

External recognition

ESG index



2020 CONSTITUENT MSCI JAPAN
ESG SELECT LEADERS INDEX
2020 CONSTITUENT MSCI JAPAN
EMPOWERING WOMEN INDEX (WIN)



External recognition related to IR and sustainability



Corporate Governance
of the Year 2019



2019 Award for Excellence
in Corporate Disclosure
Ranking First in the
Pharmaceutical Sector



A- Rating for
"Climate Change"
and A List Company for
"Water security"
in Surveys conducted by CDP



Outstanding Health &
Productivity Management
2020

Other

Included by the Government
Pension Investment Fund
among a selection of companies
with "Most-Improved
Integrated Reports"
(Three consecutive years:
from FY2017)

Commitment to society

United Nations Global Compact



Human Rights	<p>Principle 1: Businesses should support and respect the protection of internationally proclaimed human rights; and</p> <p>Principle 2: make sure that they are not complicit in human rights abuses.</p>
Labour	<p>Principle 3: Businesses should uphold the freedom of association and the effective recognition of the right to collective bargaining;</p> <p>Principle 4: the elimination of all forms of forced and compulsory labour;</p> <p>Principle 5: the effective abolition of child labour; and</p> <p>Principle 6: the elimination of discrimination in respect of employment and occupation.</p>
Environment	<p>Principle 7: Businesses should support a precautionary approach to environmental challenges;</p> <p>Principle 8: undertake initiatives to promote greater environmental responsibility; and</p> <p>Principle 9: encourage the development and diffusion of environmentally friendly technologies.</p>
Anti-Corruption	<p>Principle 10: Businesses should work against corruption in all its forms, including extortion and bribery.</p>

Disclosure and engagement

Financial information

IR Library
<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>

Policies
<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>

Environment Report
<https://www.shionogi.com/shionogi/global/en/investors/ir-library/annual-report-integrated-report.html>

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.

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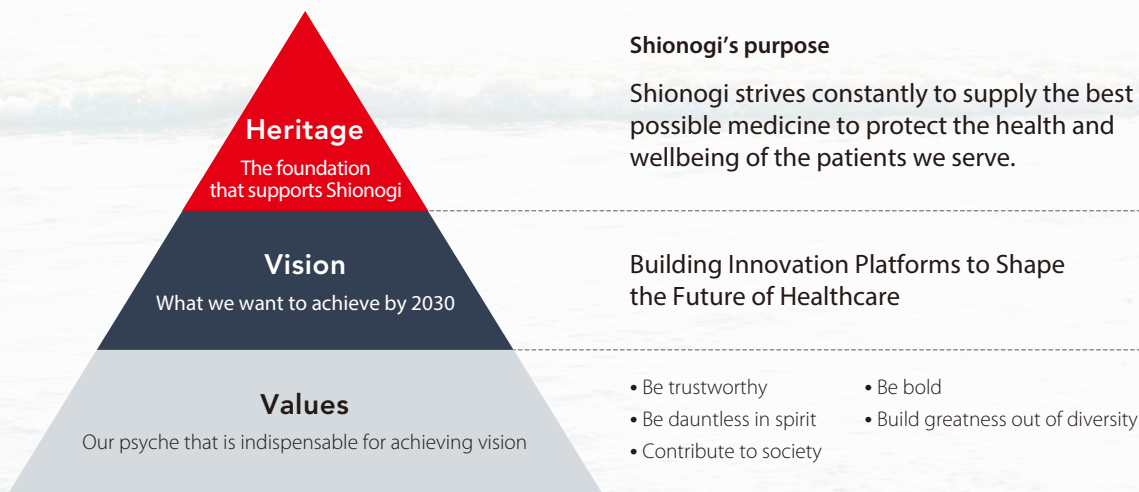
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<https://www.shionogi.com/shionogi/global/en/investors/ir-library/annual-report-integrated-report.html>



Our Philosophy — Transformed Corporate Philosophy for the Group



Heritage

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 people will be able to use these medicines.
Research, produce, and promote in an even more economical manner.

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.

As a result, Shionogi people will

Find even greater satisfaction in their daily work and in their daily lives.
Find even greater improvement in the quality of their lives.
Find even greater prosperity in their lives.

Formulated in 1957

Our Stakeholders



Message from the President

In order to continue growing during this time of change in the pharmaceutical sector environment as well as in peoples' lifestyles and values, we need to compare our Vision and Values with the needs of society and our customers, and then respond in a flexible manner.

We therefore gathered our next generation of leaders in 2018 to work together on the Oneness project to identify exactly what kind of company we want Shionogi to be in 2030 and beyond. After much discussion with the project members, we realized again that our corporate purpose is an eternal and unwavering philosophy. We defined our Company Policy as our Heritage, i.e. the foundation that supports us in all our activities, and we then went on to formulate a new Vision and new Values for Shionogi.

Vision What we want to achieve by 2030

Shionogi is evolving from a conventional drug discovery-based pharmaceutical company to become a HaaS* company that provides healthcare services, aiming to provide solutions to patient problems and social issues. Based on this concept, we developed the Vision of Building Innovation Platforms to Shape the Future of Healthcare.

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

Values Our psyche that is indispensable for achieving vision

We defined five Values that are key to achieving our Vision and describe how every employee needs to operate. Shionogi is trustworthy, unafraid of change and embracing of diversity, dauntless in spirit, and bold. These qualities allow the Company to meet the expectations of society and Transform itself to achieve our new Vision. As a corporate citizen, Shionogi is resolving social issues and helping to create a more prosperous society.

Shionogi will grow alongside all our stakeholders, while continuing to develop the Company's unique character through our operations based on this new Corporate Philosophy (of Heritage, Vision, and Values).



Isao Teshirogi, Ph.D.
President and CEO

Message from Oneness members

The members of the Oneness project met multiple times over the course of more than a year to carefully consider what kind of company we want Shionogi to be. Keeping an open mind to all possibilities, we mulled over each word through many rounds of discussion to arrive at our final resolution for the Vision and Values.

After we had formulated the Vision and Values, Shionogi came together as a single global operation to communicate these concepts to all Group companies around the world. For example, at Shionogi Inc. in the US, all employees took part in a series of workshops that featured lively discussions on the topic of What Are Shionogi's Platforms? The Vision and Values are now reflected in the New Medium-Term Business Plan STS2030 as well as organizational and individual targets, showing how the Company is weaving them into our everyday work.



Enhancing our strengths as a drug discovery-based pharmaceutical company to shape the future of healthcare

Shionogi's Strengths

Social issues that Shionogi strives to address

Business activities

Innovation skills
Skills in small-molecule drug discovery, cultivating strengths in new modalities
→ p. 11–

Alliances and collaborations
Ability to develop relationships to form positive partnerships
→ p. 13–

Expertise in infectious diseases
Solid track record over more than 60 years
→ p. 15

Human resources
Management training for strong leadership
→ p. 16


Threat of infectious diseases
→ p. 45–

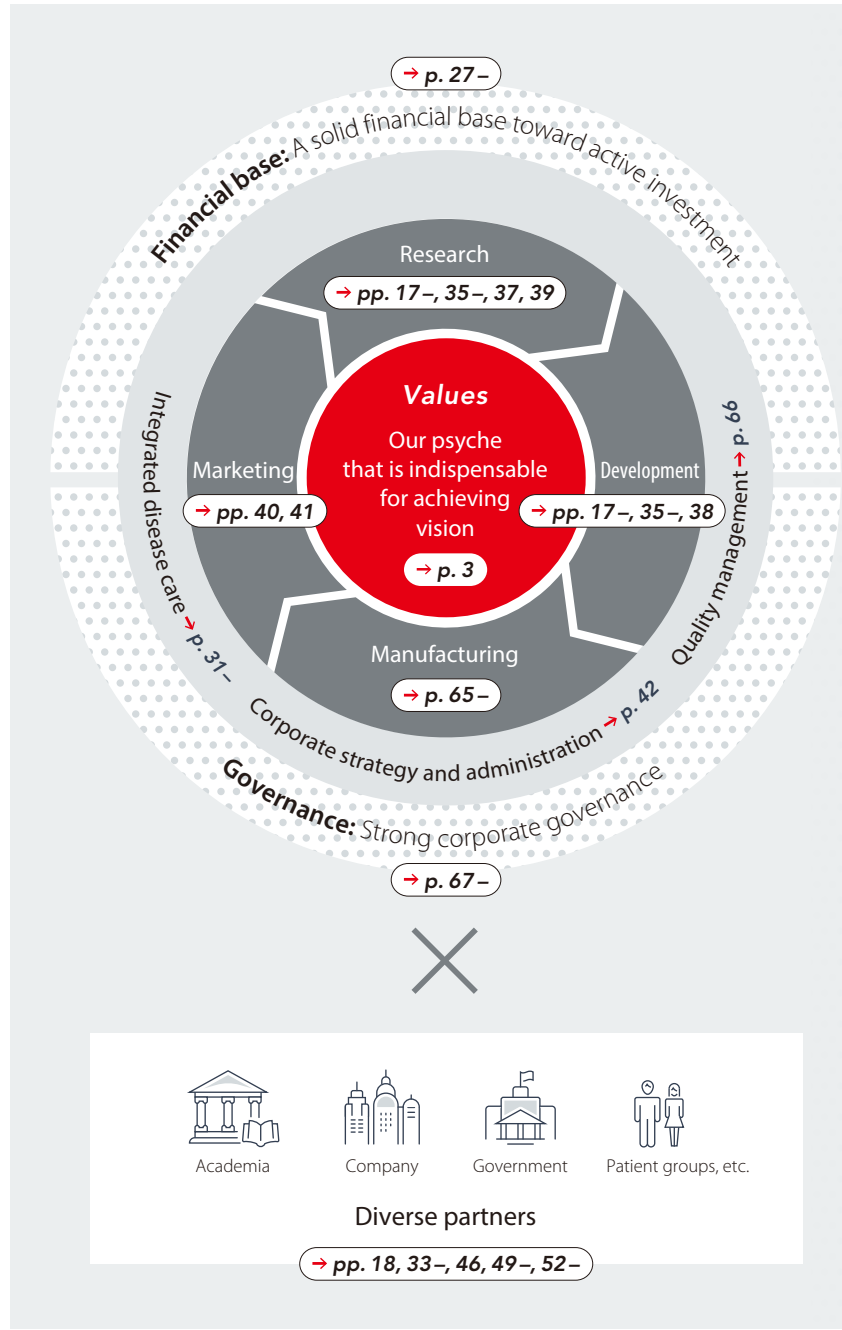

Better social productivity, healthy lifespans
→ p. 51–


Sustainability of social security
→ p. 55–

Note: See page 43 for more information on Shionogi Group's material issues (Materiality)

Our History of Value Creation
→ pp. 7–10

Heritage Company Policy
→ p. 3



We are enhancing our strengths as a drug discovery-based pharmaceutical company to create innovative products and services and to deliver value in collaboration with a diverse array of partners.

By delivering value to tackle social issues and address healthcare needs, Shionogi strives to maximize corporate value through growth and development as a company that plays a meaningful role in society and sharing the benefits of growth with all its stakeholders.

Output

Achievement of **Vision** → p. 3 and beyond

SDGs that Shionogi can help to achieve



Society

Help to achieve SDGs (creating healthy societies)

Tackle social issues, address healthcare needs

Customers

Longer healthy lifespans
Better QOL
New value co-creation

Employees

Safe workplaces
Motivating workplaces where employees can grow

Business growth

Shareholders and investors

Sustainable growth, shareholder returns

Innovative products, services

Delivering value through new platforms

→ pp. 10, 20, 45-, 52-, 58

Continued strength as a drug discovery-based pharmaceutical company

Developing strategic alliances

Focusing on drug discovery, fostering strengths, and developing profitable structures

1850 Switch from Japanese and Chinese medicines to Western medicines

1878 **Founded**

- Gisaburo Shiono, Sr., founder of the Company, launched Shiono Gisaburo Shoten as a drug wholesaler at the present site of the head office, Doshomachi, Osaka

Founder Gisaburo Shiono, Sr. (1854-1931)

Gisaburo Shiono, Sr. was born in 1854 in Doshomachi, Osaka. He learned the wholesale trade under the guidance of his father Kichibe, and launched his own drug wholesaling business in Doshomachi on his 24th birthday, on March 17, 1878. This wholesaler was the predecessor of Shionogi & Co., Ltd.



1886 **From Japanese and Chinese medicines to Western medicines**

- Shionogi switches its focus to imported Western drugs

1897 • Shionogi starts to deal directly with trading firms in Europe and the US

1900 Turning into a modern pharmaceutical manufacturer—Own innovative drugs, Shiono Seiyakusho manufacturing plant

1909 **From Western medicines to new drugs**

- **Antacidin**, an antacid agent, was launched as the first drug produced
- Registered the corporate emblem FUNDOH

FUNDOH corporate trademark symbolizing "Pursuit of accuracy"

Reliability and trust are necessary qualities for effective company management. From its founding, Shiono Gisaburo Shoten also regarded these qualities as its most valuable "capital."

The corporate emblem of Shionogi is derived from "FUNDOH," a stylized image of a balance weight historically used to dispense products. FUNDOH also symbolizes "accuracy," "honesty," and "trust," meaning we deliver confidence and peace of mind as a pharmaceutical company.



1910 • Constructed the Shiono Seiyakusho manufacturing plant, a plant for in-house R&D that would grow into Shionogi's core competency

1911 • Imported and marketed **Salvarsan** to treat syphilis Shionogi's first move into infectious diseases

1919 • Shiono Gisaburo Shoten and Shiono Seiyakusho were merged and the new company was named Shionogi Shoten Co., Ltd.

1943 • Renamed the Company Shionogi Seiyaku K.K. (now Shionogi & Co., Ltd.)

1950 Shionogi, specialists in antibiotics—Developing expertise in infectious diseases

1957 **Shionogi's Company Policy established**

- Launched macrolide antibiotic **Ilotycin**
- Launched sulfonamide drug **Sinomim**

Sinomim, the first proprietary product from Shionogi's own research (1959)

Shionogi continued to work at its research laboratories to discover better sulfonamide drugs. The Company tested around one thousand compounds as potential chemotherapy agents before discovering **Sinomim**.



1970 • Launched cephem antibiotic **Keflex**

1976 • Launched sulfamethoxazole and trimethoprim combination **Baktar**

1981 • Launched glycopeptide antibiotic **Vancomycin**

1982 • Launched oxacephem antibiotic **Shiomarin**

- Launched cephem antibiotic **Kefral**

1984 • Launched cephem antibiotic **Kefdole**

1988 • Launched oxacephem antibiotic **Flumarin**

1990 • Launched fluoroquinolone antibiotic **Romebact**

1992 • Launched cephem antibiotic **Seftem**

1993 • Launched cephem antibiotic **Broact**

1997 • Launched cephem antibiotic **Flomox**

* Text in bold indicates drugs for infectious diseases



2000

Completion of corporate restructuring to concentrate on pharmaceutical business— Blockbuster development

- 2000** Started First Medium-Term Business Plan
Concentrated on pharmaceutical business
- Transferred or sold six businesses: drug wholesaling, agrochemical, clinical laboratory, animal health products, industrial chemicals and capsules.
- 2001** • Established joint venture Shionogi-GlaxoSmithKline Pharmaceuticals LLC (now Shionogi-ViiV Healthcare LLC). Started joint R&D into HIV drugs
- 2003** • **Launched cancer pain analgesic *OxyContin*** (followed by powdered version *OxiNorm* in 2007, injectable version *OxiFast* in 2012, and extended-release *OxyContin* TR tablets in 2017)
- 2005** Started Second Medium-Term Business Plan
Established a constant flow of pipeline products through energizing and globalizing R&D
- Launched *Crestor* for hyperlipidemia (Launched *Crestor OD* tablets in 2016)
 - Launched fluoroquinolone antibiotic *Avelox*
 - Launched carbapenem antibiotic *Finibax*
- ### *Finibax* brought to market (2005)
- Finibax* was launched in 2005 as a carbapenem antibiotic with potent antibacterial activity against *Pseudomonas aeruginosa*. Shionogi out-licensed this drug in the US, Europe, and Asia. Following in the footsteps of *Flumarin* and *Shiomarin*, *Finibax* earned Shionogi the Pharmaceutical Society of Japan Award for Drug Research and Development.
-
- 2008** • Launched *Pirespa* for idiopathic pulmonary fibrosis
- 2010** Started Third Medium-Term Business Plan
Launch of multiple products developed globally and real growth
- Launched *Rapiacta* for influenza
 - Launched SNRI *Cymbalta*
- 2013** • Launched *Ospheña* (ospemifene) in the US for postmenopausal vulvar and vaginal atrophy

2014

Series of new drug launches— Rapid progress as a drug discovery-based pharmaceutical company

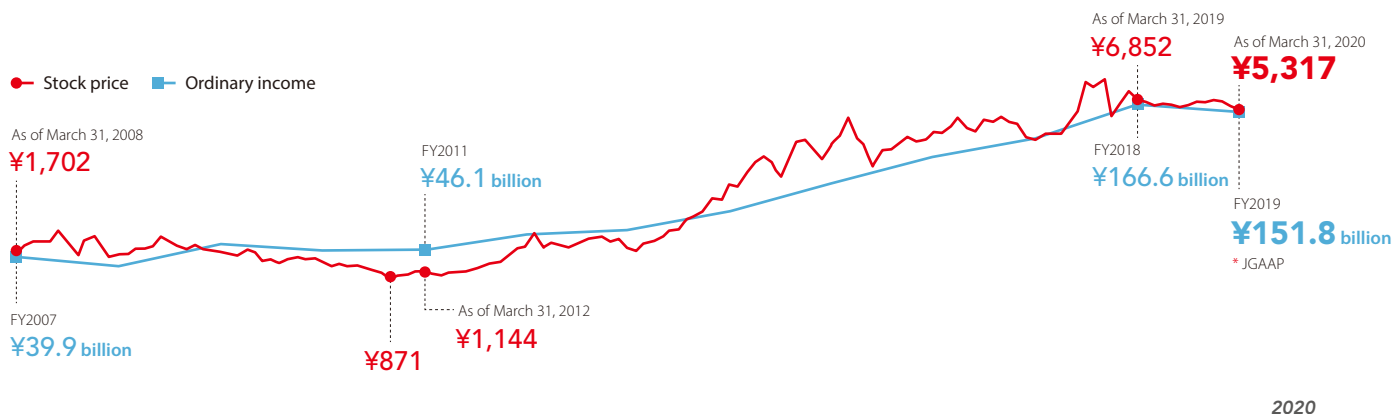
- 2014** Started Fourth Medium-Term Business Plan Shionogi Growth Strategy 2020 (SGS2020)
Grow as a drug discovery-based pharmaceutical company
- Launched *Tivicay* (dolutegravir) for HIV infection (Launched three-drug combination *Triumeq* (dolutegravir + lamivudine + abacavir) in 2015, two-drug combination *Juluca* (dolutegravir + rilpivirine) in 2018, and two-drug combination *Dovato* (dolutegravir + lamivudine) in 2020)

Winner of the Heroes of Chemistry Award (2016)

In 2016, *Tivicay* earned Shionogi the Heroes of Chemistry Award from the American Chemical Society for innovation in chemistry, and in 2017 the Company went on to claim the Pharmaceutical Society of Japan Award for Drug Research and Development.



- 2015** • Launched allergen immunotherapy *Actair*
• Launched *Mulpleta* for thrombocytopenia
- 2016** Updated the Medium-Term Business Plan, SGS2020
Grow sustainably as a drug discovery-based pharmaceutical company contributing to a more vigorous society through improved healthcare
- 2017** • Launched *Methapain* for cancer pain
• Launched *Intuniv* for attention-deficit/hyperactivity disorder (ADHD)
• Launched *Symproic* for opioid-induced constipation (OIC)
- 2018** • Launched *Xofluza* for influenza
- 2019** • Launched *Vyvanse* for attention deficit/hyperactivity disorder (ADHD)
• Made UMN Pharma a subsidiary
- 2020** • Launched the siderophore cephalosporin antibiotic *Fetroja* (cefiderocol) in the US
Started the New Medium-Term Business Plan, Shionogi Transformation Strategy 2030 (STS2030)
Transformation into a HaaS company
• Launched SARS-CoV-2 IgG/IgM antibody detection kit (research reagent)



“ Fighting infectious diseases ” for over 100 years

Over the span of some 110 years, Shionogi has been on a mission to treat infectious diseases, starting with the import and sale of *Salvarsan* for syphilis in 1911 and the in-house discovery of the sulfonamide drug *Sinomina* after the War, through to the recent launch of *Fetroja* (cefiderocol) to treat multidrug-resistant Gram-negative bacterial infections.

Service Shionogi is of service in the global battle against infectious diseases, from the first in-house product through to the present day

After the discovery of penicillin, there were very few new treatments discovered for infectious diseases that were both effective and safe, and tuberculosis and pneumonia continued to top the rankings for cause of death at that time.

Shionogi’s management team decided that, given the importance of antibiotics, the Company should move into this field as a matter of priority. Shionogi then embarked on research and development in infectious diseases. The Company poured its energies into in-house research and was rewarded with the development of its first proprietary product, *Sinomina*, in 1959. *Sinomina* was out-licensed to the Swiss company Roche and was used around the world to treat infectious diseases. Today, after more than 50 years on the market, *Sinomina* is still playing a vital role in healthcare, now formulated as the sulfamethoxazole and trimethoprim combination *Baktar*.



Advertising image for *Sinomina* in 1959

Adversity Many companies have withdrawn from the antibiotics market

Shionogi has developed a series of groundbreaking proprietary products to treat infectious diseases, starting with the world’s first oxacephem antibiotic *Shiomarin*. The number of antibiotics launched on global markets peaked in the late 1980s before starting to decline. This trend was driven by many pharmaceutical companies deciding antibiotics lacked appeal as a market, due to high development risk and the lower drug prices and shorter treatment regimens compared with anticancers and other drug types.

The decline was also exacerbated by the problem of antimicrobial resistance (AMR). To ensure doctors still have access to treatments effective against drug-resistant strains, the general consensus was that pharmaceutical companies should not pursue antibiotic sales growth. Drugmakers also found it difficult to formulate accurate production plans because of the significant regional variation in healthcare systems for AMR and the number of patients with drug-resistant infections.

The threat posed by antimicrobial resistance (AMR), where antibiotics are no longer effective against infectious diseases, has come into sharp relief once again with the COVID-19 pandemic. This has led to some positive changes in global trends and action on antibiotics, including 23 of the world’s largest pharmaceutical companies setting up the AMR Action Fund.



Oxacephem antibiotic *Shiomarin*

Mission Shionogi continues to invest in R&D as part of the Company’s social responsibilities

The threat posed by infectious diseases and drug-resistant bacteria is an enormous social issue for mankind. In the future, patients may lose their lives if doctors do not have access to new drugs. For this reason, Shionogi continues to invest in the discovery of new drugs to treat a wide range of infectious diseases. The Company has also taken the initiative in efforts to address AMR (see page 47 for more details).

Leveraging expertise built up through many years’ experience in antimicrobial drug discovery, Shionogi will make every effort to fulfill its mission of providing treatments for infectious diseases.



AMR Industry Alliance Board set up by seven global pharmaceutical companies, including Shionogi

Operating margin (fiscal 2019)

37.4%

* JGAAP

ROE (fiscal 2019)

18.0%

* JGAAP

Products launched globally (2014–2020)

5 products



HIV treatment
Tivicoy



Thrombocytopenia treatment
Mulpleta



Opioid-induced constipation (OIC) treatment
Symproic



Influenza drug
Xofluza



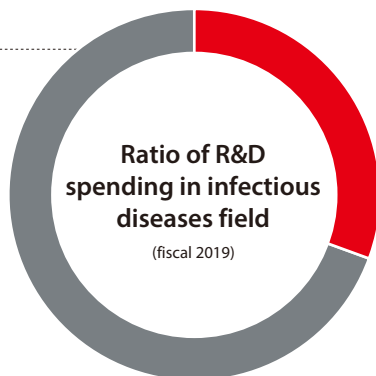
Multidrug-resistant Gram-negative bacterial infection treatment
Fetroja (cefiderocol)

Original pipeline ratio (fiscal 2019)

67%



CNS, pain, other



Ratio of R&D spending in infectious diseases field (fiscal 2019)

Infectious diseases
30.8%

Note: Labor costs and indirect spending not included

1. Innovation Skills

World-class capabilities in small-molecule drug discovery

— Applying wide range of technologies to go above and beyond



If Shionogi is to grow in a sustainable manner as a member of society, the Company needs to constantly innovate to help solve social issues and deliver new value to customers and societies. Innovation involves tackling the problems faced by patients and societies head on and taking the right approach to find the best solution to these problems. At Shionogi, we will not compromise in our efforts to bring the benefits of our innovation to as many people as possible in a time-efficient manner.

Focus on in-house drug discovery

Shionogi is constantly working on drug discovery with a particular focus on proprietary new drugs. Whereas the original pipeline ratio*¹ at most pharmaceutical companies is said to be 20–30%, we aspire to a ratio of 50–70%. At the end of March 2020, our original pipeline ratio was 67%. As a drug discovery-based pharmaceutical company, we take pride in this high ratio as we think it is indicative of our strength in in-house drug discovery.

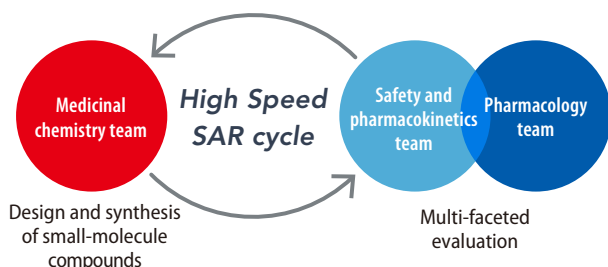
*¹ Proprietary compounds originated in-house as a percentage of the whole development pipeline (includes results of joint research with partners and development candidates)

Shionogi's drug discovery capabilities lead to innovative new drugs

Shionogi's strength in research stems from our highly efficient SAR*² engine for small-molecule drug discovery. The source of our competitiveness lies in the technological prowess of our teams in medicinal chemistry, pharmacology, and safety and pharmacokinetics, as well as our experience in problem-solving via collaboration between the three teams. Through strong teamwork, we have been able to speedily and efficiently move through the SAR cycle. As a result, during the previous SGS2020 Medium-Term Business Plan, we launched five products originated in-house onto global markets, including the anti-HIV agent *Tivicay* (launched 2014) and the influenza drug *Xofluza* (launched 2018).

*² SAR: Structure activity relationship

Team collaboration in the drug discovery research cycle



Tackling the problems faced by patients and societies

We are enhancing our existing strengths in small-molecule drug discovery and also working on a wide range of therapeutic approaches (modalities) to meet the broad range of patient and societal needs. We aim to increase our drug discovery success rate by using the best drug discovery approach for each target

therapeutic area. That means trying medium-sized molecules such as peptides and nucleic acids, as well as antibodies such as anti-CCR8*³ and cells (regenerative medicine). We are building new strengths from the base provided by this SAR engine for small-molecule drug discovery.

Theme for Fiscal 2019: Progress in peptide drug discovery

Peptides do not readily pass through cell membranes because of their high molecular weight and chemical characteristics, so they can only be used to target extracellular molecules. To tackle this issue, we combined our small-molecule drug discovery capabilities with PDPS*⁴ technology. After extensive research, we have made progress with a technology to optimize candidate peptide structures that results in a dramatic improvement in membrane permeability. This has significantly broadened the scope for the discovery of pharmaceuticals to treat diseases where there are substantial unmet clinical needs, such as conditions with limited treatment options.

R&D into new drugs has become increasingly difficult in recent years, requiring significant resources and long development times. With our in-depth understanding of disease and of patient and societal perspectives, the value that Shionogi can offer is not limited to pharmacotherapy. Medicines are not necessarily the best solution for patients if other options can improve or remove symptoms. We also recognize the social pressure on companies to engage with disease prevention and early-stage care due to significant environmental changes, such as more health conscious societies, growing government-financed healthcare expenditure, and the global disruption from the pandemic. For these reasons, Shionogi is taking a broad view across a whole range of healthcare solutions and is working diligently to create new platforms to deliver new options, such as preventive vaccines using technology from Shionogi Group company UMN Pharma and a digital treatment app under development for ADHD.

*³ CCR8: Chemokine (C-C motif) Receptor 8

*⁴ PDPS: Peptide Discovery Platform System

2. Maximizing Value through Alliances and Collaborations

Partnerships rooted in trust

— Working together to create new business models

Building relationships for win-win partnering

Ultimately, Shionogi aims to turn strong relationships of trust into business dealings that are satisfactory on both sides, allowing the development of mutually beneficial business conditions.

Rather than just battling to profit the Company, Shionogi looks for win-win contracts, taking one step back so that agreed terms also benefit the other party. This different negotiating perspective sets us apart and is the backbone of Shionogi today.

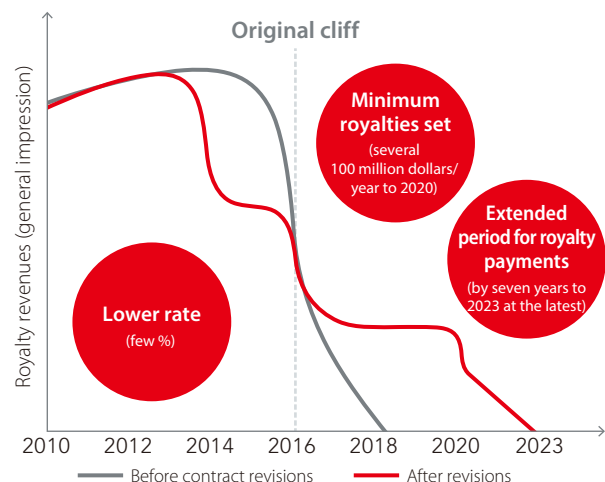
What benefits both parties may change as the operating environment evolves, so Shionogi works to deepen partner relationships further even after contracts are signed, keeping abreast of the situation at partner companies and responding flexibly even to changes in contract terms. These positive collaborations have allowed the Company to achieve sustained growth.

Finding win-win conditions by revising the Crestor terms

Shionogi successfully out-licensed the in-house hyperlipidemia treatment *Crestor* in 2013 and earned royalty revenues that drove earnings at the time. However, forecasts showed the *Crestor* patent expiry in 2016 would be a so-called patent cliff that could wipe out over ¥60 billion in operating income in a couple of years.

Rather than abandoning a potentially difficult contract renegotiation in this time of crisis because the contract terms were already fixed, Shionogi instead talked directly with the

Mitigating the patent cliff by modifying the contract



licensing partner to understand their issues, based on the relationship of trust that had developed over the years.

We learned that our licensing partner needed funds for immediate investment in new product launches and therefore agreed to modify the contract terms, significantly lowering royalties over the next two years in return for extending the period of royalty payments by seven years to 2023 at the latest.

Although this agreement meant earnings would decline over the near term, the revised conditions ensured that Shionogi would have a source of income to support growth even after the patent expired and that total royalty payments would ultimately be higher.

Shionogi was able to successfully overcome the Crestor cliff through these win-win changes to the contract as well as increased earnings from a new growth driver (the innovative HIV treatment *Tivicay*).

Looking ahead to future partnerships

Shionogi has formed crucial partnerships when faced with problems the Company cannot solve on its own. Partnerships have allowed Shionogi to overcome hurdles in drug discovery, expand the product portfolio and drug pipeline, make progress in development, and maximize product value. The Company has also forged alliances to acquire new modalities, create business synergies, and reform IT. As well as these business partnerships, Shionogi is actively involved in collaborative initiatives to address social issues, examples being the Company’s participation in the AMR Action Fund to address antimicrobial resistance and collaboration with local governments and academia on ADHD. Shionogi is also partnering in efforts to address the global threat posed by COVID-19. The Company is conducting R&D into therapeutic agents, vaccines and diagnostics in collaboration with academia, other pharmaceutical companies, and companies in other industries.

Looking ahead, Shionogi expects healthcare needs to become more diverse as the external environment changes. In order to satisfy a wider range of needs, Shionogi needs to collaborate with a more diverse array of partners in areas where the Company would be unlikely to achieve results on its own. Shionogi aims to contribute to healthcare through various approaches, while also cultivating our original strengths in drug discovery to attract potential business partners.



3. Expertise in Infectious Diseases

Expertise built up over many years

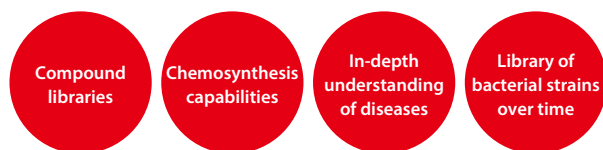
— Making most of strengths in pursuit of total care



Long-term engagement in infectious diseases R&D

Shionogi has conducted research and development in infectious diseases for over 60 years, bringing a huge number of drugs for infectious diseases to market along the way, from *Sinomim* launched in 1959 right up to *Fetroja* (cefiderocol) in 2020. Drawing on compound libraries and other resources developed through many years of research, Shionogi has built a solid platform in infectious diseases drug discovery and has been able to generate a series of products and drug candidates in this field. As more and more pharmaceutical companies withdraw from R&D in the poorly profitable field of infectious disease,

Strengths in anti-infective drug discovery



Continuous creation of products and drug candidates

Shionogi has continued to invest. In the Antimicrobial Resistance Benchmark* 2020 survey, Shionogi was recognized as having the highest annual ratio of R&D investment for anti-bacterial and anti-fungal agents of any of the companies surveyed (based on annual investment as a proportion of net sales).

* Report published by Access to Medicine Foundation that tracks and analyzes what major global pharmaceutical companies are doing to bring antimicrobial resistance (AMR) under control.

Targeting total care for infectious diseases

Shionogi considers protecting people worldwide from the threat of infectious disease to be a pressing social issue. The Company is involved in a wide range of initiatives that go beyond the scope of R&D into therapeutic agents, including disease awareness programs, prevention, diagnostics, and methods to prevent conditions becoming serious.

As well as progressing these initiatives to provide total care for infectious diseases, Shionogi is taking a global leadership role to manage the threat of infectious diseases, including efforts to ensure stable supplies and appropriate use of anti-infectives. Pages 17–20 and 45–50 of this report provide an overview of Shionogi's efforts in infectious diseases, including the Company's response to COVID-19.

Leadership that supports growth

— Developing human resources with problem-solving skills for the future

Building up human resources to support highly efficient management

One of Shionogi's characteristics is its robust management that intensively pursues efficiency to achieve the targets. This robustness is developed through strong leadership training for all tiers of management.

The CEO of the Company personally trains senior management candidates through the President's Management Seminar that was started in fiscal 2012. Each year, around ten candidates are selected to attend this program that runs roughly once a month for 12 months. The goal is to develop diverse human resources with a tenacious approach who can consider issues from a company-wide perspective and have good communication skills. Approximately one half of the current corporate officers and heads of the organization are graduates of this program.

Shionogi also carries out a system of corporate officer rotation across the value chain. This system of experiencing management in a number of divisions was built to allow corporate officers to practice management not as the representative of one division but from a company-wide perspective. Senior management candidates take on roles as presidents, non-executive directors, and auditors of Group companies, where they gain management experience. The CEO personally confirms the content of discussions at Group companies and at the twice-yearly general meeting of shareholders and at business briefing events, the CEO and officers of Group companies engage in

comprehensive discussions, providing them with a forum to hone their business instincts.

New program for manager development

In fiscal 2020, Shionogi launched PJ KANAME, a new program for manager development, as part of the Company's measures to achieve the New Medium-Term Business Plan (STS2030).

The new program is completely different from conventional management training and will be offered to all managers at Shionogi & Co., Ltd. and domestic Group companies. This major development program runs over a two-year period, during which trainees will continuously engage in a number of different assignments.

Roadmap to achieving management targets through the manager development program

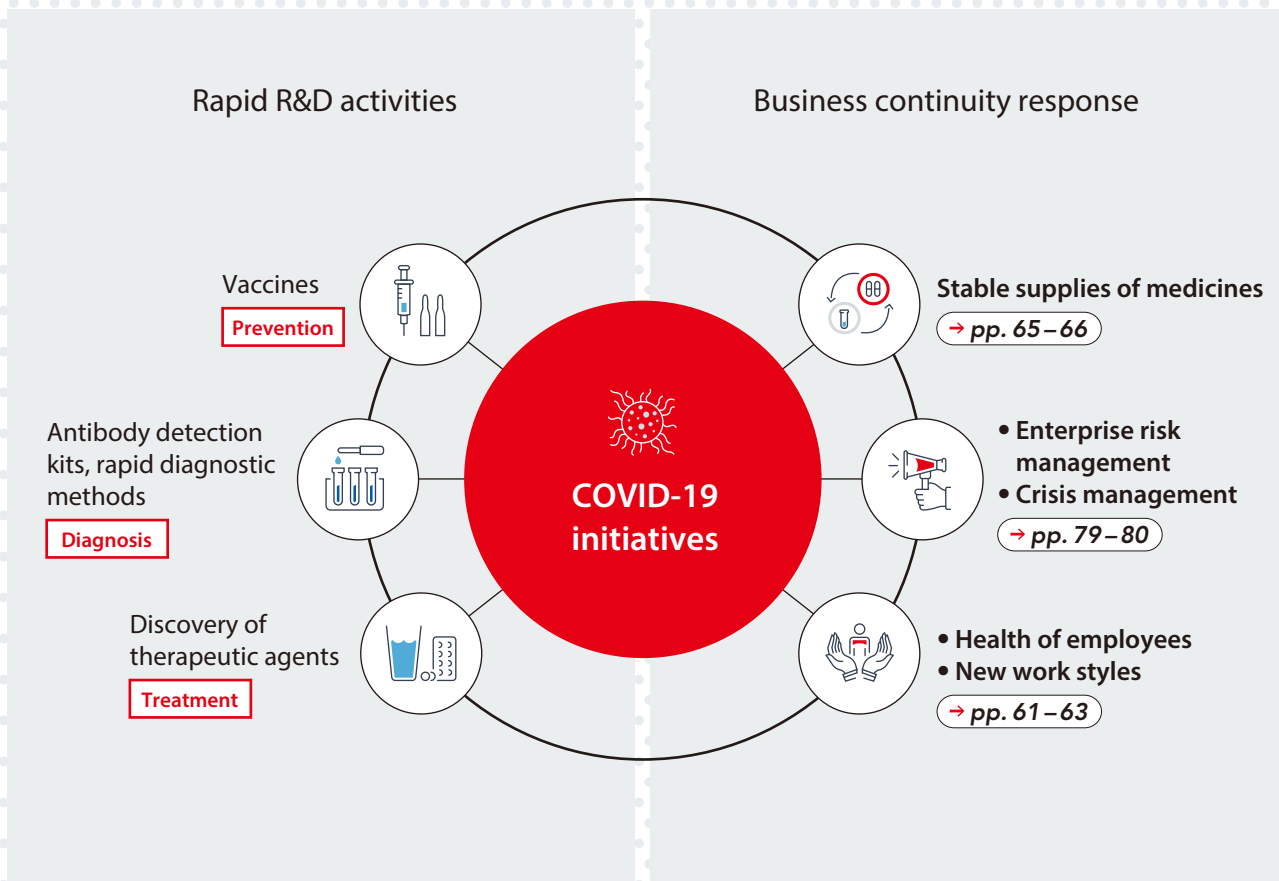


SPECIAL FEATURE 01

Battling the threat of COVID-19 and other infectious diseases

Amid the global threat posed by COVID-19, Shionogi is battling in this time of crisis to make real progress in R&D into therapeutics, vaccines, and rapid diagnostic products. As a leading company in infectious diseases, we aim to achieve a portfolio of solutions that provide “total care” for various infectious diseases caused by a wide range of pathogens.

Response to COVID-19



As a leader in this field, we are working constantly to provide total care for infectious diseases to prepare for the next infectious disease threat

→ pp. 19–20



Prioritizing our response to COVID-19

The pharmaceutical industry in particular is under significant pressure to develop treatments and vaccines as fast as possible to counter the spread of infections with the novel coronavirus (SARS-CoV-2).

While Shionogi continues to ensure the stable supply of pharmaceuticals and business continuity, as a pharmaceutical company with a major focus on infectious diseases, we are also working with public institutions, academia, and partner companies to prioritize R&D into novel therapeutics, vaccines, and diagnostic products for COVID-19. We continue to work in top gear to bring products to market as soon as possible.

Prevention Vaccine development

A global race is underway to develop vaccines to control the novel coronavirus through immunization programs. Shionogi is working with the National Institute of Infectious Diseases (NIID) and Kyushu University on R&D into a recombinant protein vaccine comprising the viral S protein as the antigen, based on a technology from UMN Pharma, which became a wholly owned subsidiary of Shionogi in fiscal 2019. This technology has already been used for a number of products, including vaccines against influenza, and they can be manufactured in large quantities, quickly, and at low cost.

Shionogi aims to start clinical trials by end-2020 and is already building vaccine manufacturing facilities in Japan, funded by grants from various government ministries and agencies, to be able to quickly supply a large number of doses once a vaccine is successfully developed. The goal is to have built a supply system by the end of fiscal 2020 and be in a position to provide doses for 30 million people by end-2021.

Diagnosis Development and marketing of diagnostic reagents

Key factors that will allow us to co-exist with or control this infectious disease, as well as fully resume economic activities, are the ability to accurately identify infected individuals (including asymptomatic carriers) and to rapidly isolate and treat positive cases. Shionogi has in-licensed SATIC,^{*1} a technology for the amplification and detection of specific genes that is rapid, highly sensitive, and convenient and was developed by Nihon University, Gunma University, and Tokyo Medical University. We are applying this technology to develop a kit that can be used for the rapid diagnosis of multiple samples in locations such as hospitals and airports.

^{*1} SATIC: Signal Amplification by Ternary Initiation Complexes

Treatment Discovery of therapeutic agents

Although most of the development projects for COVID-19 involve drug repositioning,^{*2} there have yet to be any reports of efficacious drugs capable of achieving obvious viral suppression. Research into pathogens, such as for infectious disease studies, is performed at strictly regulated facilities and it is vital that systems are in place to maintain those facilities in peacetime to be able to conduct R&D during a pandemic. Shionogi has made a smooth transition to COVID-19 research, leveraging the Company's strengths built up over many years working in this field.

We are researching therapeutic agents in collaboration with Hokkaido University, utilizing our compound libraries and experience in the discovery of various antivirals built up over our history. Shionogi is currently conducting assessments for the final selection of development candidates and aims to start clinical trials during fiscal 2020.

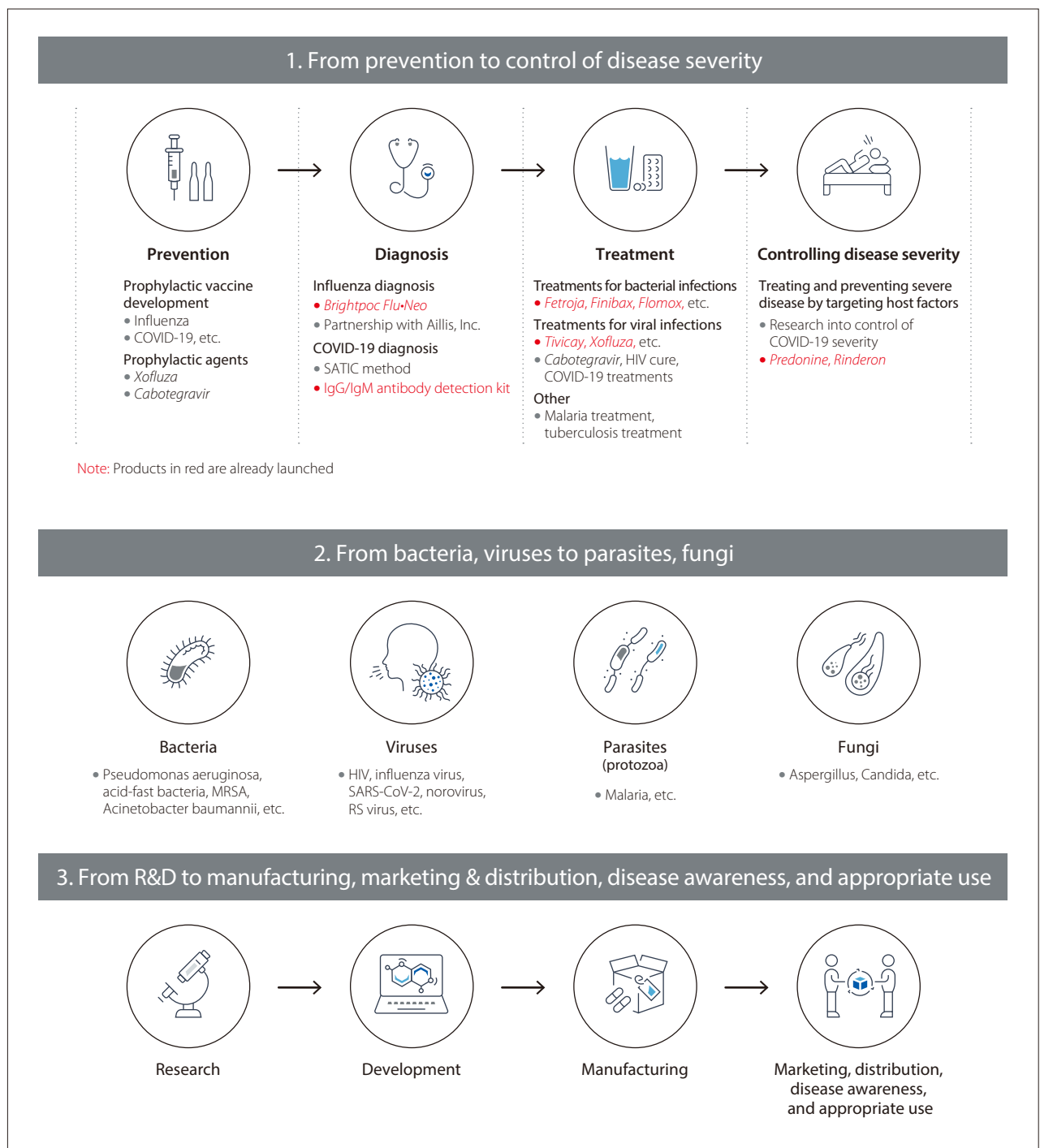
^{*2} A method of development whereby existing drugs undergo testing as potential treatments for new diseases to see if they can be put to another use

Aiming at total care for infectious diseases

The COVID-19 pandemic has caused significant loss of life and enormous socioeconomic damage. The pandemic has shaken the very foundations of our way of life and served as an important reminder of the importance of infection control measures.

Leveraging the key strengths in our integrated value chain from R&D to manufacturing and marketing, Shionogi continues

to engage in R&D into therapeutic agents for a wide range of infectious diseases, and we are also broadening the scope of our work to encompass prevention, diagnosis, and agents to control disease severity. We are also actively involved in efforts to solve the problem of antimicrobial resistance (AMR), in our role as a leading company in infectious diseases.



1. From prevention to control of disease severity

Expanding our business scope

Shionogi will only become a leading company in infectious diseases once we are in a position to provide solutions covering all stages of infectious disease. Based on this concept, we aim to provide “total care for infectious diseases” that starts with R&D into agents to treat infectious diseases, and also includes the earlier stages of raising awareness through disease education, prevention, and diagnosis through to the final stages including control of disease severity and saving lives.

As a new approach in this drive to provide total care, Shionogi made UMN Pharma a consolidated subsidiary in December 2019, with a view to enhancing our expertise, experience, and technologies in vaccines to prevent infectious diseases. We will deliver value to patients suffering from disease, and also create new value for the general population at risk of disease.

2. From bacteria, viruses to parasites, fungi

Dealing with a wide range of pathogens

There are countless pathogens across the globe that cause infectious diseases, and sometimes different pathogens combine together to cause a disease. In order to provide better treatments for infectious diseases, we need to build a wide range of treatment options against pathogens.

Shionogi continues to engage in R&D, while also utilizing partnerships with academia and other companies, in order to deliver products and services to tackle various pathogens.

3. From R&D to manufacturing, marketing & distribution, disease awareness, and appropriate use

Integrated value chain

Multiple departments work together so that the Company can create agents to treat infectious diseases and deliver them to patients.

In order to deliver products and services, the departments in the value chain, particularly in research (drug discovery, CMC), development, manufacturing, and marketing, constantly create new value by developing strategies, partnering, and executing to achieve the Company vision.

As well as products and services, the Company runs disease awareness programs to foster a deeper understanding and knowledge of infectious diseases, which also helps improve awareness of prevention and leads to reduced infections and appropriate use of pharmaceuticals.

Through these initiatives, Shionogi is helping to lessen the negative impact of infectious diseases on social activities and reduce the number of deaths by saving the lives of those who are seriously ill.

Fetroja (cefiderocol): Powerful weapon in the fight against AMR

Shionogi leveraged its strengths in in-house antibiotic research in the search for promising treatment options against infectious diseases caused by gram-negative bacteria that have acquired resistance to existing treatments. The Company discovered cefiderocol, the first ever siderophore cephalosporin antibiotic, and launched this drug in the US in February 2020 (see page 47 for more details).

Fetroja (cefiderocol) could be a powerful weapon in the fight to save the lives of patients with infections for which there are currently no treatment options. Shionogi will continue working to provide this treatment as appropriate to the patients and medical institutions where it is needed.

