# Decisive business transformation to ensure sustainable growth



# Targeting long-term growth: Next transformation will build the new Shionogi

In June 2020, we formulated our New Medium-Term Business Plan—Shionogi Transformation Strategy 2030 (STS2030)—as a strategy to achieve our 2030 Vision of "Building Innovation Platforms to Shape the Future of Healthcare." Under the key word, "Transformation," for STS2030, we are transforming our business and defining strategies to achieve further growth.

Throughout its 142-year history, Shionogi has undergone innovative changes time and again to respond to shifting patterns of disease and differing demands in different eras. One of the major turning points in our history was the first Medium-Term Business Plan, launched in fiscal 2000, when we transformed our business focus. We implemented a major business restructuring, as a result of which sales reduced by half, temporarily. However, we succeeded in divesting businesses that were too small to have meaningful future growth prospects (animal health products, agrochemical, industrial chemicals, clinical laboratory testing, and drug wholesaling), in order to fully focus on our pharmaceutical business. For the next 20 years or so, we were able to achieve more substantial growth, driven by innovation generated from our focused efforts on the pharmaceutical business. On the other hand, however, many people had to leave Shionogi during that transition. We must never forget that the Shionogi of today was born out of such pain.

In this time of unparalleled change, both in the external environment and in the priorities of society, as a company, we

## 2030 Vision

# Building Innovation Platforms to Shape the Future of Healthcare

As the Shionogi family we promise to:

- ☑ Imagine new ways to deliver innovation, and catalyze the formation of new healthcare platforms
- ✓ Create innovative products and deliver them worldwide compliantly with high quality at a fair price
- ☑ Embrace social responsibility and contribute to longer, healthier lives everywhere

are also facing a difficult period of patent expiries in our HIV portfolio around 2028 (a so-called "patent cliff"). To engineer a return to growth, our current business model—discovering, manufacturing, and marketing (detailing) pharmaceuticals—will not be enough. As advances in information infrastructure drive a diversification of needs in our customer base (patients and healthcare professionals), one of our four key stakeholder groups, we need to increase customer satisfaction by playing an active role in the full range of healthcare services, from pre-symptomatic and preventive care to diagnosis, treatment, and convalescence. We have described this concept as the creation of new "healthcare platforms." The next-generation Shionogi will forge alliances with a range of partners and work to build these new platforms, with the goal of becoming an indispensable player across the healthcare field. To achieve this, we must cultivate our original strengths as a drug discovery-based pharmaceutical company and develop a distinctive and unrivaled presence in the pharmaceutical industry such that companies with different capabilities and from different industries are highly motivated to collaborate with us. The transformation we are planning will be faster and greater than anything Shionogi has experienced before and will represent a qualitative evolution of our business.

I believe from the bottom of my heart that transformation means continued change, in an environment that is also continually changing, and that maintaining the status quo actually represents going backwards. We are absolutely determined to continue evolving and will fight to realize our vision.

## Shionogi's current position: Looking back at the previous Medium-Term Business Plan

As we approach the start of a new business plan, it is important to take stock of where Shionogi is today, before we embark on our transformation. In the Shionogi Growth Strategy 2020 (SGS2020) plan, which we initiated in April 2014 and which was updated in October 2016, we had the vision to "grow sustainably as a drug discovery-based pharmaceutical company contributing to a more vigorous society through improved healthcare." In pursuit of this vision, we worked to address social issues and especially to help protect people worldwide from the threat of infectious diseases, by launching a series of in-house-discovered products into global markets, including *Symproic, Mulpleta*,

and the anti-infectives Xofluza and cefiderocol. We maintained our original pipeline ratio at over 60%, as befitting a drug discovery-based pharmaceutical company, and proactively used alliances to acquire technologies and other resources. As a result, we were able to foster our next-generation growth drivers to overcome the patent cliff in our HIV portfolio, starting with eight core pipeline projects with the potential to achieve a paradigm shift of disease treatment. We have steadily increased our ability to compete on the world stage through our drug-discovery capabilities, including the discovery of peptide, nucleic acid, and antibody drugs, and a move into the vaccine business. Although our annual R&D budget is only around ¥50 billion, we are leveraging our resources across multiple core projects to develop therapeutics, vaccines, and diagnostics to fight the global threat posed by COVID-19. I believe that our R&D is uniquely positioned in global terms, and that we can compete on the world stage with our drug-discovery capabilities and our ability to conduct R&D with flexibility and clear prioritization.

Moreover, during SGS2020, it became clearer that Shionogi's efficient management is another strength. During a period of solid growth in global sales of the HIV drug *Tivicay* (dolutegravir) and its combination products, with our licensing partner ViiV Healthcare Ltd., Shionogi prioritized management efficiency and improved our cost management capabilities. As

**KPI achievement in SGS2020** 

	КРІ	FY2020 target (SGS2020 update in 2016)	FY2019 results (JGAAP)
Growth potential	Sales of new products*1	¥200.0 billion	¥62.9 billion
	Ordinary income	¥150.0 billion	¥151.8 billion
Efficiency	ROIC*2	Over 13.5%	13.8%
	CCC*3	Less than 7.0 months	7.7 months
	Original pipeline ratio	Over 50%	67%
Shareholder return	ROE	Over 15.0%	18.0%
	DOE	Over 4.0%	4.7%

Text in red shows FY2020 targets already met

\*3 Cash Conversion Cycle

a result, we achieved our targets for ordinary income, return on invested capital (ROIC), and return on equity (ROE) in fiscal 2020, ahead of plan. However, I regret to say that we failed our shareholders with our results in fiscal 2019, the final year of SGS2020. Not only did our run of all-time-high consolidated earnings come to an end, but we also missed net sales and other profit targets for the first time in eight years. The issues clearly arose from gaps in the growth of new products, the growth of overseas businesses, and in per-employee productivity. We recognize as valid the criticism that the Group as a whole lost its sense of urgency due to the steady progress made in profits, ROE, and other key performance indicators (KPI).

After reflecting on the results in fiscal 2019, we considered whether to continue SGS2020 through to fiscal 2020 as originally planned. However, this time of dramatic change, coupled with the evolution of information technologies, has led to a dramatic increase in the critical value of time. In light of this, we felt it was vital to change our behavior as soon as possible and to implement transformation, and yield its results, in the eight short years left before the patent cliff in our HIV portfolio. We therefore made the decision to finish SGS2020 one year earlier than planned, and to formulate and announce our new STS2030.

# Commitment to STS2030: Providing healthcare services

At the start of the new STS2030 growth strategy, the first priority is to immediately resolve the pending issues noted above and make strong progress towards building the new business model required to prepare for the HIV portfolio patent cliff. We have positioned the first five years of STS2030 (fiscal 2020–24) as Phase 1, during which we will execute this transformation. (See pages 27–42 for more details on STS2030.)

When formulating STS2030, we recognized the critical changes in the healthcare and societal environment that we need to respond to, as well as our specific challenge to overcome our impending patent cliff, and also defined the enterprise value that is our target for the future. Based on this, we communicated with our stakeholders regarding what we needed to become (vision) and how we should effect this change (strategy).

The pace of change in society overall has accelerated in recent years. COVID-19 has brought about enormous shifts in our lifestyles and social values in a short period of time. Beyond the obvious example of COVID-19, however, other major

<sup>\*1</sup> From updates to SGS2020 issued on October 31, 2016

<sup>\*2</sup> Return on invested capital = After-tax operating income ÷ (Interest bearing debt + Shareholders' equity + Non-controlling interests) × 100 (%)

developments, requiring our attention and response, were already underway, such as the astonishing progress made in Al technologies and changes in the global balance of power. Looking ahead, I think that data will play an increasingly important role in society, for example, by allowing every individual ready access to all types of medical information. It is easy to imagine that this may lead to more sophisticated, personalized, and diversified healthcare needs, accompanied by the accelerated entry into this marketplace of companies from other industries. The question is whether Shionogi is capable of responding to these changes and is capable of changing itself. The basic model of the pharmaceutical business today involves generating profits from innovation over a fixed period, based on patents (broadly speaking, intellectual property) in mature markets like the US, Europe, and Japan, and then reinvesting these profits to generate further innovation. At present, Shionogi primarily engages in this current model. This is because, to make progress in healthcare, we need to maintain a continuous cycle of innovation, and the returns need to be high to compensate for the high risks involved. From the perspective of a single company, however, it is a constant and difficult battle to overcome the next patent cliff. In addition, from the standpoint of sustainability of the pharmaceutical business in the broader context of societal priorities, it is becoming increasingly important to balance the appropriate amounts to be paid for innovation with the need to control the total amount of healthcare spending required to maintain social welfare. Against this backdrop, Shionogi will evolve from a drug discovery-based pharmaceutical company (one that mostly discovers, develops, and supplies prescription drugs) into a HaaS\*4 company that provides a much wider range of healthcare products, increasingly integrated into more complete services. Our goal is to continuously supply new value to society at acceptable cost and thus to make our business more sustainable and to provide more comprehensive solutions to the needs of patients and society.

As we set out in this new direction, we also need to transform our business models in order to grow. As mentioned earlier, our current business model is primarily based on patent-based royalties. One of the models we aim to expand in the future is selling pharmaceuticals through our own channels. We will ramp up our ability to generate income ourselves, particularly in Japan, the US, and China. Another business model is the provision of products/services other than prescription pharmaceuticals; this is a model that does not rely on patents. As well as expanding our OTC drug, vaccine, and contract manufacturing businesses, we also aim to launch new businesses to deliver new healthcare services. One of the most important themes in STS2030 is achieving a smooth transformation of our business model, where we will grow by balancing our own sales capabilities with sales through alliance partners, and by

## Direction for the new Shionogi

Old Shionogi

Drug discovery-based pharmaceutical company

Supply prescription drugs as a drug discovery-based pharmaceutical company

- Shift to the new era where patients will make healthcare choices from a range of solutions/information available
- Need for more sustainable social welfare
- Healthcare and social needs to be more sophisticated and personalized
- Promotion of technology innovation and data utilization

# Transform

#### Target direction for Shionogi

Continue to cultivate our original strengths as a drug discovery-based pharmaceutical company, develop a presence such that companies with different capabilities and from different industries hope to partner with us, build new platforms in healthcare, and deliver new value to society as a HaaS company.

#### **Future Shionogi**

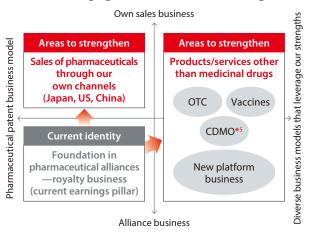
HaaS company
Healthcare as a Service

Providing value through healthcare services

- Collaborate with a wide range of partners to create new added value and provide solutions to the issues faced by patients and society
- Enhance our strengths built up through the discovery of prescription drugs and leverage those strengths to form the core of partnerships

<sup>\*4</sup> Healthcare as a Service: Provide a range of healthcare services in line with customer needs, rather than only supplying pharmaceuticals.

# STS2030—Changing business models to achieve growth



\*5 CDMO: Contract Development and Manufacturing Organization

balancing businesses that utilize patents with businesses not dependent on patents that nevertheless utilize our strengths. The goal is to build an integrated suite of business models by 2030, producing steadily and stably growing earnings that are not materially disrupted by patent expiries.

Our human resources are the key factor that will allow Shionogi to transform for our future growth and the achievement of our STS2030 plan. The only way for Shionogi to survive in this challenging world, competing with a mix of different industries, is for every single member of the Shionogi family, including executives, to maximize their talents, exhibit their individuality, and combine their expertise to enhance our strengths. As well as expanding training programs for individual employees that produce tangible results, we will also improve our management training to produce line managers who support employee growth, understand their responsibilities and the need to develop their teams, and are capable of leading the way to the best outcomes for the organization.

### To create a sustainable society

By working to resolve social issues through our business activities, Shionogi will help society to become more sustainable and to achieve the Sustainable Development Goals (SDGs), while continuing to grow as a company. In fiscal 2019, Shionogi signed the United Nations Global Compact, that comprises ten principles relating to human rights, labor, the environment, and anti-corruption. We support and practice the concepts in the UN Global Compact and accept our responsibilities as a global citizen.

In order to respond to global societal needs, we have incorporated a broader range of issues explicitly into our corporate priorities, and set new non-financial targets. One of the most pressing global issues remains freeing people from the threat of infectious diseases, and we are working on measures to address the big three infectious diseases (HIV, tuberculosis, and malaria), AMR\*6, and viral infections. The advent of the new coronavirus and the subsequent social disruption and global-scale threat is an opportunity for us to re-emphasize, and to demonstrate, how Shionogi's long-term efforts to address infectious diseases can contribute to achievement of SDGs and how much these initiatives are needed by the society. We are bringing together resources from across the Company to help address the social problems caused by COVID-19, prioritizing the development of vaccines, therapeutics, and diagnostics in order to help societies restore safety and confidence by bringing this pandemic to an end as soon as possible. For the other material issues, we will responsibly address and step up our response to various environmental, social, and governance (ESG) issues, thereby contributing to the creation of sustainable societies and driving the company's growth. Based on that approach, Shionogi will make a concerted effort to be a relevant company for all stakeholder groups well into the future.

\*6 Antimicrobial resistance



# Strengthen corporate governance: Entering the second generation of our system of governance

Shionogi fully understands that it relies heavily on four main stakeholder groups, namely, shareholders and investors, customers, society, and employees. Optimally balancing their needs is crucial to increasing corporate value. The ethos of our management approach is to ensure balanced relationships with our stakeholder groups while responding flexibly to any changes in their interests and needs. Over the 142 years since the founding of Shionogi, we have been through several difficult periods, as have other companies, but by maintaining balanced relationships with these four groups, we have enjoyed the support of our stakeholders even when business was bad, allowing us to grow into the company we are today.

Fiscal 2020 brings the retirement of all the outside directors appointed when the outside director system was introduced (fiscal 2009), so in one sense we are entering the second generation of our system of governance. In order to enhance our management further and promote diversity, we have nominated an outside director to act as chairperson of the Board of Directors, appointed female directors to two of the five positions, and ensured the Board is made up of directors with a diverse skill set and balanced age range, from their 40s to 70s. We are working to evolve our corporate governance and management even further, welcoming a greater diversity of views and opinions from the outside directors, including globally experienced or digital native concepts, and fostering lively discussions.

# Sharing the benefits of growth with shareholders

Our shareholder return policy is designed to maximize corporate value while balancing investment in growth and to share the benefits of medium- to long-term profit growth with shareholders. We will continue to promote this policy. Earnings may fluctuate from year to year, but we realize that Shionogi is in a period of sustained growth. We have increased our dividend for eight consecutive fiscal years, and look to continue this trend for as long as we can. We are also monitoring market conditions so we can be flexible on shareholder returns, including share buybacks, retirement of treasury stock, and unwinding of cross-shareholdings, and are working to improve capital



efficiency. In light of the above, we added earnings per share (EPS) to the previous targets of dividend on equity (DOE) and return on equity (ROE) as our indicators for shareholder returns under STS2030.

### A final word

As a HaaS company, Shionogi will continue to follow our basic policy, "striving constantly to supply the best possible medicine (healthcare solutions) to protect the health and wellbeing of the patients we serve." Through this, we aim to grow alongside a developing society. Toward the goal of our 2030 Vision: "Building Innovation Platforms to Shape the Future of Healthcare," I would like to declare right here that no Shionogi director or employee should fear change; instead we should welcome diversity and transform Shionogi so we are not bound by preconceived ideas. In this way, we will work to address ESG issues through our operations and contribute to the development of more sustainable societies.





# Financial policy under the New Medium-Term Business Plan (STS2030)

### Q: Can you describe how you set KPIs?

We aim to grow sales in STS Phase 1, with a particular focus on strengthening our own sales capabilities overseas. We are also working to capture new growth drivers, invest in R&D, and make other growth investments to achieve our key performance indicators (KPIs). Furthermore, even during this phase of growth and investment, we will maintain core operating profit margin at the high levels characteristic of Shionogi. Finally, as we work to build new platforms, we also aim to maintain a high original pipeline ratio, as this is a metric that attracts potential business partners including those from different industries.

As for indicators for shareholder returns, we will continue to use dividend on equity (DOE) attributable to owners of the parent and return on equity (ROE) attributable to owners of the parent, and we have now added earnings per share (EPS) as a new indicator. We will use DOE to determine dividend levels and EPS to define shareholder returns including share buybacks, and will implement shareholder returns that are balanced with investment in growth using internal reserves.

# Q: Can you explain your views on business investment and concepts built into the financial policy?

In terms of business investment, we have proposed investing ¥500 billion in overseas businesses and new business start-ups

#### STS Phase 1 KPIs and targets

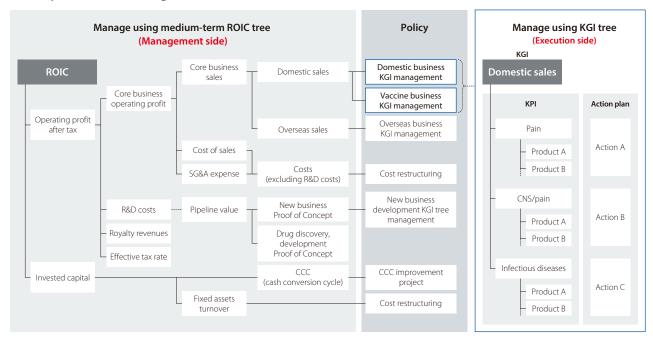
KPI	FY2024 target		FY2030 target	
Growth	١			1
Revenue	¥500.0 billion <	Revenue	Overseas	¥600.0 billion
Core operating profit	¥150.0 billion	Verseas  Overseas  Overseas  Overseas  Overseas  Overseas  50%	¥200.0 billion	
Core operating profit margin	Over 30%			
Overseas sales ratio	Over 50%	Domestic		
Original pipeline ratio	Over 60%	Domestic		
Shareholder return		Royalties		
EPS	Over ¥480	Noyalties	_	
DOE	Over 4%			]
ROE	Over 15%			

### Fund-raising and usage during STS Phase 1

- Generate positive operating cash flows from royalty revenues
- Use cash in hand and generate positive cash flows from asset conversion to cash
- Use debt financing
- Normal business investment
- Shareholder return
- Business investment to acquire next growth drivers

Flexible shareholder returns

### Overall picture of ROIC management



by fiscal 2024, the final year of STS Phase 1, and are researching and analyzing a number of investment projects.

We are considering investments to acquire sales networks or product portfolios and pipelines that meet more customers' needs, so that we can strengthen our sales capabilities overseas, particularly in the United States and China. In Japan, we aim to enhance our product portfolio based on the disease strategy and, at the same time, review the scale of our infrastructure, with the goal of improving productivity. For both overseas and domestic investment, we will mainly look at the core therapeutic areas of infectious diseases and CNS/pain disorders and build competitive sales structures in each region. We will also build new capabilities, particularly in digital applications, in order to grow as a HaaS company. We plan to make well-balanced investments to further our existing earnings drivers and also discover new growth drivers.

## Management that takes capital costs into account

# Q: Can you detail your strategy and initiatives to improve capital efficiency?

We think that ROE is the indicator to use when making commitments on capital efficiency to external stakeholders. We have managed the business with a view to improving ROE since 2000. Under the previous Medium-Term Business Plan, however, we broke ROE down so the indicator was more closely coupled with individual employee work, and we used return on invested capital (ROIC) as the target at the operational level. This provided a more widespread understanding of how we should make operating profit margin and the capital turnover ratio more efficient.

Having achieved an understanding of ROIC internally and

a certain level of awareness of capital costs, we dropped ROIC as an external KPI in STS2030, but internally we are still managing the business with the aim of improving capital efficiency based on this ROIC concept. From fiscal 2020, management will continue to use ROIC trees to get an understanding of the overall picture, while those involved in business execution will set key goal indicators (KGIs) as numeric targets for the departments responsible and will adopt a "KGI tree" formula to link KGIs to action indicator KPIs. As a result, we still get an overview of the full picture and can ensure there are no omissions or duplications, as with an ROIC tree, but we also improve usability in the workplace and promote capital efficient management using ROIC.

## **Accounting standards**

# Q: What is the purpose of changing to IFRS and what impact has this had?

The first objective behind the introduction of International Financial Reporting Standards (IFRS) is to develop more global internal governance systems as overseas sales start to account for a higher percentage of the whole. By unifying accounting standards across the Company, we will better align financial reporting processes and make financial analysis and actions based on this analysis faster to complete. The second objective is to promote rigorous economic decision-making and better capital efficiency internally. We need to have more accurate forecasts on future cash flow from assets to achieve this. Therefore, we have built an organization to ensure constantly optimized capital allocation. Under this structure, each drug candidate and product is evaluated by the Integrated Disease Care Division and Corporate Strategy Division, so the value of each candidate or product is analyzed dispassionately.

#### Overview of STS2030

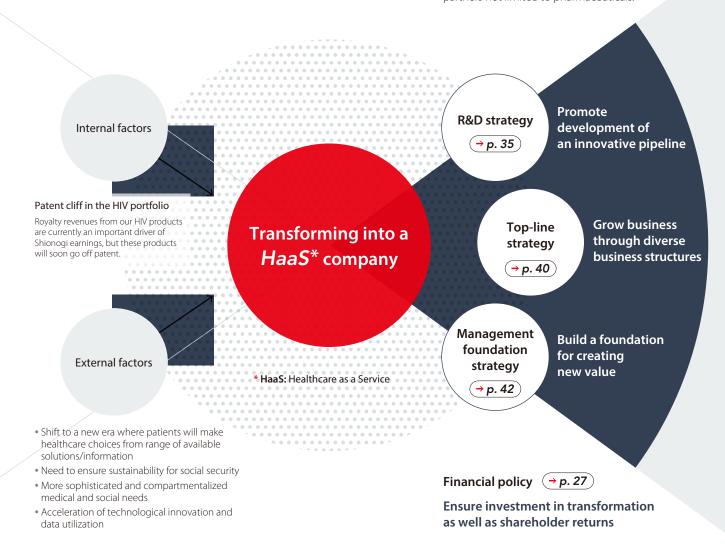
# Realize our transformation into a HaaS company by continuously enhancing our strengths as a drug discovery-based pharmaceutical company

# Why | Rationale behind HaaS goals

As we shift to a new era where patients will make healthcare choices, Shionogi will transform into a HaaS company that can deliver solutions for diverse and fluid healthcare needs and respond flexibly to change. We also aim to build a sustainable and stable earnings base and develop a business that is not reliant on patents.

# **How** | Business strategy

We will develop disease strategies that address a wide range of problems, encompassing all aspects of the disease in question, with a focus on first-class therapeutic drugs. We will deliver new value, working with a more diverse array of partners not limited to pharmaceuticals.

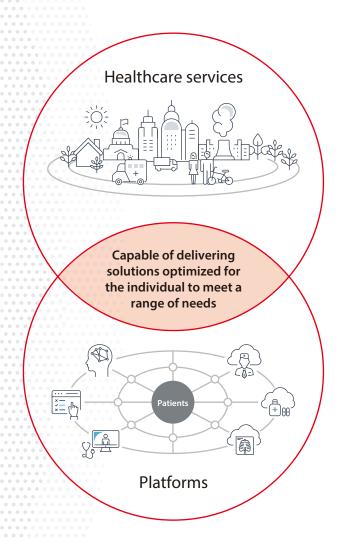


# What

Image of Shionogi as a HaaS company

## 2030 Vision

# Building innovation platforms to shape the future of healthcare



Shionogi is working to rapidly adapt and implement strategies beyond just treatment to resolve various customer healthcare needs, constantly fine-tuning what type of HaaS company we want to be.

# New disease strategies





# Value creation through partnering



Achieve disease strategy through partnering that leverages strengths

Licensing business

Current earnings pillar, also important in future Shionogi's R&D capabilities × mega-pharma company sales force

Diverse business model that achieves platforms

Build multiple structures (e.g., joint ventures, consortia, business partnerships)



### Creating patient-centric value

As Shionogi transforms into a HaaS company under STS2030, we need to think from the patient's standpoint more than ever if we are to go beyond simply supplying prescription drugs and start providing healthcare services. There is an enormous difference between improving treatment quality for the main disease symptoms versus improving treatment quality for most symptoms including peripheral ones associated with the disease.

For COVID-19, convenient diagnostics and effective vaccines are needed, but vaccines are unlikely to prevent infections completely, so therapeutics are also needed. Antivirals may improve clinical symptoms by eliminating or reducing the viral pathogen. On top of this, when the immune cells release cytokines to attack the virus, uncontrolled cytokine release can result in a "cytokine storm" that causes symptoms to become more severe and prolonged. This is a huge problem from a clinical perspective. Doctors also face the issue of managing superinfections in intubated patients. To deliver value relevant to all aspects of COVID-19, we need to look at more than just effective antivirals. We also need pharmaceuticals that control COVID-19 severity and treat superinfections. Other elements to factor in include rapid diagnostics and preventive agents, as well as mechanisms for the provision of appropriate information.

Shionogi is already working on programs against COVID-19 (see page 17 for more details), providing information and R&D into antivirals and various other products. This has been driven by discussions on delivering value that is patient-centric and

addresses all aspects of the disease.

We are looking to step up our efforts to offer total care, including solutions for the wide range of problems that accompany diseases.

### Disease strategy concept

Shionogi proposed a disease strategy concept in STS2030 to spell out this idea of patient-centric total care. When thinking about delivering value to patients, we need to consider the entire process along the "patient journey," starting with the discovery of symptoms and disease through to treatment in hospital and the daily experience in terms of behaviors, thoughts, and feelings. Based on these considerations the disease strategy comprises two key elements.

The first element involves bringing together a portfolio of key products and services that deliver value to the patient, with reference to how the patient behaves and what thought processes they go through, as well as what types of feelings they experience, during the journey from the presymptomatic and prevention stages to diagnosis and treatment. Examples that illustrate this point well include providing products and services for diagnosis and prevention, and programs to provide information.

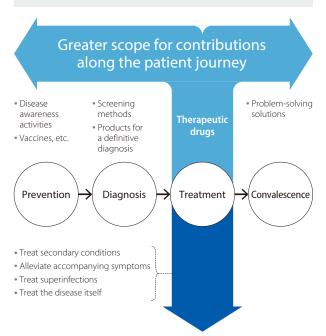
The second element is to enhance treatment options, as discussed before. With the example of infectious disease, the idea is for Shionogi to make a real contribution to the patient's treatment by bringing together a range of solutions to alleviate the symptoms caused by the disease and manage superinfections

or secondary conditions that may emerge.

A key feature with this concept is to consider an integrated strategy to deliver maximum value to patients, rather than simply maximizing sales of our own products. We aim to provide proprietary products plus supporting programs to promote proper drug use and make sure our products are prescribed to those patients that really need them, as well as enhanced follow-up through greater use of DX and other solutions. The idea is that economic growth will flow through as a natural consequence of these initiatives.

#### Disease strategy overview

Deliver maximum value to patients through two approaches, with therapeutic drugs at the core



# **Better therapeutic options**

# **Establishment of the Integrated Disease Care Division**

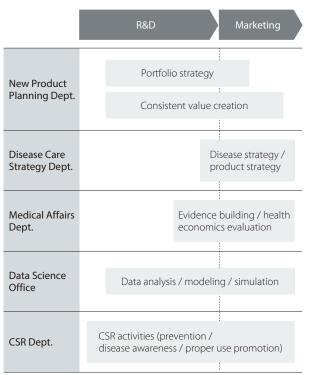
To implement this disease strategy, Shionogi needs systems to ensure the delivery of consistent value from the R&D stages onwards. Furthermore, the Disease Care Strategy, Medical Affairs, CSR, and other departments, which are responsible for creating value through communication with patients and stakeholders supporting patients after product launch, need to work together, discussing the value delivered. To achieve this, Shionogi established the Integrated Disease Care Division, bringing together functions from a number of different divisions, with the goal of creating a solid organizational structure to effectively deliver the required products and information to more patients that really need them.

The Integrated Disease Care Division is recruiting representatives from the various departments within the Division to develop disease strategy proposals. The Division has brought together younger employees who are the future of the Company, and lively discussions are taking place on how to create new value without being constrained by conventional viewpoints. We are working with various departments to maximize value as part of Shionogi's transformation into a HaaS company under STS2030.

Overview of the Integrated Disease Care Division

Structured to effectively deliver required products/information to more people globally

Cross-value chain, customer-oriented, evidence-focused, data-driven



### SPECIAL FEATURE 02

Target approach

# Shaping the future of healthcare —

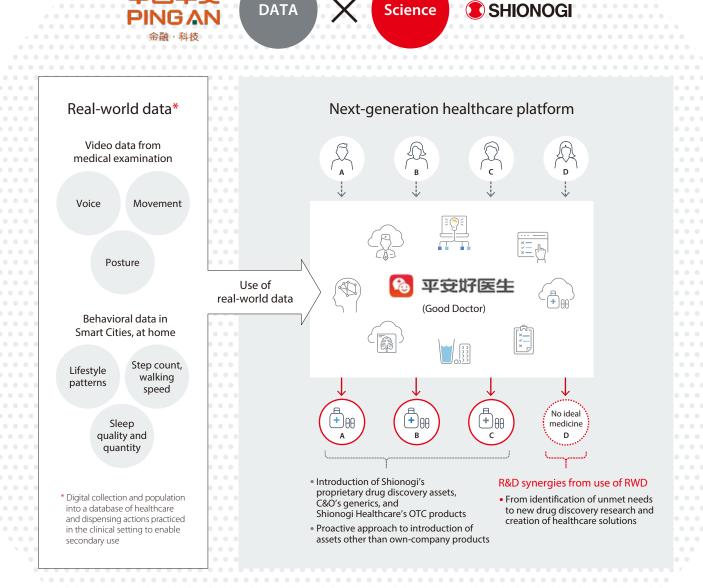
Working to establish a total healthcare platform in the Chinese growth market

Rapid advances in information technology are driving significant changes in how healthcare is provided.

For example, the foundations are being laid for the delivery of personalized treatment through aggregation and analysis of big data on individual patient health profiles.

New systems are also being worked out to allow patients to receive medical examinations and guidance on drug compliance without having to visit a medical facility and for pharmaceuticals to be delivered directly to the patient's home.

Shionogi is responding to these changes and working to build healthcare platforms, creating value with partners that have complementary capabilities and aligned visions for the future of healthcare, as part of the Company's goal of developing HaaS to shape the future of healthcare.



#### Establishment of the joint venture

Ping An Insurance (Group) Company of China has the strategic goal of becoming the world's leading technology-driven personal financial and lifestyle services provider, with a focus on customer experience. As well as its insurance business, Ping An Insurance is also focusing on IT-driven healthcare businesses, and is creating and developing new businesses, by leveraging the capabilities of Ping An Insurance as well as of their affiliated and invested companies. Ping An owns the Ping An Good Doctor healthcare ecosystem, a unique web-based health and wellbeing management service platform that utilizes big data on lifestyles accumulated through Ping An Insurance's other businesses. This platform may help to build and improve healthcare and medical services along with clinical standardization and management services, including Al-driven medical inquiries, diagnosis and advice, supporting the activities of physicians, medical appointment management, and drug delivery. Good Doctor has grown rapidly into China's largest online healthcare platform, with over 300 million registered users as of the end of 2019 and 67 million active users each month.

Shionogi and Ping An Insurance share the same vision for the future of healthcare services, and both companies have agreed to leverage their strengths to build a next-generation healthcare platform together. This has led to the establishment

of Ping An Shionogi. The two companies will work to build platforms by combining their strengths, namely science-based drug discovery and expertise in manufacturing and quality control for Shionogi, and expertise in IT-driven big data aggregation and Al analysis for Ping An Insurance.

## **Future outlook for Ping An Shionogi**

Ping An Shionogi will adapt flexibly to various environmental changes and aims to shape the future of healthcare by continuing to provide the best solutions to meet the changing needs of individuals for better lives and health. First, quality generic drugs and OTC products, which form part of the product portfolios at Shionogi Group company C&O Pharmaceutical Technology and Shionogi Healthcare, will be provided to patients as appropriate via an online diagnosis platform. In parallel, Ping An Shionogi will work on the launch of new drugs to satisfy unmet needs in the Chinese market, as well as the origination of new healthcare solutions and completely new medicines based on healthcare data.

Furthermore, the solutions originated through this innovative healthcare platform will also be launched into markets in Asia, Japan, Europe, and the US, making further contributions to better lives and health for people all around the world.

## **MESSAGE** From the CEO of Ping An Shionogi

# Creating new business not bound by accepted practice or conventional thinking

Shionogi has developed a new Vision in STS2030 and is committed to transforming its operations to achieve this Vision. The partnership with Ping An Insurance is aimed at building new business platforms by bringing together the two companies' complementary strengths. It is one of the business ventures that will allow Shionogi to realize the goals laid out in STS2030.

Ping An Shionogi combines Shionogi's demonstrated expertise (disease insight and R&D know how) with Ping An Insurance's healthcare data, online medical consultation platform, and Al technologies, creating a business model which is new and different from conventional approaches in the pharmaceutical industry. This will allow the delivery of healthcare solutions optimized for the individual and lead to the realization of HaaS across our society. Our employees are leading the transformation of the Group, taking on new challenges that go beyond old notions of our business. With



### Tatsumori Yoshida

Corporate Officer, Chairman and CEO Ping An Shionogi Company Ltd. Ping An Shionogi (Hong Kong) Company Ltd.

the new business model, they are also relishing the opportunity to support Shionogi's medium-to-long term growth.

As part of Shionogi, we aim to achieve the following goals through this partnership:

- (1) Realize true Healthcare as a Service (HaaS) operations by combining our business in new, generic, and OTC drugs with a new pharmaceutical sales and distribution model across Asia (particularly in China)
- (2) Establish a base for creating novel healthcare solutions including new drugs

We want our Company to deliver new value to society by combining the strengths from our different industries, finding synergies, and creating a new business not bound by accepted practice or conventional thinking.

## **R&D Strategy**

# Pioneering the future of healthcare with our skills in product creation

# **R&D** disease strategy

Basic Policy

Focusing on infectious and psychoneurological diseases as core fields, we will pursue other therapeutic areas with social and medical needs, while establishing a new R&D management system for flexible prioritization

#### Infectious diseases

Provide total care for infectious diseases to meet social and healthcare needs

- Prioritizing our response to COVID-19 → p. 17)
- Aiming at total care for infectious diseases (→p. 19)

# Psycho-neurological diseases

Paradigm shift in the treatment of psycho-neurological diseases

- Objective diagnostics/stratification through biomarker discovery and real-world data/big data analysis → p. 33
- Discovery of innovative drugs with new mechanisms of action → p. 52

## New growth areas

## Pursue therapeutic areas with high social and medical needs

We will pursue drug discovery in other disease areas in addition to those listed at left, in order to keep contributing. Our researchers are all skilled scientists who are passionate about solving the problems faced by patients and their families. Making full use of limited resources and never giving up, Shionogi's strengths in R&D have even led to the discovery of compounds in the field of oncology, including an inhibitor of regulatory T-cells and S-540956. Shionogi will respond to unmet medical needs and reshuffle priorities flexibly according to the potential candidates which may "blossom" later on.

#### MESSAGE

Oncology has not been a key area in our drug discovery efforts thus far, but joint research with Osaka University led to the discovery of a new target molecule CCR8, which has significant potential. Through our ability to flexibly shift resources, we are focusing on this drug discovery program. We are making every effort to fulfill the hopes of all those patients who are not suited to conventional therapies.

#### Hidekazu Tanaka

Principal Scientist, Oncology 2 Group Laboratory for Innovative Therapy Research



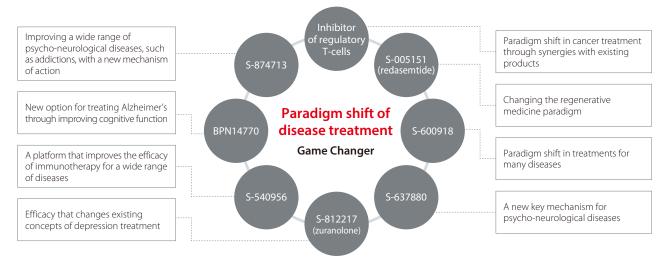
# Core pipeline

# Striving for innovative value, not incremental improvements

Shionogi is progressing development in eight core pipeline projects, aiming to deliver innovative value that clearly embodies new approaches, not just incremental improvements. Each pipeline project is a potential game changer that could cause

a paradigm shift in treatment of that disease. Shionogi is also working to maximize product value at the earliest stage possible, by careful consideration of mechanisms of action and more parallel development for multiple indications. By developing these pipeline projects, the Company aims to manage the patent cliff in the HIV portfolio and achieve sustained growth.

#### The outcome we envision from our core pipeline



Creating products and services for diseases with high unmet medical needs

# From drug discovery to HaaS

### **Timeless core competencies**

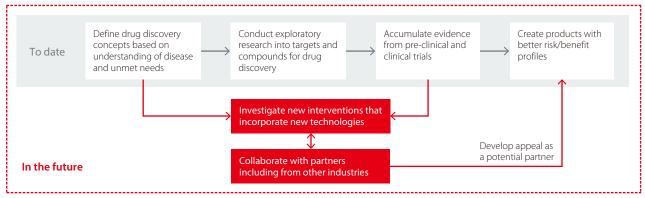
Shionogi has engaged in innovative research to create original pharmaceuticals to support patient health and QOL since *Sinomin* in 1959. Under the previous Medium-Term Business Plan, SGS2020, Shionogi was positioned as a drug discovery-based pharmaceutical company, targeting growth through new drugs originated in-house. Drug discovery will still be a core competency at Shionogi and a key part of the Company's value to society even after the transformation into a HaaS company as proposed in STS2030.

To realize the HaaS concept, Shionogi needs to enhance its strengths in identifying unmet medical needs through an in-depth understanding of disease, develop logical theories, and build evidence to unlock the science. Creating HaaS solutions involves determining what healthcare services we are providing,

with pharmaceuticals at the core. Partnership, rather than working alone, will be vital during this process. One key factor is whether Shionogi is seen as an attractive potential business partner. Solidifying Shionogi's position as a drug discovery-based pharmaceutical company will be increasingly important in this regard. Shionogi has already created pharmaceuticals in collaboration with academia and other partners, and this has fostered our open-mindedness as an organization. This quality will be a key element to bring to future partnerships with a wide range of organizations including from other industries.

Shionogi marked the 140th anniversary of the Company's founding in 2018. Shionogi aims to continue enhancing its core competencies in R&D to support healthcare in order to still be addressing social needs on its 150th and even 200th anniversaries.

## Shionogi's initiatives to achieve STS2030



# Pharmaceutical research



# Constant stream of innovative products at the heart of our healthcare platforms

Ryuichi Kiyama, Ph.D.

Senior Executive Officer, Senior Vice President, Pharmaceutical Research Division

# Restructuring the Pharmaceutical Research Division to achieve our Vision

The Pharmaceutical Research Division is being restructured to better position the Company to achieve its Vision. One of the changes involves giving consideration to a business exit strategy at the research stages, instead of researchers expecting other departments to handle the end stages of the lifecycle as long as they create good products. Under STS2030, as well as stepping up drug discovery, Shionogi also needs to create new businesses and platforms. The Company has therefore set up two new pioneering departments, the Laboratory for Advanced Medicine Research and the Laboratory for Innovative Therapy Research.

This organizational restructuring and personnel reassignment merely open the door to potential change. It is the researchers themselves that will breathe new life into their work and transform the organization. As Shionogi becomes a HaaS company, our researchers are expected to think through social and patient problems even more, working proactively and with conviction to deliver solutions. The Division is therefore reshaping the organizational landscape to draw out our researchers' passion for their work as they take on new challenges.

## Enhancing existing strengths in research

Shionogi's strengths still lie in drug discovery. The Company maintains an original pipeline ratio of over 60% through this focus on in-house drug discovery. Shionogi's product creation capabilities are a point of differentiation that can attract potential business partners including those from different industries.

The Division is cultivating an eye for unsolved social issues and scientific thinking to develop approaches that provide real solutions. We will look at a wide range of therapeutic approaches (or modalities) to resolve diverse patient needs and make further advances in our small-molecule drug discovery engine that has been so effective in bringing innovative new products to market.

### Overcoming the HIV patent cliff

It will not be possible to overcome the huge patent cliff looming around 2028 through one product alone. The Company realizes that it needs to build up its product pipeline, including maximizing the value of the eight core projects currently in the pipeline; turn vaccines and other new fields into platforms as quickly as possible; and transform itself into an organization capable of continuously creating innovative new pipeline projects.

## MESSAGE

To turn the Vision into reality, our Laboratory's mission is to create a strong research base from which we can build our healthcare business and continuously create unique and innovative therapeutic and preventive approaches. We need very advanced research capabilities to achieve this, and we are working to develop Shionogi researchers who can work alongside our partners to shape the future of healthcare.



Vice President, Laboratory for Innovative Therapy Research



# Pharmaceutical development



# Understanding value from the patient's perspective and developing products that embody this value through agile and appropriately targeted global operations

Toshinobu Iwasaki, Ph.D.

Senior Executive Officer, Senior Vice President, Drug Development and Regulatory Science Division

# Maximizing product value from the patient's perspective

To deliver new value to patients and societies as a HaaS company, Shionogi must drill down into the issues and develop the best products to solve them. Shionogi is creating medicines with maximized product value, but sometimes the products delivered do not fully meet patient needs. Although Shionogi talks about customer focus, business perspectives may dictate the value delivered.

To achieve Shionogi's Vision, the Global Development Division recognizes the need to better understand value from the patient's perspective. The Division aims to develop products that embody this value through agile and targeted global operations.

### Parallel Investigation into multiple diseases

To maximize product value, as well as taking a patient-centric approach, the Pharmaceutical Research and Integrated Disease Care Divisions must be involved from the early stages in scientific discussions with specialists in Japan and overseas before any development plans are drafted. Novel compounds are increasingly difficult to develop. Rather than searching for multiple compounds, it may be better to investigate the use of one compound in multiple applications. The Global Development Division has worked out a development strategy to run parallel clinical studies (PoC trials) on multiple diseases to determine at an early stage which diseases may be a suitable target, given the profile of that particular compound.

When S-600918 was originated in-house, chronic cough was the original development target. The mechanism of action showed potential effects for sleep apnea, so studies for this target indication were initiated as well. Another example is redasemtide. The compound was being developed for epidermolysis bullosa and stroke, but evidence emerged suggesting potential effects in knee osteoarthritis and chronic

liver disease. Physician-led clinical testing is currently being planned for these two target indications as well.

Targeting more diseases to maximize value

#### S-600918

#### In progress

- Refractory chronic cough
- Neuropathic back pain
- Sleep apnea syndrome

#### Redasemtide (S-005151)

#### In progress

- Epidermolysis bullosa
- Acute ischemic stroke

Preparations in progress

- Liver cirrhosis
- Knee osteoarthritis
- Cardiomyopathy

# Becoming a highly productive organization

Resources are limited, so we will focus on productivity even more. The Division will introduce new methodologies to improve development efficiency, such as digital studies or clinical trials using real-world data, and efficient working practices to generate results faster. A rigorous focus on the quality of data and study design will also support successful trials.

## CMC research



# Creating unexpected value from Shionogi's production technology to drive the development of HaaS

Yasuyoshi Isou, Ph.D.

Corporate Officer, Senior Vice President, CMC R&D Division

# Three elements driving evolution of the CMC R&D Division

The CMC R&D Division is committed to shaping the future of healthcare through a continued focus on world-class, cutting-edge scientific research and technology development characterized by originality and utility. We are leveraging our strengths in three areas:

- (1) Provide solutions for research and development with high probability of success
- $\begin{tabular}{ll} \textbf{(2) Create completely new added value through product research} \\ \end{tabular}$
- (3) Improve industrial productivity

We aim to enhance these areas while also creating greater added value in order to improve product value as we work to deliver HaaS.

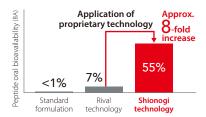
As well as R&D, the CMC R&D Division needs to work closely together with other groups inside and outside the Company, such as the Integrated Disease Care Division, Shionogi Pharma, and technology licensing partners, in order to accurately identify and respond to stakeholder needs.

### Working towards sustainable growth from fiscal 2020

We are developing our technology capabilities and supplementing areas where we lack particular skills for process development that facilitates progress in development projects, with an eye to achieving sustainable growth from fiscal 2020 and beyond. We have been able to increase product value utilizing technologies developed through our work with smallmolecule drugs. Examples include the development of a more stable formulation of cefiderocol API applying an original formulation technology. Looking ahead, we will expand the scope of our work from small-molecule to medium-sized molecule modalities and even to macromolecules, including vaccines and novel biopharmaceuticals using UMN Pharma's expertise. We will also develop devices and materials to enable new routes of administration or drug-delivery systems (DDS). In order to maximize product value through this type of creative added value, we will build platforms by taking a proactive approach to partnering. As a result, we aim to supply new solutions to a broader range of social issues.

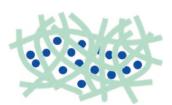
## Examples of completely new added value

# (1) Development of oral formulations for peptides and medium-sized molecules



We are developing a technology to improve oral absorption of peptides. We have discovered a way to achieve an eight-fold increase in oral bioavailability by applying our own proprietary technology that uses interactions at the absorption site in the intestine.

# (2) Basic research on sustained-release injectables with a view to application in various modalities



We are researching sustained-release formulations to reduce the medication burden for patients. We are using a type of polymer that swells due to water absorption and then gradually releases the small-molecule API held within the polymer structure. Our research is investigating the potential application of this technique in a sustained-release injectable formulation.

# (3) Building frameworks for device development through partnering



We are moving forward with the development of devices that make possible a wide range of administration routes. We are working to build frameworks that will allow us to work with the best partners and create the best products, by sharing our experience and expertise in pharmaceutical quality and making it easier for organizations from other industries to work with us.

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

# Promoting diverse business structures and partnering

# Japan



# Building new business models to transform organizational efficiency

#### Kazuhiro Hatanaka

Senior Executive Officer, Pharmaceutical Commercial Division

# Transforming the Japan business to achieve the Company Vision

### Japan business vision

Become an indispensable partner in infectious diseases and CNS/pain

Emphasize customer access and understanding to solve healthcare problems

### Execute disease strategy

#### Establish Integrated Disease Care Division

Provide total care from prevention to diagnosis, treatment, and convalescence

# Rebuild domestic sales structures

- Information-delivery methods tailored to each customer
- Respond to diversifying

Under STS2030, the Japan business aims to become an indispensable partner in infectious diseases and CNS/pain. To achieve this, Shionogi is executing a disease strategy and rebuilding sales structures.

## **Executing a disease strategy**

In our focus areas of infectious disease and CNS/pain, we think it is important to provide information relevant to the disease as a whole, rather than taking the conventional route of only providing product information. During sales activities for therapeutic agents, we need to provide information as part of a total package that spans everything from prevention to diagnosis, treatment, and convalescence. By executing this disease strategy, we aim to respond to the needs of physicians, healthcare professionals, and other customers. In order to provide a total package of services, the Pharmaceutical Commercial Division must work hand-in-hand with the newly established Integrated Disease Care Division.

# Developing more channels to provide information to customers

We expect societies to use digital applications more and more in the future. The effective use of digital data will be crucial to improving productivity when providing information on pharmaceutical products. However, we will still find opportunities for face-to-face communication with customers. The Pharmaceutical Commercial Division is therefore accelerating moves to reorganize and establish IT infrastructure in order to combine real-world and digital applications and transform into a highly efficient organization. By working in closer partnership with Stream-I, our joint venture with M3, Inc., Shionogi will beef up its digital approaches to provide the right information to meet customer needs, including to those who we could not previously access with predominantly face-to-face communication. Moreover, we need to have an in-depth understanding of regional characteristics because of the slight differences in healthcare systems in different parts of the country. To respond to different customer needs in different regions, Shionogi must be able to satisfy true customer needs through information provision that combines both real-world and digital applications as described above. To achieve this, in fiscal 2020, the four regional functions in the domestic sales operations were reorganized into seven sales regions to make the sales force more mobile and improve customer access and information provision in line with regional characteristics. These changes are aimed at transforming the Company into a more efficient organization that is striving to resolve customers' issues.

# Respond to customers' increasingly diverse needs

We will improve our disease knowledge and detailing skills for all aspects of CNS/pain and infectious diseases, including COVID-19, to be able to respond to customer needs. This will allow our MRs to fully understand customer problems and be able to propose patient-focused solutions, such that customers view Shionogi MRs as trustworthy advisors.

## **Overseas**



# Providing new value by transforming our global business

John Keller, Ph.D.

Senior Executive Officer, Senior Vice President, Global Business Division

## Transforming our global business to achieve our vision

Global business transformation is one of STS2030's key strategic themes. To that end, we need to transform our business in key regions such as the US, Europe, and China.

In the US and Europe, we will commercialize both drugs that we have discovered, as well as those from alliances, to build a strong sales presence focused on hospitals and specialist physicians. The seed for the expansion of our own sales presence in the US and Europe is the antibacterial agent cefiderocol. In China, we will establish both a sales and an R&D presence, as well as create entirely new healthcare platforms, in collaboration with Ping An Insurance Company of China, Ltd. We have great opportunities ahead of us to open up new prospects and new markets.

# Expansion of business in Europe and the US, beginning with cefiderocol

The SARS-CoV-2 pandemic has heightened social awareness of the threat by untreatable infectious diseases, and this increased awareness is driving receptivity to understanding the role and value of cefiderocol in Europe and the US.

Cefiderocol's sales in the US have exceeded our initial targets, and we have made a great start. However, this is only the first step in expanding our business in the US. To achieve our goals, we need to continue to broaden the knowledge of cefiderocol. Furthermore, we will seek to expand our product portfolio to strengthen our presence in hospitals and specialty focus areas, building a synergistic portfolio and laying the groundwork for our upcoming pipeline products as we build an ever stronger and more effective commercial presence.

In major EU countries, such as Italy, Spain, and France, the prevalence of drug-resistant Gram-negative bacterial infections is substantially higher than in the US, and thus the medical need for cefiderocol is even greater. We will utilize our tightly focused specialized sales platform, and continue to build

strong professional relationships with healthcare providers, to establish our position as a leading company in the field of infectious diseases in Europe, contributing to the achievement of our global goals.

## Toward expansion of business in China

In order to achieve our vision, it is essential to expand our business in China, the world's second largest market. Through our recent collaboration with Ping An Insurance Group, we will integrate the strengths of both companies to build a new business platform that further evolves and develops the drug discovery-based pharmaceutical company model. Leveraging Ping An's Good Doctor platform, we will contribute to top-line growth, utilizing first our existing generic and OTC products, and then following soon after with the registration and launch of our new global drugs in China.

We expect that this joint venture can contribute to the health of all people and to shaping the future of healthcare by continuously discovering, developing, and providing new healthcare solutions, from new drugs arising from Al-driven R&D, to newly efficient manufacturing systems, through to previously unimagined healthcare products arising from the fusion of cutting-edge technologies.

#### Establishing the Foundations to Create Value

# Building a productive organization capable of creating new value

Basic policy

Create value by transforming structure and the processes that shape structure and developing the right human resources to administer processes

To become a HaaS company as targeted under STS2030, Shionogi needs to build highly productive organizational infrastructure that is capable of creating new value. The Corporate Strategy Division is drafting and implementing strategies to transform the business to achieve this Vision,

while the Administration Division is developing systems to improve implementation of the Vision. Both Divisions are working closely together on programs to strengthen the foundations of the business.



# Transformation through strategy development and execution to evolve into a HaaS company

Kohji Hanasaki, Ph.D.

Senior Executive Officer, Senior Vice President, Corporate Strategy Division

For Shionogi to evolve into a HaaS company, the Company needs to hone its expertise as a drug discovery-based pharmaceutical company and also tackle new fields at a faster pace than experienced before. The Corporate Strategy Division is working to develop and implement company-wide strategies for optimal allocation and utilization of business resources, as well as promoting innovation and strengthening stakeholder engagement, in order to achieve the Company Vision. Specifically,

the Division is looking to utilize all functions across the Company in the transformation of Shionogi as a HaaS company capable of sustained growth, including strategic planning and execution for management, finance, and supply chains; increased brand value through promotional activities; further ESG management; maximized intellectual property value; stronger risk management; and greater business innovation through digital applications.



# Increasing the speed and quality of decision-making and stepping up human resources development to achieve transformation

Noriyuki Kishida

 $Senior\ Executive\ Officer,\ Senior\ Vice\ President,\ Administration\ Division$ 

Shionogi needs to increase the speed and quality of its business decision-making if the Company is to tackle new areas. Shionogi is therefore building a new decision-making system that consolidates the control of all the information and review processes needed for each individual decision, to allow the Company to move effectively through the PDCA cycle, to reflect on and clarify the relationship between process and outcomes, and to improve the Company's capabilities and determination to take on business risk.

Furthermore, our employees are the Company's most important "capital" for the creation of new value for society. The Shionogi Way is our newly formulated vision for Shionogi's human resources that states "Be the best you can be to take on new challenges." In order to realize the Shionogi Way on the path to achieving the goals in STS2030, we are stepping up human resources development by implementing a range of different programs, including more programs to support personal development and training for management tiers.