p.66-67	Strengthen monitoring systems	Ensure strict observance of laws, regulations, and guidelines related to the manufacture and sale of pharmaceutical products	17 PARTNERSHIPS FOR THE GOALS
5	Strengthen corporate	High-performing corporate governance framework	Disclose the topics deliberated by the Board of Directors	<b>***</b>
5	governance p.72-85, 87-89	Strengthen risk management	Build an Enterprise Risk Management framework	
5	Ensure compliance p.86	Instill compliance awareness	<ul> <li>Have all employees identify issues in SHIONOGI corporate culture</li> <li>Discuss identified issues by organization, and formulate countermeasures (to be implemented in all organizations and Group companies)</li> </ul>	_
	Drotost the environment	Climate change: Reduce of greenhouse gas (GHG) emissions	• FY2030: Reduce Scope 1+2 by 46.2% and Scope 3 Category 1 by 20% (FY2019 baseline) FY2050: Achieve zero emissions	_
	Protect the environment p.70-71	AMR: Reduce the impact of antimicrobials manufacturing on the environment	Have proper control, including of the supply chain, by FY2030 (completion of audit follow-up)	

For details and results of each initiative and associated indicators, please refer to the respective pages.

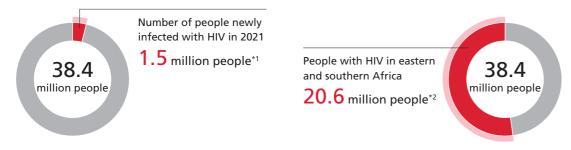
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## **Market and Performance**

#### HIV

## **Number of HIV-positive people**

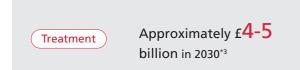
In 2021, the number of people infected with HIV was approximately 38.4 million, with more than half of these in eastern and southern Africa. The number of infected people is still increasing. In addition, approximately 650,000 people died from AIDS-related diseases\*1.



- \*1 UNAIDS Global HIV Statistics factsheet, updated 2021. Medicines Patent Pool 'Access to Medicines tracker'. Data as of March 2021
- \*2 HIV.gov, The Global HIV/AIDS Epidemic

## **Market Forecast for Long-Acting Formulations**

Currently, it is common to take multiple daily oral medications, but by 2030 the market for treatment and prevention with longacting formulations that enable a higher quality of life is projected to expand.

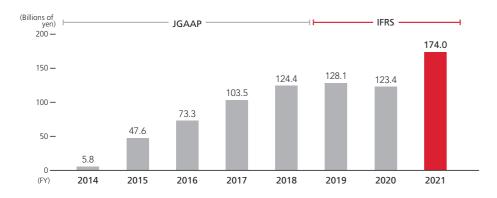




\*3 Meet GSK Management Getting ahead of HIV, 29 Nov. 2021

## Royalty income related to HIV franchise from ViiV Healthcare Limited

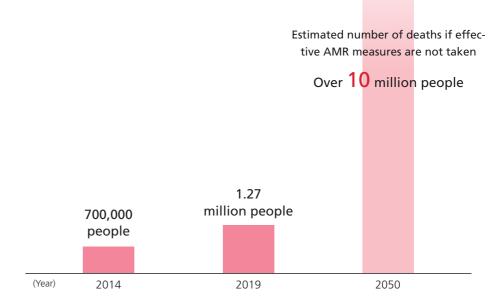
SHIONOGI receives royalty income on sales of HIV franchises licensed out to ViiV in the UK. As sales grow, royalty income received is also on an upward trend.



## **Antimicrobial resistance (AMR)**

## Deaths due to AMR bacteria (annual)

AMR is estimated to have killed approximately 700,000 people\*4 in 2014 and 1.27 million\*5 in 2019. It is estimated that if effective AMR measures are not taken in the future, approximately 10 million people will die annually by the year 2050, causing an economic impact of \$100 trillion.\*4



- \*4 O'Neill J., "Tackling drug-resistant infections globally: final report and recommendations", London: Review on Antimicrobial Resistance (2016)
  \*5 Antimicrobial Resistance Collaborators, "Global burden of bacterial antimicrobial resistance in 2019: a systematic analysis", The Lancet (2022)

## Cefiderocol\*6, a treatment for multidrug-resistant bacterial infections

Sales of cefiderocol in FY2021 were approximately  $\pm 6.2$  billion in the U.S. (up 268.7% YoY) and approximately  $\pm 3.6$  billion

Our partnership with GARDP and CHAI will pave the way for access to cefiderocol for 135 countries, including all low-income countries and most lower- and upper-middle-income countries.

\*6 U.S. brand name: Fetroia: European brand name: Fetcroia

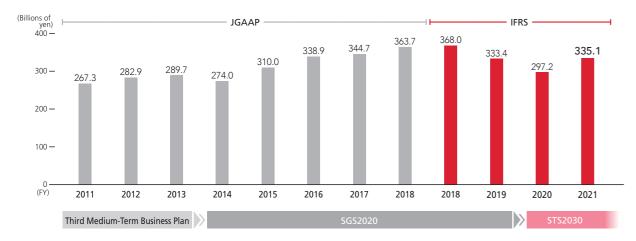


## **Financial Highlights / Non-Financial Highlights**

SHIONOGI has adopted International Financial Reporting Standards (IFRS) from fiscal 2019.

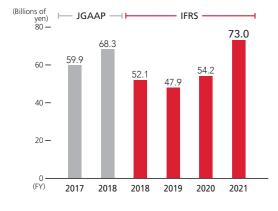
The financial figures for fiscal 2018 are shown according to both Japanese Generally Accepted Accounting Principles (JGAAP) and IFRS.

#### ■ Revenue

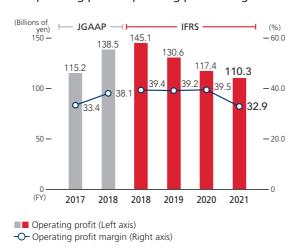


Revenue was ¥335.1 billion, a 12.8 percent increase year on year. Domestic revenue of prescription drugs were ¥89.1 billion, a decrease of 5.9 percent year on year, as a result of the launch of a generic version of Cymbalta. On the other hand, revenue from overseas subsidiary sales and exports was ¥34.4 billion, a 39.5 percent increase year on year, due to the growth in sales of cefiderocol in the U.S. and Europe. Royalty income was ¥181.3 billion, a 25.3 percent increase year on year, due to the growth in royalty income from the HIV franchise.

#### ■ R&D expenses

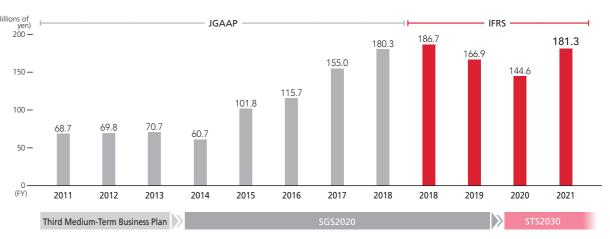


#### ■ Operating profit/Operating profit margin



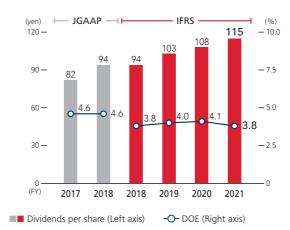
Operating profit was ¥110.3 billion, a 6.1 percent decrease year on year, as research and development expenses increased due to aggressive investment in projects related to COVID-19. Core operating profit, which excludes non-recurring items, was ¥110.6 billion, an increase of 17.7 percent year on year.

#### ■ Royalty income



Royalty income was ¥181.3 billion, a 25.3% increase year on year, as sales of the HIV franchise out-licensed to UK-based ViiV Healthcare Limited. grew, and royalty income accompanying the settlement of the patent infringement litigation against U.S.-based Gilead Sciences, Inc. was recorded.

#### ■ Dividends per share/DOE



Dividends per share were ¥115, up ¥7 from the previous year, making this our tenth consecutive year of dividend growth. DOE was 3.8%.

### **■** ROE



ROE was 12.5%. The introduction of IFRS resulted in a lower ROE, due to the impact of an increase in equity items (equity attributable to owners of the parent).

## **Financial Highlights / Non-Financial Highlights**

#### ■ Code of Conduct signature rate (FY2021)

100%

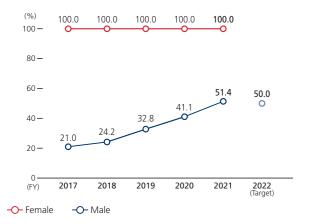
 $\ensuremath{^{\star}}$  Shionogi & Co., Ltd. and its domestic group companies

## ■ Education and training expenses per person

# ¥48 thousand

\* (Education and training expenses + amount of self-investment support)/number of employees (Domestic consolidation)

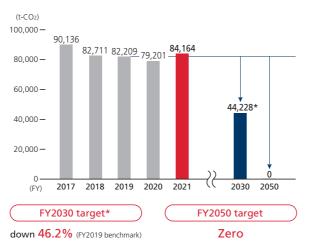
#### ■ Acquisition rate of childcare leave



Acquisition rate of childcare leave/days off for childcare purposes of 50% or more for male employees

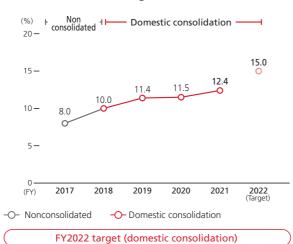
FY2022 target (Male)

### ■ GHG emissions (Scope 1 and 2)



\* This includes emissions by UMN Pharma Inc. and Nagase Medicals Co., Ltd., (currently Shionogi Pharma Co., Ltd., Itami Plant) since 2019, the reference year, because that is the boundary for fiscal 2030 targets (SBT).

#### ■ Ratio of female managers



Rate of female employees occupying management positions:at least 15%

#### ■ External evaluations

	FY2019	FY2020	FY2021
CDP	Climate change: A- Water Security: A	Climate change: A- Water Security: A SER*: Leaderboard	Climate change: A- Water Security: A- SER: Leaderboard
FTSE	Not selected/2.9	Selected/3.4	Selected/3.7
MSCI	AA	AA	AA
DJSI	No response/19 points	Response/45 points	Response/53 points
S&P/JPX Carbon Efficient Index	Third decile	Fourth decile	Fifth decile
Toyo Keizai CSR Ranking	63rd of 1,593 companies	34th of 1,614 companies	53rd of 1,631 companies
SOMPO Sustainability Index	Selected	Selected	Selected
Survey on Health and Productivity Management	White 500	White 500	Certified Health & Productivity Management Outstanding Organizations

<sup>\*</sup> SER: Supplier Engagement Rating

## At a glance

■ Core operating profit margin (FY2021)

■ ROE (FY2021)

■ Internally-discovered pipeline ratio (as of Mar. 2022)

33.0%

12.5%

73%

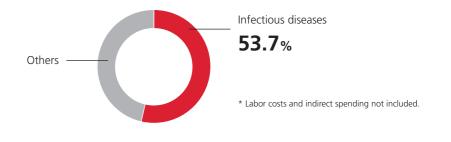
#### ■ COVID-19 pipeline (as of August 1, 2022)

Area Pipeline		Indication	Status	
	S-217622 (ensitrelvir)	COVID-19 treatment	Japan: Application, phase2/3 clinical trials in progress Global: Phase 3 clinical trials in progress	
Infectious	S-268019	COVID-19 prevention (muscular injection)	Japan/global: Phase 3 clinical trials in progress	
disease	S-555739 (asapiprant)	Control of the aggravation of COVID-19	US: Phase 2	
	S-875670	COVID-19 nasal vaccine	Nonclinical studies in progress	

#### ■ Main pipeline (as of August 1, 2022)

Area	Pipeline	Indication	Status
Info	S-872600	Influenza nasal vaccine	Nonclinical studies in progress
Infectious disease	S-540956	① Infectious disease ② Cancer	Preparing for Phase 1 clinical trials
	S-600918 (sivopixant)	Refractory/unexplained chronic cough	Preparing for Phase 3 clinical trials
Neuropsy- chiatric disease	S-812217 (zuranolone)	Depression	Preparing for Phase 3 clinical trials
discuse	BPN14770 (zatolmilast)	Fragile X syndrome	Phase 2b/3 clinical trials in progress
	S-531011	Solid tumors	Phase 1b/2 clinical trials in progress
New growth areas	S-005151 (redasemtide)	<ol> <li>Epidermolysis bullosa</li> <li>Acute ischemic stroke</li> <li>Knee osteoarthritis</li> <li>Chronic liver disease</li> <li>Cardiomyopathy</li> </ol>	Started additional clinical trials     Preparing for Phase 3 clinical trials     (1) Investigator-initiated clinical trials (Phase 2 clinical trials) in Progress     (2) Preparing for investigator-initiated clinical trials

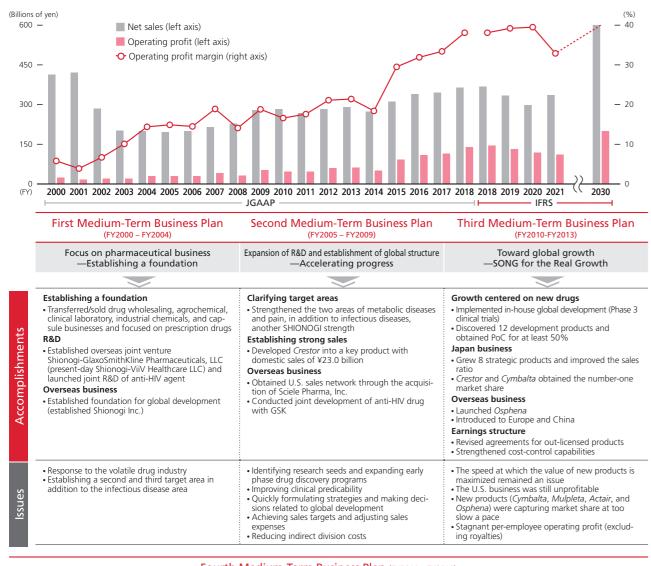
#### ■ Proportion of R&D expenses for the infectious disease area (FY2021)



## **Medium-Term Business Plan**

#### **Looking Back at Our Previous Medium-Term Business Plans**

In fiscal 2021, the COVID-19 pandemic continued to rage, which had a major impact on the business environment in which SHIONOGI operates. In particular, the infectious disease business, which includes influenza-related products, was dramatically impacted by the massive market contraction due to strict precautions against contagions. On the other hand, there was major progress in the development of the therapeutic drug S-217622 (ensitrelvir) and the COVID-19 vaccine S-268019, making it possible to raise the Company's presence as a leading infectious disease company in Japan.



## Fourth Medium-Term Business Plan (FY2014 - FY2019

Grow as a drug discovery-based pharmaceutical company —Shionogi Growth Strategy 2020

Grow sustainably as a drug discovery-based pharmaceutical company contributing to a more vigorous society through improved healthcare KPIs —Shionogi Growth Strategy 2020

We accomplished the following regarding the 4th Medium-Term Business Plan (SGS2020) and achieved the main KPIs given in SGS2020 (ordinary profit, efficiency KPI, and shareholder return KPIs)

Continued creation of in-house products • Xofluza, Mulpleta, Symproic, cefiderocol, cabotegravia

Strengthening of business operations • Improvement of cost management • Global development of all in-house products, launches in overseas markets

Maximize value of new products • Cymbalta and Intuniv have achieved growth, but targets are unmediately

Issues with information provision concerning Xofluza have emerged (insufficient marketing capabilities overall)

Grow overseas businesses • US business: Targets not met for strategic products (Osphena, Symproic) • Still in process of establishing business infrastructure for the EU and China Improve per-employee productivity

## **Shionogi Transformation Strategy 2030 (STS2030)**

SHIONOGI Group Vision What SHIONOGI wants to accomplish by 2030



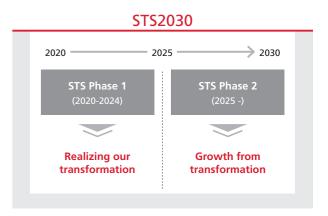
### **Building Innovation Platforms to Shape the Future of** Healthcare

- · Continuously creating innovative products/services, with a well-established and rapidly-growing global business
- Continuing to offer solutions to health issues facing society
- Excellent business persons who never take a break from building their expertise and capabilities, leveraging their individual strengths, and creating new value

## Strategy to Achieve SHIONOGI Group Vision

In June 2020, SHIONOGI stated the goals it wants to achieve in ten years, by 2030, as SHIONOGI Group Vision and formulated STS2030, a strategy to achieve that vision. It positioned the period through 2024 as Phase 1, and developed concrete plans to undertake the transformation from a traditional pharmaceutical company into a HaaS\* company by providing society with innovative solutions required to solve social problems, not only traditional prescription drugs. During phase 2, the period starting in 2025, SHIONOGI will continue to grow as a HaaS company and further raise its corporate value by becoming an entity that can continue to supply this type of innovative solutions.

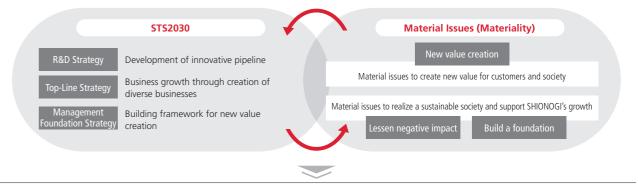
\* Healthcare as a Service: Provide a range of healthcare services in line with customer needs, rather than only providing pharmaceuticals



#### STS2030 and Material Issues (Materiality)

To realize a transformation to new growth as a total healthcare company, the basic policy for STS Phase 1, we have formulated three strategies—R&D strategy, top-line strategy, and management foundation strategy. Furthermore, material issues (materiality) include factors related to achieving the SHIONOGI Group Vision through new value creation and factors to lessen the negative impact related to issues such as human rights and the environment, and maintain medium- to long-term initiatives to build a foundation to achieve that. Factors related to

achieving the SHIONOGI Group Vision are tackled strategically in STS2030, and SHIONOGI has positioned STS2030 and material issues (materiality) as two elements that complement each other. We will achieve sustainable growth as a company by incorporating these two elements into the goals for various business activities, implement business transformation and reduction in negative impact by achieving those goals, and delivering created value to all stakeholders.



#### SHIONOGI Group Heritage

SHIONOGI strives constantly to supply the best possible medicine (healthcare solutions) to protect the health and wellbeing of the patients we serve.

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## **Management Strategy/Financial Strategy**

In STS2030, SHIONOGI is promoting growth through transformation and pursuing a strategy that sets forth growth through a business make-over.

In the pharmaceutical business, our major business segment, we are working to maximize product value, which had been an issue in our previous medium-term business plan, SGS2020, based on efforts to create innovative products as a drug discovery-based pharmaceutical company. The royalties we obtain from alliances with licensees and external partners will serve to maximize the earnings we need for achieving STS2030, and we will focus on new product introductions at our overseas Group companies and redouble our efforts to strengthen our in-house marketing without involving partners so that we can improve the growth and profitability of each global region.

In addition, in businesses newly proposed in STS2030 that are outside the framework of prescription drugs, we are proactively pursuing the co-creation of new healthcare solutions with various partners, so that we can capitalize on our strengths and expand our vaccine, OTC drugs and contract development and manufacturing organization (CDMO) businesses. We are tackling the challenge of creating healthcare for the future by developing our Healthcare as a Service (HaaS) business so that we can solve the many problems of society.

Developing a new well-balanced business model that has the pharmaceutical and the HaaS businesses as its major pillars will enable us to break free from a business structure that relies mainly on royalty income and transform us into a total healthcare company that goes beyond the existing pharmaceutical company framework and maintain high profitability as well as a stable management foundation. In addition, SHIONOGI works hand in hand with society to bring about a world with sustainable growth by solving social issues through innovative healthcare solutions.

## Strengthening our portfolio with new growth drivers to achieve total care for diseases

The areas that we are working on for achieving STS2030 are providing products and services that provide total care for diseases and accelerating the broadening and strengthening of our product portfolio, which includes tackling diseases where unmet medical needs remain, especially infectious diseases, psychoneurological diseases, and pain.

Fiscal 2021 was a year during which the world continued to be ravaged by the COVID-19 pandemic. Placing our top priority on freeing the world from the pandemic as soon as possible, even if only by a day, we made progress in organizing our products and services so that we can provide total care. These efforts included developing the COVID-19 therapeutic drug S-217622 and vaccine S-268019, providing wastewater-based epidemiology surveillance services through the establishment of AdvanSentinel Inc., developing and supplying COVID-19 diagnostic drugs, and the out-licensing of asapiprant, which suppresses the exacerbation of the disease. We plan to con-

#### Financial foundation

	FY2019	FY2020	FY2021
Total assets	¥873.7billion	¥999.0billion	¥1,150.6billion
Equity attributable to owners of parent	¥765.2billion	¥846.1billion	¥975.7billion
Cash and cash equivalents	¥208.9billion	¥276.2billion	¥254.4billion
Ratio of equity attribut- able to owners of parent to total assets	87.6%	84.7%	84.8%
Payout ratio	26.0%	29.6%	30.4%

tinue beefing up our development portfolio by launching such initiatives as the discovery of S-217622 follow-up compounds and development of a nasal vaccine as a next-generation vaccine for COVID-19. With the COVID-19 pandemic, society has renewed awareness of the importance of programs for dealing with infectious diseases. As a leading company in the infectious disease area that has adopted the material issue (materiality) of "protecting people worldwide from the threat of infectious diseases," SHIONOGI is incorporating the lessons of the COVID-19 pandemic and providing solutions from the perspective of total care, vis-à-vis all types of infectious diseases, including antimicrobial resistance (AMR), the three major infectious diseases, and neglected tropical diseases (NTDs).

Besides infectious diseases, STS2030 also addresses psychoneurological diseases and pain as key areas where we are working to maximize the value of our existing products and to accelerate the expansion of our portfolio. For atten-

#### Financial KPIs

		FY2021(results)	FY2022	FY2024
S	Revenues	¥335.1billion	¥400.0billion	¥500.0billion
ator	Core operating profit	¥110.6billion	¥120.0billion	¥150.0billion
indic	Core operating profit margin	33.0%	Over 30%	Over 30%
Growth indicators	Overseas revenue ratio (excluding royalities)	22.3%	Over 25%	Over 50%
g	Internally-discovered pipeline ratio	73%	Over 60%	Over 60%
eholder indicators	EPS	¥378.75	Over ¥370	Over ¥480
Shareholder turn indicato	DOE	3.8%	Over 4%	Over 4%
Shar	ROE	12.5%	Over 13%	Over 15%

tion-deficit/hyperactivity disorder (ADHD), we are in the process of developing a digital therapeutic app (SDT-001), as well as two types of treatment drugs that have differing mechanisms of action. Pharmaceutical services with differing modalities not only provide patients with more treatment options, but are also an effective way to deal with the patent cliff problems that are constantly confronting the pharmaceutical business. In fiscal 2021, we also got involved in efforts to provide new solutions for insomnia, thus adding to our portfolio. We entered into a memorandum of understanding with

## Investment strategy for value creation

To maintain our global growth while tending to the many problems in the healthcare field, SHIONOGI needs to improve our performance by expanding our portfolio through the creation of growth drivers, to get new businesses up and running as soon as possible, and to develop a greater presence in overseas markets. The financial policy set forth in Phase 1 of STS2030 includes establishing an investment budget of 500 billion yen, in addition to R&D expenses. This investment budget is the financial driver that will increase SHIONOGI's corporate value as we strengthen the competitiveness of our new businesses, beef up our development pipeline, and carry out flexible and speedy social implementation, in other words, undergo a transformation. In Japan, we are seeking out and making investments in products that will contribute to our revenues in the short term and to businesses that can be expected to contribute to our productivity and profitability over the longer term, as well as products in the early stages of development. In the U.S. and Europe, we are taking steps to acquire products that will contribute to our business immediately, and expand sales of cefiderocol, which we are also hoping will provide synergies. In China, we are accelerating our pursuit and execution of investment opportunities to provide innovative new products and services through Ping An-Shionogi

Mochida Pharmaceutical Co., Ltd. regarding a marketing rights license for the insomnia therapeutic drug daridorexant, and we entered into a commercialization agreement with SUSMED, Inc. regarding a digital therapeutic application for insomnia. Also, regarding pain, we entered into a license agreement with Grünenthal GmbH for the pain control medicine resiniferatoxin, adding it to our portfolio. In STS2030, we are putting together a solid portfolio so that we can overcome our patent cliff while maintaining a balance between our pharmaceutical business and our HaaS business.

Co., Ltd., our joint venture with the Ping An Insurance Group. Along with these investments in new businesses and portfolio acquisitions, we are also making investment to enhance our existing strengths and improve our profitability. Because we

proceeded with an aggressive investment in infectious disease projects, particularly for COVID-19-related R&D in fiscal 2021, we spent the highest amount ever, 73 billion yen (up by 18.7 billion from the prior year) on R&D expenses. In the five years of STS2030 Phase 1, we anticipate making R&D investments of an amount equivalent to more 120% of what we spent on R&D over the five-year period from fiscal 2015 through fiscal 2019. The increase in R&D expenses will be an investment in the creation of innovative healthcare solutions for solving the social issues of 2030, and we are planning to invest flexibly to maximize the value of our new product developments.

Also, to strengthen our base of competitiveness, we at SHIONOGI are promoting the use of AI technologies in drug discovery and are in the process of building a data management platform (DMP) for marketing, as well as speeding up investment in building a digital foundation so that we can grow as a HaaS company. Furthermore we are making investments in building a manufacturing and logistics system so that

## **SHIONOGI Transformation**



Takeaki Dohda Vice President Investment Strategy

Department

Message from an employee

## Taking the same approach as a startup to face unmet medical needs

The Investment Strategy Department's mission is to create new value for SHIONOGI during the post-2030 period after we achieve STS2030. We are adopting a new value system that strives to ascertain unmet medical needs by taking the same flexible and rational approach as would the founder of a startup. We will speed up business by engaging in mutual learning and encouragement with the managements of the firms in which we have invested. We believe that, through these cumulative efforts, SHIONOGI will be able to transform itself into the Company that, with its business partners, is the best in the world at providing healthcare solutions that meet customers' needs. SHIONOGI has already invested in some excellent partners both in Japan and overseas. Going forward, we will proactively work to create businesses with a grander vision so that we will be able to provide customers with the fruits of our endeavors as soon as possible.

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we can quickly deliver the solutions that we have designed to the patients who need them. In fiscal 2021, we spent a total of 27.3 billion yen on capital investments in vaccine manufacturing equipment and in manufacturing facilities at our Settsu Plant. In particular, with respect to vaccine manufacturing, we teamed up with Unigen, Inc. and Api Co., Ltd., an alliance that employed about 37.3 billion yen of grant funds from the Ministry of Economy, Trade and Industry and the Ministry of Health, Labour and Welfare to conduct clinical trials in tandem with the construction of manufacturing facilities and the optimization of manufacturing methods for mass production so that we can deliver a vaccine to people as soon as possible.

SHIONOGI is thus actively seeking investment opportunities that will contribute to our revenues in both the short term and longer term as well as investment opportunities that can help strengthen our corporate foundation in order to keep increasing our corporate value. Also, each investment candidate undergoes a balanced assessment of its benefits and risks based on our investment evaluation process so that we can create new value through rapid implementation.

## Promoting management that is both aggressive and defensive

Despite the tough business climate in fiscal 2021 due to such factors as the minimal spread of influenza from increased hygiene awareness and global travel restrictions brought on by the COVID-19 pandemic, SHIONOGI's revenues, core operating profit, and profit attributable to owners of parent exceeded our financial forecast. Again, in fiscal 2022, we will have our sights fixed on growth opportunities, and will advance operations considering both aggressive and defensive risks.

#### Investment in growth drivers

Achieving our SHIONOGI Group Vision absolutely requires that we create innovative products and services that will solve social problems in the field of healthcare. To do this, we must use cutting-edge drug-discovery technologies so that we can come up with innovations that meet the needs of society.

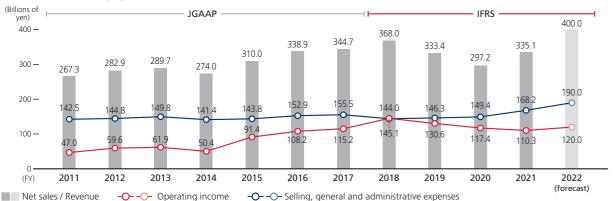
During STS Phase 1, which runs through fiscal 2024, we plan to allocate 500 billion ven into investment that will be new growth drivers. We did not succeed in making any largescale business investments in fiscal 2021, due to an environment of underlying risk in which the COVID-19 pandemic showed no sign of ending and the global instability increased as a result of the Russian invasion of Ukraine. However, we set up a new Investment Strategy Department in July 2022, which will take a more strategic approach toward future investment opportunities by employing investigation and analysis so that we can make business investments that are aggressive.

Meanwhile, in fiscal 2021, our R&D investments were larger than in any prior year in SHIONOGI's history, so that we could provide society with solutions to COVID-19 as soon as possible. From fiscal 2022 onward, we will allocate earnings from COVID-19 related projects to investments in equipment and the formation of an IT foundation, and we will be pursuing initiatives that will improve our corporate value over the medium and long term.

#### Securing a solid financial structure

To achieve sustained growth when resources are limited, we will need to procure and allocate funding that will give us both agility and strength while maintaining a stable financial foundation. At SHIONOGI, we are also taking advantage of grants and other external funding, and in fiscal 2021, we were chosen for the Ministry of Health, Labour and Welfare's support project for the practical application of COVID-19 therapeutic drugs. Infectious diseases cause severe shifts in markets, depending on the extent of their spread, and while they involve sustainability risks for our business to survive as a stand-alone company, we are making proactive investments while securing a solid financial foundation by developing a business model that combines our own funds with external grant funding. SHIONOGI currently has a good reputation for the stability of its management, and we have been assigned an AA- rating by Rating and Investment Information, Inc. (as of August 2022).

#### Sales, and Selling, general and administrative expenses



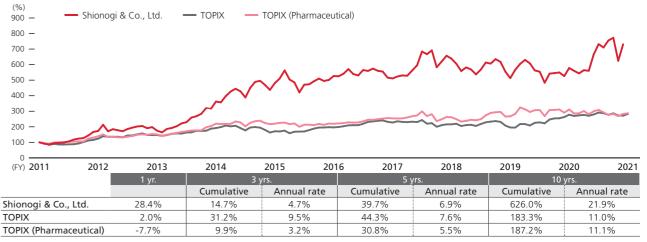
## Sharing the joys of growth with our shareholders

As SHIONOGI strives to increase our profit and maximize our corporate value through investment in new growth drivers and continued strengthening of our business operations, one of our basic principles is to implement a dividend policy that will enable all of our shareholders to actually feel our growth.

In STS2030 Phase 1, a targeted dividend on equity (DOE) attributable to owners of the parent of at least 4% is the shareholder return indicator, as our policy is to increase returns steadily and sustainably over the long term. Other target shareholder return indicators are earnings per share (EPS) of at least 480 yen and return on equity (ROE) attributable to owners of the parent of at least 15%, so we are going to return profits to all of our shareholders by steadily increasing dividends in line with SHIONOGI's growth. Our results for fiscal 2021 were a dividend per share of 55 yen at mid-year and 60 yen at year-end, so our full-year dividend of 115 yen was our tenth consecutive dividend increase. Going forward, we will continue implementing a dividend policy whereby all shareholders will be able to continue sharing in SHIONOGI's

Another shareholder return measure besides dividends is to enhance our capital efficiency through share buybacks, cancellation of treasury shares, and unwinding of cross-shareholdings. In fiscal 2022, we plan to acquire up to 7.2 million (or 50 billion yen) of treasury shares, which is equivalent to 2.39% of our total shares issued and outstanding, and to cancel 4.2 million of treasury shares, and we will increase our shareholder returns, improve our capital efficiency, and implement a flexible capital policy that is responsive to the business environment with a view to further improving our corporate value.

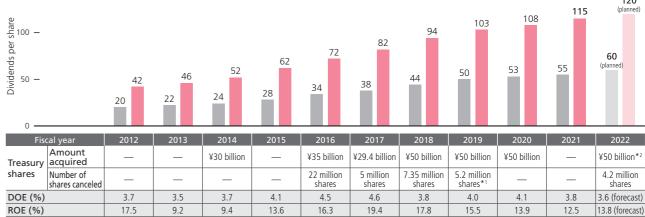
#### ■ Total shareholder return (TSR)



- Notes: 1. Total shareholder return (TSR): The total return to the shareholder, or the total return on investment, including dividends and capital gains
  - 2. TSR is calculated as the amount of cumulative dividends plus the change in Shionogi's stock price, while TOPIX is a stock price index that includes dividends (prepared by Shionogi using data from Bloomberg and other sources)
- 3. The values in the graph are TSR-indexed market prices, taking the closing price on March 31, 2012, as 100 (with a holding period until March 31, 2022)

#### Dividends

(yen) 150 —



- \*1. Resolution passed on March 30, 2020, and treasury shares canceled on April 6
- \*2. Upper limit of share buybacks planned at 50 billion ve

Note: Values from fiscal 2018 on were calculated based on IFRS

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## **R&D Strategy**

Even as COVID-19 wrought great turmoil across the world, the pandemic created opportunities for transformation. Taking this opportunity to turn vision into reality, SHIONOGI will accelerate the discovery and development of COVID-19 solutions and subsequent drivers of growth.

### **Our 2030 Vision and Strategy**

SHIONOGI has set "Offer solutions to health issues facing society" and "Continuously create innovative products/services" as key elements of our Vision in STS2030. To achieve these key elements, we are applying our R&D capabilities across a range of fields, including those where we have considerable experience, such as infectious diseases, psychoneurological diseases, as well as newer fields for us, such as vaccines and cancer, and even further areas, all driven by the magnitude and urgency of the medical need. By intelligently applying the broader solution space offered by new modalities and technologies to our long-standing strength in small molecule discovery, and through a committed effort to expand our external networks and to advance the capabilities of our human resources, we expect that both our speed, and our likelihood of success, in resolving whatever healthcare challenges we choose to undertake will be increased.

#### Deploying new modalities and technologies, starting with infectious diseases

SHIONOGI aims to realize total care for disease, going beyond conventional pharmaceutical-based treatment to comprehensively address, and where possible, avoid, the burden created by the disease on patients and society. We will work to offer suites of products that can provide a comprehensive solution to disease challenges, including prevention, diagnosis, and recovery support, as well as the traditional pharmaceutical focus on treatment. One clear preparatory action in this direction was the acquisition of UMN Pharma Inc. in 2019, providing us with a platform for vaccine R&D and thereby for the creation of a new business area.

For the COVID-19 pandemic, the establishment of this new platform allowed us to undertake with top-priority the development of a recombinant protein vaccine (S-268019) based on the BEVS\* technology. We are further expanding our vaccine platform by development of different forms of vaccine delivery, such as a nasal delivery systems with enhanced convenience and with the aim of effective immunoinducibility, and we now have nasal vaccine programs for COVID-19 (S-875670) and influenza (S-872600), using technology from HanaVax, Inc.

\* BEVS (Baculovirus Expression Vector System): A protein expression technology that uses insect and other cells

#### Advancement of product creation through co-creation with external parties

A long-standing strength of SHIONOGI's research is our small

molecule drug discovery engine that is capable of efficiently producing innovative drugs. The high level of technical skill in each of our departments and the accumulation of experience in its utilization, with efficient collaboration amongst departments, constitutes a source of competitive strength that we have been able to leverage in our COVID-19 drug discovery. During the pandemic, we were able to establish and demonstrate further evolution in key areas, including rapid and sophisticated decision-making ability. At the same time, we became keenly aware of our limits when proceeding on our own. In an environment with rapidly-changing circumstances, gathering external knowledge and leveraging our collaborative networks have become ever more central to empowering us to deliver the solutions that people want, at the right time. Accordingly, we believe that SHIONOGI must pay careful attention to nurturing and expanding our network of external collaborations. In fiscal 2021, we were able to launch and to advance a number of new businesses through the power of collaboration across companies, and even across industries, as seen in the establishment of AdvanSentinel Inc. This time, in addition to moving the Business Development Department inside the R&D Supervisory Unit, we have formed an Investment Strategy Department that will work alongside the Business Development Department. With these two organizations at the core, we will expand our network with partners that have differing strengths and advance R&D that uses those

### Human resource development to ensure broad, cutting-edge research and development capabilities

As important as it is to establish and leverage our external network, if we are to be truly capable, respected, and an attractive partner to other capable companies, we must continue to nurture and expand our own internal R&D capabilities. We remain committed to maintaining a high internally-discovered pipeline ratio, which stands at 73% as of March 2022. The key to achieving this is having a highly-skilled and highly-capable human resource. Whether working alone, in-house, or in collaboration with external parties, we must continually generate the "seed" ideas that lead to product discovery, as these are the key starting points. In order to make sure we are creating and progressing these seeds in the right, societally productive direction, we must have a deep understanding, shared throughout the R&D organization, of the true healthcare concerns of society. From there, we must take action with energy and focus, and a

Message from the Senior Executive Officer, **R&D Supervisory Unit** 

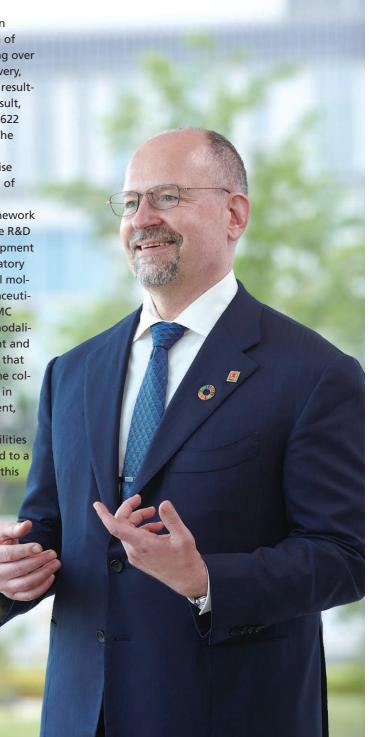
We will more rapidly create products addressing critical healthcare needs through transformation rooted in our experience from responding to COVID-19.

Following the outbreak of the COVID-19 pandemic in 2020, SHIONOGI has undertaken a bold re-allocation of resources, focusing as never before and concentrating over 70% of our research efforts on COVID-19 drug discovery, to release society from the suffering and constraints resulting from the COVID-19 as quickly as possible. As a result, we were able to advance the therapeutic drug S-217622 and the vaccine S-268019 at unprecedented speed. The capability we established through this experience, enabling us to deploy maximal resources and expertise with agility, which we can now apply to the creation of our next growth drivers.

To achieve this mission, we renewed our R&D framework in July 2022. We launched this new framework as the R&D Supervisory Unit, under which we placed our Development Division, integrating clinical development and regulatory activities, our Research Division, containing our small molecule discovery and CMC capabilities, our Biopharmaceutical Research Division, including our discovery and CMC capabilities for vaccines, biotherapeutics, and new modalities, as well as the Business Development Department and the new Investment Strategy Department, to ensure that our network of external relationships required for the collaborative creation and advancement of innovation, in partnership with industry, venture capital, government, and academia, are all in one organization.

As these divisions and departments all have capabilities and resources that can flexibly and rapidly be applied to a wide range of medical needs and therapeutic areas, this new structure supports the flexible yet intensively focused approach we developed during the course of the pandemic. With this structure and approach, the R&D Supervisory Unit will pioneer the future of healthcare through products built on innovation and will contribute to the continuous growth of SHIONOGI.

John Keller, Ph.D. **R&D Supervisory Unit** 



willingness to always attempt the unprecedented, based on a natural and unbridled curiosity. In matters of great urgency, such as responding to the COVID-19 pandemic, that curiosity must be harnessed through a brute force approach to pushing ahead. But both are required – we cannot produce new growth drivers through brute force alone.

SHIONOGI's independent research and development function is designed to allow broad exploration while maintaining the highest rigor, and to thereby create an environment that nurtures human resources motivated by genuine curiosity. This system is designed to evaluate people based on the innova-

tion and rational creativity reflected in their attempts rather than their failures, to foster a culture in which researchers are free to take on challenges without fear. Nearly 100 research themes have been proposed under this system, several of which have progressed to project status.

While developing and reinforcing this system, we will solidly nurture the human resources who will be responsible for creating the next generation of SHIONOGI innovation so that we can continually generate valuable products and to realize the benefits from them, in alignment with society.

### Making SHIONOGI Group Vision a reality

In these initial five years (through fiscal 2024) of STS2030, we have been working to achieve the transformation of the company. In fiscal 2021, in the continued intense period of the pandemic, as in the previous year, we devoted much of our resources to COVID-19 drug discovery. Even in this challenging period, through the dedicated efforts of our employees, we were able to continue to make steady progress toward the realization of SHIONOGI Group Vision.

In COVID-19 drug discovery, progress toward the development of the aforementioned S-217622 and vaccine S-268019, as well as the creation of a successor candidate for S-217622, has been our primary focus. We also embarked on the creation of a new business sector for SHIONOGI, founding a vaccine business that we will continue to strengthen and

expand in the medium to long term.

In this area, in addition to signing of a licensing agreement with HanaVax Inc. for the development of nasal vaccines, we established a joint research initiative at Chiba University Hospital, focusing on the research and development of vaccines that induce mucosal immunity. We are also expanding our range of vaccine and adjuvant modalities and tools, both internally generated and accessed through external collaboration. We intend to use this expanded toolkit, along with an increased fundamental understanding of the still-unclear immune induction mechanisms of vaccines, to contribute to global health through the creation and provision of innovative vaccines that are effective in preventing contagion.

## Key elements remaining to be achieved

In fiscal 2021, we devoted intensive effort to the infectious disease business, seeking an early end to the COVID-19 pandemic. Unfortunately, we were unable to supply COVID-19 therapeutic drugs and vaccines during the current fiscal year, leaving this last and most important step to be achieved in the following fiscal year. Also in fiscal 2022, in addition to promptly completing ongoing trials, we plan to progress into prophylactic studies and further pediatric studies, and to seek approval in overseas regions, with the goal of maximizing the value of our COVID-19 portfolio to society.

In the Research Division, our creation of new growth drivers outside of the COVID-19 area was affected considerably by our bold shift of resources onto COVID-19 programs. However, even under these difficult circumstances, multiple nonclinical and research projects in the fields of infectious diseases and, psychoneurological diseases were advanced, clearly targeting important unmet medical needs in society and embodying our corporate transformation in terms of our ability to make maximum use of limited resources. By applying the focused resourcing and rapid decision-making approach, we piloted during the COVID-19 pandemic, to other projects, we expect to make considerable advances in our efforts to create next growth drivers.

Our Drug Development and Regulatory Science Division focused on "development at unprecedented speed" for our COVID-19 therapeutic drugs and vaccines as a core theme for fiscal 2021. This focus led to the acquisition of a wide range of know-how and new development techniques, such as the clinical trial in hotels and homes that we worked on for S-217622, and the close communication with regulatory authorities from early on aiming for the early authorization of therapeutic drugs and vaccines for COVID-19. We intend to apply these newly acquired skills to other products to improve the capabilities of the Division overall. Furthermore, as in discovery, we must always ask ourselves whether our efforts are truly aligned to delivering the solutions demanded by patients and society. In order to show that we are truly delivering these solutions, our development packages must not only achieve registration but also show the full value and benefit of the product, not solely efficacy and safety, but also healthcare economic value, impact on overall health and productivity, quality of life, and benefit over existing treatments, as well as global accessibility. With thorough commitment and deep understanding, we will continue to pursue these challenging goals in fiscal 2022 and onward, to drive SHIONOGI's global growth.

#### **Development Pipeline Status** (as of August. 1, 2022) :Global development ■ Infectious Disease Nonclinical Submission Phase1 Phase2 Phase 3 ● S-872600 S-880008 ● S-217622\*1 ■ S-217622\*1 (ensitrelvir) Influenza nasal COVID-19 treatme (ensitrelyir) vaccine (peptide) COVID-19 treatment COVID-19 treatment \*1 Phase 2/3 ● S-875670 S-540956 ● S-268019 COVID-19 nasal Nucleic acid COVID-19 Prophylactic vaccine vaccine • S-268019 • S-337395 S-554110 cefiderocol Nontuberculous RSV infections COVID-19 mycobacterial Prophylactic vaccine infection cefiderocol Xofluza Aerobic Gram-negative bacte-rial infection (Pediatric) Influenza virus infection (Granules. < 20kg) • F901318 Invasive Aspergillosis • S-555739 Out license S-365598 Xofluza Xofluza (US) (asapiprant) Influenza virus infection Influenza virus infection HIV infection (Pediatric, < 1 year old) (Pediatric,>= 1 year old) Treatment by suppressing aggravation of COVID-19 Xofluza Influenza virus infection ■ Psychonourological Disease

Nonclinical	Phase1	<u> </u>	Phase2		Submission
• S-874713 Psychoneurological diseases	• S-600918 (sivopixant) Neuropathic pain	• S-600918 (sivopixant) Refractory chronic cough	• S-600918 (sivopixant) Refractory chronic cough	• S-812217 (zuranolone) Depression	
• S-109802 Post-stroke spasticity	• S-010887 Neuropathic pain	BPN14770 (zatolmilast)  Alzheimer's disease	<ul> <li>BPN14770 (zatolmilast)</li> <li>Alzheimer's disease</li> </ul>	● BPN14770*³ (zatolmilast) Fragile X Syndrome	
• S-151128	• S-120083	Alzifelifiel 3 disease	• Rizmoic*2	*3 Phase 2b/3	
Chronic pain	Inflammatory pain		Opioid-induced constipation (pediatric)	• SDT-001 Inattentive ADHD	
			*2 Phase 1/2	(pediatric)	
	• S-117957 insomnia		S-120083 Inflammatory pain		Out license S-0373 (rovatirelin)

## ■ New Growth Areas

Nonclinical	Phase1		Phase2	Phase3	Submission
• S-540956 Nucleic acid adjuvant	• <b>S-770108</b> Idiopathic pulmonary	• <b>S-237648</b> Obesity	• S-005151 (redasemtide) Acute ischemic stroke	• S-588410 Esophageal cancer	
	● S-588210	● S-588410	● S-005151	● SR-0379	
	Solid tumor	Bladder cancer	(redasemtide) Epidermolysis bullosa	Cutaneous ulcer	
	• S-309309	● ADR-001*4	● S-488210*5		
	Obesity	Decompensated liver cirrhosis	Head and neck squamous cell carcinoma		
		*4 Phase 1/2			
	Out Passes		● S-588410		
	Out license		Bladder cancer		
	• <b>S-723595</b> NASH		• S-222611*5 (epertinib)	*5 Phase 1/2	
			Malignant tumor		
			● S-531011*6	*6 Phase 1b/2	
			Solid tumor		

Spinocerebella Degeneration

## **Top-Line Strategy**

SHIONOGI will engage in total care for illnesses through a variety of approaches that include prevention, diagnosis, and conventional therapeutic drugs, with a focus on our priority fields of infectious diseases and psychoneurological diseases. In our overseas business, we plan to strengthen our businesses in Europe, the U.S., China, and elsewhere in Asia through expanded sales of our infectious disease drugs, building a stable foundation for earnings.

## Japan

## Meeting diversifying customer needs and executing on our disease strategy

Earning people's trust in SHIONOGI's products and services is of utmost importance in growing our top line. Toward that end, we must properly communicate information about our products and services so that healthcare professionals can understand their value in aiding patients.

In addition to accurately communicating information on our pharmaceuticals, we are working to strengthen the two-way communication skills of medical representatives (MRs) to enable better understanding of patients' concerns through dialogue with healthcare professionals. Utilizing hospital MRs and the online electronic MRs (e-MRs) that we put into place in fiscal 2021, we will accurately and quickly grasp the real needs and the future needs of opinion leader doctors and medical workplaces, and will connect these not only to the

growth of our current pharmaceutical business but also to the formulation of future disease strategies.

In July 2022, we placed the newly established New Business Promotion Department under the Integrated Disease Care Division, and consolidated this together with the Pharmaceutical Commercial Division, Regulatory Affairs Department, and the newly established Vaccine and Diagnostic Drug Department under the Healthcare Business Supervisory Unit. Through close coordination among these organizations in the Supervisory Unit, we will speedily incorporate understood medical needs into disease strategies and new business planning and will continue to offer solutions that contribute to solving patients' problems, further growing our top line.

## Expanding means of providing information to customers through digital technology

Healthcare professionals' means of acquiring information have rapidly diversified under the COVID-19 pandemic, making systems for providing information in a digital environment increasingly important. In fiscal 2021, SHIONOGI engaged in activities to promote the registration and use of our owned sites and of information provision platforms built under SHIONOGI's lead. These activities have significantly increased the number of people who access information digitally. In the current fiscal year, we plan to continue our focus on activities to increase the frequency of use.

Analyzing the activity logs generated through everyday use of the digital platforms will allow us to more quickly grasp changes in the needs and interests of healthcare professionals, and will lead to efficient activities such as prioritizing the presentation of needed information. Through a virtuous cycle of connecting data obtained through the increase in digital communication to more efficient and high-quality information provision, we will engage in information provision activities that align with customers' needs.

## **SHIONOGI Transformation**



Shinichiro Iwamatsu

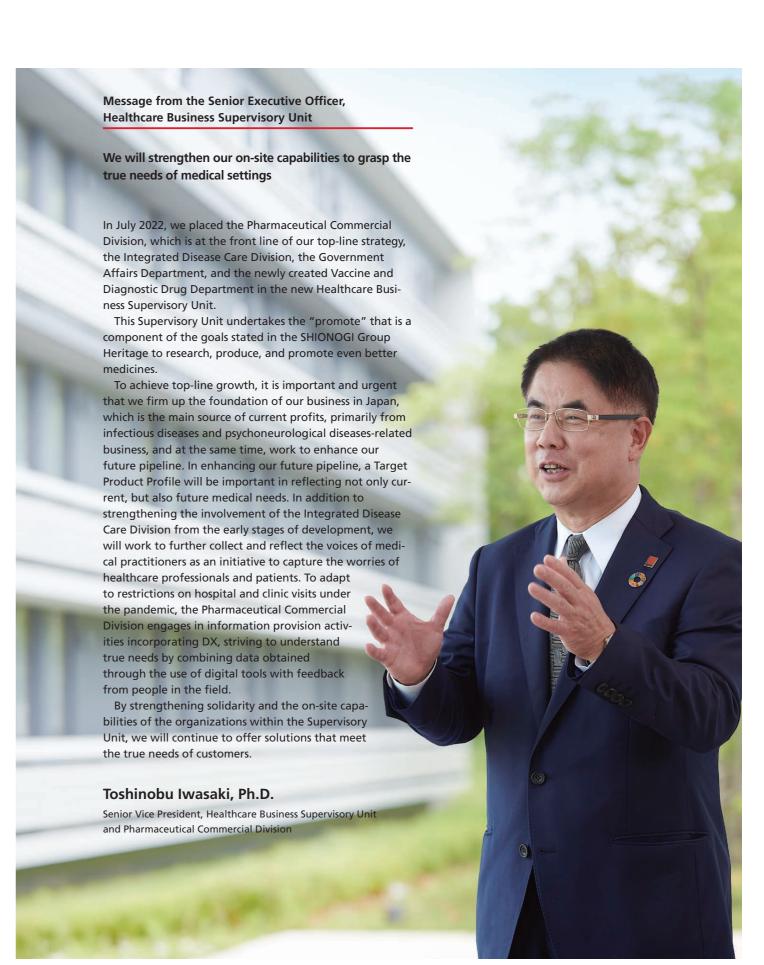
Digital Marketing Group Manager, New Product Planning
Department, Integrated Dis-

ease Care Division

Message from an employee

# Initiatives to construct a customer-centric information provision system utilizing digital technology

When developing digital tools as a means of providing information, our consideration focuses not on how individual tools are used but rather on development under a clear image of the entire system, integrated and used with maximum effectiveness. We believe that the key to integrating and analyzing the data obtained from digital tools and physical sales activities, and to making use of this data in activities, lies in how we can deliver information that meets the needs of healthcare professionals, with optimal timing. To that end, as we engage in our work we constantly think about the linkage of the digital and the real, in terms of what information will be handled by digital tools and what will be directly communicated from MRs.



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#### **Top-Line Strategy**

## Overseas

## The transformation of our global business to achieve the SHIONOGI Group Vision

Under STS2030, we have positioned the expansion of our global business as a key strategy. In the field of HIV, we are expanding business in partnership with ViiV Healthcare Limited. As partnering with governments and external support organizations will also be vital for cefiderocol, a growth driver in Europe and the U.S., we are further bolstering our bargaining power through specialized human resources. At the same time, for COVID-19-related items, such as the upcoming priority product S-217622, we will push ahead with transformation so that we

can provide these on our own in overseas markets. Toward this end, we will further strengthen collaboration among manufacturing, distribution, and marketing to achieve stable product supply, while undertaking proper inventory controls, cost reductions, and effective facilities investments. SHIONOGI will promote the expansion of its overseas business by developing a global system that enables flexible changes in business models, including in-house sales, partnering, and pull incentives, matched to conditions in specific regions and markets.

### Expansion of our Europe and U.S. businesses, centered on cefiderocol

As a leading company in the field of infectious disease, SHIONOGI has identified protecting people worldwide from the threat of infectious diseases as a key material issue (materiality). In our Europe and U.S. businesses, we are advancing efforts aimed at collecting and publishing real world data (RWD) evidence in clinical practice, as well as the improvement of access to healthcare. As a result of such actions, cefiderocol received a high economic value evaluation from the UK National Institute for Health and Care Excellence (NICE), and was approved for the UK's subscription-style payment model. Moreover, to improve access to drugs for the treatment of antimicrobial resistant infections in low- and

middle-income countries, we entered into partnership agreements with the Global Antibiotic Research and Development Partnership (GARDP) and Clinton Health Access Initiative (CHAI) and successfully created an environment in which cefiderocol can contribute to antimicrobial resistance (AMR) measures in 135 countries.

Establishing a sustainable business model for acute infectious diseases is not easy, as market scale fluctuates greatly in line with epidemics. Our aim is to promote maximization of the value of cefiderocol while flexibly making changes to its business model, to achieve both overseas business expansion and contribution to global health.

## **Toward expansion of our Chinese and Asian businesses**

Major changes in the environment have occurred in China, including the imposition of city lockdowns in response to the spread of COVID-19. We must flexibly respond to these in our business plans under STS2030. Currently, we seek to expand our infectious disease-focused new drug business by coordinating closely with Ping An-Shionogi Co., Ltd., our joint venture with the Ping An Group, through products including

cefiderocol, S-217622, and olorofim. We launched naldemedine in Taiwan in April 2022, and will continue working to aid patients suffering from opioid-induced constipation in Taiwan. We will further expand Shionogi Healthcare's OTC drugs in Asia as we push ahead to become a world-leading healthcare service provider.

## **SHIONOGI Transformation**



**Gareth Morgan** Shionogi Inc. Senior Vice President

Global Portfolio Management Manager Message from an employee

#### Innovative solutions for providing cefiderocol to low- and middleincome countries

Antimicrobial resistance (AMR), called a "silent pandemic," is already directly responsible for 1.3 million deaths through AMR infections, the majority of these in low- and middle-income countries. Providing access to new antibiotics such as cefiderocol in low- and middle-income countries has been a difficult challenge, but SHIONOGI has taken a major step toward establishing a new access model that assures responsible manufacturing and proper use. After over a year of discussions and negotiations, we have signed landmark license and collaboration agreements with the non-profit organization GARDP, which is tackling AMR, and the non-profit organization CHAI, which works to resolve access issues in low- and middle-income countries. There is still much to be accomplished, but we are on track to provide patients in 135 low- and middle-income countries with access to cefiderocol. Who knows how many lives we will save!

# Message from the Senior Executive Officer, **Supply Supervisory Unit** Delivering SHIONOGI Quality to people the world over

The Global Business Division is working to deliver SHIONOGI products and services to markets in Europe, the U.S., China, and elsewhere in Asia. And in July 2022, we launched the Supply Supervisory Unit as a new system, encompassing Group companies responsible for production. In addition to expanding the overseas sales ratio, which we set as a goal for STS2030 Phase 1, we will achieve our mission of delivering SHIONOGI products and services at the right quality, at the right price, and with the right information to people worldwide, and connect it to growing the top line.

To achieve this mission, we will pursue transformation of Creation, Speed, and Quality. Within Creation, we will not only expand the pipeline of products and services that we deliver to patients around the world, but we will also undertake the development of more efficient manufacturing methods and smart factories so that we can meet our necessary and sufficient supply responsibilities. To address markets where the infectious disease or other epidemic situation fluctuates drastically, we will transform our activities to always stay mindful of Speed without adhering to past ways of doing things. By earnestly tackling quality and legal compliance issues in pharmaceutical products, a topic frequently making news in recent years, we will continue our improvement efforts in the pursuit of Quality that does not embarrass the brand of SHIONOGI.

## Koji Hanasaki, Ph.D.

Senior Vice President, Supply Supervisory Unit and Global Business Division



## **Management Foundation Strategy**

To become a HaaS company, we must transform ourselves into a high-productivity organization that can create new value. Therefore, we are building a strong management foundation that can flexibly respond to rapid changes in the environment by changing the "structure," changing the "processes" that drive the structure, and developing the "human resources" that operate the processes.

## Reinforcing the foundation for achieving STS2030 through organizational restructuring

In order to respond to the rapidly changing business environment and social needs, and to provide comprehensive solutions to the problems faced by patients and society, it is important to continue to change into an organization that is capable of rapid and high-level decision-making and efficient business execution. In July 2022, SHIONOGI revised its organizational structure and shifted to a governance structure in which each major value chain (R&D, healthcare business, supply, and corporate) is its own supervisory unit.

Each supervisory unit oversees related organizations, and by deepening discussions across divisions and by mutually sharing opinions compiled by each division, we will promote the medium-term business plan with a greater sense of unity and make prompt and decisive decisions.

We have been implementing a system to accurately assess business risks, both positive and negative, and make decisions in a timely manner according to the level of business risk. However, by reorganizing the organization into four broad areas of jurisdiction, unlike in the past, we are clarifying where the responsibility for business execution lies and further accelerating decision-making.

#### ■ Definition of business risk

### **Business risk**

Targets (performance, etc.)

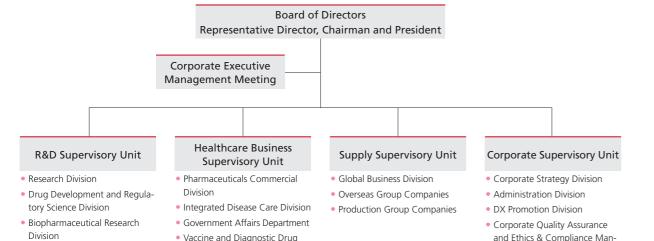


- Decision-making in business involves uncertainty to a greater or lesser extent, and the impact can be large or small.
- Understanding the magnitude of decision-making "range" (i.e., business risk) from the perspective of impact and uncertainty and using this information to improve the quality and speed of decision-making.

agement Division

• Corporate Group Companies

#### ■ Organizational Chart



Message from the Senior Executive Officer, Senior Vice **President of the Corporate Supervisory Unit** The Corporate Supervisory Unit contributes to maximizing results produced by each value chain and promoting STS2030 As the environment surrounding business and the needs of society change rapidly, companies must continue to update their management strategies and reconsider whether their allocation of management resources (people, goods, money, time, and information) are being used effectively and efficiently. The Corporate Supervisory Unit will assist each department in improving the accuracy of its planning by managing management resources in an integrated manner and proposing allocations that will maximize the results produced by each department in the On the other hand, it also serves as a check function on risk management. The impact of COVID-19 has caused various paradigm shifts globally. In order to realize SHIONOGI's transformation and promote STS2030 in the post-COVID era, it is important to discuss both positive and negative risks thoroughly in each department, make proposals that maximize results, and make appropriate, balanced, and high-quality decisions promptly. Each organization under the Corporate Supervisory Unit will contribute to the realization of STS2030 by providing full support to all departments of SHIONOGI to improve the quality and speed of decision-making and to ensure efficient operations. Noriyuki Kishida Corporate Supervisory Unit

Business Development Department

• Investment Strategy Department

• R&D Group Companies

## **Secure Human Resources to Support Growth**

With a view to realizing the SHIONOGI Group Vision, we have set forth our vision for human resources that our employees should aspire to as the "Shionogi Way: Be the best that you can be to take on new challenges." To see to it, that each one of our employees grows into human resources that materialize this Shionogi Way, in addition to facilitating the permeation of the "SHIONOGI Group Values" that are indispensable in the achievement of the SHIONOGI Group Vision through training and other endeavors, we promote the acquisition of "Capability/Knowledge" that constitute the skills that all of our members should outfit themselves with as well as the skills required in their individual roles. Moreover, to stimulate employees to autonomously refine their skills and grow into human resources with exceptional talent, we have enhanced our programs for encouraging self-development and new challenges while simultaneously introducing more flexible work systems that allow for learning outside of work. In these and various other aspects, we are pursuing the development of an environment for our human resources.

Initiatives	Related indicators	Current progress	-	Remaining challenges/needs
Secure diverse human resources	<ul> <li>Fulfill necessary human resources in each of our organizations</li> <li>Number of employees who took advantage of internal open recruitment: 34</li> <li>Number of mid-career hires: 34</li> </ul>	<ul> <li>Consolidate and visualize human resource data that takes full advan- tage of HR management systems</li> <li>Promote fluidity in internal human resources</li> <li>Present basic skill requirements necessitated by each organization</li> </ul>	<b>)</b>	Reinforce the integration of human resource data and analytical capability with a view to building an optimum human resource portfolio
Develop exceptionally talented human resources	<ul> <li>Manager training 100 hours/ employee, total cost: ¥55 million</li> <li>Percentage of users of the self-invest- ment assistance program: 44.6%</li> <li>Human resource pool that oversees future management (number of Associate Corporate Officers): 20 (cumulative number over last two years)</li> <li>Number of IT/digital human resources developed: 44</li> <li>Number of side work program applicants: 59</li> </ul>	<ul> <li>Implementation of all-manager reinforcement program</li> <li>Establishment of a system for providing education to meet autonomous growth aspirations that are focused on our self-investment assistance program</li> <li>Development of human resources necessitated through various forms of training</li> </ul>	<b>)</b>	Evolution of educational programs that allow for the autonomous utilization of Off-JT/OJT for the purpose of securing human resources with exceptional talent
Foster an envi- ronment and cul- ture in which everyone can work comfortably	<ul> <li>Continually implement programs to improve workstyles</li> <li>Ratio of female managers: 12.4%</li> <li>Childcare leave acquisition rate: Women: 100%; Men: 51.4%</li> </ul>	Introduce flextime system and remote work system with no core times to support diverse work styles     Introduce workweek with voluntary three day weekends	-	Enhance diverse, flexible work environments to meet the careers and needs of each individual employee
Healthcare and occupational safety and health	<ul> <li>Improve health literacy</li> <li>Health checkup implementation rate: 100%</li> <li>Ratio of employees who smoke: 7.1%</li> <li>Severity rate: 0.0049</li> <li>Frequency rate: 0.20</li> </ul>	<ul> <li>Establish Shionogi Group Health Policy and promote no-smoking</li> <li>Implement remedial measures as a result of stress checks</li> <li>Work constantly toward improvement with the goal of 0 work- place accidents</li> </ul>	<b>)</b>	Promote better health management by beefing up non-smoking initiatives and health promotion policies



Development of strong individuals capable of emerging victorious amid global competition and establishment of organizations that leverage the diversity of its human resources through the materialization of the Shionogi Way

## Vision for SHIONOGI's Human Resources (Shionogi Way)



## The goals of the Human Capital Strategy Office

The roles of the Human Capital Strategy Office, which was established in July 2022, are to maximize our human capital through devising and executing HR strategies aimed at achieving STS2030 and presenting that maximized human capital to our various shareholders.

Our view at SHIONOGI is that "people are the source of competitiveness." Investment in human capital is indispensable for the purpose of elevating our corporate value over the medium to long term. We have been introducing a myriad of programs and systems in recent years based on that idea. Examples of these are voluntary three day weekends and the easing of side work program standards, which we started applying in fiscal 2022. Even should we experience a temporary shortage of internal resources, we can absorb various forms of knowledge, personal networks, skills and other elements outside of our organization. Our expectation is that ensuring reskilling will end up yielding internal benefits and greater potential for innovation in our organization as a whole. Moreover, we have given employees who seek to temporarily reduce their workload due to life events the ability to take three days off per week. We believe that this flexible workstyle will lead to employee retention and enable us to secure diverse human resources.

Going forward, we will continue to do our utmost to acquire human resources that "be the best that they can be to take on new challenges," which constitutes our vision for human resources, and present the results of those efforts to our stakeholders.

### HR system reforms whose aim is to have diverse human resources play active roles in accelerating the growth of SHIONOGI

As employee awareness and needs surrounding lifestyles and career-building become increasingly diverse, it will be important to put in place an environment that employees find easy to work in and boost their individual sense of satisfaction in order to have them fully manifest the ability that they possess and elevate their productivity to do their part for SHIONOGI's growth.

In fiscal 2021, SHIONOGI introduced a remote work system, abolished core times for flextime workers, and even reduced designated work times by 45 minutes per day. We have preserved compensation for the amount of time reduced in the form of disbursing it as discretionary pay, enabling employees to efficiently work in shorter amounts of time. Our expectation is that these initiatives, by virtue of allowing diverse human resources to flexibly choose workstyles, will link to the improved awareness of work efficiency and the acquisition of exceptional talent by each individual employee. Employees who were forced to limit their work due to childrearing, nursing care and other life events have in fact are now able to work full-time. Moreover, by using their work time efficiently, other employees are able to create time for learning and to take on the challenge of new job duties. We believe that in this and other ways, the environment that we now offer is easy for many employees to work in and fosters a sense of satisfaction in them.

Additionally, in April 2022, we introduced voluntary three day weekends and eased side work program standards. The latter in particular stood out in that we approved applications from roughly 100 employees as of July 2022. Those employees are now building work experience at their new second sites of employment, such as that in consulting, IT, education and learning assistance.

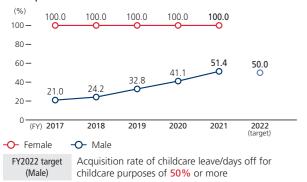
#### Ensuring diversity through HR and labor administration

In order to develop a workplace environment that its employees find easy to work in and fosters a sense of satisfaction in them, in addition to reforming its HR and work shift systems, SHIONOGI is also promoting the reform of various programs. In recent years, we have implemented a self-investment assistance program with an upper limit of ¥250,000 per annum that utilizes funds resulting from a revision of individualistic allowances and other areas and we have enhanced options for work locations by eliminating the practice of transferring employees without their families following the popularization of remote work. Additionally, for each division, we are verifying the outcomes of enhancing programs with the use of engagement survey results and other data and ascertaining challenges and needs to facilitate further improvements to our workplace environment. Alongside these and other efforts, we are continuously tackling the improvement of our workplace environment and enabling diverse work styles. In turn, our indicators such as the ratio of female managers and the childcare leave acquisition ratio for male employees have also continuously risen.

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## **Secure Human Resources to Support Growth**

#### ■ Acquisition rate of childcare leave



#### ■ Ratio of female managers



### The goals of the Career Development Office

The mission of the Career Development Office, which we started up in July 2022, is to contribute to the achievement of STS2030 through assisting with the skill development and career-building of the employees who will materialize the "Shionogi Way."

This fiscal year, based on our approach that "people are the source of competitiveness," we will further bolster our twopronged initiative of "further clarifying the human resources and skills that are needed" and "realizing personal growth through autonomous learning." For the first of those prongs, due to the challenges faced by SHIONOGI becoming increasingly complex and necessary human resources and skills also becoming increasingly diversified as a result of dramatic changes in our business environment and greater society, we seek to further clarify the human resource requirements and skills necessitated by each of our organizations and operations, push forward with the establishment of a framework that allows for the provision of optimal educational programs, and tie those efforts into the development of human resources that fulfill those various requirements. For the second prong of that initiative, we will evolve upon a unified educational framework that aims to realizing the leveling-up our employees, which has yielded a certain degree of results through our efforts in the last several years. Using "autonomy" and "actual practice" as our keywords, we will proceed to facilitate the development of a framework that enables employees to personally identify the skills that are ideal for them to build on and required of them and to autonomously study for the purpose of acquiring those skills.

#### Acquiring the skills needed to achieve STS2030

To achieve STS2030, it is absolutely necessary that we trigger a discontinuous series of changes in the form of "providing value from the perspective of healthcare services overall," "improving productivity through technological innovations and data utilization" and "significantly increasing our overseas sales ratio." Through ample training intended to reinforce managers as well as systems for developing management executive candidates at an early stage, we are bolstering business creation/value maximization, overseas handling and DX management skills. Simultaneously, through handpicking participants from our entire employee pool and conducting open-

recruitment training, we are tackling the devising of a transformation that leverages both IT and digital platforms and endeavoring to utilize data science. In this and other ways, we are carrying out training suited to each employee hierarchy and, in doing so, are working towards developing human resources to drive forward change.

#### Initiatives aimed at employee career development

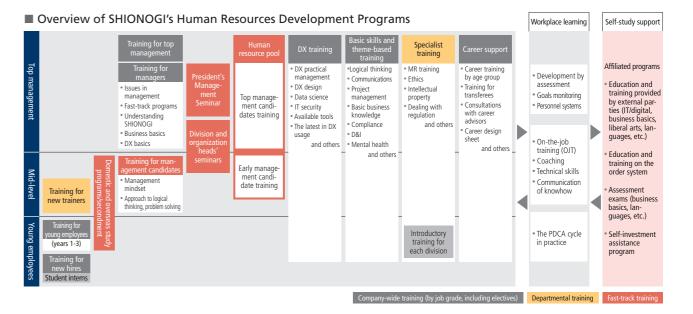
At SHIONOGI, we aim to have each employee demonstrate their individual characteristics and strengths and tie their personal growth through their work into the growth of their organization. With a view to the startling environmental shifts both inside and outside our company and the diversification of career challenges, based on the concept of "enabling all employees to autonomously think about their careers and translate that into action when turning points in their individual careers require them to do so," in fiscal 2021, we revised the career training that we had implemented according to age group (30s/40s/50s) until now and improved it so that any employee can undergo that training regardless of their age.

In fiscal 2022 as well, under the leadership of the Career Development Office that was newly established in the Human Resources Department, we will continue to further enhance career development and growth assistance for employees.

Main initiatives	Number of viewers/participants			
Constantly providing E-learning vid- eos that enable employees to study fundamental methods of approach- ing and outlining their careers	42% (2,216 out of 5,329 employees)			
Periodically holding workshops for each career challenge	Workshop record in fiscal 2021: 2 themes, 9 workshops, 87 participants Workshop schedule in fiscal 2022: 6 themes, total of 25 workshops sched- uled, approx. 600-participant capacity			
Offering career interviews by inter- nal career advisors that address individual career challenges	Interview record in 2021: 294 interviewees Interview schedule in 2022: Approx. 250- 300 interviewees (approx. half of workshop participants envisioned to undergo interview)			

#### Initiatives for cultivating diverse strengths

In fiscal 2021, we endeavored to enhance self-learning training (Affiliate Program) that assists employees with their self-development



so that they autonomously refine their skills and grow into human resources with outstanding talent. To be specific, we have intensified our provision of programs that positively serve the development of the knowledge, skills and mind that link to the materialization of the Shionogi Way and the achievement of STS2030. As a result of pro-

**Promoting health management** 

We at SHIONOGI view health management as part of our corporate strategy. Our aim is to establish a workplace where each individual employee can maintain their physical and mental health and demonstrate their ability to the fullest. With the Senior Executive Officer and Head of the Administration Division as the supervisor in charge of EHS, we continue to carry out health maintenance and promotion measures with the cooperation of health insurance societies. The progress of initiatives is verified at the Corporate Executive Management Meeting, meetings of the "Central EHS Committee" that is in charge of EHS at SHIONOGI, and the "Health Management Project Promoters' Meeting" held by personnel overseeing the promotion of collaborative health, where further initiatives are reviewed. In fiscal 2021, we promoted health management from the following three standpoints stated in the Shionogi Group Basic Health Policy: "improving the health literacy of employees," "supporting the maintenance and improvement of physical and mental condition of employees and their families" and "sustaining and continuously improving a supportive and productive working environment, as well as the employees' home environment."

## Improving the health literacy of employees: Implementing E-learning

Based on the impact of the COVID-19 pandemic on work styles and other aspects of modes of living, in fiscal 2021, we implemented E-learning covering the dual themes of "food and sleep" (The participation rate for this E-learning was 82% for "food" and

viding those programs to employees in beneficial forms, including the establishment of SHIONOGI-specific courses and the provision of training that cannot be applied for on an individual basis, approximately 1,000 employees took advantage of self-learning training in fiscal 2021, and continue their efforts to acquire outstanding talent.

83% for "sleep."). After participating, employees are given a verification test to entrench what they learned, one of the ways we are endeavoring to improve the effectiveness of that E-learning.

# Supporting the maintenance and improvement of physical and mental condition of employees and their families: Further promoting no-smoking

We are implementing a "Smoke-Free Promotion Project" with the aim of achieving a zero smoking rate among our employees as espoused in the SHIONOGI Group's Smoke-Free Declaration. This project involves the aggressive implementation of activities such as publishing a "no-smoking email magazine" on the 22nd of every month and following up on smoke-free challengers who volunteer themselves for that challenge. As a result, the ratio of employees who smoke at SHIONOGI decreased from 11.0% in fiscal 2020 to 7.1% in fiscal 2021.

#### Sustaining and continuously improving a supportive and productive working environment, as well as the employees' home environment: Implementing measures based on the results of stress tests

SHIONOGI scores better than the nationwide average in stress tests conducted every year. In order to preserve and improve a more favorable workplace environment, we hold hearings on the situation at organizations with those that scored relatively low and conduct training and other measures for improvement.

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## **Protect People Worldwide from the Threat of Infectious Diseases**

Materiality

One of the material issues (materiality) that SHIONOGI prioritizes in particular is "protect people worldwide from the threat of infectious diseases." We feel that above anything else, the realization of that materiality constitutes our mission as a leading company in the area of infectious diseases. At SHIONOGI, we aim to simultaneously achieve the resolution of challenges surrounding such diseases and the establishment of a sustainable business model.

Initiatives	Related Indicators	Current Progress	-	Remaining Issues/Needs
Providing products and services for acute infectious diseases	<ul> <li>Number of acute infectious disease-related pipelines: 4 products</li> <li>Number of serious infectious disease-related pipelines: 2 products</li> <li>Number of countries adopting subscription-type reimbursement model: 2</li> <li>Number of countries where cefiderocol can be supplied through partnership with GARDP and CHAI: 135</li> <li>Number of contracts for wastewater-based epidemiology (WBE) survey services</li> </ul>	(1) R&D for solutions for a wide range of acute infectious diseases  • Influenza virus,     SARS-CoV-2, norovirus,     RS virus, and other diseases.  • Stockpiling of Xofluza by the national government  (2) Handling of antimicrobial resistance (AMR)  • Launch of cefiderocol in U.S. and Europe  • Adopting subscription model for cefiderocol in two countries	<b>)</b>	(1) Provide solutions for a wide range of acute infectious diseases  • Provide solutions for various viruses  • Provide therapeutic drugs that are effective and safe against COVID-19  • Maximize the value of Xofluza and prepare against mass outbreaks of influenza virus infections  (2) Further handle serious infectious diseases that include AMR bacteria  • Expand the number of countries of sale and countries adopting the subscription model  • Create new solutions
Providing products and services for chronic infectious diseases	Number of HIV-related products in pipeline: 1 product     Contributing to improvement of QOL with cabotegravir     Developing antimycobacterial disease drugs, antimalarial drugs and a malaria vaccine	(1) Initiatives targeting HIV infections  • Launch of long-acting therapeutic and preventive drugs  (2) Initiatives targeting mycobacterium tuberculosis (TB)/Nontuberculous Mycobacterial (NTM) diseases  • Research into new action mechanism mycobacterial treatments  (3) Initiatives targeting malaria  • Research into innovative antimalarial drugs	<b>)</b>	(1) Initiatives targeting HIV infections  • Further improving QOL through remedying side-effects and drug administration frequency  (2) Initiatives targeting mycobacterium tuberculosis (TB)/ Nontuberculous Mycobacterial (NTM) diseases  • Providing therapeutic drugs that are effective against resistant bacteria  (3) Initiatives targeting malaria  • Handling resistance to antimalarial drugs  • Providing an effective vaccine
Building a vaccine business	<ul> <li>Providing a COVID-19 vaccine</li> <li>Establishing vaccine manufacturing facilities</li> </ul>	<ul> <li>(1) Building a vaccine business</li> <li>Developing a COVID-19 vaccine</li> <li>Establishing manufacturing facilities aimed at stable supply</li> </ul>	•	(1) Building and bolstering a vaccine business  • Providing a COVID-19 vaccine  • Providing a nasal vaccine  • Providing a combined, polyvalent vaccine  • Providing a universal vaccine  • Expanding the vaccine to cover other illnesses

Value Created

Provision of wide-ranging solutions and contributions to protect people worldwide from the threat of infection through total care as a leading company in the area of infectious diseases

### Initiatives targeting acute infectious diseases

SHIONOGI continues to create innovative infectious disease treatment drugs and provide them to society. These include the anti-HIV drug dolutegravir and cabotegravir, the influenza antiviral drug Xofluza, and the siderophore cephalosporin antibiotic cefiderocol. It is the possession of knowhow cultivated over more than 60 years of continued research and development for infectious diseases that has enabled us to bring forth new drugs in that domain on an ongoing basis. Today, we continue to leverage that knowhow in promoting initiatives targeting the creation and provision of wide-ranging solutions that include the likes of wastewater-based epidemiology, preventive vaccines and diagnostic drugs in addition to therapeutic drugs to counter acute infectious disease pathogens such as the influenza virus, the norovirus, the RS virus and the like.

#### Help to tackle serious infectious diseases including AMR bacteria

By bringing forth new drugs to counter serious infectious diseases that include AMR bacteria, while simultaneously promoting the proper use of infectious disease treatments, SHIONOGI prevents the outbreak of new resistant bacteria and viruses and continuously works towards ensuring that patients can keep receiving treatment both now and in the future.

AMR is a real, pressing global threat. It is estimated that if there continues to be no measures taken against it, the number of resulting deaths will exceed those from cancer by the year 2050, and will reach 10 million people per year. As a leading company in the area of infectious diseases, SHIONOGI is reinforcing its cooperation with national governments, international agencies, pharmaceutical companies, doctors who prescribe antibiotics and other stakeholders to push forward with initiatives geared towards AMR countermeasures.

#### Providing cefiderocol

Among AMR, gram-negative bacteria, which has gained resistance to existing drugs, has a high incidence rate and is exhibiting a greater trend of infection, is cited as a priority

challenge in healthcare. As a promising treatment option to address that challenge, we created cefiderocol, the world's first siderophore cephalosporin antibiotic. We initiated sales of cefiderocol in the U.S. and Europe in 2020, after which it was included on the WHO's Model List of Essential Medicines.

Moreover, cefiderocol was granted application of New Technology Add-on Payment (NTAP), a system of reimbursing hospitalization and treatment costs to hospitals for encouraging the introduction of new medical technology, by the U.S. Department of Health and Human Services. This is leading to improved access to drugs for patients who require cefiderocol. Furthermore, a subscription-type reimbursement model (a system in which countries can receive antibiotics as necessary in exchange for the payment of fixed remuneration from their national government to SHIONOGI) was adopted in both the UK and Sweden.

Up until now, numerous patients, particularly those in the U.S. and Europe, have benefited from the use of cefiderocol. Meanwhile, however, AMR has been exerting even more serious effects on low- and middle-income countries, not just their developed countries. We therefore executed a partnership agreement with GARDP and CHAI for the global provision of cefiderocol to low- and middle-income countries as well. This represents the first agreement that a pharmaceutical company and NGOs that tackle public health as a priority issue have entered with respect to therapeutic drugs for serious bacterial infections. We believe it to be a significant step towards addressing the challenges posed by AMR. While also promoting initiatives by the three parties to this agreement, going forward, we will continue to endeavor towards ensuring that we can get such medicines into the hands of patients who need them without delay.

Please see p. 65 for details on initiatives for promoting proper use and p. 63 for details on improving access to cefiderocol

#### Initiatives targeting serious infectious diseases

In May 2022, SHIONOGI executed a new agreement with F2G for the development and exclusive distribution of olorofim, a

#### ■ Actions that SHIONOGI believes are necessary in order to tackle the problems posed by AMR



Creating predicable, sustainable markets for AMR therapeutic drugs with the introduction of new value evaluation for pull incentives and insurance reimbursement



Harmonizing international regulations on the development and approval of new



Building networks that enable clinical trials and research with greater efficiency



Promoting the proper use and management of antibiotics, including that for animals, and surveying resistant bacteria epidemiology over time



Creating new effective antibiotics on our own or in cooperation with other companies



Mitigating the impact of antibiotic manufacturing processes on the environment

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### Protect People Worldwide from the Threat of Infectious Diseases

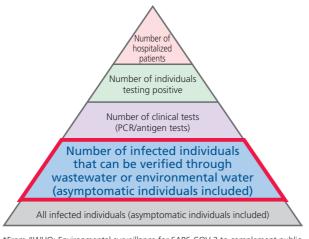
new antifungal drug intended to treat invasive aspergillosis, in the European and Asian regions. Invasive aspergillosis is a fungus infection with a high case mortality rate that occurs when the functions of the immune system decline. Expectations are that olorofim, given its new action mechanism, will provide a new treatment option for patients who cannot use existing therapeutic drugs due to having resistance to them or for tolerance or drug interaction-based reasons.

## Initiatives geared towards wastewater-based

It is difficult to predict exactly when and where pandemics of infectious diseases will occur and what kind of pathogens will be behind them. Wastewater-based epidemiology (WBE) surveys are an effective method of detecting such signs early on. As such, they are anticipated to be used as an objective indicator when taking preventive measures against the spread of

infections. Viewing outbreak projections as a key element in realizing total care for infectious diseases, in June 2021, we commenced the provision of WBE survey services for COVID-19. Through these services, using high-sensitivity detection technology developed through joint research with Hokkaido University, we regularly monitor the concentration of the virus content in wastewater and survey the state of infection in the affected region. These surveys were also implemented in the Tokyo 2020 Olympic and Paralympic Village, and was reported to have prevented cluster infections from occurring when paired with individual tests.

Additionally, in January 2022, SHIONOGI and Shimadzu Corporation established AdvanSentinel, a joint venture intended to monitor wastewater and otherwise assess public health risk. AdvanSentinel aims to do its part for infection countermeasures by establishing an all-Japan framework aimed at efforts such as ascertaining the next pandemic beyond COVID-19 and the risk to public health that it poses.



#### \*From "WHO: Environmental surveillance for SARS-COV-2 to complement public health surveillance - Interim Guidance" following partial modification

## epidemiology (WBE)

## AdvanSentinel

#### Implementing wastewater monitoring in Japanese society at an early stage

- Partnering with Shimadzu Corporation
- Technology that is not susceptible to the effects of bias in clinical tests and is required in ascertaining the state of infection of society as a whole with greater accuracy
- Developments in social implementation in the U.S. and Europe as triggered by the pandemic

#### Initiatives for fiscal 2022

- Activities to popularize and build evidence for WBE surveys through supplementary budgets and Ministry of Land, Infrastructure, Transport and Tourism (MILT) projects
- Selling kits for new methods with super-high sensitivity that can

## Developing solutions for the three major and other chronic infectious diseases

Among chronic infectious diseases, the three major infectious diseases in particular constitute a massive threat and challenge from the standpoint of global health, and are positioned as infectious diseases that necessitate countermeasures in order to achieve SDG Goal 3: Good Health and Well-Being. As a leading company in the area of infectious diseases, in addition to expanding its preexisting forte of HIV research to that on the three major infectious diseases, SHIONOGI tackles these challenges through various forms of collaboration with external parties.

#### Initiatives targeting HIV

Since discovering *Tivicay* (dolutegravir), a highly effective, highly safe HIV integrase inhibitor with minimal risk of drug resistance, SHIONOGI has continued to tackle HIV infections. By keeping up the challenge of addressing troubles experi-

enced by patients, we have successfully mitigated side effects and reduced drug administration frequency and otherwise made considerable contributions to improving the QOL of HIV patients while preserving the effects of drug treatment.

For the mitigation of side effects, the adoption of dolutegravir as key drug made it possible to treat patients with a two-drug combination. In turn, this led to the launch of Juluca (dolutegravir + rilpivirine) and Dovato (dolutegravir + lamivudine). Today, prescriptions of this two-drug treatment centered on Dovato, which was added to the U.S. guidelines on the management of HIV infection, are expanding.

For the reduction of drug administration frequency, SHIONOGI discovered a long-acting formulation of the HIV integrase inhibitor cabotegravir (generic name). Given the expectation that the significant reduction in the number of days taken per year will help improve patient QOL and adherence to the drug regimen, there are considerable patient and

medical institution needs that are expected to translate to a larger market for long-acting pharmaceuticals. Prolonged action preparation with the simultaneous use of cabotegravir and rilpivirine (U.S. product name: CABENUVA) enables treatment with administration intervals of once every two months. This is being supplied to a large number of countries, starting with the U.S. and European nations. Additionally, regarding uses intended to prevent HIV infection, while it was necessary up to now to ingest oral medication daily, the launch of Apretude (a cabotegravir prophylaxis) has made it possible to prevent HIV infection with bimonthly administration.

Presently, drug administration intervals are once every two months for both treatment and prevention. We will continue our research and development for new drugs with the aim of prolonging those intervals even further to once every three or six months. S-365598, which SHIONOGI out-licensed to ViiV in fiscal 2021, is a compound expected to prolong those intervals to three or more months. Nonclinical studies are currently underway at ViiV with the goal of commencing clinical trials in fiscal 2022.

#### Initiatives targeting mycobacterium tuberculosis (TB) and Nontuberculous Mycobacterial (NTM) diseases

Mycobacterial diseases are caused when patients are infected with mycobacteria (mycobacterium TB and NTM). In recent years, a rise in the number of such patients has been reported in developed countries, Japan included. As existing therapeutic drugs involve long treatment times and do not yield sufficient therapeutic effects, hopes are being placed on the development of new, highly effective drugs.

In May 2018, SHIONOGI commenced joint research with

Hsiri Therapeutics with the goal of discovering drugs with new mechanisms of action to treat mycobacterial diseases, and has since pursued research on drug discovery together. In October 2019, as an endeavor to further bolster this joint research, we entered a new licensing agreement aimed at the discovery of therapeutic drugs for mycobacterial diseases that have different mechanisms of action.

#### Initiatives targeting malaria

According to a report by the WHO, in 2020, over 240 million people developed malaria during the year, predominantly in tropical regions. Moreover, this infectious disease took the lives of more than 600,000 people that year, most of which were children aged five and under. While the number of malaria patients had been trending downwards due in part to improved public health, that trend has reversed in recent years, and strains resistant to mainstay drugs are currently spreading. Additionally, the habitats of the Anopheles mosquito, a known carrier of malaria, have expanded due to the impact of climate change, with concerns that infection will possibly spread to nations in the northern hemisphere, including Japan and North America. SHIONOGI has been promoting drug discovery efforts by establishing a collaborative system with Nagasaki University since 2019 and with the National Institute of Infectious Diseases and Kitasato University since 2020. Going forward, we will continue to bolster our collaboration as we aim to discover innovative antimalarial drugs.

Please see the below website for details on the WHO report. https://www.who.int/teams/global-malaria-programme/ reports/world-malaria-report-2021

## Developing vaccines aimed at total care for infectious diseases

The COVID-19 pandemic resulted in elevated levels of interest in vaccines. The fact is that ever since the discovery of the smallpox vaccine by Edward Jenner, vaccines against numerous infectious diseases have been put into use over our long history. For years, it has been an earnest wish at SHIONOGI to move into the vaccine business with a view to realizing total care for infections that goes beyond therapeutic drugs. By welcoming UMN Pharma as a wholly-owned subsidiary of SHIONOGI, we have taken a major step towards our transformation into a HaaS\* company.

We have been moving along with vaccine development efforts with the use of BEVS, a recombinant protein vaccine manufacturing technology owned by UMN Pharma that uses viral antigen proteins. As a technology, BEVS is well-suited to high-speed, low-cost mass production, with multiple products having already been approved and put to use. For that reason, it is known as a technology whose effectiveness and safety have already been established. Furthermore, SHIONOGI is the sole company in the world to have established rhabdo-free insect cell cultivation technology without the inclusion of rhabdoviruses,

which we recognized as one of our competitive advantages.

At present, we have been tackling the development of a COVID-19 vaccine with priority. At the same time, we are also moving along with preparations to divert that vaccine to those for influenza virus, pneumococcus bacteria, RS virus and other acute infectious diseases and to develop mixed vaccines. Furthermore, we are also working towards developing nasal vaccines in addition to general intramuscular injections. As of now, we are pursuing nonclinical studies for nasal vaccines targeting COVID-19 and influenza virus infections. Nasal vaccines have the merits of allowing immunity to be effectively induced in the respiratory mucosa, the area that becomes infected, as well as in the entire body, and not necessarily requiring administration using an advanced medical care system or by healthcare professionals. To accelerate the development of these vaccines, in April 2022, we jointly established a research department with Chiba University. Endeavors aimed at reinforcing our vaccine business continue to progress steadily.

\* Healthcare as a Service: Provide a range of healthcare services in line with customer needs, rather than only providing pharmaceuticals

## Improve Social Productivity and Extend Healthy Lifespans

Materiality

Around the world, the average lifespan continues to increase thanks to improvements in public health and advances in medical technology. How to extend healthy lifespans—the period during which people can live without restrictions on daily living due to health issues—and how to lessen differences from average lifespan are matters that SHIONOGI has identified as material issues. In the fields of psychoneurological disease and pain, factors that threaten healthy lifespans in developed countries and other aging societies, we will undertake improvement of the societal environment and the provision of products and medical services that go beyond conventional medicines, to help achieve a society of healthy longevity in which all can enjoy more rewarding lives.

Initiatives	Related Indicators	Current Progress	Remaining Issues/Needs
Creation of products and services for psychoneuro- logical diseases, which have a high level of unmet medi- cal needs	Number of psychoneurological diseases-related pipelines: 7 products	<ul> <li>Provision of ADHD medicines with differing mechanisms of action</li> <li>Sales alliances for insomnia thera- peutic drugs</li> <li>Development and sales alliances for therapeutic digital apps (ADHD, insomnia)</li> </ul>	Provision of additional support and new treatment options for psychoneu- rological disease patients
Provision of optimal treatment choices for the causes of pain	• Number of pain-related pipelines: 3 products	Development of pain therapeutic drugs with different mechanisms of action	Provision of treatment options with mechanisms of action different from those of existing medicines
Securing of new assets to deal with the super-aging society	Number of oncology-related pipelines: 5 products	Continued development of the cancer area pipeline	Provision of more effective solutions optimized for individual patients
Programs to promote public understanding of disease traits and the problems of people affected	Number of educational activities held via webinars, etc.     Number of support services pro- vided in the area of developmen- tal disorders	<ul> <li>Achieved the target amount of crowdfunding for initiatives to support persons with disabilities (educational comics to future healthcare professionals)</li> <li>Conclusion of a business coopera- tion agreement with various municipalities regarding a bright future for children</li> </ul>	Total support for patients with disabilities Provision of enhanced support for social issues involving developmental disorders Further strengthening of cooperation with municipalities and educational organizations

**Value Created** 

Contribution to a society in which everyone can live longer, more fulfilling, and more active lives

## Achievement of medical services tailored to individual concerns

Under STS2030, SHIONOGI is advancing initiatives to solve social issues with a focus on the areas of the psychoneurological diseases and pain that threaten healthy lifespans, while also battling the threat of infectious diseases that lessen people's average lifespans. With the aim of achieving a society in which everyone can live longer, more fulfilling, and more active lives, we have provided therapeutic drugs to treat depression, ADHD, and pain. Because CNS disorders are caused by a combination of factors, solving all issues with a single solution is difficult. Solutions that consider the environment and the symptoms of each individual patient are neces-

**P** Observe Communicate Diagnose Cure

Bringing about a world in which patients can receive the appropriate

healthcare products and services in a timely manner.

an image for ourselves as a HaaS company that provides wide-ranging healthcare services extending beyond conventional prescription drugs, SHIONOGI will provide a wide range of solutions that go beyond conventional pharmaceuticals to

sary. Acting under the concept of total care and setting out

address not only treatment but also disease awareness programs, prevention, and diagnostics. We do so with the aim of bringing about a world in which patients can receive the healthcare products and services appropriate for each patient to solve his or her issues in a timely manner.

### Development of solutions optimized for individual patients

In the area of psychoneurological and other CNS disorders, mechanisms of pathology remain largely unknown, and many patients do not get the full therapeutic effect of treatment due to the complex factors behind onset. In some cases, efficacy can be realized through therapeutic drugs with different mechanisms of action, yet some patients may be unable to continue medication due to side effects. Two applications currently in development, insomnia therapeutic

app from SUSMED Co., Ltd. and ADHD digital therapeutic app AKL-T01(approved in the U.S.) from Akili Interactive Labs, Inc., are examples of solutions that embody the HaaS concept to meet the needs of such patients. By providing innovative treatment options that go beyond conventional medicines, we will contribute to the enhancement of productivity and QOL for patients and their families.

### Toward the achievement of the SHIONOGI Group VISION

Under STS2030. SHIONOGI seeks to undergo a transformation from a drug discovery-based pharmaceutical company to a HaaS company. To expand the breadth of our existing business and achieve this transformation, collaboration with a variety of partners in industry, government, and academia is vital. In July 2022, we reorganized the company's structure and established the Investment Strategy Department to handle strategic investment outside the company and further strengthen co-creation from the research and development stage onward.

To strengthen the vaccine business that we entered into in 2019 as well as the diagnostic drug business that is indispensable in prevention and prediction, we consolidated the Vaccine Business Department and the business functions of the Biomarker R&D Department to establish the Vaccine and Diagnostic Drug Department. We have placed the Diagnostic Drug Office and the Partnership Promotion Office under this new department and are accelerating the integrated development of our vaccine business.

#### SHIONOGI Transformation



Tatsuya Yanagawa Business Creation Group Manager, New Business Promotion Department

Message from an Employee

#### A world realized through the HaaS concept

We have already begun providing new value that extends beyond the treatment of diseases, as seen in the launch of AdvanSentinel Inc., a company that aims to detect infections. We are working to bring about a society in which the signs and characteristics of diseases and the condition of affected people can be accurately grasped and in which solutions can be provided in a way that reduces the burdens on the individuals concerned as well as on those around them. Leveraging strengths of SHIONOGI including the scientific capabilities we have built up as a drug discovery-based pharmaceutical company, we will advance efforts to create brand new value in collaboration with partners wielding other strengths.

Shionogi & Co., Ltd. Integrated Report 2022 Shionogi & Co., Ltd. Integrated Report 2022 Materiality

Over 60 years have passed since the introduction of Japan's universal health insurance system in 1961. During that time, Japan has become the country with the world's highest average lifespan and healthy lifespans. The World Health Organization (WHO) has commended Japan's universal health insurance system for its level of achievement of uniform health and the fairness of its cost burden. At the same time, the burden on the working generation is growing under environmental changes in Japan including a declining birthrate, aging population, and low economic growth, threatening the sustainability of the system. While the advance of medical care has made great contributions to defeating diseases that had been difficult to treat, it has also led to financial pressures today.

SHIONOGI defines its primary mission as the provision of new treatment options that can free patients from the suffering caused by illnesses. However, it is also necessary to address the social issue of increasing medical costs. To do this, SHIONOGI is working not only on conventional small-molecule drug discovery, but also on self-medication, and raising awareness about disease prevention. We seek to be a company that continues contributing to the extension of healthy lifespans and sustainable social security.

Initiatives	Related Indicators	Current Progress		Remaining Issues/Needs
Extending healthy lifespans by providing new treat- ment options	Provision ratio for each modality of products and services	<ul> <li>Development of new modal- ity products and services including vaccines, antibody drugs, and treatment apps</li> </ul>	•	<ul> <li>Balance between medical care resources and prices of new modality products</li> <li>Selection of appropriate modality matched to dis- ease/application</li> </ul>
Promotion of self-medication	Number of OTC drugs and sales results	<ul> <li>Launch of four switch OTC drugs</li> <li>Operation of OTC and health food internet sales sites</li> </ul>	<b>)</b>	Provision of new options for OTC drugs and self- medication
Enhancement of awareness and knowledge of illness	Number of visits to sites for patients and their families	Enhancement of infectious disease-related information websites	•	Provision of more substantial information on diseases

**Value Created** 

Contribution to the extension of healthy lifespans and sustainable social security

## Providing services at appropriate prices

Antibody drugs, nucleic acid drugs, regenerative medicines, and other innovative biopharmaceuticals have undergone remarkable advances in recent years. While these biopharmaceuticals contribute greatly to the prevention and treatment of diseases that had been difficult to treat, concern exists that high prices of the drugs will place pressure on medical insurance finances. From a standpoint of risk versus benefit, SHIONOGI believes that conventional small-molecule drugs

and biopharmaceuticals should continue to coexist. While holding to our goal of providing patients with innovative treatment options that include biopharmaceuticals, in response to addressing the growing cost of medical care as well, we will maintain our commitment to the creation of the small-molecule drugs that we see as our strength. By doing so, we will contribute to both the extension of healthy lifespans and sustainable social security.

#### **Promotion of self-medication**

To control the rising costs of social security and to maintain Japan's world-class universal health insurance system amid an ultra-low birthrate and aging society, it is increasingly necessary that people adopt a mindset of guarding their own health. To promote self-medication, SHIONOGI is advancing the development of new OTC products and is switching from prescription drugs to OTC drugs such as Rinderon. On our

patient-oriented websites, we also provide information that lets people learn more about infectious diseases and other illnesses, to raise people's interest in their own health. By deepening understanding of disease and by making use of OTC drugs for the maintenance of health and the prevention and treatment of illnesses, we seek to maintain both people's health and the social security system.

## Initiatives by Shionogi Healthcare Co., Ltd.

Amid a growing need for self-medication, Shionogi Healthcare is undertaking the following initiatives to enhance the familiarity and proper practice of self-care under the business concept of "easy, correct, and enjoyable self-care for all."

#### Expanded lineup of switch OTC drugs with the same components as prescription drugs

In response to requests by customers for pharmaceuticals that can be purchased without prescriptions or hospital visits, we have made efforts to expand our lineup of switch OTC drugs, making a wide range of familiar pharmaceuticals available at drug stores and EC sites.

#### Introduction of easy-to-use universal packaging

To ensure the proper use of Shionogi Healthcare's medicines, we have changed to universal packaging that visually and tactilely communicates information on the medicine and how to open the packaging, starting with products of our main brands in particular. Products' descriptions are translated into multiple languages and their packaging is debossed with "accessible codes" using QR Translator technology that assists understanding by reading text aloud. This makes the products easy to use for the elderly, the visually impaired, and those who speak primarily other languages.



#### Pursuing ways to make information easy to understand

#### 1 Design of reader-friendly package inserts

Through the use of illustrations and icons in multiple colors, we design package inserts for OTC drugs to be easy to read, easy to understand, and conducive to safe use. The content goes beyond pharmaceutical information to provide consumers with helpful information that is useful in self-care.

#### 2 Strengthening of information provision on our websites and social media

In addition to supplying products, we also make efforts to provide a wealth of information on our websites. The Shionogi Healthcare website and our brand websites offer a store search function\* that lets consumers easily search for stores that handle Shionogi Healthcare products. We are also working to enhance information on diseases through means such as our "Hifushiru Wakaru" website that offers self-care support information related to skin diseases. As an initiative to lower the hurdles of self-care and to provide readily accessible support for the easy and comfortable practice of selfcare, we are expanding our information communication channels to embrace social media and other outlets. We are also actively distributing rich media content that incorporates video and audio, offering techniques for lifestyle improvement closely tied to sleeping, diet, exercise, and other elements of everyday life. We also carry out projects that people can physically take part in, such as public lectures and events.

As customers' needs diversify in line with changes in the social environment, Shionogi Healthcare is meeting those needs and is contributing to the extension of healthy lifespans and sustainable social security through excellent products, information, and services.

\* The store search service was jointly developed with ONE COMPATH Co., Ltd. in

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## Improve Access to Healthcare

Materiality

Access to medicines is a critical issue for many people through the world. At SHIONOGI, we collaborate with a variety of international agencies to earnestly tackle that issue.

To improve access to medicines, in addition to getting them into the hands of people, it is vital to properly convey medical knowledge and improve the recognition of illnesses, the rate of diagnosis and the proper use of medicines. Based on this idea, in January 2022, we revised the "Shionogi Global Health Access Policy Statement" to add items pertaining to that proper use.

### Shionogi Global Health Access Policy Statement

Developing innovative
therapies to address
unmet medical needs

Promoting proper use of medicines

Improving access for patients in need

Strengthening healthcare systems

Please see SHIONOGI's website for details on this policy.

https://www.shionoqi.com/qlobal/en/company/policies/shionoqi-group-global-health-access-policy-statement.html

Initiatives	Related indicators	Current progress		Remaining challenges/needs
Developing innova- tive therapies	Number of globally-developed products: 16	<ul> <li>Launch of cefiderocol, an anti-infective drug against multidrug-resistant bacteria, to the market in the U.S. and Europe</li> </ul>	•	<ul> <li>Threats caused by spreading of drug-resistant bacterium</li> <li>Addressing unmet medical needs in the psychoneurological domain</li> </ul>
Promoting proper use	Frequency of the provision of information aimed at proper use and the understanding of illnesses     -Number of website views: 1.8 million     -Number of events: 8     -Number of event participants: 2,516     -Preparing and distributing communication tools aimed at patients with hearing impairments     Number of over-the-counter drugs whose packaging was given universal design: Approx. 60	<ul> <li>Collaboration agreement with GARDP and CHAI</li> <li>Providing information aimed at proper use and understanding of illnesses</li> <li>Promoting activities to eliminate barriers to communication regarding the taking of medicine by patients with disabilities</li> </ul>	•	Remedying improper use of medicine     Improving correct knowledge of illnesses and understanding of pharmaceutical information     Improving access to pharmaceutical information by patients who require a guarantee of information accessibility
Improving access	<ul> <li>Executed agreements for access to cefiderocol in 135 countries</li> <li>Number of countries where ViiiV provides dolutegravir and cabotegravir globally: Over 140</li> <li>Number of countries adopting subscription-type reimbursement model: 2</li> </ul>	<ul> <li>Securing access to low- and middle-income countries through partnering with GARDP and CHAI</li> <li>Inclusion of cefiderocol on the WHO Model List of Essential Medicines</li> <li>Disclosed intellectual property policy</li> </ul>	•	<ul> <li>Improved access to cefiderocol</li> <li>Improved access to vaccines</li> </ul>
Strengthening healthcare systems	Number of programs for strengthening medical infrastructure in lowand middle-income countries: 2     Mother to Mother SHIONOGI Project:     Prevalence of diarrhea down by 58%; percentage of childbirth at public health facilities increased twelvefold	Executed Letter of Intent that included transfer of technology for vaccine manufacturing to Vietnam     Mother to Mother SHIONOGI Project:     Prevalence of diarrhea and nutritional condition of children improved; number of users of mother and child public health services increased	•	Strengthened health care systems in low- and middle-income countries     Mother to Mother SHIONOGI Project: Challenges with mother and child public health in Kilifi County, Republic of Kenya

## **Value Created**

### Contribution to universal health coverage

### Contributions to global health

#### Made global to access to healthcare



- Partners: GARDP and CHAI
- Solution: Cefiderocol
- Number of countries where it can be provided: 135

#### Contributions aimed at improving access to antiinfective drug against drug-resistant bacterium

Cefiderocol, a new anti-infective drug against multidrug-resistant bacteria, is effective against all three types of carbapenem-resistant pathogens that WHO requires the highest priority measures (Acinetobacter baumannii, Pseudomonas aeruginosa and Enterobacteriaceae), and is also included on the WHO Model List of Essential Medicines. With cefiderocol, the product of our accomplishments in research and development, as the focus, we at SHIONOGI believe that we can do our part for global health by endeavoring to address serious AMR issues on a global plane.

In improving global access to antibiotics, a major challenge is promoting proper use and preventing further resistance to antibiotics. However, the regions that need access to antibiotics the most do not have an environment in place where they can be used properly due to social factors such as healthcare systems, poverty and public health education. This presents barriers to improving access to antibiotics.

For the purpose of improving that access in countries around the world, in June 2022, SHIONOGI entered a licens-

#### • Partner: ViiV • Solutions: Dolutegravir and cabotegravir HIV • Number of countries where provided: Over 140

ing agreement that included technology transfer with the Global Antibiotic Research and Development Partnership (GARDP) as well as a collaboration agreement with GARDP and a third party, the Clinton Health Access Initiative (CHAI).

Under this licensing agreement, the road to accessing cefiderocol will open up in 135 countries across the world, including all low-income countries, numerous lower-middle-income countries and upper-middle-income countries. Additionally, the collaboration agreement covers regulations intended to reinforce stewardship programs at medical institutions that are necessary in order to ensure the proper use of antibiotics. Through this partnership with an NPO, the very first of its kind in the world for antibiotics, SHIONOGI will provide patients who require cefiderocol with that drug across various barriers, and do its part for global health in the process. Simultaneously, we will go on to present the ideal nature of vigorous, promising collaborations for access to antibiotics in our capacity as a leading company in the area of infections.

Please see SHIONOGI's website for details on this collaboration agreement for cefiderocol.

https://www.shionogi.com/global/en/news/2022/06/e220615.

Implementing clinical trials

New initiatives for improving access to cefiderocol

A three-way collaborative framework

**SHIONOGI** 

**GARDP** 

Licensing

agreement

#### Fusing the strengths of SHIONOGI, GARDP and CHAI Dealing with issue of access

- A wealth of experience with AMR challenges A strong relationship with the WHO
- Deployment capability in Latin America
   Medium- to long-term commitment

#### The advantages of CHAI and its value proposition Record and specialization in the manage

- ment of access programs for HIV in low- and middle-income countries
- Broad deployment capability to southern African and Asia
- Intensive support and cooperation over the short to medium term



- - expertise in manufacturing Responsibility for access to medicines
- Sublicensing agreement Multiple sublicenses envisioned



ing manufacturers and transferring technology

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#### Improve Access to Healthcare

#### Contributions aimed at improving access to therapeutic drugs for HIV

Out of worldwide quantities of the anti-HIV drug dolutegravir that we out-licensed to ViiV and combination drugs containing it, over 40% are accounted for by developing countries. Dolutegravir is registered in the Medicines Patent Pool. Because we released the use of the patent for that drug free of charge, it is now possible for generic drug manufacturers to manufacture dolutegravir as a stand-alone drug or as a combination with other anti-HIV drugs and supply them to over 140 low- to middle-income countries. SHIONOGI contributes to access to such anti-HIV drugs as one of the patent rights holders for dolutegravir.

#### Accelerating clinical trials and transferring technologies

Two challenges in improving access to patients who require pharmaceuticals by SHIONOGI and contributing to global health are establishing infrastructure for large-scale clinical trials to realize early development and securing a manufacturing framework that is able to accommodate required quantities.

To address such issues, in November 2021, we executed a Letter of Intent regarding countermeasures for infectious diseases, COVID-19 included, with the Ministry of Health of Vietnam. In tackling the immediate challenge that COVID-19 poses, we have been promoting clinical trials in that country for vaccines and orally-delivered therapeutic drugs in middevelopment as well as pursuing discussions areas such as cooperating with the Vietnamese government on the transfer of manufacturing technologies for vaccines. Additionally, in December 2021, we commenced global Phase 3 clinical trials for the COVID-19 vaccine S-268019 in Vietnam.

#### Support for maternal and child health in Africa: Mother to Mother SHIONOGI Project

In Sub-Saharan Africa, the mortality rate of pregnant woman and children under the age of five is exceedingly high, with considerable challenges still remaining in the accomplishment of SDG Goal 3: Good Health and Well-Being. Concrete initiatives aimed in achieving universal health coverage (UHC) are

In realizing a sustainable society, an environment where the next generation of children can healthily grow is indispensable. Since 2015, together with the international NGO World Vision, we have been engaged in activities the Republic of Kenya aimed

at realizing a community where the health of mothers and their children can be independently and continuously managed.

#### Second-Term Project (Kilifi County, Republic of Kenya, April 2020 – March 2023 (tentative))

We handed over the maternity building, clinical laboratory and other facilities that we had been developing under the project to the county government. The locally-based public health management team that oversees public health administration thanked us for the infrastructure-based support at clinics as well as training in preserving and managing that infrastructure and support for activities to educate local residents, which we combined to yield considerable effects in the improvement of access to healthcare. Furthermore, we are also pursuing the development of water supply facilities and the education of local residents in nutrition and water hygiene.

At one of the three clinics that we rendered assistance to, with the aim of providing stable medical services, we elicited the cooperation of Panasonic Holdings Corporation in installing a solar power generation system. Through cross-sectoral partnerships, we will continue to leverage the strengths of each sector and tackle the improvement of access to healthcare in Africa and the achievement of UHC as we move forward.

#### Accomplishments up to 2021

Total number of individuals who received medical services (cumulative number for both First-Term and Second-Term Projects)

Clinics

104,522

Traveling treatment

21,728





The maternity building handed over to Kilifi The clinic with solar panels installed

Please see SHIONOGI's website for details on the Mother to Mother SHIONOGI Project.

https://www.shionogi.com/global/en/sustainability/society/ social-contribution-activities/mtom.html

## Tackling improved access to healthcare in Japan

At SHIONOGI, we believe that it is vital to properly convey medical knowledge and improve the recognition of illnesses, the rate of diagnosis and the proper use of medicines in order

to improve access to healthcare. In Japan, we are working towards improving that access by providing medical professionals, patients and families with the correct information.

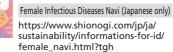
#### Promoting the proper use of anti-infective drugs and conducting learning and development activities

We believe that controlling the outbreak of drug-resistant bacteria and resistant viruses is a necessary part of our responsibility as a corporation in the business of anti-infective drugs.

At SHIONOGI, we keep the sales volumes of anti-infective drugs by MRs and HR evaluations separate from the standpoint that doing so will lead to the proper use of those drugs and the continuity of medicines. Additionally, we aggressively pursue initiatives aimed at the widespread education and learning and development of the general public on correct knowledge of areas such as the prevention and control of illnesses and infectious disease, which is an absolute must for the proper use of anti-infective drugs.

In fiscal 2021, we collaborated with external entities such as World Vision Japan, the Tokyo Association of Public Health Center Directors and the Women's Healthcare Awareness & Menopause Network Society to hold learning and development seminars and practical classes for the general public. Furthermore, for website-based enlightenment efforts, we opened "Female Infectious Diseases Navi" as a means of countering such diseases particular to women, "Senior Infectious Diseases Navi" to do the same for elderly individuals while also helping to preserve their health, and "Learning about HIV/AIDS through Comics" as a means of enlightening others on correct information regarding HIV infections on a widespread basis. Additionally, we proactively communicate the above activities using SHIONOGI's official Twitter account.







Senior Infectious Diseases Navi (Japanese only) https://www.shionogi.com/jp/ja/ sustainability/informations-for-id/ senior\_navi.html?tgh



Learning about HIV/AIDS through Comics (Japanese only)

https://www.shionogi.com/jp/ja/ sustainability/informations-for-id/

#### Initiatives for promoting the understanding of psychoneurological diseases and pain

Over a period of thirty years, SHIONOGI has worked together with governments, academic societies and medical professionals to engage in activities to realize greater pain relief for cancer patients. Going forward, we will continue to resolve misconceptions surrounding medical narcotic drugs and conduct learning and development activities aimed at realizing a society where patients who suffer from cancer pain can feel more at ease with

using such drugs. Additionally, for developmental disorders, we are working on providing information on treatment and assistance for affected individuals and their families as well as holding seminars and publishing articles for promoting understanding among members of society, starting with parents and guardians raising small children. Additionally, in the course of collaborating with local governments and other entities to promote the development of human resources who assist persons with developmental disorders and members of their families, we have received positive feedback from participants in associated training such as citing how children with such disorders are enjoying longer time spent in a relaxed state. SHIONOGI will aim to realize total care through these activities.

#### Communications Barrier-Free Project (CBF-PJ)

As part of its Vision, SHIONOGI is implementing the Communication Barrier-Free Project (CBF-PJ) to eliminate communications barriers with hearing/visual impairments and medical personnel when they are accessing medicine. Since 2017, we have been holding seminars with employees with hearing impairments employees serving as instructors to enlighten medical professionals on the attributes of such impairments and how they should be ideally handled (These seminars have a 98% satisfaction rate.). From fiscal 2020, we have been offering these seminars in an online format, using them to provide numerous medical professionals with information. In addition to producing and supplying enlightenment materials and communication tools aimed at patients, through local governments with whom we have entered collaborative agreements, we distributed guide cards at COVID-19 vaccina-

Additionally, we took on the challenge of crowdfunding the production of a comic to communicate the troubles experienced by persons with hearing impairments at medical institutions and how to handle them to students in medical disciplines who will be involved in healthcare in the future. Thanks to the support of many individuals, we were able to reach our target amount. We will effectively use these funds with the hope that having as many people as possible become familiar with hear-



ing impairments will result in greater social approval for associated initiatives.

Crowdfunding (from READYFOR website)

Please see SHIONOGI's website for details on initiatives aimed at the proper use of medicines and understanding of illnesses. https://www.shionogi.com/global/en/sustainability/improveaccess-to-healthcare/proper-use.html

Please see SHIONOGI's website for details on the CBF-PJ. https://www.shionogi.com/global/en/sustainability/society/ social-contribution-activities/cbf.html

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## **Supply Socially Responsible Products and Services**

Materiality

It is SHIONOGI's duty as a life-related company to protect people's health by providing a stable supply of essential, high-quality products and services. Our entire Group is focused on product quality, safety, and providing information about proper usage so that people can trust and use SHIONOGI products or services with peace of mind.

Initiatives	Related Indicators	Current Progress		Remaining Issues/Needs
Stable supply of products and services	<ul> <li>Monitoring of and improvements to procurement management indicators and delivery indicators set by SHIONOGI</li> <li>Routine/non-routine consultations with suppliers to achieve stable supply</li> <li>Routine evaluation of contract manufacturers and support for building business continuity plan (BCP)-related systems</li> </ul>	<ul> <li>Quick detection and response to abnormal values through monitoring of procurement management indicators</li> <li>Implementation of all measures necessary to eliminate supply chain risks that have materialized</li> <li>Identification of supplier risks and support for construction of BCP-related systems</li> </ul>	•	Reduction and dispersion of risks through construction of BCP-related systems to respond to SHIONOGI supply chain risk and use of multiple suppliers     Identification of supplier risks and continuation and expansion of support for construction of BCP-related systems
Strengthening of the monitoring system	Strict adherence to laws, ordinances, and guidelines related to production and sales of pharmaceuticals	<ul> <li>Strict adherence to related policies</li> <li>Regular audits of manufacturing sites and other locations</li> <li>Assessment of risks related to procurement and manufacturing and strengthening of the level of management appropriate for risks</li> </ul>	•	Well-timed, proper audits of manufacturing sites (in conjunction with remote audits)     Response to diversification of customer needs regarding quality, such as disclosure of countries where APIs are manufactured     Strict response to compliance violations related to the manufacturing and sales of medicines
Ensuring proper use of medicines and creation of an in-house system	Regular meetings of the Promotion Review and Oversight Committee Training achievement level for department responsible for providing marketing information Improved and more efficient detection of inappropriate cases of provision of marketing information through the use of AI	Establishment of appropriate information provision system     Establishment of Al-based monitoring system	<b>)</b>	Strengthening of compliance review and monitoring system for overall SHIONOGI     Response to the demand for timely, appropriate information provision     Training to reinforce provision of information on proper use



Delivering high-quality SHIONOGI products and services along with peace of mind to society while pursuing responsible support for ensuring credibility and stable supply



## Efforts to achieve stable supply

#### Stable supply of our products

SHIONOGI routinely conducts quantitative assessments of its procurement risk related to suppliers and contract manufacturers so that we will never run out of product supplies, and we implement various risk response measures, including asking risky suppliers to make improvements, selecting alternate suppliers, and procuring from multiple companies. In addition, we have set strict targets for product delivery indicators and have built a system that makes it possible to deliver a stable supply of our products and services to patients and healthcare professionals.

In fiscal 2021, procurement risks materialized because of not only instability in the procurement of raw materials due to the global spread of COVID-19 but also electricity problems in China and Russia's invasion of Ukraine, which resulted in shortages of raw materials and transportation. Even under these circumstances, we were able to deliver products without stockouts by gathering information both in Japan and overseas, regularly checking with various suppliers, and implementing other measures to secure raw materials in addition to making advanced purchases of overseas raw materials and storing them in Japan. In addition, SHIONOGI has positioned developing, quickly obtaining approval for, and then promptly starting to supply the COVID-19 therapeutic drug S-217622 (ensitrelyir) and the COVID-19 vaccine as top priority issues. SHIONOGI has united to build a raw material procurement, manufacturing, and supply system to do that.

#### Contribution to other company's products

Recently, there have been a series of stockouts of antibiotics manufactured by other companies because all key intermediates are manufactured overseas. As antibiotics are indispensable for conducting surgeries, stockouts of these products have a major impact on efforts to maintain the medical system. Therefore, in response to requests by the government and related academic associations, SHIONOGI is moving forward with newly installing antibiotics manufacturing equipment at SHIONOGI's Kanegasaki Plant in order to bring production of key intermediates back to Japan.

## **Quality assurance**

SHIONOGI has clearly stipulated the roles and scope of responsibilities of officers in charge based on the amended Pharmaceutical and Medical Device Act so as to avoid incidents like those that have occurred at other companies in recent years and caused a loss of trust in companies because of compliance violations related to drug manufacturing. In addition to working to raise compliance awareness through training for the employees of SHIONOGI as part of the quality assurance system, we continue to create not only a system for collaboration among the SHIONOGI Group companies that conduct manufacturing and sales but also update applications

for approval.

Furthermore, SHIONOGI is attempting to strengthen compliance-oriented attitudes throughout its supply chain through initiatives to instill a "quality culture."

At the same time, due to COVID-19 limitations on overseas travel and visits, it has been difficult to perform site inspections that we had been doing. However, in the near future we will mainly conduct on-site audits of manufacturing sites and will implement management and oversight of our domestic and overseas plants more efficiently and with higher quality than ever before.

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Building relationships of trust and collaborating with business partners is essential if a company is to fulfill its social responsibilities. In view of the recent changes in the external environment, SHIONOGI revised the Shionogi Group Procurement Policy and formulated the Shionogi Group Business Partner Code of Conduct. We are strengthening supply chain management in order to conduct sustainable procurement that takes into consideration not only traditional QCD (quality, cost, and delivery) but also human rights, working environment, global environment, and ethics.

Initiatives	Related Indicators	Current Progress	Remaining Issues/Needs
Formulation of policy and code of conduct	<ul> <li>Formulation of policies and education for the employees of domestic consolidated companies (84% of employees have completed)</li> <li>Establishment of an independent advising desk to handle suppliers</li> </ul>	<ul> <li>Revision of Shionogi Group Procurement Policy</li> <li>Formulation of Shionogi Group Business Partner Code of Conduct</li> <li>Confirmation of agreement</li> </ul>	<ul> <li>Greater in-house awareness of sustainable procurement, which includes overseas Group companies</li> <li>Revision, formulation, etc., of various procurement-re-</li> </ul>
Supplier sustainability evaluations	<ul> <li>Percentage of all suppliers evaluated: 6.5% (28 of 430 companies)</li> <li>Companies audited: 2 (including remote audits)</li> <li>Companies that completed questionnaire-based audit: 9</li> <li>Number of suppliers asked to participate in EcoVadis evaluation, 23; number of suppliers that provided valid responses, 17; percentage of suppliers that meet set standards: 64.7% (11 of the 17 companies)</li> </ul>	with sustainable procurement and code of conduct demanded of business partners  • Assessment and management of business partners based on Shionogi Business Partner Assessment Rules  • Identification of risks that global supply chains will be disrupted and procurement and supplies will be cut off as a result of COVID-19 or other infectious disease, natural disaster, or geopolitical incident	lated standard operating procedures  Regular assessments of key business partners



Promotion of sustainable procurement through collaboration with business partners

#### Revising procurement policy and formulating Business Partner Code of Conduct

In fiscal 2021, SHIONOGI revised its Shionogi Group Procurement Policy and newly formulated a Shionogi Group Business Partner Code of Conduct. We also not only revised various SOPs and conducted related training, including at domestic consolidated companies, but also launched a Supply Chain Working Team that will examine various topics that are important to tackle issues within the supply chain, including human rights and the environment, through a Group wide structure. As SHIONOGI agrees with the spirit touted by the

Council on Promoting Partnership Building for Cultivating the Future, which members of the business community and related government ministers participate in, we formulated and made public a Declaration of Partnership Building in May 2022. We will continue to demand that business partners adhere to this code of conduct and work with them to promote effective activities to solve social problems throughout the whole supply chain.

See our website for the policy and code of conduct. https://www.shionogi.com/global/en/company/policies.html

## Evaluating the sustainability of key suppliers using instruments such as EcoVadis

Using EcoVadis, a rating platform for fairer and more objective evaluations of a company's social responsibility-related efforts and sustainable procurement, SHIONOGI is conducting evaluations of its business partners, which started with high priority ones. Key suppliers for SHIONOGI are defined as suppliers from whom a large amount of purchases are made and that are necessary to provide a stable supply of the SHIONOGI's products to

the market. And starting with suppliers that do a large volume of business with SHIONOGI or that are important in terms of antimicrobial resistance infectious disease products and products whose supply should be maintained from a social responsibility or corporate management perspective, SHIONOGI conducts sustainability evaluations, including whether there are any human rights or environment-related risks.

## **Respect Human Rights**

Materiality

SHIONOGI recognizes the importance of respecting the human rights of all stakeholders in the course of its business activities. We promote initiatives that are in line with the Shionogi Group Human Rights Policy, which was established based on the UN Guiding Principles on Business and Human Rights (UNGPs).

Initiatives	Related Indicators	Current Progress	Remaining Issues/Needs
Responding to Human Rights Issues	Responding to the UK Modern Slavery Act 2015     Conducting Human Rights Impact Assessments     Investigation of labor conditions in manufacturing regions that produce raw materials and basic materials     Investigation of labor conditions for foreign workers      Validity assessments by external experts     Dialogue with overseas human rights experts (once a year)	<ul> <li>Consideration of statements in accordance with the UNGPs</li> <li>Identification and investigation of human rights risks through assessments</li> <li>Continuing dialogue with external experts to improve initiatives</li> </ul>	<ul> <li>Disclose statements in line with the UNGPs</li> <li>More precise identification of potential human rights risks and consideration of how to respond to them</li> <li>Validation of SHIONOGI's efforts and incorporation of expert input in activities to improve issues</li> </ul>
Implementation of education and training on Busi- ness and Human Rights	Implementation of E-learning for employees (participation rate: 89.6%)	<ul> <li>Raise awareness of human rights among executives and employees</li> </ul>	<ul> <li>Provide input on the latest information on business and human rights to executives and employees</li> </ul>

Value Created

## Respect for the human rights of all people involved with SHIONOGI and compatibility with sustainable business

### **Human Rights Impact Assessment**

SHIONOGI conducts human rights due diligence to promote the identification, prevention, and reduction of human rights risks. In fiscal 2021, we conducted human rights impact assessments, particularly on labor conditions in manufacturing regions that produce raw materials and basic materials, and labor conditions for foreign workers.

#### Labor conditions in manufacturing regions that produce raw materials and basic materials

Based on external reports and SHIONOGI's procurement status, cellulose, glass, ethanol, and aluminum were identified as key commodities for SHIONOGI, and in fiscal 2021 we began investigating the risk of human rights violations, starting with cellulose. For eucalyptus, one of our raw materials, we conducted online dialogues with farmers in India to check local labor conditions. We will share the findings from this case



with our business partners and continue to further check for human rights risks in the supply chain.

#### Labor conditions for foreign workers

In response to the issue of technical interns in Japan, SHIONOGI conducted a survey of domestic group companies and dialogues with three subcontractors in fiscal 2021, and found that none of them employed technical interns. We communicated SHIONOGI's policy to our outsourcing contractors, explaining the matters of consideration when hiring technical interns and requesting these to be respected. Going forward, SHIONOGI will expand the scope of the survey to the supply chain and proceed with the investigation of technical interns.

For more information on our human rights initiatives, please visit our website.

https://www.shionogi.com/global/en/sustainability/society/ respect-human-rights/human-rights-policy.html

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#### Materiality

SHIONOGI is promoting efforts to address environmental issues, such as climate change, conservation of biodiversity, resource conservation, and resource recycling with the aim of realizing a sustainable society through the preservation of the global environment. SHIONOGI has formulated the Shionogi Group EHS Policy and its accompanying SHIONOGI Group EHS Action Targets, and we are striving to reduce the burden on the environment caused by our business activities, including by our supply chain.

Initiatives	Related indicators	Current Progress	-	Remaining Issues/Needs
Climate change Reduce greenhouse gas (GHG) emissions	<ul> <li>FY2030: 46.2% reduction for Scopes 1+2; 20% reduction for Scope 3, category 1 (FY2019 benchmark)</li> <li>FY2050: Achieve zero emissions</li> </ul>	Obtain SBT approval     Express its support for the recommendations of TCFD     Participate in the TCFD     Consortium	<b>)</b>	<ul> <li>Expand climate change- related information disclo- sure in accordance with the TCFD framework</li> <li>Consider measures to achieve SBT and implement them</li> </ul>
Reduce the envi- ronmental impact of the antibiotic manufacturing process	Strict controls, including the supply chain, by FY2030 (completion of audit follow-ups)	<ul> <li>Establish a system of strict controls at SHIONOGI plants and some suppliers to reduce the impact of antimicrobials manufacturing on the environment</li> </ul>	<b>)</b>	Strict controls, including the supply chain
Resource conserva- tion/circulation Reduce waste and improve recycling rates	• FY2030: Recycle 65% of plastic waste	Promote use of biomass plastics and recycled plastics	•	Further reduce amount of waste generated and land- fill amount, and improve recycling amount
Water Control the volume of water resources used	• FY2030: Reduce the volume of water resource usage to 1,340 thousand m³ or less	<ul> <li>Conduct a water risk assessment for SHIONOGI</li> <li>Acquire an understanding of suppliers' water risks</li> <li>Reduce the volume of water resources used</li> </ul>	<b>)</b>	Further reduce water resources used in view of increased water stress risk going forward

#### Contribution to a sustainable society through preservation of the global environment

#### **Climate Change Initiatives**

Risks relating to climate change and the process of transitioning to a carbon-free society affect almost all industrial sectors. At SHIONOGI, we are assessing and working to minimize climate change risks by establishing governance structure with respect to climate change.

In October 2020, Japan joined other countries in declaring its goal of carbon neutrality by 2050, further accelerating the movement toward decarbonization. SHIONOGI also set SBTs as fiscal 2030 targets for carbon neutrality by 2050, and

received approval from the SBT Initiative in June 2021. In order to achieve the fiscal 2030 targets, SHIONOGI is following a plan to switch to electricity derived from renewable energy sources, which was drafted for SHIONOGI's main sites, and has completed its introduction at the head office building in fiscal 2021 and at the Aburahi Research Center in fiscal 2022. However, in fiscal 2021, we were unable to achieve our fiscal year target due to an increase in CO2 emissions caused by factors such as our proactive efforts to create each solution

#### Supplier Engagement Implementation Process

Understanding suppliers' CO2 emission amounts and current efforts to reduce CO<sub>2</sub> emissions (e.g., setting of reduction targets, implementation status of reduction activities, etc.) through interviews, etc.

Briefings were held to share SHIONOGI's policies and useful information on reducing CO2

Individual negotiations (reduction requests, individual support) with key suppliers

aimed at total care for COVID-19 as well as the expedited manufacturing of the therapeutic drug for prompt supply after approval. We will continue to study and implement further reduction measures, including the proactive introduction of electricity derived from renewable energy sources, in order to achieve the SBTs.

In addition, since Scope 3 emissions account for approximately 60% of total emissions at SHIONOGI, it is essential to work with suppliers to reduce emissions throughout the entire supply chain in order to achieve the SBTs.

SHIONOGI participated in "the Fiscal Year 2021 Model Project for Supporting Achievement of the Decarbonization targets of the Entire Supply Chain," a project by the Ministry of the Environment to support the achievement of greenhouse gas (GHG) emission reduction targets for the entire supply

chain. SHIONOGI is working to achieve the SBTs by implementing the supplier engagement process established through this project, as well as establishing a cooperative framework including Group companies to promote supplier engagement.

As of June 2022, we are conducting supplier engagement activities for our top 21 suppliers in terms of purchase amount, including checking the status of CO<sub>2</sub> emission reduction efforts and holding briefings to promote understanding of SHIONOGI's policies regarding climate change. Going forward, SHIONOGI will identify key suppliers in terms of CO2 reduction and prioritize them for reduction requests and support.

For more information on the supplier engagement process, please visit the following website (Japanese only) and page 93: Guidebook for Developing GHG Emission Reduction Plans to Achieve SBTs, etc.

https://www.env.go.jp/earth/datsutansokeiei\_mat02\_20220418.pdf

#### Climate change-related disclosures under the TCFD

#### Expression of its support for the recommendations of TCFD and participation in the TCFD Consortium

The importance of companies recognizing the risks and opportunities of climate change and taking measures to address them has been emphasized by institutional investors and financial institutions that make ESG investments and loans, and is mentioned in the recommendations of the Task Force on Climate-related Financial Disclosures (TCFD). In addition, climate change-related information disclosure is becoming increasingly important as the Corporate Governance Code revised in June 2021 requires companies listed on the Prime Market to disclose information based on the TCFD or an equivalent framework.

In March 2022, SHIONOGI announced its support for the TCFD recommendations and joined the TCFD Consortium, a group of Japanese companies and financial institutions that support the TCFD recommendations. Along with promoting the study of strategies and specific measures, the Corporate Planning Department, Procurement Department, Sustainability Management Department, and other departments are collaborating to conduct a detailed assessment of the impact of SHIONOGI's business activities on climate change using the TCFD framework, with the aim of disclosing information by the end of fiscal 2022. We will continue to focus on address-

ing climate change issues to enhance SHIONOGI's resilience and meet the demands of society through appropriate disclosure of information.



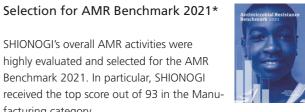
#### AMR initiatives to decrease environmental emissions from the antimicrobial manufacturing process

In order to reduce the environmental impact of the antimicrobial manufacturing process, SHIONOGI plans to establish an appropriate control system to control environmental release of antimicrobials throughout the supply chain by fiscal 2030 through auditing SHIONOGI plants and suppliers. To this end, SHIONOGI aims to maintain the antimicrobial management system at the Kanegasaki Plant and complete an initial audit of all relevant suppliers by fiscal 2024. In these audits, we are controlling and managing the release of antimicrobials into the environment in accordance

with the Guidelines for Antimicrobial Release Control published by the AMR Industry Alliance.

highly evaluated and selected for the AMR Benchmark 2021. In particular, SHIONOGI received the top score out of 93 in the Manufacturing category.

SHIONOGI's overall AMR activities were



- \* AMR Benchmark: The world's first report by the Access to Medicine Foundation, a Netherlands-based NGO, which analyzes and evaluates AMR initiatives
- For more information on our environmental initiatives. please visit our website:

https://www.shionogi.com/global/en/sustainability/environ-

Please refer to our website for the Environmental Report: https://www.shionogi.com/global/en/investors/ir-library/annual-report-integrated-report.html

#### **Outside Directors Roundtable**

#### Outside Directors Roundtable

#### Keiichi Ando X Hiroshi Ozaki X Fumi Takatsuki

# **Corporate Governance Supporting** SHIONOGI's Growth

Professor Emeritus Tetsuo Kitagawa, Ph.D. of Aoyama Gakuin University was invited as a facilitator to discuss with the three outside directors the features and challenges of governance at SHIONOGI, which aims to promote transformation into a HaaS company.

#### Role of Outside Directors on the Board of Directors

**Kitagawa** Corporate governance, in a word, varies from company to company depending on its stage of growth, and the role required of outside directors is also very fluid.

Based on your personal experience, could you all tell us your impression of SHIONOGI's governance and how you view the role of an outside director?



Ando At SHIONOGI, management recognizes the importance of corporate governance more strongly than anyone else, and they have a very solid governance structure in place. One of the major roles of an outside director is to supervise the execution framework. The six outside directors and auditors provide appropriate advice and wide-ranging discussions at board meetings based on their different experiences, and I believe that management is conducted in a transparent and satisfying manner.

Ozaki In SHIONOGI's business, engagement with all stakeholders, including society and employees, as well as customers, shareholders and investors, is very important. My impression is that SHIONOGI's governance is very well done, as there is appropriate communication between management and employees, with even bad information immediately coming to upper management, and a high level of information disclosure to society. However, maintaining the status quo is the first step toward deterioration. It is important for management to constantly consider areas for improvement, and it is the role of outside directors to oversee this.

**Takatsuki** Discussions at the Board of Directors meetings are very active, and there is a multifaceted exchange of opinions that makes good use of the perspectives of each board member. As a lawyer, I have helped with fraud investigations mainly for companies operating in China and Southeast Asia. As SHIONOGI's business continues to expand globally, I would like to offer my opinions from a different perspective than the executive side. **Kitagawa** I can see that there is open discussion at the board meetings, including with the auditors. Speaking of auditors, in Japan there are three recognized forms of governance organization, of which SHIONOGI has chosen to establish a company with a board of corporate auditors. What kind of discussions do you have on this point at your board meetings? **Ando** In Europe and the U.S., many companies have chosen to establish a company-with-committees system compared to Japan. In the case of SHIONOGI, the Company has chosen to establish a company with a board of auditors, but it recognizes that there are no problems with our current system, as the six outside directors and auditors are able to express their candid opinions. Discussions by the Nomination Advisory Committee and the Compensation Advisory Committee, which are voluntary committees, are diligently reported to the Board of Directors.



Ozaki The importance of governance structure and voluntary committees is not the form, but the quality, i.e., whether appropriate discussions are taking place. Some companies may have the same form, but completely different results. **Takatsuki** For foreign investors, a company with a board of





Independent Outside Director



Hiroshi Ozaki

Independent Outside Director



Fumi Takatsuki Independent Outside Director

corporate auditors is an unfamiliar format. Perhaps it is necessary to explain its advantages and how the check-and-balance function works in a way that is easy to understand.

#### What the Board of Directors is looking out for as we transform into a HaaS company

Kitagawa In STS2030, SHIONOGI has set the goal of transforming itself from a drug discovery-based pharmaceutical company to one that pursues the quality of health that people truly desire and delivers unprecedented new value to society. I believe this goal is highly compatible with the SDGs and ESG, which are receiving increasing attention as demands

What are your thoughts on the background of SHIONOGI's transformation into a HaaS company and the challenges that come with it?

**Ando** In a sense, the pharmaceutical business is a high-risk business. SHIONOGI needs to change their conventional business model in which the expiration of patents on core products (patent cliffs) significantly affects business performance. The recent COVID-19 pandemic has reaffirmed the importance of not only treatment but also total health care, including diagnosis and prevention. I believe that their initiatives for COVID-19 will be a major touchstone for the transformation of their business model toward becoming a HaaS company by 2030.

**Ozaki** Health as a concept has changed. Drug discovery must always be a core competence of SHIONOGI, but in addition to that, they must incorporate peripheral fields such as big data and environmental measurement, and change the mechanisms for healthy living, which I believe will lead to HaaS. **Takatsuki** Rights (patents) are a part of the pharmaceutical business that is very regulated and institutionalized in Japan and abroad. And, as SHIONOGI aims to become a HaaS company, they will increasingly have to deal with laws in different areas more than before, such as responding to digitalization and providing information to consumers. Furthermore, from a global perspective, the services sector is affected in part by

cultural differences, political, and economic conflicts. I make a point of speaking up about these things, as I am always looking from a different perspective than pharmaceuticals one.

#### Utilizing finite human resources to enhance SHIONOGI's competitive advantage

**Kitagawa** In their ESG initiatives, I suspect that efforts related to human resources, particularly diversity and the utilization of human resources, will affect SHIONOGI's corporate value in the future.

What are your thoughts on human resource development? **Takatsuki** The impact of Japan's declining population is a serious issue for all companies, who need to utilize their limited human resources to increase their competitive advantage. SHIONOGI has a position of "Associate Corporate Officer" as a candidate for the next generation of leaders, and they provide opportunities for these Associate Corporate Officers to explain their own initiatives to us outside directors. Through dialogue with these Associate Corporate Officers, I have learned that over the past two years, SHIONOGI employees have been working hard and involving others in the COVID-19 project, contributing to the sustainability of society through SHIONOGI's core business.

**Ozaki** The skills that SHIONOGI's personnel currently possess will not be sufficient in transforming them into a HaaS company. In addition to recurrent training, they need to be prepared to stay half a step ahead of the changes Japan will undergo as a whole by considering external collaborations and M&A opportunities. In addition, since global expansion means that the world will be watching them from an environmental perspective as well, they must consider human resource development not only within SHIONOGI, but also along the supply chain.

**Ando** Drug discovery is the foundation of SHIONOGI. With the HIV product patent expiring in 2028, there is a great sense of urgency as to whether SHIONOGI will be able to continue to produce new drugs solely through its drug discovery capabilities. The Board of Directors has agreed to invest all management resources in further strengthening the Company's R&D capabilities. In par-

ticular, they are being asked to raise the level of human resources, which form the foundation of SHIONOGI, and to this end they need to visualize their investments in human resources. They must also continue to look into industry-academia collaborations, collaborations with partners, and the use of Al.

Kitagawa On a macro basis, some say that Japanese companies have not invested enough in human resources over the past 20 years, but it seems that SHIONOGI is already tackling that issue head on. What are your thoughts on the skills matrix for the Board of Directors? Also, do you think it is necessary to increase the composition of the Board of Directors, which consists of two internal and three external members? Ozaki I believe that the skills matrix shows that SHIONOGI is looking for diversity. If it is necessary for management, they can invite experts, and the role of management is to define SHIONOGI's business and what it requires of these experts. I think it is important for outside directors to be able to provide advice, based on their experience and knowledge, on whatever the business needs.



**Takatsuki** Although there is a risk of discussions losing their focus if there are too many directors, and despite there being an executive officer system in place, it may become necessary to consider increasing the number of internal directors in the medium to long term, in anticipation of the succession of top management. **Ando** Succession is definitely the greatest challenge. In order for SHIONOGI to achieve sustainable growth, they need to increase the number of directors from within the Company, and have them speak out with a sense of direction based on an awareness of the issues facing the Company and the content of the discussions. Through speaking out in this way, they can further hone their sense of management. However, I also believe it is necessary to continue to maintain the system in which outside directors make up the majority of the board.

#### Corporate governance issues from a medium- to long-term perspective

Kitagawa Finally, as an outside director, what are some of the corporate governance issues that you will be keeping a close eye on from a medium- to long-term perspective? **Takatsuki** My main concern is global governance and the compliance promotion system. When a company expands, if management cannot keep up and there is no proper governance

and support, the risk of various incidents increases. I believe that SHIONOGI has effective governance right now, but, as they expand their overseas business, they need to be well prepared to maintain a certain level of governance throughout the world.



**Ando** The pharmaceutical industry is an industry that can contribute to the achievement of the SDGs as its core business. It is necessary to take pride in this and return even greater benefits to society, and for each and every employee to be working on the same page to promote this transformation into a HaaS company. Furthermore, it is important to think long-term and ensure that this direction is followed by the next potential successors.

Ozaki SHIONOGI is a leader in infectious diseases and this position must not be shaken. While the revenue from infectious diseases is highly volatile as it depends on the presence or absence of epidemics, this business needs to be stable because, as we learned in the COVID-19 pandemic, it plays a significant role in society. And I believe that the vaccine business is one answer to this. Figuring out how to create a system that generates profits in order to respond to new technologies and make them a viable business is key. SHIONOGI also needs to foster and instill loyalty for the Company among its stakeholders, such as overseas customers and employees. I believe that this is the challenge to ensuring stable business growth going forward.

#### Keiichi Ando

An outside director of the Company since 2016. He has served as Chairman of the Board of Directors since 2020, advising on budget planning and management as well as capital policy, including investments.

#### Hiroshi Ozaki

An outside director of the Company since 2019. He has extensive practical experience and broad knowledge of corporate and organizational management, and provides advice on business and marketing matters.

An outside director of the Company since 2020. She provides advice from the perspective of international corporate legal affairs, particularly with respect to conducting business in China.

#### Tetsuo Kitagawa

Emeritus Professor of Aoyama Gakuin University. After working as a researcher at both a think tank and an investment institution, he became a professor at Aoyama Gakuin University Graduate School in 2005, and assumed his current position in 2019. His areas of expertise are corporate governance, financial analysis, and ESG investment.

#### **Corporate Governance**

To ensure business execution based on appropriate management decisions, SHIONOGI has strengthened the monitoring function of the Board of Directors, which deliberates on matters mainly relating to the Company's corporate philosophy, business plans, and important matters concerning business execution by tapping into the management experience and professional knowledge of outside directors and outside auditors. This has resulted in the establishment of a framework in which each executive organization ascertains the progress of business execution related to matters for which a management decision was made and reports to the Corporate Executive Management Meeting, the Board of Directors meeting, etc., on a timely basis. SHIONOGI has opted to be a company with a Board of Corporate Auditors to ensure such duties are performed in a legally compliant and smooth manner by linking the Board of Directors' oversight function, the Board of Auditors' audit function, and business audits based on internal audits.

#### Features of SHIONOGI's Corporate Governance

#### Consider balancing among our four types of stakeholders

SHIONOGI incorporates the perspectives of its four groups of stakeholders—customers, society, shareholders and investors, and employees—in maintaining transparent and proper business management that treats its stakeholders fairly and is responsive to the expectations of society.

#### Diversity of the Board of Directors and Board of Auditors

To further strengthen our framework in view of the progress in our business development, SHIONOGI is building the necessary framework from the standpoint of diversity and such factors as expertise and experience. We have appointed two female directors, directors and auditors with a wide diversity of skills and age groups.

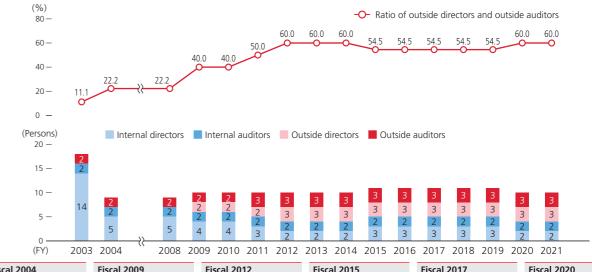
#### Emphasis not only on complying but also on explaining

SHIONOGI has no plans to mechanically comply with all the items contained in the Corporate Governance Code. It is important that we always strive for the best compliance system, clearly express our thoughts about points with which we will not comply, and thoroughly discuss any differences of opinion with

#### Management transparency

A majority of SHIONOGI's directors and auditors are independent and outside officers, which increases the transparency of our management. Also, based on our Disclosure Policy, we continue to disclose our corporate information to all of our stakeholders in a fair, timely, and appropriate manner.

#### Changes in Corporate Governance Structure



#### Fiscal 2004

- Number of internal directors reduced to five from fourteen
- Introduction of corporate officer system

#### Introduction of an outside

- Establishment of Nomination Advisory Committee
- Establishment of Compensation Advisory Committee Start of opinion exchanges

# Majority passes to outside directors and outside

# auditors

## Start of Information share

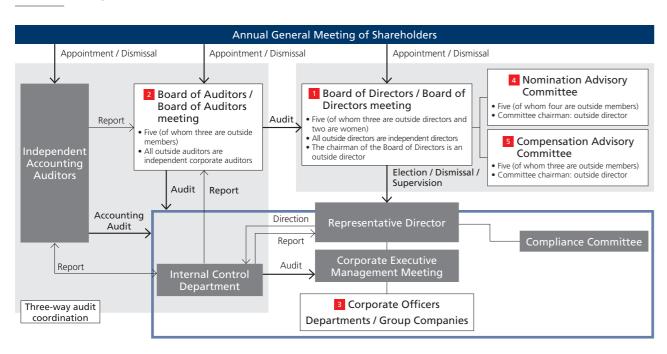
ing meetings with outside · Advent of a female director

Changing composition of Nomination Advisory Com mittee and Compensation Advisory Committee (to majority of members now being outside directors)

#### Outside director appoin chairman of Board of Directors

Increase in number of female directors (Increase in proportion of women

#### Corporate governance structure



#### 1 Board of Directors / Board of Directors meeting

To further strengthen directors' oversight of business execution, make management even more transparent, and promote equitable management by drawing on perspectives from outside the Company, the Board currently consists of five members, three of whom are outside directors. All three outside directors are independent appointments who understand SHIONOGI's corporate responsibility, and they contribute to greater transparency in management. In addition, two of the five directors are women. The Board of Directors meeting is chaired by an outside director and in principle held once a month.

#### 2 Board of Auditors /Board of Auditors meeting

To ensure that the directors and each organization in SHIONOGI conduct their duties in a legally compliant and appropriate manner, the Company has established systems to enable members of the Board of Auditors and the Internal Control Department, which is responsible for conducting internal audits, to carry out audits and exchange opinions with the representative directors to take necessary measures. The Board of Auditors consists of two standing members and three outside auditors. The members of the Board of Auditors attend meetings of key management bodies, such as the Board of Directors and the Corporate Executive Management Meeting, providing their opinions as necessary. Also, in accordance with corporate auditing standards, members of the Board of Auditors conduct business and accounting audits to verify the legality and validity of the duties carried out by the directors

and corporate officers responsible for business execution. They also receive reports from the Internal Control Department and the independent accounting auditors and exchange opinions.

#### Business execution framework

SHIONOGI has introduced an executive officer system to support dynamic and flexible business operations, enabling the Group to respond rapidly to significant changes in the operating environment. SHIONOGI has established the Corporate Executive Management Meeting, which is attended by directors, standing corporate auditors, and parties responsible for business execution, and the meeting is generally held once a week. At the meeting, there is exhaustive deliberations on topics ranging from items concerning the execution of duties to important management matters. Business is executed within a system in which each of the ten divisions are under one of four supervisory units—the R&D Supervisory Unit, Healthcare Business Supervisory Unit, Supply Supervisory Unit, and Corporate Supervisory Unit. When executing business, issues are fully deliberated on at the Corporate Executive Management Meeting, and the Board of Directors makes decision regarding issues that impact management.

- R&D Supervisory Unit: Research Division, Drug Development and Regulatory Science Division, Biopharmaceutical Research Division
- Healthcare Business Supervisory Unit: Pharmaceutical Commercial Division, Integrated Disease Care Division
- Supply Supervisory Unit: Global Business Division
- Corporate Supervisory Unit: Corporate Strategy Division, Administration Division, DX Promotion Division, Corporate Quality Assurance and Ethics & Compliance Management Division

#### 4 Nomination Advisory Committee

The Nomination Advisory Committee consists of the President, three Outside Directors, and one Outside Corporate Auditor, and is chaired by an Outside Director. Topics discussed included the balance of expertise among the members of the Board of Directors, including outside directors, and corporate officer nominations. The committee also delivers reports and makes proposals at Board of Directors meetings and conducts in-house inspections that give outside officers the opportunity to review our human resources by talking with division heads and heads of our major organizations. It was held once in fiscal 2021.

#### 5 Compensation Advisory Committee

The Compensation Advisory Committee consists of the President, three Outside Directors, and one Standing Corporate Auditor, and is chaired by an Outside Director. Main topics discussed in fiscal 2021 included the performance evaluation of Directors and Executive Officers in fiscal 2020, performance evaluation indicators for fiscal 2021, and the ideal form of the executive compensation system, etc. It was held two times in fiscal 2021.

- 6 Outside officer and the President opinion exchange meetings
- 7 Informal meetings with Associate Corporate Officers

Meetings that serve as a venue for the outside officers and the President to exchange opinions are in principle held three times per year. These opinion exchanges take place with the objective of enhancing the quality of discussions at the Board of Directors meetings. Opinion exchange meetings are convened with the Outside Directors, all of the Corporate Auditors, and the President in attendance, and topics for discussion include recent trends in the healthcare industry and Company business, as well as plans for executive training and the status of that training. In fiscal 2021, two rounds of meetings were held with Associate Corporate Officers who will be candidates for future executive officers.

#### 8 Outside officer information exchange/study sessions

In order to deepen understanding of SHIONOGI's business, the Standing Corporate Auditor hosts the outside officer information exchange and study sessions, which are attended by outside officers and senior management of SHIONOGI. In fiscal 2021, the sessions were held twice, once in August 2021 and once in March 2022. The topic of the August study session was "Ping An-Shionogi's business expansion," and information regarding the business expansion in the Asian market was shared. The topic of the March study session was "revisions to the Pharmaceutical and Medical Device Act and introduction of an emergency approval system," which deepened understanding of changes in and the present state of the pharmaceutical approval system for the pharmaceutical industry.

#### No. of meetings held

(Times)

		2021									2022		
	April	May	June	July	August	September	October	November	December	January	February	March	
1 Board of Directors meeting	1	2	1		2	1		2	1	1	1	2	
2 Board of Auditors meeting		1	2	1	1	1	1	1	1	1		1	
4 Nomination Advisory Committee											1		
5 Compensation Advisory Committee	1										1		
Outside officer and the President opinion exchange meetings					1			1			1		
7 Informal meetings with Associate Corporate Officers								1	1				
Outside officer information exchange/study sessions					1							1	

#### Approach to Succession

At SHIONOGI, appointments to the executive team are among the most important decisions made by the Board of Directors, and these are thoroughly deliberated under the strong leadership of the President, and CEO. In an era of fast-moving

change in the external environment, the criteria for assessing candidates are changing, and SHIONOGI recognizes the need to groom successors from various aspects, based on what the SHIONOGI of the future should be. As mentioned above, we

#### **Corporate Governance**

have created opportunities for early dialogue between the Associate Corporate Officers who will be candidates for future executive officers and outside officers. In addition to the Nomination Advisory Committee, discussions are also held at the outside officer/the President opinion exchange meeting, where outside directors and corporate auditors provide a great deal of advice.

Of the Associate Corporate Officers in fiscal 2021, four were newly elected as executive officers in fiscal 2022.

Also, through the President's Management Seminar, where the President himself does the teaching, we are implementing human resources training that aligns with our qualifications for a successor.

#### **Deliberations at Board of Directors meetings**

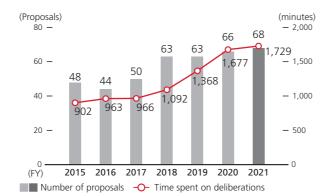
SHIONOGI's Board of Directors engages in lively discussions that incorporate a variety of opinions and advice from outside directors and Outside Corporate Auditors alike. Based on their diverse experience and expertise, each director takes a broad view toward promoting our sustainable growth and maximizing value for all our stakeholders while engaging in managerial decision-making and oversight of management.

At the Board of Directors meetings in fiscal 2021, there were lively deliberations on a wide range of topics, including the establishment and business plan of a new joint venture with Shimadzu Corporation, an investment in a continuous Active Pharmaceutical Ingredient (API) manufacturing business and establishment of a joint venture following the carveout of the investigative drug API business, a proposal to conclude a basic agreement with a new partner related to SHIONOGI's IT operations, and SHIONOGI Group branding activities and changes in the visual identity.

As an example of the animated discussions at our Board of

Directors meetings, this section has a summary description of the two topics of the new joint venture with Shimadzu Corporation and business plan and proposal to conclude a basic agreement with a new partner related to SHIONOGI's IT operations.

#### Number of proposals and time spent on deliberations



#### State of response to Corporate Governance Code

SHIONOGI has responded to all the principles in the Corporate Governance Code. See the Corporate Governance Report for details. https://www.shionogi.com/content/dam/shionogi/global/company/cg/basic/pdf/cg\_report\_en\_202207.pdf

#### Example 1 of deliberations: Establishment of and Business Plan of a new joint venture with Shimadzu Corporation

The involved parties made a proposal regarding not only establishing a joint venture with the Shimadzu to create a COVID-19 wastewater surveillance service platform by integrating and standardizing the related strengths that each group has acquired and promote the related business throughout Japan but also future business plans.

In response to the proposal, outside directors and Outside Corporate Auditors expressed a wide range of opinions based on their particular expertise and conducted lively deliberations. These opinions included ones regarding issues related to broadening the platform by expanding the service to other pathogens than COVID-19 and undertaking further collaboration with other companies that possess particular strengths: standardization of technology with an eve toward overseas expansion and the related patent strategy; scope of responsibility due to the provision of products and services; relationship with entities such as the responsible government ministries and agencies and local governments; and matters in the agreement that both parties should adhere to.

After the chairman consulted with attendees and the proposal was deliberated on, the proposal was approved as proposed, and the new joint venture AdvanSentinel Inc. was established in January 2022.

#### Example 2 of deliberations: Proposal to conclude a basic agreement with a new partner related to SHIONOGI's IT operations

The business environment is such that DX is accelerating in all fields, including the use of digital technology for drug discovery and clinical development and optimization of the overall value chain, even procurement, manufacturing, and logistics. SHIONOGI also faces various management issues, such as further increasing the efficiency of IT operations and reinforcing the strategy and planning functions within SHIONOGI. Taking these factors into consideration, the involved parties made a proposal to conclude with Hitachi, Ltd. a basic agreement regarding a medium- to long-term strategic partnership related to IT operations and to transfer some of SHIONOGI's operations and human resources to Hitachi Pharma Information Solutions, Ltd.

In response to the proposal, outside directors and Outside Corporate Auditors conducted lively deliberations following comments regarding various issues, including clarifying operations that should be strengthened by securing and training human resources in-house and operations that should try to be made more efficient by transferring them to a partner, the ideal form of governance to prioritize DX/IT projects and achieve an optimal allocation of resources, the continuing need to examine solutions to DX/IT issues, and appropriate disclosure.

After the chairman consulted with attendees and the proposal was deliberated on, the proposal was approved as proposed, and a close partnership with the Hitachi Group was launched in January 2022.

#### **Analysis/evaluation of effectiveness**

The Board of Directors performed an analysis and assessment of the effectiveness of the Board of Directors in fiscal 2021 that focused on SHIONOGI's Basic Views and Guidelines on Corporate Governance, Article 6. Directors and the Board, (1) Framework, (3) Roles and Responsibilities, and (6) Operation, by conducting questionnaires and interviews with each director and corporate auditor. Below is a summary of the findings.

#### Summary of analysis and evaluation results for fiscal 2021 and response

Our assessment is that the Board of Directors has currently secured the necessary framework from the standpoint of diversity and such factors as expertise and experience. As a future topic and based on our business expansion and transformation, from the standpoints of further diversity and succession, the need to appoint a foreign national as a director and develop and recommend candidates for the next successor was mentioned.

The Board of Directors will continue to consider ways to further strengthen the governance framework while taking into account the status of SHIONOGI's business expansion.

#### **Roles and Responsibilities**

Regarding the reporting and supervision of the status of senior management development, reports were continuously provided at opinion exchange meetings with the Outside

Directors and the President, and issues were discussed and shared at two opinion exchange meetings with Associate Corporate Officers (senior management candidates), a new job position established in 2021, and outside directors. In addition, the status of compliance activities was reported on twice in the year and there was an exchange of opinions at Board of Directors meetings. Also, ESG-related matters were proposed and reported on several times, and deliberations and resolutions were made on these matters at the Board of Directors meetings.

Future challenges were raised, including the need for further enhancement of reporting on the progress of the medium-term business plan and reporting on non-financial information, such as risk management and responses to climate change.

The Board of Directors will continue to explore ways to improve its roles and responsibilities.

To further stimulate discussion at Board of Directors meetings, we continued to hold preliminary briefings on the agendas of Board of Directors meetings on a regular basis and delivered the appropriate reports on the matters decided at Board of Directors meetings.

As a future topic, a suggestion was made regarding the efficient running of Board of Directors meetings to further enhance discussions.

We will continue to consider ways to enrich management of the Board of Directors.

# ernance to Create Value and Implement Strat

#### **Corporate Governance**

#### **Cross-shareholdings**

After due consideration of the relationship with the cost of capital, cross-shareholdings are only held in cases where it is judged that they will increase SHIONOGI's corporate value and contribute to a sustainable improvement of corporate value. In other cases, we are proceeding with sequential sell-offs in consideration of stock prices and market trends.

Since the end of fiscal 2017, the number of stocks held and the value of shares have been reduced by 30% and 45%, respectively. In addition, the economic rationale for continuing to hold individual cross-shareholdings is verified annually at a Board of Directors meeting.



#### **Remuneration for directors and corporate auditors**

#### Process for determining remuneration

The Compensation Advisory Committee deliberates carefully on the matter of directors' compensation and discusses various issues concerning remuneration for directors and executive officers, verifies the levels of remuneration every year, and deliberates the remuneration system, and performance evaluation system for the following fiscal year.

#### Remuneration Framework

Total director remuneration is determined within limits set by resolution of the General Meeting of Shareholders. This consists of base monthly remuneration, performance-linked bonuses determined by results for the fiscal year and other factors, and since fiscal 2018, restricted stock compensation (medium-term performance-linked and long-term). Also, outside directors receive only base remuneration.

Base remuneration is determined based on the base remuneration table according to the position and role of directors with due consideration of the management environment and global trends.

Performance-linked remuneration (bonus) is paid as cash remuneration, which reflects performance indicators (core operating profit excluding sales of assets, etc., profit attributable to owners of the parent and other total performance evaluation as directors) to heighten the awareness of improving performance for each fiscal year. As short-term incentives, they are determined based on the calculation table according to performance such as achievement of targeted profits and

other factors in each fiscal year and paid in June of each year. Non-monetary remuneration (stock-based compensation) is

granted in July of each year based on the stock-based compensation table according to directors' rank and job responsibilities. For medium-term performance-linked stock compensation in particular, the performance evaluation will be based on the degree of achievement in fiscal 2022 for the portion to be granted in the three years from fiscal 2020 through fiscal 2022 during the STS2030 Phase 1 period (fiscal 2020 through fiscal 2024) to determine the ratio of lifting the transfer restriction (100% to 0%). In addition, when lifting the transfer restriction, 50% of the amount of stock-based compensation, translated into the share price at the time of lifting, is paid as monetary compensation. Performance evaluations use such quantitative indicators as revenue, overseas net sales, core operating profit, ROE and the ranking in total shareholder return (TSR) among 12 competitors including SHIONOGI (relative TSR) and also incorporate the status of ESG, compliance, and the status of initiatives associated with COVID-19.

The Compensation Advisory Committee discusses the ratio of remuneration by type for executive directors in consideration of remuneration levels, using as its benchmark companies that have a similar business size to SHIONOGI and are included among the relevant business types and categories, and the Board of Directors, in respect of the recommendations given by the Compensation Advisory Committee, determines the details of the remuneration system, etc. so that the ratio of remuneration by type is in line with the recommendations. The policy for determination thereof is set in accor-

dance with the separately defined "Policy for Determination of Details of Individual Remuneration, etc. for Directors." In addition, pursuant to the resolution at the Board of Directors meeting held on February 22, 2021, it is considered appropriate that base remuneration and individual bonus amount, etc. are evaluated and determined by a person who bears the ultimate management responsibility, and thus, such evaluation

and determination are entrusted to the President. The Compensation Advisory Committee deliberates the policy and criteria for the entrustment and provides the Board of Directors with the results as recommendations for their resolution, and the President, to whom such determination is entrusted, shall make decisions in accordance with said recommendations and the abovementioned resolution by the Board of Directors.

#### Composition of remuneration

The targeted ratio for each type of remuneration is set at base remuneration: performance-linked remuneration<sup>\*1</sup>, etc.: non-monetary remuneration<sup>\*1</sup>, etc. = 1:1:1 on the premise that all KPIs are achieved.

\*1 Performance-linked remuneration, etc. consists of executive bonuses, and non-monetary remuneration, etc. consists of restricted stock.

#### Base remuneration

Determined based on the basic remuneration table according to the position and role of each director, taking into consideration the business environment and public trends.

#### Performance-linked remuneration

Determined based on a calculation table based on performance, such as achievement of target profits for each fiscal year, as a short-term incentive.

#### Non-monetary remuneration

Incentives to further increase the linkage with medium- to long-term business performance and to promote sustainable enhancement of corporate value for the Company's directors, excluding outside directors.

#### Actual remuneration

Actual remuneration for fiscal 2021 was as follows.

#### ■ Total amount of remuneration for Directors and Corporate Auditors (fiscal 2021)

(Millions of yen)

		Total amount of remuneration, etc. by type								
Category	Persons	Base remuneration	Performance-linked remuneration*2	Non-monetary remuneration*3	Total					
Directors (of which Outside Drectors)	5 (3)	189 (57)	137 (—)	98 (—)	426 (57)					
Corporate Auditors (of which Outside Corporate Auditors)	5 (3)	124 (54)	— (—)	— (—)	124 (54)					
Total	10	314	137	98	550					

<sup>\*2</sup> The amount of "Performance-linked remuneration, etc." above is the amount of provision for Directors' bonuses for the fiscal year.

#### Total consolidated remuneration, etc. by director (fiscal 2021)

(Millions of yen)

		Total amount of remuneration, etc. by type							
Name	Position	Base remuneration	Performance-linked remuneration	Non-monetary remuneration	Total				
Isao Teshirogi	Director	84	87	73	245				
Takuko Sawada	Director	48	50	25	123				

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<sup>\*3</sup> The amount of "Non-monetary remuneration, etc." above is the amount recorded as an expense in the fiscal year



#### Members of Boards (as of July 1, 2022)

#### Directors

# 1 Isao Teshirogi, Ph.D. 57,900 shares Representative Director, Chairman and President

April 1982 Joined the Company January 1999 General Manager, Secretary Office and General Manager, Corporate Planning Department

ager, Corporate Planning Department

June 2002 Director of the Company

October 2002 General Manager, Corporate Planning Department
April 2004 Executive Officer and Executive General Manager, Pharmaceutical Research & Development Division

April 2006 Senior Executive Officer and Executive General Manager, Pharmaceutical Research & Development Division

April 2007 Senior Executive Officer

oril 2008 Representative Director and President and CEO of the Company

June 2021 Outside Director of Sumitomo Mitsui Banking Corporation (incumbent)

March 2022 Outside Director of AGC Inc. (incumbent)

July 2022 Representative Director, Chairman and President

#### Major concurrent posts:

Outside Director of Sumitomo Mitsui Banking Corporation Outside Director of AGC Inc.

(incumbent)

# 2 Takuko Sawada 40,850 shares Director and Vice Chairperson of the Board

pril 1977 Joined the Company
oril 2002 Executive General Manager. Pharmaceutical Develop-

ment Division

April 2007 Officer and Executive General Manager, Pharmaceutical
Development Division

April 2010 Executive Officer and Executive General Manager, Pharmaceutical Development Division

Senior Executive Officer and Executive General Manager,
 Global Development Office
 Senior Executive Officer and Senior Vice President.

April 2013 Senior Executive Officer and Senior Vice President,
Global Development Office and, Pharmaceutical Development Division

April 2014 Senior Executive Officer and Senior Vice President, Global Pharmaceutical Development Division

April 2015 Senior Executive Officer and Senior Vice President, Corporate Strategy Division

June 2015 Director of the Company and Senior Executive Officer and Senior Vice President, Corporate Strategy Division
October 2015 Senior Executive Officer and Senior Vice President, Corporate Strategy Division, and General Manager, Corporate Planning Department

April 2016 Senior Executive Officer and Senior Vice President, Corporate Strategy Division

April 2017 Senior Executive Officer and Senior Vice President, Corporate Strategy Division

April 2018 Director of the Company and Executive Vice President
April 2020 Director and Executive Vice President and Senior Vice
President of Integrated Disease Care Division

ly 2022 Director and Vice Chairperson of the Board (incumbent)

#### 3 Keiichi Ando

#### Independent Outside Director

April 1976 Joined Sumitomo Bank Limited (now Sumitomo Mitsui Banking Corporation)

April 2003 Executive Officer, Sumitomo Mitsui Banking Corporation
April 2006 Managing Executive Officer, Sumitomo Mitsui Banking

April 2009 Director and Senior Managing Executive Officer, Sumitomo Mitsui Banking Corporation

April 2010 Representative Director and Deputy President and Executive Officer, Sumitomo Mitsui Banking Corporation

April 2012 Representative Director and President, NEW KANSAI INTER-NATIONAL AIRPORT COMPANY, LTD.

July 2012 Representative Director and President and CEO, NEW KAN-SAI INTERNATIONAL AIRPORT COMPANY, LTD.

June 2016 Outside Director of the Company (incumbent)
June 2016 Representative Director and President, GINSEN CO., LTD.
June 2017 Outside Director of Tsubakimoto Chain Co. (incumbent)

June 2019 Outside Director of DAIHEN Corporation (incumbent)
Major concurrent posts:

Outside Director, Tsubakimoto Chain Co. Outside Director of DAIHEN Corporation

#### 4 Hiroshi Ozaki

#### Independent Outside Director

May 1972 Joined Osaka Gas Co., Ltd.
June 2000 Director, Osaka Gas Co., Ltd.

June 2002 Director and Tokyo Representative, Osaka Gas Co., Ltd., on loan to the Japan Gas Association

June 2005 Managing Director and General Manager of LNG Termi-

0 shares

nal and Power Generation Business Unit, Osaka Gas Co., Ltd.

June 2007 Managing Director and General Manager of Commercial & Industrial Energy Business Unit. Osaka Gas Co., Ltd.

& Industrial Energy Business Unit, Osaka Gas Co., Ltd.
April 2008 Representative Director and President, Osaka Gas Co.,
Ltd.

June 2008 Director, Osaka Gas Chemicals Co., Ltd.
June 2009 Representative Director and President, Operating Execu-

tive Officer, Osaka Gas Co., Ltd.

June 2009 Director of OGIS-RI Co., Ltd.

June 2011 Outside Director of Asahi Broadcasting Corporation
(now Asahi Broadcasting Group Holdings Corporation)

April 2015 Representative Director and Chairman, Osaka Gas Co., Ltd.

2019 Outside Director of the Company (incumbent)

January 2021 Director and Senior Advisor, Osaka Gas Co., Ltd.
June 2021 Senior Advisor, Osaka Gas Co., Ltd. (incumbent)
June 2021 Outside Director, The Royal Hotel Ltd. (incumbent)

Major concurrent posts:
Outside Director, The Royal Hotel, Ltd.

#### 5 Fumi Takatsuki

#### Independent Outside Director

October 2000 Registration of Attorney at Law

October 2000 Joined Oike Law Offices
December 2003 Joined Anderson Mon & Tomotsune Law Offices
February 2004 Service at Beijing Office of Anderson Mon & Tomotsune

Law Offices

April 2006 Joined Oh-Ebashi LPC & Partners

January 2009 Partner of Oh-Ebashi LPC & Partners (incumbent)

June 2020 Outside Director of the Company (incumbent)

Maior concurrent posts:

Partner of Oh-Fhashi I PC & Partners

Number of the Company's share owned

# $\begin{bmatrix} 2 & 4 & 1 & 3 \\ 2 & 4 & 1 & 3 \end{bmatrix} \begin{pmatrix} 8 & 6 & 9 & 7 & 10 \\ 8 & 6 & 9 & 7 & 10 \end{pmatrix}$

#### **Auditors**

#### 6 Akira Okamoto 6,657 shares

# Standing Members of the Board of Auditors April 1978 Joined the Company April 2006 General Manager, Business Support Center

April 1978 Joined the Company
April 2006 General Manager, Business Support Center
April 2007 General Manager, General Affairs & Personnel

Department
April 2008 General Manager, Human Resources Department

April 2008 General Manager, Human Resources Department
April 2011 General Manager, Internal Control Department
2015 Standing Member of the Board of Auditors of the Company (incumbent)

#### 7 Ikuo Kato

#### 0 shares

#### Standing Members of the Board of Auditors

October 1988 Joined the Company

April 2007 General Manager, Development Research Laboratories
April 2010 General Manager, Drug Development Research

September 2010 General Manager, Drug Development Research Laboratories and Representative Director and President, Shionogi TechnoAdvance Research & Co., Ltd.

pril 2013 General Manager, Drug Development Research Laboratories and Representative Director and Chairman, Shionogi TechnoAdvance Research & Co., Ltd. pril 2014 Representative Director and Chairman, Shionogi Tech-

noAdvance Research & Co., Ltd.

2016 Standing Member of the Board of Auditors of the Company (incumbent)

#### 8 Takaoki Fujiwara Independent Outside Auditor

#### 0 shares

oril 1975 Joined Hanshin Electric Railway Co., Ltd.

une 2005 Director, Hanshin Electric Railway Co., Ltd. 2007 Managing Director, Hanshin Electric Railway Co., Ltd. April 2011 Representative Director and President, Hanshin Electric

Railway Co., Ltd.

lune 2011 Director, Hankyu Hanshin Holdings, Inc.

April 2015 Chairman and Representative Director, Hanshin Hotel

April 2013 Chairman and Representative Director, Harishin Hotel

Systems, Co., Ltd.

April 2017 Chairman of the Board of Directors and Representative

Director, Hanshin Electric Railway Co., Ltd. (incumbent)

June 2017 Representative Director, Hankyu Hanshin Holdings, Inc.
2017 Outside Director, Sanyo Electric Railway Co., Ltd.

December 2017 Director, Hanshin Hotel Systems Co., Ltd. (incumbent)
June 2018 Outside Member of the Board of Auditors of the Company (incumbent)

#### Major concurrent posts:

Chairman of the Board of Directors and Representative Director, Hanshin Electric Railway Co., Ltd.

Outside Director, Sanyo Electric Railway Co., Ltd.

#### 9 Tsuguoki Fujinuma

# Independent Outside Auditor pril 1969 Joined Horie Morita Accounting Firm ine 1970 Joined Arthur & Young Accounting Firm lay 1986 Partner and Representative Partner of Asahi Shinwa

Accounting Firm (now KPMG AZSA LLC)

1993 Managing Partner of Ota Showa & Co. (now Ernst & Young ShinNihon LLC) (Resignation in June 2007)

2000 Pecident of the International Enderation of Accounts in Commentary Comments in Comments i

May 2000 President of the International Federation of Accountants
July 2004 Chairman and President of the Japanese Institute of Certified Public Accountants

tified Public Accountants

February 2005 Trustee and Vice Chairman of the IFRS Foundation

Trustee

July 2007 Advisor of the Japanese Institute of Certified Public
Accountants (incumbent)

August 2007 Outside Director of Tokyo Stock Exchange Group (now

Japan Exchange Group), Inc.
October 2007 Governor of Tokyo Stock Exchange Regulation (now Japan Exchange Regulation)

Japan Exchange Regulation)

April 2008 Specially appointed Professor of Chuo Graduate School of Strategic Management

June 2008 Outside Corporate Auditor of Sumitomo Corporation

June 2008 External Outside Corporate Auditor of Takeda Pharmaceutical Company Limited

June 2008 Outside Director of Nomura Holdings, Inc.

June 2008 Outside Director of Nomura Securities Co., Ltd.

July 2008 Outside Director of Sumitomo Life Insurance Company

April 2010 Visiting Professor at Kansai University (incumbent)

May 2010 Outside Corporate Auditor of Seven & i Holdings Co., Ltd.

April 2015 Fellow and Advisory Board Member at Chuo Universit Business School (incumbent)

July 2017 Auditor, Chiba Gakuen (incumbent)
June 2018 Chairman, Association of Certified Fraud Examiners
(AFCE Japan) (incumbent)
June 2019 Outside Member of the Board of Auditors of the Com-

June 2019 Outside Member of the Board of Auditors of the pany (incumbent)

Major concurrent posts:

Major concurrent posts: Auditor, Chiba Gakuen

#### 10 Shuichi Okuhara

Independent Outside Auditor

1994 Joined Andersen Consulting Co., Ltd. (now Accenture

0 shares

Japan Ltd.)
January 1998 Joined Nippon Venture Capital Co., Ltd.

January 1998 Joined Nippon Venture Capital Co., Ltd.

2008 Director and Manager of Investment Department, Nippon Venture Capital Co., Ltd.

pon Venture Capital Co., Ltd.

April 2009 Representative Director and President of Nippon Venture

ril 2009 Representative Director and President of Nippon Ventu Capital Co., Ltd. 2019 Representative Director and Chairman of Nippon Ven-

ture Capital Co., Ltd. (incumbent)

2020 Outside Member of the Board of Auditors of the Company (incumbent)

Major concurrent posts:

Representative Director and Chairman of Nippon Venture Capital Co., Ltd.

#### Corporate Officers

Senior Executive Officers

Koji Hanasaki, Ph.D.
John Keller, Ph.D.
Toshinobu Iwasaki, Ph.D.
Noriyuki Kishida
Kazuhiro Hatanaka

Ryuichi Kiyama, Ph.D.

Yasuyoshi Isou, Ph.D.

Corporate Officers

Takeshi Shiota, Ph.D.
Akira Kato, Ph.D.
Tatsumori Yoshida
Masashi Deguchi, Ph.D.
Yasunori Aoyama, Ph.D.
Yousuke Miharu
Takeki Uehara, Ph.D.

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#### **Skill Matrix**

#### ■ Directors (as of July 1, 2022)

	of	FY2	021 attenda	ance					Sk	ills				
Name	Number of years in post	Board of Directors	Nomination Advisory Committee	Compensation Advisory Committee	Manage- ment experience	Financial accounting	Law/Compli- ance/Risk Manage- ment	R&D	Sales/ Marketing	Manufac- turing	IT/Infor- mation manage- ment	Interna- tional experience	HR/HR Develop- ment	Internal Audit
Isao Teshirogi, Ph.D. (62/Male) Representative Director, Chairman and President	20 years	14/14 (100%)	1/1 (100%)	2/2 (100%)	•		•	•		•		•		
Takuko Sawada (67/Female) Director and Vice Chairperson of the Board	7 years	14/14 (100%)	_	_	•			•	•		•	•		
Keiichi Ando (70/Male) Independent Outside Director	6 years	14/14 (100%) Chairman	1/1 (100%) Committee Chairman	2/2 (100%)	•	•						•	•	
Hiroshi Ozaki (72/Male) Independent Outside Director	3 years	14/14 (100%)	1/1 (100%)	2/2 (100%) Committee Chairman	•			•		•	•	•		
Fumi Takatsuki (47/Female) Independent Outside Director	2 years	14/14 (100%)	1/1 (100%)	2/2 (100%)			•					•	•	•

#### ■ Auditors (as of July 1, 2022)

	ර ් FY2021 attendance					Skills									
Name	Number of years in post	Board of Directors	Board of Auditors	Nomination Advisory Committee	Compensa- tion Advisory Committee	Manage- ment experience	Financial account- ing	Law/Com- pliance/Risk Manage- ment	R&D	Sales/ Market- ing	Manu- facturing	IT/Infor- mation manage- ment	Interna- tional experi- ence	HR/HR Develop- ment	Internal Audit
Akira Okamoto (67/Male) Standing Member of the Board of Auditors	7 years	14/14 (100%)	11/11 (100%)		2/2 (100%)			•		•				•	•
Ikuo Kato (68/Male) Standing Member of the Board of Auditors	6 years	14/14 (100%)	11/11 (100%)	_	_	•		•	•						
Takaoki Fujiwara (70/Male) Independent Outside Auditor	4 years	14/14 (100%)	11/11 (100%)	1/1 (100%)	_	•				•				•	
Tsuguoki Fujinuma (77/Male) Independent Outside Auditor	3 years	14/14 (100%)	11/11 (100%)	_	_		•	•					•		•
Shuichi Okuhara (54/Male) Independent Outside Auditor	2 years	14/14 (100%)	11/11 (100%)	_	_	•	•					•		•	•

# **Engagement with Stakeholders**

#### Creating corporate and social value through engagement

SHIONOGI aims to build a sustainable society by creating corporate and social value through engagement with its four stakeholder groups: shareholders and investors, customers, society, and employees.

#### ■ SHIONOGI-style "engagement"



#### Approaching our diverse stakeholders

In order to reach out to a wide range of stakeholders, we focus on proactively disseminating information to the press and the public at large through our website, social media, and

a variety of other tools. We are also working to enhance our information by posting the latest initiatives for COVID-19 on our website and revamping our pages for individual investors.



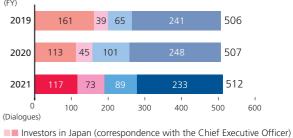
#### IR activities during the pandemic

In fiscal 2021, in addition to financial results and other such briefings, SHIONOGI held several briefings for investors and the media on COVID-19-related products, which are in particularly high demand. Through these various briefings, SHIONOGI disclosed information and engaged in dialogue, as appropriate, on strategies and progress toward achieving STS2030 and our efforts to resolve COVID-19 issues.

#### ■ Major IR Activities (FY2021)

- Number of dialogues with institutional investors and securities analysts: approximately 500, of which approximately 200 were handled by the Chief Executive Officer
- Briefings for investors and securities analysts: 8

#### ■ Number of dialogues with investors



- Investors in Japan (correspondence with the Chief Executive Officer)
   Investors in Japan (correspondence with the Corporate Communications Department)
- Overseas investors (correspondence with the Chief Executive Officer)
   Overseas investors (correspondence with the Corporate Communications Department)

#### Launch of the new brand

On July 1, 2022, the Group launched a new SHIONOGI brand in order to promote business transformation and achieve STS2030, as well as to gain recognition of SHIONOGI and appreciation of our activities among more people in Japan and abroad. By working together as a united Group under the new brand, we will continue to take on the challenge of transformation so that we can become a company that will be needed by all of our stakeholders in the future.

#### Capability and Vision, unified.





#### **Ensure Compliance**

For SHIONOGI, compliance is the basis for the company's survival and development. Compliance means compliance not only with laws, rules, and regulations, but also with social standards, and it also includes ethical behavior as a company and as a member of society. This stance is set forth in the Shionogi Group Code of Conduct and the Shionogi Group Compliance Policy, and all of our executives and employees are in strict adherence.

Initiatives	Related Indicators	Current Progress	Remaining Issues/Needs
Fostering of compliance awareness	Identification of SHIONOGI culture issues among all employees (April–July)     Deliberation and implementation on identified issues within the organization and formulate countermeasures (by whole organization, and Group companies)	<ul> <li>Establishment of a compliance promotion system headed by the President</li> <li>The Compliance Promotion Unit was established within the General Administration Department to plan compli-</li> </ul>	Aiming for zero compliance violations  Collecting information on corporate culture-related issues and reflecting that in Group overall activities
Strengthening of tie-ups with compliance units both in Japan and overseas	Meetings between the Compliance Promotion Unit and other divisions and among Group company Compli- ance Committees and compliance offi- cers and promoters (August)     Formulation of rules on the payment of compensation to healthcare provid- ers when undertaking global activities in coordination with compliance unit in each region	ance activities, support promotion, conduct education and training, and conduct awareness surveys  Interviews with domestic and overseas Group companies  Revised and made employees aware of the Shionogi Compliance Handbook (6th edition)	Making use of Shionogi Compliance Handbook Early detection and pre- vention of violations through use of internal reporting desks
Employee education	Top managers (division and organization heads) Education for compliance officers and promoters Education for new hires E-learning regarding the four main compliance risks for all employees	Integration of internal reporting desks	
Internal reporting system  Compliance awareness survey	Times the reporting desk was used (about 70)		
	Administered a questionnaire on com- pliance (100% response rate)		

Value Created

#### Trust of stakeholders

#### Fostering of compliance awareness

Having positioned compliance as the cornerstone of all activities, SHIONOGI encourages officers and employees to improve their understanding and awareness of its importance. As SHIONOGI works to implement STS2030, there are a growing number of situations involving unprecedented collaboration with entities in other industries that require novel but difficult decisions related to compliance. In order for each and every SHIONOGI employee to respond to these changes, possess a strong awareness of compliance, and act based on proper

decisions, SHIONOGI has undertaken various efforts. These include ensuring that all officers and employees know of the fully revised Shionogi Compliance Handbook (revised March 2021) and getting employees to view issues of the organization they belong to as their own problem, share diverse ways of thinking through repeated discussions at workplaces, consider such issues and ways of thinking independently as an individual and organization, and make it a habit to act.

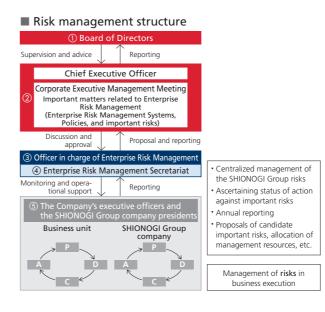
## **Risk Management**

In the age of VUCA, business uncertainty is increasing as the pace of social change increases, and it is essential to properly manage various internal and external risks in the process of change and corporate activities that STS2030 aims to achieve. In fiscal 2022, we have revised the SHIONOGI Group Enterprise Risk Management Policy, aiming to foster a risk culture and further strengthen our resilience through strategic management of both offensive and defensive risks.

#### **Promotion of risk management system**

SHIONOGI is committed to the appropriate management of business risks, including the creation of business opportunities and the avoidance and mitigation of risks, and has established an Enterprise Risk Management (ERM) system to oversee risks throughout the Group as an important mechanism for management strategy and management infrastructure, which we are striving to promote. A fundamental of the SHIONOGI Group is to have each organization identify risks associated with its decision making and business execution and then take the initiative to manage and deal with those risks. In particular,

the Corporate Executive Management Meeting and the Board of Directors deliberate and make decisions on policies for responding to significant risks that could have an impact on management, and based on the response policy, the supervising department works with the related organizations to implement these measures. In addition, the Internal Control Department, which is the internal audit division, conducts independent verification in accordance with the "Basic Policy for Construction and Operation of Internal Control System".



		Role
1	Board of Directors	Provides supervision, advice, etc. on the planning, progress, and results of ERM promotion activities
2	Chief Executive Officer, Corporate Executive Meeting	The Corporate Executive Meeting, chaired by the Representative Director, President discusses important matters concerning SHIONOGI's ERM, which are approved by the Representative Director, President
3	Officer in charge of Enterprise Risk Management	The Corporate Supervisor is Chief Risk Management Officer (CRO), overseeing SHIONOGI's risk management and assuming responsibility for the promotion and operation of the ERM system.
4	Enterprise Risk Management Secretariat	The enterprise risk management secretariat consists of the Sustainability Management Department, the General Administration Department, and the Corporate Planning Department.
5	The Company's executive officers and the SHIONOGI Group company presidents	Each business unit and Group company is responsi- ble for the execution of risk management in the execution of its operations

#### **Crisis Management and Incident Management**

In line with the revision of the "SHIONOGI Group Risk Management Policy," we revised our crisis management-related regulations and established a management system that includes a Business Continuity Plan (BCP). In the event of a crisis, we will promote management focused on respect for human life, consideration for and contribution to local communities, and prevention of damage to corporate value, and strive to guickly overcome the crisis by taking prompt action.

Since fiscal 2021, we have been taking steps to build an IT-BCP, identifying critical systems with high recovery priority and revising rules that stipulate procedures for IT recovery in the event of a cyber incident. In fiscal 2022, we will conduct a BCP drill assuming an earthquake in the Nankai Trough for management to verify the system and procedures, and test

the effectiveness of related rules and regulations.

Furthermore, an incident is defined as "a negative event caused by SHIONOGI's action or omission," and we have a system in place so that when an event occurs that may affect management, information is promptly communicated to the Crisis Management Manager, the executive officer in charge, the CRO, and the President, who responds in cooperation with the person in charge of the department or office where the incident occurred. To create an organizational culture to achieve such a system, we are working to foster a culture of "Bad News First," in which negative information is reported more promptly than positive information, in coordination with the Group-wide compliance measures.

Shionogi & Co., Ltd. Integrated Report 2022

#### **Business and other risks**

Risk category	Summary	Response
Systemic and Regulatory Risk	There could be an impact from trends on government regulations such as revisions to Japan's National Health Insurance (NHI) system, drug price control measures, including the NHI drug price system, and COVID-19 related regulations and systems  Tougher Japanese and overseas regulations in areas such as the development and manufacturing of pharmaceuticals could present us with additional expenses or make it difficult for our products to comply with regulations	Provide innovative new drugs at an acceptable price to society Build evidence to show the value of the innovations created Promote the value of innovation through industry group activities Obtain the latest information on revisions to the drug pricing system and related regulations, etc. and promptly make appropriate changes
Risk of Adverse Reactions	Pharmaceuticals entail the risk of unanticipated adverse drug reactions that could lead to the termination of sales, product recalls, and other outcomes	Construct systems to appropriately convey side effect and other information     Educate all employees to limit the spread of side effects and control damage     Obtain insurance for medical damage compensation based on side effects, etc.
R&D Risk	Pharmaceutical R&D requires substantial commitment of resources and time. In addition, new drugs are subject to numerous uncertainties prior to the start of actual sales     Drastically reduce the time it takes to conduct R&D globally in order to fight the spread of COVID-19	Identify development compounds and key drug discovery programs, such as vaccines and medicines to treat COVID-19, and concentrate investments in resources to manage these programs     Develop efficient drug discovery research; leverage strengths in disease fields and small-molecule drug discovery     Maintain and improve productivity with global top-level R&D     To foster new growth areas and improve drug discovery success rates, build drug discovery technology for new drug discovery modalities other than small molecules (such as medium-sized molecule drugs and antibody drugs)     Invest in the management resources necessary for acquiring technologies such as peptide drugs and vaccines and collaborate with outside parties through alliances     Undertake rigorous determination of development possibility based on R&D data,
Risk of Dependence on Certain Products	Sales declines or discontinuation of sales due to the expiration of intellectual property rights of key products and the accompanying launch of generic products, drug price revisions and the appearance of competitors, the scale of epidemic, or other unforeseen circumstances	Accelerate R&D through in-licensing and out-licensing of compounds      Market launch of product groups and review contracts based on the latest information on drug price systems and competitive position     Collaborate and express opinions in industry groups that promote the importance and value of innovation creation     Promote business transformation from pharmaceuticals to provide general healthcare services, including pharmaceuticals
Risk of Part- nerships with Other Companies	Modification or cancellation of agreements, delays or stagnation of alliances with other companies for research, development, manufacturing and joint research in marketing, joint development, technology licensing and joint marketing	Judge whether or not to cooperate by analyzing and evaluating from various perspectives     Enter into agreements that incorporate assumed risks and hold continuous discussions and formulate agreements aimed at risk reduction     Establish and maintain a governance system with alliances, understanding the risks of alliances, and respond with measures to resolve them
Supply Chain Risk	There could be a significant impact on the stable supply of pharmaceutical products in the event of raw material or product supply disruptions due to factors such as natural disasters, pandemics, or geopolitical influences	Inventory management based on standards for the amount of inventory held     Selection of second vendors for items with high geopolitical risk     Establishment of a domestic manufacturing system for drugs contained in some products     Establishment and periodic review of BCP items to be supplied on a priority basis
Quality Risk	In the event of a quality problem of equipment origin, including contamination, quality defects, or lot failure,  • Damage to reputation originating in product  • Recalls, quality defects, and administrative action due to inconsistencies between the approval documents and actual manufacturing conditions  • Product recall due to inadequate data integrity, or serious findings during inspections by the regulatory authorities  • Possible serious impact on business performance, etc., due to loss of credibility of the company, etc.	Establishment of the Shionogi Group Quality Policy     Promoting the importance of quality by holding the SHIONOGI Global Quality Week     Fostering a Quality Culture     Responding to inspections by the authorities
IT Security and Data Management Risks	As we use many IT systems (including outsourcing companies) and possess a large volume of confidential information, including personal information, in the event that security problems occur or systems are shut down due to carelessness or deliberate actions on the part of employees or outsourcing providers or due to cyber-attacks and viruses from malicious third parties or other causes  • Our business activities, operating performance, financial circumstances, and credit ratings could be seriously affected  • We could be subject to damage claims or other legal claims or incur costs related to post-incident measures	Strengthen data management rules, etc. in light of the regulatory system and guidelines and appoint a CIO <sup>-1</sup> to be in charge of data management and set policies to protect data and ensure data security, a CDO <sup>-2</sup> to be in charge of integrating the use and management of data and documentation, and a Global Head of IT to be in charge of IT management.  Formulate a Global Privacy Policy regarding personal information  Make all employees cognizant of the importance of information management and personal information and of the need to obey laws and regulations concerning the protection of personal information  Launch a project to build an IT-BCP system that can handle cyber-attacks, major disasters, and other crisis events  Bolster the IT infrastructure, and strengthen the data security base and improve its management  Perform a global security assessment in response to the cyber-attack on our Taiwan facilities in order to prevent a recurrence and to ward off attacks on our other global locations, and take steps that include a drastic overhaul of our network systems through the entire Group

Risk category	Summary	Response
Risks Related to Securing / Training Human Resources	<ul> <li>Impact of not being able to recruit and train enough people who will think logically from a company-wide viewpoint in supporting the Group's highly efficient management, peo- ple who can bring about Shionogi's transformation into a HaaS company with sustainable growth, and people who will lead the resolution of social issues and view as golden opportunities such environmental changes as the employ- ment situation, increasing demand for ESG management; and workstyles for the post-COVID era</li> </ul>	Secure and train human resources with diverse values and expertise Practice diversity and inclusion Provide opportunities for self-growth and strengthen systems and mechanisms that help individuals realize their potential Implement manager education that supports development and human resource development that will contribute to the realization of the SHIONOGI Group Vision Implement business transformation/value creation training that uses IT and digital technology to facilitate our transformation into a HaaS company as set forth in STS2030 Train prospective executives through attendance at The President's Management Seminar and promotion to Group company officers
Environmen- tal and Safety Risks	Effects on the human body and ecosystems of substances used and generated in the research and manufacturing processes of pharmaceuticals     Temporary closure of facilities, countermeasures and restoration as well as legal liability attributable to environmental pollution or other hazards	Establish integrated management system and management regulations for environment, safety and health     Ensure compliance with laws and regulations, formulate stricter self-management star dards and goals, implement responses and measures, and confirm their appropriateness
Risk of Natu- ral Disasters or Pandemics	Closure of offices and suspension of plant operations due to natural disasters such as major earthquakes, climate change-related storms and floods, unforeseen accidents, outbreaks of pandemics, etc., and consequent delays and suspension of product supply	BCP formulation and training, and plan reviews     Confirm and request improvement for environmental and safety conditions in respons to supplier audits     Consider diversifying raw material suppliers to ensure the stable supply of products
Intellectual Property Risk	Concerns surrounding inadequate protection of the intellectual property of drugs discovered or infringement of the intellectual property of third parties     Impact of the expiration of intellectual property rights of pharmaceuticals developed and the launch of generics	Strengthen the appropriate management system for intellectual property rights     Strengthen the system for preventing infringement by investigating infringement prevention in business activities and conducting intellectual property due diligence on licensing
Litigation Risk	Possibility of litigation related to medication side effects, product liability, workplace disputes, fair trading and other issues	Strengthen internal systems as necessary to reduce risk     Appropriately respond through consultation with experts such as lawyers and patent attorneys
Capital Mar- ket and For- eign Exchange Risk	Fluctuations in stock and foreign exchange markets could increase retirement benefit obligations and affect royalty income from overseas partners	Diversify investment of pension assets among multiple investment products     Utilize forward exchange contracts with respect to foreign exchange fluctuation risk
Compliance Risk	<ul> <li>In executing our business activities, we are subject to regulations and various laws on pharmaceuticals, product liability, and the like, and we are required to uphold very high ethical standards as a pharmaceutical company that is directly involved in people's lives. Therefore, behavior that violates laws and regulations or runs contrary to social needs could lead to a loss or decline in SHIONOGI's credibility among its stakeholders and even have an impact on our financial performance.</li> </ul>	As strict compliance is always a top priority in our business endeavors, the topic of compliance will always be addressed in the President's quarterly message  Work to strengthen compliance awareness among employees  Formulate a compliance policy and set compliance as a goal in the Shionogi Group Code of Conduct  Establish a Compliance Committee and Internal Reporting Desks (inside and outside the Company)  The Compliance Committee, which will meet four times per year and be headed by the President, will discuss compliance-related topics and implement the necessary educational and other programs (harassment, data leaks, bribery prevention, etc.)
The Spread of COVID-19	If our business becomes constrained by the further spread of COVID-19, shutdowns or slowdowns in the procurement of raw materials and other parts of the supply chain could have a significant impact on obtaining a stable supply of medicines  Restrictions on programs that use MRs to supply information or delays in research and clinical experimentation could have a significant impact on the approval, launch, and commercialization of new products and on the collection and supply of drug safety information and information on proper usage	Restrict on-site work to prevent the further spread of the pandemic Programs to establish new workstyle needed to maintain and improve productivity Fulfill our social responsibility as a pharmaceutical company by maintaining business continuity through employing our existing pandemic BCP in a response that prioritizes a stable supply of our proprietary drug products As a marketing initiative during the pandemic, change the mechanism and content of information supply in accordance with the Ministry of Health, Labour, and Welfare's Guidelines on the Provision of Marketing Information

For more information on our risk management, please visit our website.

https://www.shionogi.com/global/en/sustainability/governance/risk-management.html

<sup>\*1</sup> CIO: Chief Information Officer
\*2 CDO: Chief Data Officer
The Company is subject to many other risks related to its business activities in addition to the above, so the risks discussed here do not comprise all of SHIONOGI risks.

Third Medium-Term Business Pla	ır
SONG for the Real Growth	

Progress toward global growth

Grow as a drug discovery-based pharmaceutical

Shionogi Growth Strategy 2020 Grow sustainably as a drug (October FY2016-FY2019)

discovery-based pharmaceutical company contributing to a more vigorous society through improved healthcare

**Shionogi Transformation** Strategy 2030

**Building Innovation Platforms to** Shape the Future of Healthcare

				company (FY2014-Septer	mber FY2016)			
JGAAP	2012	2013	2014	2015	2016	2017	2018	2019
For the years ended March 31:								(Millions of yen)
Net sales	¥ 267,275	¥ 282,903	¥ 289,717	¥ 273,991	¥ 309,973	¥ 338,890	¥ 344,667	¥ 363,721
Cost of sales	77,753	78,574	77,993	82,189	74,758	77,777	73,911	54,880
Selling, general and administrative expenses	142,518	144,764	149,848	141,436	143,808	152,934	155,537	170,303
Operating income	47,003	59,565	61,875	50,365	91,406	108,178	115,219	138,537
Ordinary income	46,093	58,922	62,225	77,880	100,869	123,031	138,692	166,575
Profit before income taxes	41,494	58,306	63,188	82,051	97,452	122,695	137,378	170,343
Profit attributable to owners of parent	27,101	66,727	40,618	44,060	66,687	83,879	108,866	132,759
Net cash provided by operating activities	54,724	59,276	79,496	45,604	102,290	111,903	129,790	145,684
Net cash used in investing activities	(38,290)	(19,959)	(20,040)	(31,696)	(32,894)	(31,643)	(51,238)	(36,349)
Net cash used in financing activities	(27,749)	(37,687)	(53,798)	(46,211)	(18,525)	(57,411)	(53,893)	(87,011)
Research and development expenses	53,599	53,021	53,605	48,870	49,787	59,907	59,945	68,325
Capital investments	13,233	11,447	8,962	8,163	9,943	9,659	5,678	7,900
Depreciation and amortization	16,282	11,912	12,912	12,672	12,578	13,362	15,972	16,479
As of March 31:								(Millions of yen)
Property, plant and equipment, net	¥ 74,282	¥ 78,473	¥ 78,976	¥ 77,022	¥ 78,673	¥ 78,788	¥ 75,956	¥ 74,653
Intangible assets	106,694	70,464	72,824	80,328	71,626	91,125	75,060	54,769
Total assets	522,161	574,882	580,566	595,067	631,599	661,499	711,463	778,741
Total long-term liabilities	92,899	53,041	33,721	48,427	45,739	44,692	34,056	17,203
Total net assets	347,198	423,633	467,836	478,883	513,877	526,211	604,840	672,429
Per share amounts:								(Yen)
Profit attributable to owners of parent	¥ 80.93	¥ 199.25	¥ 121.29	¥ 132.67	¥ 204.83	¥ 259.88	¥ 342.71	¥ 424.31
Net assets	1,027.83	1,254.44	1,385.11	1,456.70	1,564.73	1,638.46	1,911.36	2,144.33
Dividend	40	42	46	52	62	72	82	94
Other:								(%)
Equity ratio	65.9	73.1	79.9	79.7	80.7	79.0	84.5	85.7
Return on equity [ROE]	8.1	17.5	9.2	9.4	13.6	16.3	19.4	20.9
Payout ratio	49.4	21.1	37.9	39.2	30.3	27.7	23.9	22.2
Notes: 1. From the fiscal year ended March 31, 2015, th	he Company has add	opted a new accour	nting standard for r	esearch and develor	oment expenses (bu	siness research		

International Financial Reporting Standards (IFRS)	2019	2020	2021	2022
For the years ended March 31:				(Millions of yen)
Revenue	¥ 367,960	¥ 333,371	¥ 297,177	¥ 335,138
Cost of sales	(55,591)	(56,782)	(52,523)	(55,415)
Selling, general and administrative expenses	(87,668)	(95,094)	(91,902)	(91,771)
Research and development expenses	(52,058)	(47,949)	(54,249)	(72,996)
Operating profit	145,081	130,628	117,438	110,312
_	_	_	_	_
Profit before tax	174,043	158,516	143,018	126,268
Profit attributable to owners of parent	137,191	122,193	111,858	114,185
Net cash provided by operating activities	165,000	131,940	109,039	102,068
Net cash used in investing activities	(56,256)	(29,144)	(5,261)	(96,204)
Net cash used in financing activities	(89,912)	(88,174)	(43,891)	(36,615)
Capital investments	7,900	9,954	27,371	27,274
Depreciation and amortization	14,431	14,115	14,779	16,351
As of March 31:				(Millions of yen)
Property, plant and equipment, net	¥ 70,986	¥ 71,350	¥ 90,883	¥ 108,893
Intangible assets	47,804	51,705	76,558	81,223
Total assets	938,540	873,695	998,992	1,150,601
Total equity	813,087	765,203	864,550	993,285
Non-current liabilities	29,303	27,372	34,261	32,920
Per share amounts:				(Yen
Basic earnings per share	¥ 438.47	¥ 395.71	¥ 365.03	¥ 378.75
Equity attributable to owners of parent per share	2,598.16	2,518.74	2,806.67	3,236.21
Dividend	94	103	108	115
Other:				(%)
Ratio of equity attributable to owners of parent	86.2	87.6	84.7	84.8
Return on equity attributable to owners of parent (ROE)	17.8	15.5	13.9	12.5
Payout ratio	21.4	26.0	29.6	30.4

Notes: 1. From the fiscal year ended March 31, 2015, the Company has adopted a new accounting standard for research and development expenses (business research expenses). This change has been reflected in figures for the fiscal year ended March 31, 2014.

<sup>2.</sup> In the fiscal year ended March 31, 2019, the Company changed the presentation method for tax effect accounting. The change has been reflected in figures for the fiscal year ended March 31, 2015, and subsequent periods.

<sup>3.</sup> International Financial Reporting Standards (IFRS): Accounting standards defined by the non-government organization International Accounting Standards Board (IASB) headquartered in London.

<sup>4.</sup> IFRS adopted from the fiscal year ended March 31, 2020.

#### (Millions of ven)

# **Consolidated statement of financial position**

		(Millions of yen)
	As of March 31, 2021	As of March 31, 2022
Assets		
Non-current assets		
Property, plant and equipment	¥ 90,883	¥ 108,893
Goodwill	9,357	9,638
Intangible assets	76,558	81,223
Right-of-use assets	4,827	3,524
Investment property	26,759	26,672
Other financial assets	217,437	242,479
Deferred tax assets	11,729	12,907
Other non-current assets	5,200	6,055
Total non-current assets	442,754	491,396
Current assets		
Inventories	38,003	45,892
Trade receivables	78,047	122,965
Other financial assets	142,151	210,757
Income taxes receivable	164	51
Other current assets	21,697	25,117
Cash and cash equivalents	276,173	254,420
Total current assets	556,238	659,205
Total assets	998,992	1,150,601

	(Millions of yen)		
	As of March 31, 2021	As of March 31, 2022	
Equity and liabilities			
Equity			
Share capital	¥ 21,279	¥ 21,279	
Capital surplus	13,733	14,455	
Treasury shares	(57,989)	(57,857)	
Retained earnings	752,248	832,958	
Other components of equity	116,836	164,824	
Equity attributable to owners of parent	846,108	975,661	
Non-controlling interests	18,442	17,624	
Total equity	864,550	993,285	
Liabilities			
Non-current liabilities			
Lease liabilities	4,608	3,729	
Other financial liabilities	5,242	5,616	
Retirement benefit liability	16,318	15,412	
Deferred tax liabilities	7,749	7,807	
Other non-current liabilities	341	354	
Total non-current liabilities	34,261	32,920	
Current liabilities			
Lease liabilities	3,379	2,945	
Trade payables	9,902	16,372	
Other financial liabilities	21,383	22,027	
Income taxes payable	28,033	17,973	
Other current liabilities	37,481	65,078	
Total current liabilities	100,180	124,396	
Total liabilities	134,442	157,316	
Total equity and liabilities	998,992	1,150,601	

ata Section

Consolidated statement of profit or loss		(Millions of yen
	Year ended March 31, 2021	Year ended March 31, 2022
Revenue	¥ 297,177	¥ 335,138
Cost of sales	(52,523)	(55,415)
Gross profit	244,654	279,722
Selling, general and administrative expenses	(91,902)	(91,771)
Research and development expenses	(54,249)	(72,996)
Amortization of intangible assets associated with products	(3,209)	(3,476)
Other income	26,403	3,384
Other expenses	(4,257)	(4,551)
Operating profit	117,438	110,312
Finance income	26,522	16,797
Finance costs	(941)	(841)
Profit before tax	143,018	126,268
Income tax expense	(30,956)	(12,829)
Profit	112,061	113,439
Profit attributable to		
Owners of parent	111,858	114,185
Non-controlling interests	203	(746)
Profit	112,061	113,439
Earnings per share		(yen)
Basic earnings per share	365.03	378.75
Diluted earnings per share	364.89	378.63

## Consolidated statement of comprehensive income

(Millions	of yen)
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	Year ended March 31, 2021	Year ended March 31, 2022
Profit	¥ 112,061	¥ 113,439
Other comprehensive income		
Items that will not be reclassified to profit or loss		
Net change in fair value of equity instruments designated as measured at fair value through other comprehensive income	(4,677)	17,846
Remeasurements of defined benefit plans	(96)	(333)
Total of items that will not be reclassified to loss	(4,774)	17,513
Items that may be reclassified to profit or loss		
Exchange differences on translation of foreign operations	36,049	29,793
Effective portion of cash flow hedges	(5,828)	1,023
Total of items that may be reclassified to profit or loss	30,221	30,817
Total other comprehensive (loss) income, net of tax	25,447	48,330
Comprehensive income	137,509	161,769
Comprehensive income attributable to		
Owners of parent	137,407	161,865
Non-controlling interests	101	(95)
Comprehensive income	137,509	161,769

## **Consolidated statement of changes in equity**

		3		-5				(Millions of yen)
	Share capital	Capital surplus	Treasury shares	Retained earnings	Other components of equity	Equity attributable to owners of parent	Non- controlling interests	Total equity
Balance as of April 1, 2020	¥ 21,279	¥ 21,025	¥ (77,292)	¥ 708,291	¥ 91,848	¥ 765,152	¥ 51	¥ 765,203
Profit				111,858		111,858	203	112,061
Total other comprehensive income, net of tax					25,548	25,548	(101)	25,447
Comprehensive income	_	_		111,858	25,548	137,407	101	137,509
Purchase of treasury shares			(50,013)			(50,013)		(50,013)
Disposal of treasury shares		(4,705)	38,404			33,698		33,698
Cancellation of treasury shares		(30,912)	30,912			_		_
Dividends				(32,543)		(32,543)		(32,543)
Changes in scope of consolidation						_	10,696	10,696
Changes in ownership interest in subsidiaries		(7,593)				(7,593)	7,593	_
Transfer from other components of equity to retained earnings				71	(71)	_		_
Other		35,919		(35,430)	(488)	(0)		(0)
Balance as of March 31, 2021	21,279	13,733	(57,989)	752,248	116,836	846,108	18,442	864,550
Profit				114,185		114,185	(746)	113,439
Total other comprehensive income, net of tax					47,679	47,679	650	48,330
Comprehensive income	_			114,185	47,679	161,865	(95)	161,769
Purchase of treasury shares			(14)			(14)		(14)
Disposal of treasury shares		(5)	147			141		141
Dividends				(33,162)		(33,162)		(33,162)
Transfer from other components of equity to retained earnings				(308)	308	_		_
Other		727		(5)		722	(722)	_
Balance as of March 31, 2022	21,279	14,455	(57,857)	832,958	164,824	975,661	17,624	993,285

#### **Consolidated statement of cash flows**

Consolidated statement of cash flows		(Millions of yen)
	Year ended March 31, 2021	Year ended March 31, 2022
Cash flows from operating activities		
Profit before tax	¥ 143,018	¥ 126,268
Depreciation and amortization	14,779	16,351
Impairment losses	825	141
Finance income and finance costs	(25,836)	(15,597)
Decrease (increase) in trade and other receivables	2,993	(43,417)
Decrease (increase) in inventories	(3,435)	(7,133)
Increase (decrease) in trade and other payables	(2,380)	11,686
Other	(16,524)	15,087
Subtotal	113,438	103,387
Interest and dividends received	28,111	24,807
Interest paid	(256)	(87)
Income taxes paid	(32,254)	(39,324)
Income taxes refund	_	13,286
Net cash provided by operating activities	109,039	102,068
Cash flows from investing activities		
Payments into time deposits	(230,468)	(260,380)
Proceeds from withdrawal of time deposits	269,696	234,685
Purchase of property, plant and equipment	(28,182)	(26,185)
Purchase of intangible assets	(4,762)	(5,379)
Payments for acquisition of subsidiaries	(3,636)	_
Purchase of investments	(120,478)	(139,396)
Proceeds from sale of investments	116,265	99,511
Other	(3,694)	940
Net cash used in investing activities	(5,261)	(96,204)
Cash flows from financing activities		
Repayments of lease liabilities	(3,648)	(3,453)
Purchase of treasury shares	(50,134)	(14)
Proceeds from sale of treasury shares	33,534	_
Dividends paid	(32,529)	(33,146)
Payments for acquisition of interests in subsidiaries from non-controlling interests	(1,575)	——————————————————————————————————————
Capital contribution from non-controlling interests	10,464	_
Other	(0)	_
Net cash used in financing activities	(43,891)	(36,615)
Effect of exchange rate changes on cash and cash equivalents	7,425	8,998
Net increase (decrease) in cash and cash equivalents	67,312	(21,752)
Cash and cash equivalents at beginning of period	208,861	276,173
Cash and cash equivalents at end of period	¥ 276,173	¥ 254,420

# **Non-Financial Data**

Information on the	No. of employees	Mar. 31, 2018	Mar. 31, 2019	Mar. 31, 2020	Mar. 31, 2021	Mar. 31, 2022	Remarks
number of employees	No. of employees  Consolidated	5,120 persons	5,233 persons	5,222 persons	5,485 persons	5,693 persons	The figures in parentheses are calculated
Information about only Shionogi & Co.,	Shionogi & Co., Ltd.	3,677 persons	(4,554 persons) 3,596 persons	(4,527 persons) 2,667 persons	(4,617 persons) 2,589 persons	(4,507 persons) 2,510 persons	for domestic consolidated companies.
Ltd. unless otherwise stated)	Rate of female employees	27.8%	28.1% (32.2%)	24.1% (32.2%)	25.4% (32.7%)	25.8% (33.8%)	The figures in parentheses are calculated for domestic consolidated companies.
	Average age						
	Total	41.4 years old	41.7 years old	41.3 years old	41.2 years old		Excluding seconded persons
	Male Female	41.9 years old 40.0 years old	42.2 years old 40.4 years old	41.9 years old 39.2 years old	41.8 years old 39.3 years old	42.2 years old 39.7 years old	
	Length of service	10.0 years ord	10.1 years ord	33.2 years ord	33.3 year3 ord	33.7 years ord	
	Total	17.3 years	17.3 years	15.9 years	15.7 years	16.0 years	Excluding seconded persons
	Male	16.9 years	17.1 years	16.1 years	16.0 years	16.3 years	
	Female	17.4 years	17.8 years	15.0 years	15.0 years	15.2 years	
	Average salary  No. of new recruits	9,193,748 yen	9,042,130 yen	9,431,304 yen	9,028,578 yen	8,574,848 yen	
	Total	110 persons	101 persons	94 persons	71 persons	63 persons	Recruits who will enter the company on
	Male	71 persons	59 persons	56 persons	37 persons	43 persons	April 1 of the following fiscal year
	Female	39 persons	42 persons	38 persons	34 persons	20 persons	
	Turnover rate of recruits enrolled for	6.5%	3.0%	4.5%	6.0%	4.5%	Recruits who entered the company on A 1 three years ago
	Turnover rate of employees	1.9%	1.6%	1.9%	1.9%	3.5%	Excluding retired persons
	No. of labor union members	2,758 persons	3,012 persons	2,806 persons	2,728 persons	2,606 persons	100% participation every year As of the end of March. The figures in parentheses are calculated for special ca
	Employment rate of people with disabilities	2.2%	2.0% (2.5%)	2.0% (2.6%)	2.0% (2.7%)	1.8% (2.7%)	parentieses are calculated for special cal in affiliated companies. Shionogi Smile Heart Co., Ltd. establishe in April 2018 and certified as a special st sidiary company in July 2018.
	No. of female managers	47 persons	40 persons (63 persons)	39 persons (68 persons)	37 persons (71 persons)	40 persons (74 persons)	As of April 1 of the following fiscal year. The figure in parentheses is calculated for domestic consolidated companies.
	Rate of female managers	8.0%	9.9% (10.0%)	10.7% (11.4%)	10.4% (11.5%)	11.4% (12.4%)	As of April 1 of the following fiscal year. The figures in parentheses are calculated for domestic consolidated companies. Target: 15% (Domestic consolidation at end of March 2023)
	Rate of female heads of organizations	7.7%	8.6%	14.3%	12.7%	12.3%	As of April 1 of the following fiscal year
	Rate of female corporate officers	1/14 7.1%	1/13 7.7%	0/10 0.0%	0/10 0.0%	0/10 0.0%	As of April 1 of the following fiscal year
	Rate of female members of the Board	16.7%	16.7%	16.7%	40.0%	40.0%	As of April 1 of the following fiscal year
nformation on	Annual regular working hours for employees	1,860 hours	1,852 hours	1,845 hours	1,837 hours	1,762 hours	
labor management (Shionogi & Co., Ltd.)	No. of paid holidays	Up to 24 days	Up to 24 days	Up to 21 days	Up to 21 days	Up to 21 days	The number of legal annual holidays bar on the Labor Standards Act is up to 20 days.
	Average No. of paid holidays taken by employees	12.0 days	12.5 days	12.6 days	12.6 days	13.0 days	days.
	Acquisition rate of childcare leave						
	Female	100%	100%	100%	100%	100%	Rate of employees who have taken child care leave during the year when their ba
	Male No. of employees who have taken nurs-	21.0%	24.2%	32.8%	41.1%	51.4%	was born
	ing care leave						
	Female Male	4 persons 0 person	2 persons 0 person	4 persons 1 person	1 person 0 person	1 person 0 person	- Total number
	No. of employees who have worked on	o person	o persori	i persori	o persori	o person	
	short work hours due to child rearing Female	162 persons	119 persons	136 persons	130 persons	146 persons	
	Male	1 person	1 person	1 person	1 person	2 persons	Total number
	Volunteer leave	1 person	0 person	1 person	1 person	1 person	
	Leave for bone marrow transplant donors	0 person	0 person	1 person	1 person	0 person	
	Frequency rate	0.39	0.81	0.19	0.19	0.20	
	Severity rate	0.003	0.018	0.0002	0.0047	0.0049	
	Legal violations with serious fines or other sanctions	0 case					
Health Domestic consoli-	Smoking rate	16.4%	15.2%	14.2%	11.0%	7.1%	
lated companies)	Rate of stress check attendance	94%	96%	95%	94%	94%	
	Participation rate in a healthy walk  Rate of health checkup attendance	42.2% 100%	41.5% 100%	41.5% 100%	40.4% 100%	31.4% 100%	
	Rate of riedal Crieckup atterioralice	0.4%	0.4%	0.5%	0.6%	0.7%	
nvironment	GHG emissions (Scope 1 and 2)	90,136 tons-CO <sub>2</sub>	82,711 tons-CO <sub>2</sub>	82,209 tons-CO <sub>2</sub>	79,201 tons-CO <sub>2</sub>	84,164 tons-CO <sub>2</sub>	Note 1
Information about Iomestic consoli-	Total energy consumption	327,441MWh	314,174MWh	299,760MWh	305,339MWh	333,548MWh	Note 2
ated companies nly unless other-	Water use (Thousand)	1,389m³	1,315m³	1,263m³	1,217m³	1,366m³	
vise stated)	Amount of waste generated	3,486 tons 78%	3,824 tons 81%	3,062 tons 83%	4,180 tons 87%	5,169 tons 89%	
	Recycling rate  Landfill rate	1.0%	0.8%	1.0%	0.6%	0.9%	
	Hazardous waste	1,162 tons	1,830 tons	1,227 tons	1,722 tons	2,177 tons	
	Type 1 chemicals designated under the PRTR Act Amount handled	251 tons	274 tons	203 tons	257 tons	560 tons	
	Amount released	35 tons	43 tons	34 tons	94 tons	37 tons	
	Amount transferred	177 tons	156 tons	131 tons	114 tons	498 tons	
	No. of complaints about the environment	2 cases	1 case	0 case	0 case	3 cases	
Compliance Domestic consoli- lated companies)	Number of disciplinary dismissals of employees due to violations of laws for the prevention of corruption and bribery*	_	0 case	0 case	0 case	0 case	*FCPA in the U.S., Bribery Act in the UK - Unfair Competition Prevention Act in
uuteu companies)	Costs related to fines, punishments, and settlements of violations of laws for the prevention of corruption and bribery*	_	0 yen	0 yen	0 yen	0 yen	Japan
S.I.	Market capitalization	¥1,743.8 billion	¥2,170.5 billion	¥1,684.4 billion	¥1,854.6 billion	¥2,346.2 billion	
Information about		V/4 0000 ''''	1/0	V/4 OCT	1/4 000		
Information about only Shionogi & Co., td. unless otherwise	Donations	¥1,020 million	¥949 million	¥1,065 million	¥1,069 million	¥817 million	
Other Information about only Shionogi & Co., td. unless otherwise stated)	Donations	¥1,020 million	¥949 million	¥1,065 million	¥1,069 million 100%	¥817 million 100% 100%	- Domestic consolidated companies

stitute the boundary for SBT targets, included as of fiscal 2019.

Note 2: Including Nanjing Plant (Nanjing Chang'ao Pharmaceutical Co., Ltd.). Energy consumption by Nagase Medicals Co., Ltd. (currently Shionogi Pharma Co., Ltd., Itami Plant) included as of fiscal 2021.

#### **Environmental Data**

SHIONOGI calculates energy consumption and greenhouse gas (GHG) emissions using calorie conversion factors and CO2 emission factors for fuels and electricitv used each fiscal vear

GHG emissions and energy consumption data in fiscal 2021 marked with 🗹 were subject to third-party assurance by KPMG AZSA Sustainability Co., Ltd.

Indicators			Unit	2017	2018	2019	2020	2021
	Total of Scope 1, 2 ar	nd 3 (Location-based)	tons-CO <sub>2</sub>	287,356	209,171	226,883	200,519	221,295
		(Market-based)	tons-CO <sub>2</sub>	286,898	204,031	218,614	194,129	217,184
	Total of Scope 1 and	2 (Location-based)	tons-CO <sub>2</sub>	90,595	87,850	85,208	81,730	88,275
		(Market-based)	tons-CO <sub>2</sub>	90,136	82,711	76,939	75,339	84,164
	Scope 1		tons-CO <sub>2</sub>	43,456	41,349	37,519	37,537	41,264
Greenhouse		(Intensity per unit of sales*2)	tons-CO <sub>2</sub> /¥1 million	0.1261	0.1124	0.1125	0.1263	0.1231
gas (GHG)*1	Scope 2	(Location-based)	tons-CO <sub>2</sub>	47,139	46,501	47,690	44,193	47,011
gas (arra)		(Intensity per unit of sales*2)	tons-CO <sub>2</sub> /¥1 million	0.1368	0.1264	0.1431	0.1487	0.1403
	Scope 2	(Market-based)	tons-CO <sub>2</sub>	46,681	41,362	39,421	37,802	42,900
	(Intensity per unit of sales*2)		tons-CO <sub>2</sub> /¥1 million	0.1354	0.1124	0.1182	0.1272	0.1280
	Total of Scope 3		tons-CO <sub>2</sub>	196,761	121,321	141,675	118,789	133,020
	Category 3		tons-CO <sub>2</sub>	2,876	2,798	5,732	5,710	6,424
	Other categories		tons-CO <sub>2</sub>	193,885	118,523	135,943	113,079	126,596
	Total energy consum	otion*3	MWh	327,441	314,174	299,760	305,339	333,548
		(Intensity per unit of sales*2)	MWh/¥1 million	0.9500	0.8538	0.8992	1.0275	0.9953
	Gasoline		kl	1,749	1,598	1,382	779	798
Energy		osene, light oil, heavy oil A)	kl	54	87	49	64	28
consumption*1	Liquefied petroleur	m gas (LPG)	tons	808	830	580	347	301
consumption	Liquefied natural gas (LNG)		tons	8,067	7,932	7,113	7,876	8,330
	Town gas		thousand Nm³	6,860	6,138	5,771	5,786	6,961
	Electricity		MWh	90,497	89,107	93,245	92,111	102,436
	Steam*3		MWh	0	0	4,406	8,159	5,314

<sup>\*1:</sup> Effective from fiscal 2021 results, Nagase Medicals Co., Ltd. (currently Shionogi Pharma Co., Ltd., Itami Plant), which became a consolidated subsidiary in October 2020,

#### Calculation methods for environmental performance data

Boundary of	calculation Sco	pe 1 and 2:		SHIONOGI Group (excluding overseas Group companies [administrative offices]): SHIONOGI Group companies in Japan and Nanjing Plant (Nanjing Chang'ao Pharmaceutical Co., Ltd.)			
	Sco	pe 3	Category 3:	SHIONOGI Group companies in Japan (Shionogi & Co., Ltd. in or before fiscal 2018)			
			Other category	SHIONOGI Group companies in Japan (Shionogi & Co., Ltd. in or before fiscal 2018) (For other categories besides Category 5, UMN Pharma, Inc. and Nagase Medicals Co., Ltd. (currently Shionogi Pharma Co., Ltd., Itami Plant) are not included.			
	Ene	ergy consumption	:	SHIONOGI Group (excluding overseas Group companies [administrative offices]): SHIONOGI Group companies in Japan and Nanjing Plant (Nanjing Chang'ao Pharmaceutical Co., Ltd.)			
Calculation r	methods						
Indicators				Calculation methods			
Scope 1		Calculation me Environment ar CO <sub>2</sub> emission f	nd the Ministry of Eco actors: Based on the	re "Greenhouse Gas Emissions Accounting and Reporting Manual (Ver. 4.8)" of the Ministry of the onomy, Trade and Industry of Japan "Greenhouse Gas Emissions Accounting and Reporting Manual (Ver. 4.8)" of the Ministry of the onomy, Trade and Industry of Japan			
		CO <sub>2</sub> emissions Calculation me	resulting from purcha thods: Based on the ' nd the Ministry of Eco	ise of electricity and steam "Greenhouse Gas Emissions Accounting and Reporting Manual (Ver. 4.8)" of the Ministry of the nomy, Trade and Industry of Japan			
Scope 2		Electricity (Japa GHG emissions Trade and Indu	n) (location-based): N by specified emitters stry of Japan (Februar				
		emissions by sp and Industry of	Electricity (Japan) (market-based): Adjusted emissions factors from "Emission Factors by Power Suppliers (for the calculation of GHG emissions by specified emitters) (FY 2020 results)" published by the Ministry of the Environment and the Ministry of Economy, Trade and Industry of Japan (February 17, 2022)  Electricity (overseas) (both location-based and market-based): Emissions Factors (2019) of the International Energy Agency (IEA)				
		Steam (both lo Manual (Ver. 4.	cation-based and mar .8)" of the Ministry of	rket-based): Emissions factors from the "Greenhouse Gas Emissions Accounting and Reporting f the Environment and the Ministry of Economy, Trade and Industry of Japan			
Scope 3	Category 3	Calculation me 2.4)" of the Mi Values per Use	thods: Based on the ' nistry of the Environn of Electricity and Hea	ement of fuels required for the generation of electricity purchased "Basic Guidelines on Accounting for Greenhouse Gas Emissions Throughout the Supply Chain (Ver. nent and the Ministry of Economy, Trade and Industry of Japan, calculated using "7. Emission Unit tt" in the "The Database on Emissions Unit Values for Calculation of Greenhouse Gas Emissions, he Supply Chain (Ver. 3.2)" of the Ministry of the Environment of Japan			
·	Other categories	Total of Categories 1, 2, 4, 5, 6, 7 and 12, excluding Categories 8, 9, 10, 11, 13, 14 and 15 that are not included in our own cor activities or are reported under other categories  Calculation methods: Based on the "Basic Guidelines on Accounting for Greenhouse Gas Emissions Throughout the Supply Chair (Ver.2.4)" of the Ministry of the Environment and the Ministry of Economy, Trade and Industry of Japan					
	Total energy consumption	Total calorie-co Calculation me Fuel is expresse Rationalizing et	nverted values for puthod: d as the sum of calorics. Energy Use" conve	rchased energy (gasoline, other fuel oils, LPG, LNG, town gas, electricity, steam) ies calculated using calorie conversion factors under the "Ordinance for Enforcement of the Act on rted into MWh units with a rate of 3.6GJ per MWh. Note that calorie conversion factors disclosed . Electricity is expressed as the sum of purchase volumes (MWh) without conversion to primary			
_	Gasoline		oline purchased, inclu	uding fuel for sales force vehicles			
Energy	Other fuel oils		osene, light oil, heavy				
consumption	Liquefied petroleum gas (LPG)	Amount of LPG purchased from gas suppliers					
	Liquefied natural ga (LNG)	Amount of Live	g purchased from gas	**			
	Town gas		n gas purchased fron				
	Electricity		tricity purchased from				
	Steam	Amount of stea	am purchased from st	ream suppliers			

## **Third-Party Assurance of Environmental Data**



#### Independent Assurance Report

To the Chief Executive Officer of Shionogi & Co., Ltd.

We were engaged by Shionogi & Co., Ltd. (the "Company") to undertake a limited assurance engagement of the environmental performance indicators marked with "☑" (the "Indicators") for the period from April 1, 2021 to March 31, 2022 included in its SHIONOGI INTEGRATED REPORT 2022 (the "Report") for the fiscal year ended March 31, 2022.

#### The Company's Responsibility

The Company is responsible for the preparation of the Indicators in accordance with its own reporting criteria (the "Company's reporting criteria"), as described in the Report.

#### Our Responsibility

Our responsibility is to express a limited assurance conclusion on the Indicators based on the procedures we have performed. We conducted our engagement in accordance with the 'International Standard on Assurance Engagements (ISAE) 3000, Assurance Engagements other than Audits or Reviews of Historical Financial Information' and the 'ISAE 3410, Assurance Engagements on Greenhouse Gas Statements' issued by the International Auditing and Assurance Standards Board. The limited assurance engagement consisted of making inquiries, primarily of persons responsible for the preparation of information presented in the Report, and applying analytical and other procedures, and the procedures performed vary in nature from, and are less in extent than for, a reasonable assurance engagement. The level of assurance provided is thus not as high as that provided by a reasonable assurance engagement. Our assurance procedures included:

- Interviewing the Company's responsible personnel to obtain an understanding of its policy for preparing the Report and reviewing the Company's reporting criteria.
- Inquiring about the design of the systems and methods used to collect and process the Indicators.
- Performing analytical procedures on the Indicators.
- Examining, on a test basis, evidence supporting the generation, aggregation and reporting of the Indicators in conformity with the Company's reporting criteria, and recalculating the Indicators.
- Visiting one of the Company's offices selected on the basis of a risk analysis.
- Evaluating the overall presentation of the Indicators.

#### Conclusion

Based on the procedures performed, as described above, nothing has come to our attention that causes us to believe that the Indicators in the Report are not prepared, in all material respects, in accordance with the Company's reporting criteria as described

#### **Our Independence and Quality Control**

We have complied with the Code of Ethics for Professional Accountants issued by the International Ethics Standards Board for Accountants, which includes independence and other requirements founded on fundamental principles of integrity, objectivity, professional competence and due care, confidentiality and professional behavior. In accordance with International Standard on Quality Control 1, we maintain a comprehensive system of quality control including documented policies and procedures regarding compliance with ethical requirements, professional standards and applicable legal and regulatory requirements.

KPMG AZSA Sustainability Co., Ltd.

Osaka, Japan October 24, 2022

<sup>\*2:</sup> Intensity per unit of sales based on International Financial Reporting Standards (IFRS) is calculated from fiscal 2018 results. (On and before fiscal 2017, the Company cal-

<sup>\*3:</sup> While these were calculated in GJ units until fiscal 2020, they have been calculated in MWh units as of fiscal 2021. Total energy consumption and steam in or before fis-

Page*	Term	Explanation
1	SHIONOGI Group Heritage	SHIONOGI's corporate philosophy. Our basic polic and the foundation that makes up the core of all of our activities.
1	HaaS	Stands for "Healthcare as a Service." Refers to the Provision of a range of healthcare services in line with customer needs, rather than only the provi- sion of pharmaceuticals.
2	Clinical trials	Trials conducted to verify the effectiveness, safety and other aspects of candidate compounds, medical equipment, etc. as they apply to humans.
4	Wastewa- ter-based epide- miology survey service	Service for investigating the state of spreading of local infectious diseases by detecting pathogens is wastewater.
4	Recombinant pro- tein vaccines	Vaccines whose effective component is recombinant protein created based on the genes of protein that exists in antigens.
4	Antigen tests	Testing methods that detect particular proteins (antigens) on the target using antibodies of the target to be tested.
4	Biomarkers	Indicators used in diagnoses of ailments that are objectively measured and evaluated.
4	PCR tests	Testing method that detects the genes to be tested by amplifying them. PCR stands for "Polymerase Chain Reaction."
5	Total care	Care for ailments overall that includes pre-symptomatic, preventive, diagnostic and recuperative care in addition to treatment.
8	Chronic infectious diseases	Infectious diseases that include those contracted over a period of several years after symptoms appear such as tuberculosis, those for which the period between infection and the onset of symptoms is long such as human immunodeficiency viru (HIV), and those for which it difficult to distinguish the carrier or onset of symptoms such as hepatitis E
9	Acute infectious diseases	Infectious diseases period between infection and the onset of symptoms is short and whose progress in symptoms is rapid.
9	GE drugs	Stands for "Generic drugs."
9	AMR	Stands for "Antimicrobial Resistance." Indicates the decreasing effectiveness or ineffectiveness of antimicrobial drugs.
9	BARDA	Stands for the "Biomedical Advanced Research and Development Authority," which is based in the U.S.
9	CARB-X	Stands for the "Combating Antibiotic Resistant Bacteria Biopharmaceutical Accelerator." A public-private partnership that emphasizes support for antimicrobial research.
9	GARDP	Stands for the "Global Antibiotic Research and Development Partnership." A Swiss-based NPO that develops new therapeutic drugs for infec- tions caused by antimicrobial-resistant bacteria.
9	CEPI	Stands for "Coalition for Epidemic Preparedness Innovations." An international foundation that contributes funds to pharmaceutical companies and research institutions that engage in vaccine research.
9	CHAI	Stands for "Clinton Health Access Initiative." A global health organization that works towards saw ing the lives of people in low- to middle-income countries and mitigating the burden of illness.
11	Nonclinical studies	Testing for evaluating the effectiveness, safety, pharmacokinetics and other aspects of candidate compounds for drug discovery, medical equipment, etc. in in-vitro and animal experiments as they apply to non-humans. Synonymous with preclinical studies.
11	mRNA vaccines	Vaccines that employ mRNA, which serve as a schematic for target proteins.
15	ADHD	Stands for Attention Deficit/Hyperactivity Disorder
17	Multi-drug resis- tant bacteria	Bacteria for which numerous antimicrobial drugs have limited effectiveness or are ineffective.

	Term	Explanation	
18	Library of bacte- rial strains	A stock of bacterial strains from past years that are used in R&D for new antimicrobial drugs an for other applications.	
18	Small-molecule drug discovery engine	SHIONOGI's proprietary internal drug discovery system and expertise that enables us to bring forth innovative small-molecule pharmaceutical with speed and efficiency.	
18	Continuous manufacturing	A system through which raw materials or mixture thereof are continuously fed to the manufacture process, and homogeneous, high-quality production are manufactured on an ongoing basis through production control and quality control methods that were appropriately configured based on scentific knowledge. This system can be expected yield shorter development times, higher efficient through manpower- and space-saving, and advanced quality assurance for pharmaceuticals	
18	Manufacturing facilities for high-potency drugs	Facilities where substances that result in strong potency with small quantities can be safely manufactured.	
18	BEVS	Stands for "Baculovirus Expression Vector System." A protein expression technology that use insect cells.	
22	OTC drugs	General-use pharmaceuticals that can be purchased at a pharmacy, drugstore or other such location without a prescription. OTC stands for "Over The Counter."	
24	Patent cliff	Refers to a considerable decline in sales caused by replacement of pharmaceuticals with their generic counterparts once patents on the former expire.	
24	Royalties	Usage fees received by a company in accordance with the nature of the associated contract in return for permitting the use of intellectual property rights held by that company.	
24	HIV franchise	A product lineup that contains the anti-HIV dru dolutegravir and cabotegravir discovered by SHIONOGI as components.	
26	ViiV	Refers to ViiV Healthcare Limited. A specialty pharma firm in the HIV infection domain invest in by GSK, Pfizer and SHIONOGI.	
32	SBT	Stands for "Science Based Targets." Greenhous gas emission reduction targets based on scienti proof that conform to the levels required under the Paris Agreement.	
36	CDMO	Stands for "Contract Development and Manufaturing Organization." An organization for pharmaceutical development and manufacture on consignment.	
36	Three major infectious diseases	Refers to HIV/AIDS, tuberculosis and malaria, which are all global concerns.	
36	Neglected tropical diseases	General name given to parasitic diseases and infections caused by bacteria, etc. that are rampant predominantly in tropical regions.	
42	Mucosal immuni- ty-inducing vaccines	Vaccines that can be used to efficiently induce musal immunity in the nasal cavity, throat, etc. These play a key role in preventing pathogenic infection.	
44	MR	Stands for "Medical Representative." Personne who are in charge of medical information.	
53	EHS	Stands for "Environment, Health and Safety."	
55	Model List of Essential Medicines	Refers to types of pharmaceuticals believed to be required in order to maintain modern healthcare standards as formulated by the WHO. Contains approx. 300 pharmaceutical articles as sample sel tions upon gathering important pharmaceuticals.	
60	Switch OTC drugs	Pharmaceuticals for medical use that have been diverted to OTC drugs due to their high level of	
		safeness and limited side-effects.	

<sup>\*</sup>Indicates page where the term first appears.

## **Attestation of Validity**



#### On the issuance of the SHIONOGI **Integrated Report 2022**

Senior Executive Officer, Senior Vice President Corporate Supervisory Unit

#### Noriyuki Kishida

In order to realize the SHIONOGI Group Vision "building innovation platforms to shape the future of healthcare", we have expanded the definition of "medicine" to include "healthcare solutions". And in order to deliver the best healthcare solutions to the world, we aim to transform ourselves from a "drug discovery-based pharmaceutical company" to a HaaS company in our medium-term business plan STS2030 (Shionogi Transformation Strategy 2030).

SHIONOGI publishes its integrated reports, based on integrated thinking, to provide our stakeholders with a better understanding of our efforts. "SHIONOGI Integrated Report 2022", our seventh edition issued, details SHIONOGI's response as a leading company in infectious diseases toward the end of the COVID-19 pandemic, and reports on the status of development of therapeutic drugs and vaccines. This report also covers SHIONOGI's efforts to prepare for emerging and re-emerging infectious diseases that may occur in the future, as well as its initiatives in psychoneurological diseases, which is a core disease area along with infectious diseases. In order to communicate the evolution of our value creation framework in an easy-to-understand manner throughout the report, we have enhanced the layout to include descriptions of progress and specific initiatives, and summaries of our strategies for material issues (materiality) that should be given special priority and how SHIONOGI will transform itself into a HaaS company.

This report was produced with the cooperation of relevant organizations of SHIONOGI, with the Sustainability Management Department, Corporate Communications Department, and Corporate Planning Department playing a central role in discussions. As the senior executive officer responsible for the production of the report, I attest that the process of preparing the report is legitimate and that its content is accurate.

SHIONOGI will continue to evolve and grow as a company that pursues innovation, continuously challenges itself to create the future of healthcare, and contributes to solving social issues on a global scale. We hope that this report will help readers to better understand these efforts. We will continue striving to further enhance these reports so they will serve as an aid in dialogues with our stakeholders. Please give us your honest feedback and requests upon reading this report.

# **Corporate Information/Stock Information**

#### Corporate Data (As of March 31, 2022)

Company Name	Shionogi & Co., Ltd
Established	March 17, 1878
Incorporated	June 5, 1919
Paid-in Capital	¥21,279 million
Number of Employees	5,693 (Consolidated)
Fiscal Year-End	March 31
Website	https://www.shionogi.com/global/en/

#### **Stock Information** (As of March 31, 2022)

#### ■ Stock (Securities) Listings:

Tokyo (#4507) (Shares listed in 1949)

#### ■ Stock Status:

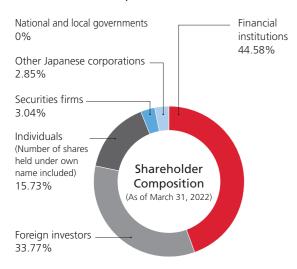
Common Stock Authorized: 1,000,000,000 shares

Issued: 311,586,165 shares

(Including 10,103,385 shares of treasury shares)

Number of shareholders: 98,031

#### ■ Shareholder Composition



Note: Treasury shares included in Individuals.

#### ■ Major Shareholders

Name	Number of shares (Thou- sands)	Percent- age of total shares (%)
The Master Trust Bank of Japan, Ltd. (Trust account)	63,344	21.01
Custody Bank of Japan, Ltd. (Trust account)	19,271	6.39
Sumitomo Life Insurance Company	18,604	6.17
SMBC Trust Bank Ltd. (as a trustee for retirement benefit of Sumitomo Mitsui Banking Corporation)	9,485	3.14
Nippon Life Insurance Company	8,409	2.78
JP MORGAN CHASE BANK 385632	7,582	2.51
BANK OF CHINA (HONG KONG) LIMIT- ED-PING AN LIFE INSURANCE COMPANY OF CHINA, LIMITED	6,356	2.10
STATE STREET BANK WEST CLIENT - TREATY 505234	4,973	1.64
NORTHERN TRUST CO. (AVFC) SUB A/C AMERICAN CLIENTS	4,931	1.63
Sumitomo Mitsui Banking Corporation	4,595	1.52

- The Company owns 10,103,385 shares of treasury shares but the Company is not included in the major shareholders listed above (top 10).
   The percentage of total is calculated as the proportion of shares to 301,482,780 shares of total issued stock (excluding 10,103,385 shares of treasury shares).