## SMBC Nikko Web IR for Retail Investors SHIONOGI's Solution of Social Issues and Increase in Corporate Value



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Vice President, Corporate Communications Department and Corporate Secretariat, Corporate Strategy Division March 4, 2022



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## Agenda



## **1. Pharmaceutical Business**

- Japanese Pharmaceutical Market
- Challenges and Prospects for the Pharmaceutical Business

## 2. What's SHIONOGI

**3. Sustainable Growth as a Leading Company in Infectious Diseases** -Aiming to Protect People Worldwide from the Threat of Infectious Diseases-

### 4. Shareholder Return





## **1. Pharmaceutical Business**

- Japanese Pharmaceutical Market
- Challenges and Prospects for the Pharmaceutical Business



## **Classification of Drugs**

- Drugs are generally classified into *prescription drugs* and OTC<sup>\*</sup> and quasi-drugs
- Prescription drugs are further classified into New Prescription drugs and generic drugs

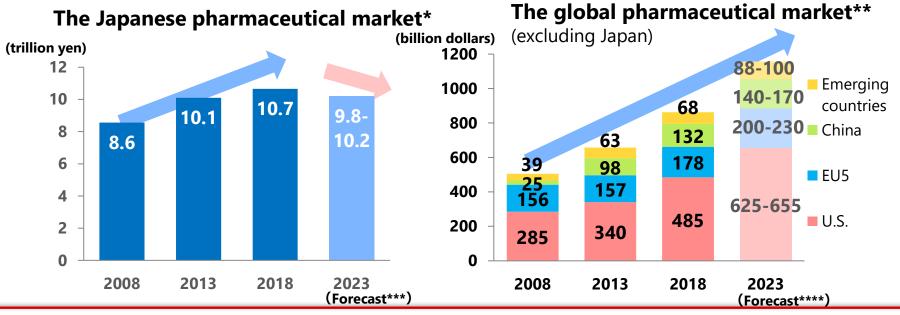




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## **Changes in the Pharmaceutical Market Size**

- The Japanese pharmaceutical market is worth around 10 trillion yen/year
- Among developed countries, only the Japanese market is forecast to post negative growth in 2023
- The global pharmaceutical market, mainly the U.S. and China, is expected to expand



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\*MIDAS Dec. 2008-Dec. 2018 \*\* IQVIA World Review Analyst 2008,2013. 2018: Global Use of Medicine in 2019 and Outlook to 2023, IQVIA Market Prognosis, Sep 2018 \*\*\* Global Use of Medicine in 2019 and Outlook to 2023, IQVIA Market Prognosis, Sep2018 (calculated based on 1\$ = 110 yen)

\*\*\*\* Global Use of Medicine in 2019 and Outlook to 2023, IQVIA Market Prognosis, Sep2018 (Calculated Dased on 15 = 110 yen)

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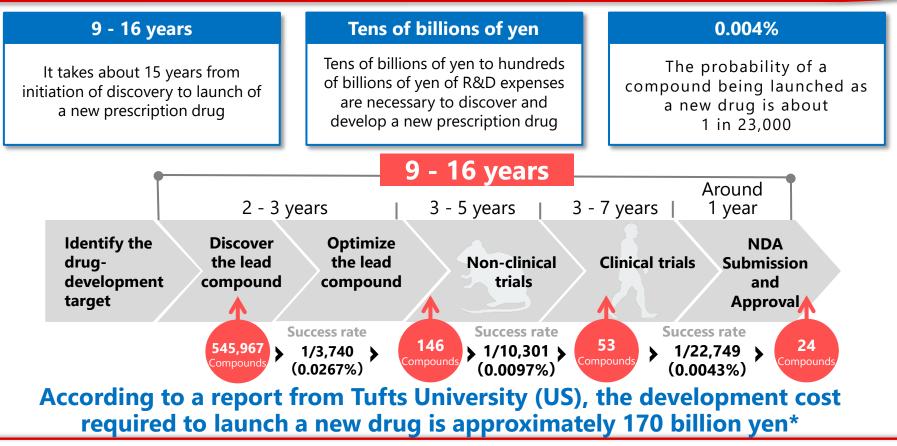
## **1. Pharmaceutical Business**

- Japanese Pharmaceutical Market
- Challenges and Prospects for the Pharmaceutical Business



## **Process to Launch New Prescription Drugs**





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Source: Data from JPMA (FY2015-FY2019 \* Tufts Center for the Study of Drug Development Cost of Developing a New Drug (2014)

## **Patent Term and Generic Drugs**

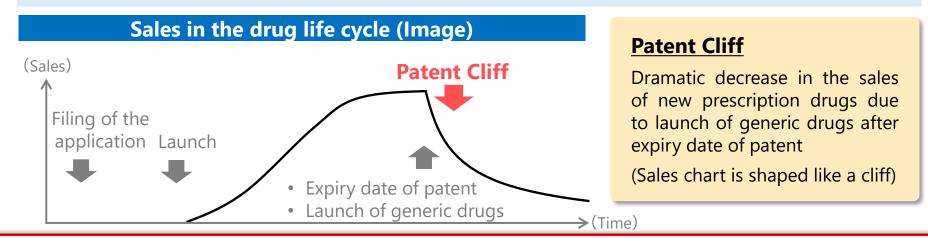
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Patent Term is twenty years from the filing date of the application

Patent expiration

Other companies can manufacture the same drug

## **Generic drugs are launched**



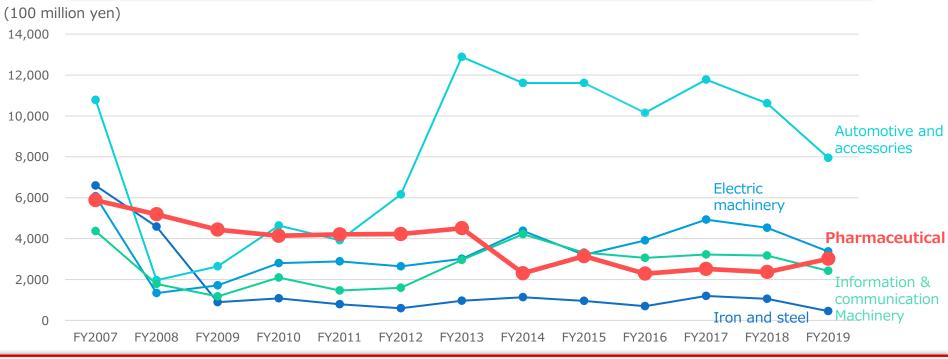


## Domestic Tax Payments of Japan's Major Manufacturing Sectors

• The pharmaceutical sector contributes to the Japanese economy with its stable tax capacity

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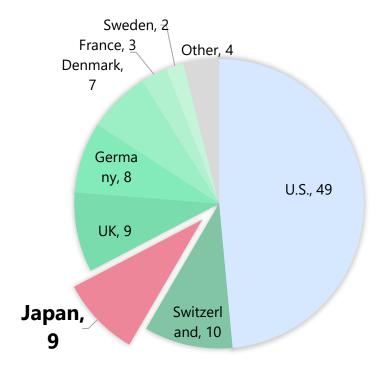


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Source: Pharmaceutical Industry Vision 2021 Materials by the Ministry of Health, Labour and Welfare for the pharmaceutical sector; "Income taxes - current" section of the Financial Statements Statistics of Corporations by Industry by the Ministry of To Finance for other sectors

## Number of Drugs Developed by Major Country (FY2019)

- Only a handful of countries can discover new drugs
- Japan ranks third in the world for new prescription drug discovery
- Japan is the only Asian country that discovers new prescription drugs



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## **Contributions and Challenges by the Pharmaceutical Industry**



12

# Development and spread of scientific technology

- Industry-academic-government cooperation
- Challenge of cutting-edge fields
- Fostering and use of advanced and diversified human resources

#### Mission as a liferelated industry

"Contributions to the improvement of health and welfare of people in the world"

### **Contributions to economic growth**

- Stable and high-level tax-bearing capacity
- Pharmaceutical industry as a high-value added industry
- Investment in R&D

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### Realization of a society of health and longevity

- Contributions by new drugs
- Efforts to satisfy unmet medical needs
- Efforts to overcome intractable diseases
- Elimination of drug lag

#### **Contributions to the global** health community

- Global development of new drugs
- Alliance with Asian countries
- Role of Japan in the creation of new drugs
- 3 major infectious diseases and NTDs\*

#### **Contributions to COVID-19**

- Stable supply of pharmaceuticals
- Promotion of R&D of therapeutic drugs and vaccines, etc.



## 2. What's SHIONOGI



### Shionogi Known for "MUSIC FAIR," "SEDES," "Popon S," etc.



- Broadcast for more than 50 years since August 31, 1964, under the sole sponsorship of Shionogi
- The longest running music program on commercial TV in Japan



Designated class 2 OTC drug



Designated class 2 OTC drug





Designated class 2 OTC drug



Designated quasi-drug



Class 3 OTC drug



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Designated class 2 OTC drug



Class 2 OTC drug



## What's SHIONOGI - philosophy -



#### 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 people will need to:

Strive ceaselessly day after day to improve their skills.

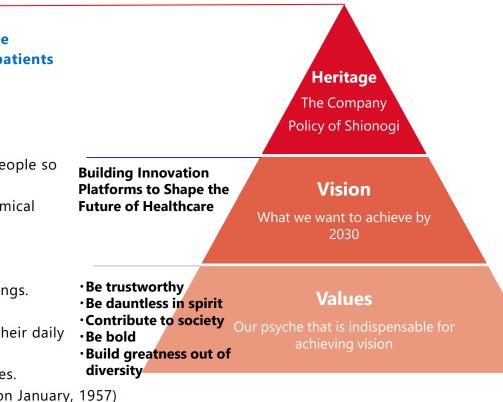
Strive ceaselessly day after day to improve as human beings.

#### 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. (Established on January, 1957)





## SHIONOGI – company profile –



Shionogi & Co., Ltd., based in Osaka, is a prescription drug-based pharmaceutical company founded more than140 years ago, aiming to contribute to people's health as a "HaaS<sup>\*\*</sup> company" that provides healthcare services

Corporate Name	Shionogi & Co., Ltd.	<b>SHIONOGI</b>
Chief Executive	President and CEO: Isao Teshirogi, Ph.D.	
Established	March 17, 1878 in business for 144 years	
Incorporated	June 5, 1919	
Head Office	Doshomachi, Chuo-ku, Osaka, Japan	
Number of Employees	5,485 (consolidated)	
Category of Business	Marketing and Manufacturing of Drugs	
Type of Business	Manufacturing and distribution of pharmaceuticals, diagnostic reagents and medical devices, etc.	
Consolidated Revenue	¥ 297.2 billion <sup>**</sup> (Prescription drugs 96% and OTC and quasi-drugs 4%)	
Operating profit	¥117.4 billion** (Operating profit margin: 39.5%)	
HONOGI	* HaaS; Healthcare as a Service: Providing a range of healthcare s other than only supplying pharmaceuticals.	ervices in line with customer need ** as of March 31, 2021 (IFR

## What's SHIONOGI -global expansion -

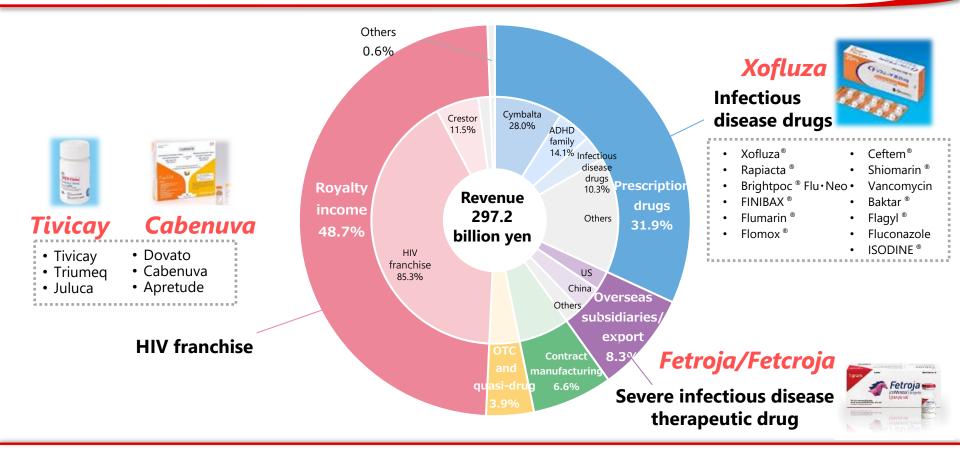




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## What's SHIONOGI - revenue composition (FY2020)-



SHIONOGI <FY202

<FY2020 Revenue> Prescription drugs 94.7B yen: Cymbalta 26.5B yen, ADHD family (Intuniv+Vyvanse)13.4B yen, Infectious disease drugs 9.8B yen Overseas subsidiaries/export 24.6Byen: Fetroja 1.7B yen Royalty income 144.6B yen: HIV franchise 123.4B yen 18

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## What's SHIONOGI - Shionogi's strengths-



#### R&D

More than 10 new, in-house discovered drugs have been launched since 2000 when we embarked on transformations

#### **Know-how of infectious diseases**

Pursue total care of infectious diseases by harnessing our know-how accumulated over more than 60 years through R&D of infectious diseases



#### **Diverse partnering**

Discover innovative new drugs in-house and provide to patients across the world through partnering that maximizes the value of compounds

#### **Human resources**

Promote the "development and building of strong individuals and organizations capable of surviving global competition"



### Shionogi's History in Infectious Disease Area -In-house discovered Infectious Diseases Drugs-





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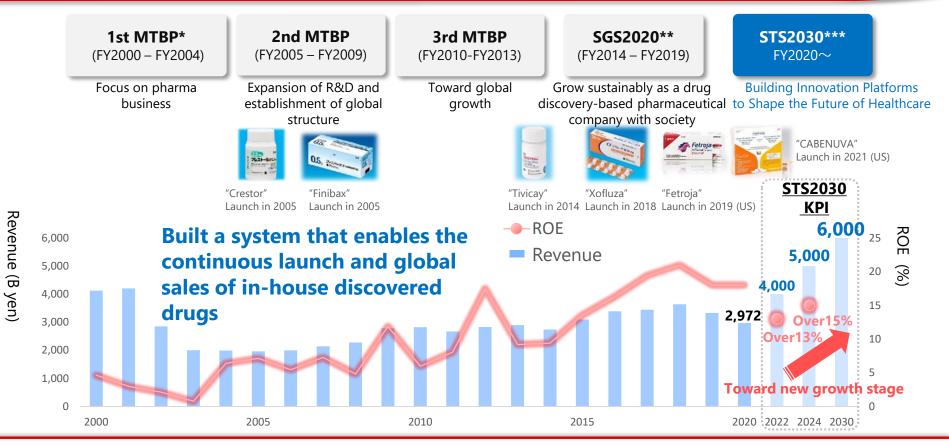
## 3. Sustainable Growth as as a Leading Company in Infectious Diseases

-Aiming to Protect People Worldwide from the Threat of Infectious Diseases-



## Shionogi's Growth History





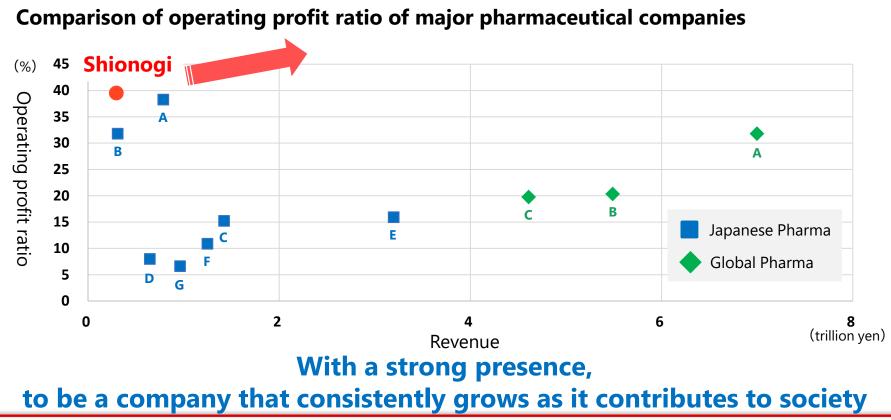
\* MediumTerm Business Plan \*\* Shionogi Growth Strategy 2020 \*\*\* Shionogi Transformation Strategy 2030



Until 2018 : Japanese Generally Accepted Accounting Principles (JGAAP) After 2019 : International Financial Reporting Standards (IFRS)

22

## **High Operating Profit Margin**





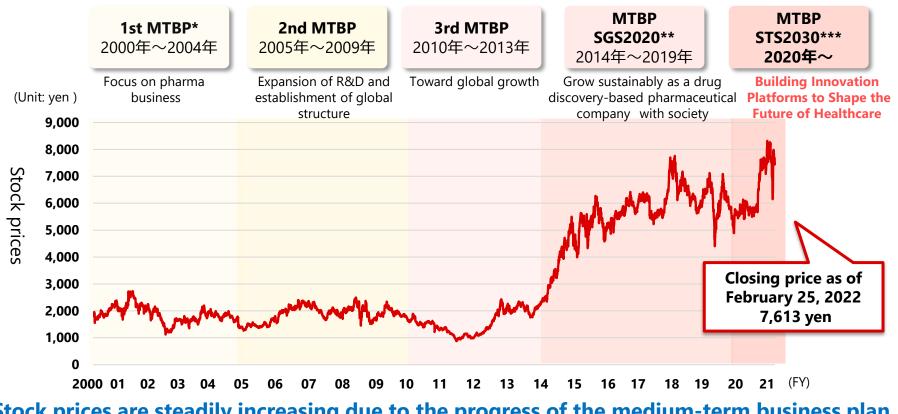
From FY2020 annual report of each company Converted at 1 dollar = 108 yen, 1 Swiss franc = 115 yen 23

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## **Stock Price Changes**





#### Stock prices are steadily increasing due to the progress of the medium-term business plan



\* Medium-Term Business Plan

\*\* Shionogi Growth Strategy 2020 \*\*\* Shionogi Transformation Strategy 2030



## 2030 Vision, Shionogi Transformation Strategy 2030 (STS2030)

### Vision 2030

### Strategy to achieve 2030 Vision

## Building Innovation Platforms to Shape the Future of Healthcare

# **STS2030**

- Shionogi Transformation Strategy 2030 -

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STS2030 STS Phase 1 ('20-'24) STS Phase 2 ('25-)



## **Medium-Term Business Plan STS2030**

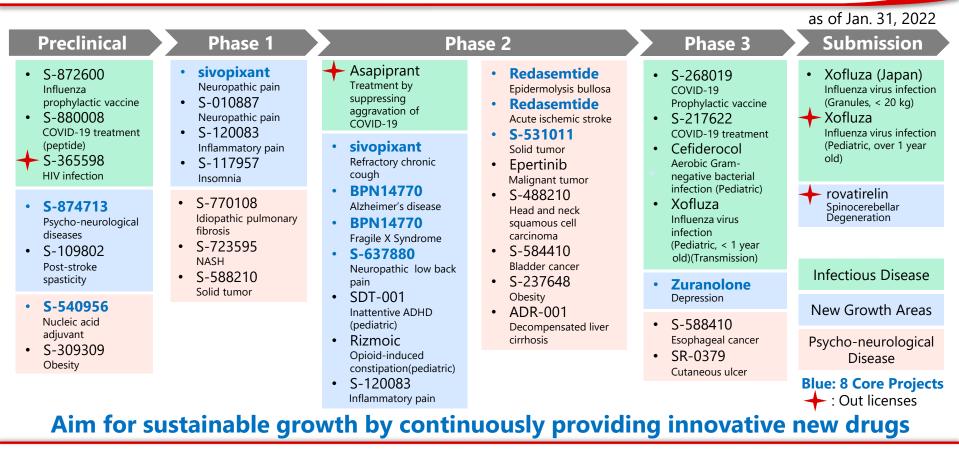






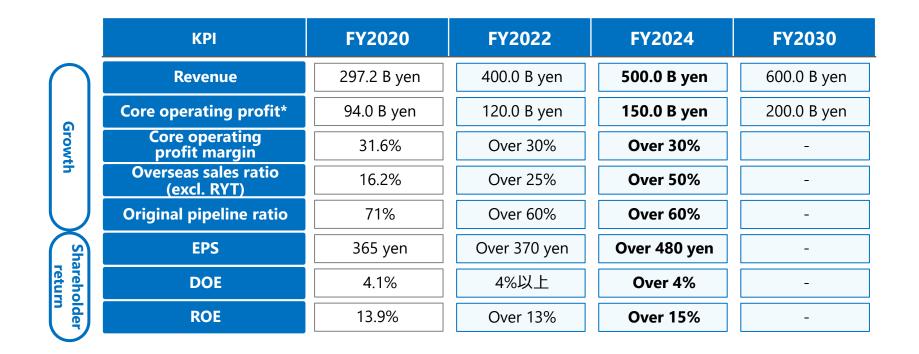
## **Pipeline Forming the Basis of Growth**













\* Core operating profit: Operating income adjusted for one-time factors (asset impairment, gains on sale of tangible assets, etc.)

## Social Issues to be Tackled by Shionogi



### **Contribution to SDGs**



- SDGs that Shionogi can help to achieve
  - Goal 3: Good health and well-being
  - Goal 8: Decent work and economic growth
  - Goal 9: Industry, innovation, infrastructure
  - Goal 12: Responsible consumption, production
  - Goal 17: Partnerships for the goals



### **Priority tasks**

- Protect people worldwide from the threat of infectious diseases
  - Develop infectious-disease-related products and communicate accurately about them
  - Three major infectious diseases (HIV, TB, malaria)
  - AMR/viral infectious diseases (influenza, corona, etc.)

## • Improve social productivity and extend healthy lifespans

- Contribute to increasing productivity (address chronic pain, depression, etc.)
- Meet the needs of the super-aging society (address dementia, cancer, etc.)

#### Contribute to sustainable social security

- Provide medical care optimized for the individual
- Deliver healthcare solutions at prices that are commensurate with their value



## As a Leading Company in Infectious Diseases



### Shionogi's strengths

- Know-how of infectious diseases
- R&D
  - Small-molecule drug discovery
- Diverse partnering
- Human resources



## Key material issue

Protect people worldwide from the threat of infectious diseases

### Infectious disease initiatives

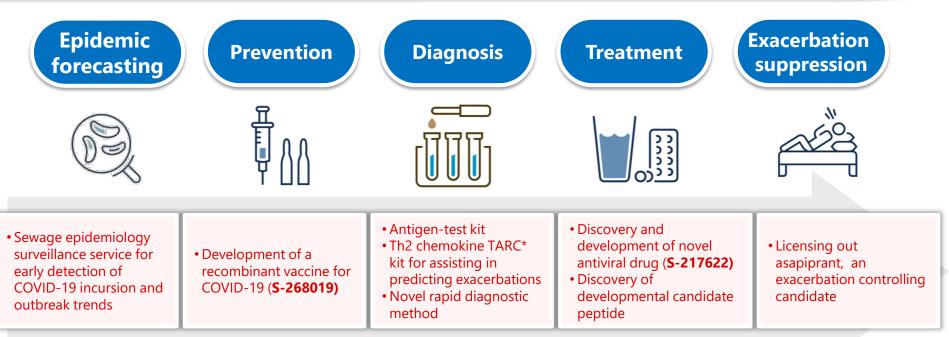
- 1. Viral infectious disease initiatives
  - Initiatives for early containment of COVID-19\*
  - Influenza initiatives
- 2. Development of drugs for the three major infectious diseases
  - HIV franchise advancement
- 3. Contribution to tackling serious infectious diseases incl. AMR bacteria
  - Launch of Cefiderocol and promotion of proper use
- 4. Establishment of new business model for infectious diseases
  - Establishment of a sustainable business model

### Achieve medium to long-term growth

while solving social issues mainly in our core area of infectious diseases



### 1. Viral infectious disease initiatives (COVID-19) Actions for Early Containment of COVID-19



## **Providing solutions for the overwhelmed medical system**



\* TARC (thymus and activation-regulated chemokine)
One of the chemokines driving migration of Th2 cells, a type of lymphocyte, to the site of inflammation 31

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### 1. Viral infectious disease initiatives (COVID-19) COVID-19 Therapeutic Drug: S-217622



The environment surrounding the COVID-19 oral therapeutic drug and the significance of a domestic therapeutic drug

- Only two drugs are available in the world
  - Molnupiravir (Merck) = US: EUA\*; Japan: specially approved
  - PAXLOVID (Pfizer) = US: EUA\*; Japan: specially approved
- Planned global supply
  - Merck : 20 million doses by end of 2022
  - Pfizer : 120 million doses by end of 2022

Even mega pharmas that have provided billions of doses of vaccines

in a short span of time can only provide a limited amount of oral therapeutic drug

- Significance of a domestic therapeutic drug
  - Shionogi plans to produce 1 million doses of S-217622 in FY2021 and 10 million doses in FY2022
  - Ensure stable production and supply prioritizing Japan



### 1. Viral infectious disease initiatives (COVID-19) COVID-19 Therapeutic Drug: S-217622



#### Profile

- 3CL protease inhibitor
- Once-daily oral administration for five days
- Confirmed antiviral activity against the omicron variant strain as strong as against existing variant strains (nonclinical trial)
- Assumed patients
  - Irrespective of high risk factors or vaccination
  - Patients with mild or moderate symptoms and asymptomatic patients

#### **Development status**

- Applied for approval of production and sales (February 25, 2022)
  - Top-line results of the Phase 2b Part
    - A significant antiviral benefit against placebo
    - A significant improvement compared to placebo in respiratory symptoms characteristic of the omicron variant
    - No adverse event of concern has been recognized

### Supply

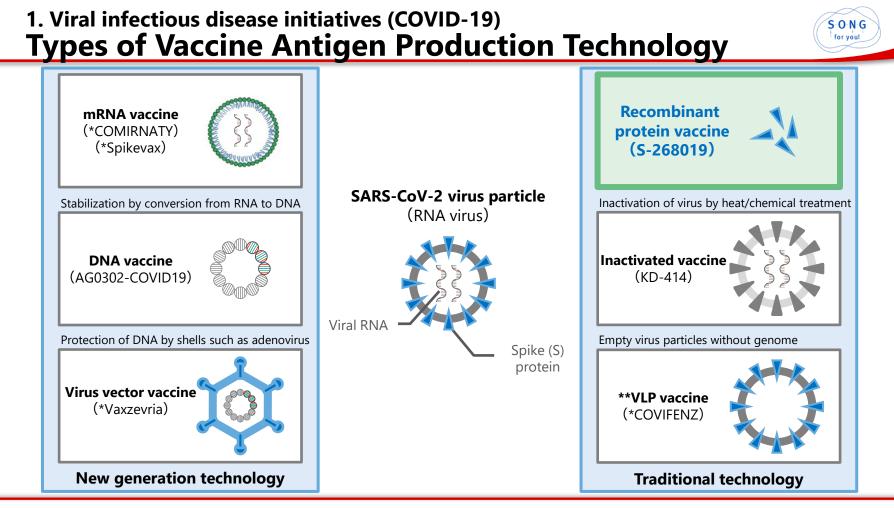
- Production plan
  - 1 million doses in Japan by end of March 2022
  - More than 10 million doses per year in FY2022



#### **Future time schedule**

- Japan
  - Mild/moderate: ongoing Phase 3 part
  - Asymptomatic/only mild symptoms: ongoing Phase 2b/3 part
- Global
  - Global Phase 3 trial scheduled to be initiated







34

### 1. Viral infectious disease initiatives (COVID-19) COVID-19 Vaccine: S-268019

#### Profile

- Recombinant protein vaccine
- Aim to be approved both priming and booster indication

### Supply

 The development of a supply system for more than 30 million doses is planned in cooperation with UNIGEN (antigen production) and API (formulated product manufacturing)

#### **Future time schedule**

- Intend to initiate prior consultations on the results of ongoing clinical trials
- Consult with the authorities for domestic application

#### **Ongoing Clinical trials**

- Pivotal 5 clinical trials are ongoing (on the following page)
  - Phase2/3 trial
  - Active control, neutralizing antibody titer trial
  - Placebo control, onset prevention trial
  - Phase 2/3 booster trial
  - Phase 3 booster trial

Significance of being the only domestic vaccine undergoing a comparative study in Asia to prevent the onset of symptoms

- Realization of a domestic vaccine that can be provided globally
  - Japan's contribution to global health and future growth of the industry
- Realization of "100 DAYS MISSION"
  - Prepare for any pandemic, beyond COVID-19



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### 1. Viral infectious disease initiatives (COVID-19) COVID-19 Vaccine: S-268019



### **Ongoing Clinical Trials**

- Phase 2/3 trial\*<sup>1</sup>: 3,100 subjects
  - Completed observation through Day 57 with no major safety concerns
  - There are no major safety concerns
  - Topline results will be presented at Annual Meeting of Japanese Association for Infectious Diseases in April 2022

#### Active control, neutralizing antibody titer trial\*<sup>2</sup>

- : 1,000 subjects
  - Superiority trial to compare to VAXZEVRIA intramuscular injection
- Completed the 1<sup>st</sup> inoculation of all subjects
- Placebo control, onset prevention trial\*<sup>3</sup>
  - : 54,915 subjects
    - Initiated in Vietnam from December 2021

- Phase 2/3 booster trial\*<sup>4</sup>: 204 subjects
  - Non-inferiority verification with COMIRNATY intramuscular injection by booster immunization after 2 doses of COMIRNATY
  - Top-line results: scheduled to be disclosed in early March
- Phase 3 booster trial\*<sup>5</sup>: 150 subjects
  - Evaluate the safety of booster immunization after two SPIKEVAX intramuscular injections

\*<sup>1</sup> jRCT2031210383, \*<sup>2</sup> jRCT2051210151, \*<sup>3</sup> NCT05212948, \*<sup>4</sup> jRCT2031210470, \*<sup>5</sup> jRCT2031210613



### 1. Viral infectious disease initiatives (COVID-19) Direction of Future Vaccine Actions



#### **Development of nasal vaccine**

A drug discovery venture company originating at the HanaVax University of Tokyo

Cationized nanogel delivery system

- Simple administration with no pain caused by conventional needles
- Able to effectively induce immunity in respiratory mucosa, which is the area that becomes infected, as well as the entire body





- Vaccines using BEVS\* are widely used, with established efficacy and safety
- Speedy, low cost, and suited to mass production



- Specializes in immunization studies
- Will establish a joint search department for human mucosal vaccines, scheduled to open in April 2022
- Plan to develop a nasal vaccine against COVID-19, influenza and pneumococcal in cooperation with an outside partner
- Aim to initiate clinical trials in FY2022



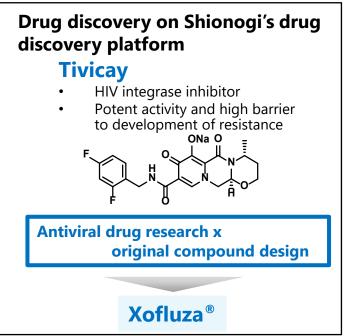
# 1. Viral Infectious disease initiatives (Influenza) Influenza Actions

### **Development of Xofluza®**

# Innovative therapeutic drug for influenza discovered in-house

- High antiviral effect
- Single-dose oral drug for both adults and children
- Early approval, emergency listing
  - $\Rightarrow$  Approved after approx. 4 months of examination





Promptly provide drugs needed by all of society based on know-how of infectious diseases



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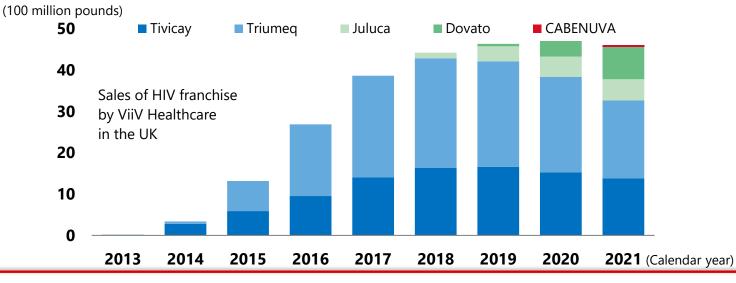
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### 2. Development of drugs for the three major infectious diseases **Progress of HIV Franchise by ViiV Healthcare**



Growth of sales of HIV franchise out-licensed to ViiV\*

- Progress of a two-drug regimen with Tivicay as the key drug
- Increase in RYT and dividends due to advancement of the HIV franchise
  - RYT income from ViiV: 123.4 billion yen; dividends: 23.4 billion yen (FY2020)





### 2. Development of drugs for the three major infectious diseases **Progress of HIV Franchise by ViiV Healthcare**



### **Further progress with long-acting formulations**

- HIV market shifts to long-acting formulations for both treatment and PrEP •
  - The treatment and PrEP market for long-acting formulations will grow to £ 4-5 billion each in 2030\*

**CABENUVA (CAB/RPV\*\*)** The first and only long-acting injectable formulation

#### A Treatment administered once every two months

Reduce the burden of continuing treatment



**Apretude (cabotegravir)** Long-acting formulation for **PrFP** 

- A prevention administered once every two months
  - Freedom from daily oral administration
- Paradigm shift in the PrEP ٠ market
  - Higher preventive effect than existing drugs

S-365598 Third-generation HIV integrase inhibitors

- Administration once every three months or more
  - Further improvement of convenience
- Intend to initiate Phase 1 trial by 2023

### Achieve further growth of the HIV franchise with long-acting formulations





#### 3. Contribution to tackling serious infectious diseases incl. AMR bacteria Launch of Cefiderocol and Promotion of Proper Use

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### **Antimicrobial Resistance (AMR)**

AMR is difficult to detect and spreads relatively slowly, a serious problem, being referred to as "a slow tsunami that threatens to undo a century of medical progress"

- Deaths due to AMR (annual)
- Deaths attributable to AMR per year by 2050
- Estimated economic impact

 $\Rightarrow$  0.7 million people

- ⇒ Over 10 million people\*
- $\Rightarrow$  \$100 trillion

## AMR measures are "issue to be tackled on a global scale"



#### In parallel with the launch of a multidrug-resistant gram-negative bacterial infection therapeutic drug Fetroja\*\*,continue to promote the proper use to prevent the outbreak of new resistant bacteria and viruses

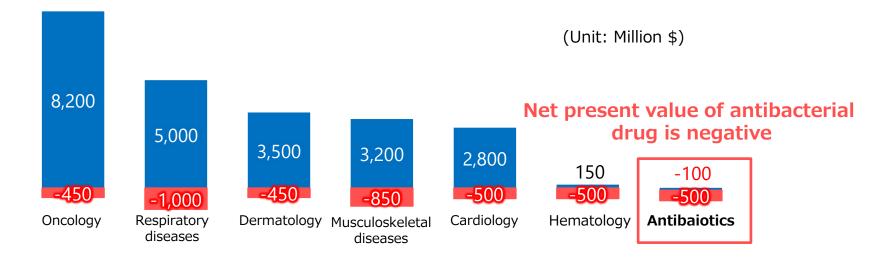


\* Estimate when AMR measures are not taken: The Review on Antimicrobial Resistance, 2016 (O'Neill report) \*\* effective against all three types of carbapenem-resistant pathogens (Acinetobacter baumannii, and Enterobacteriaceae) **41** that the World Health Organization considers as requiring priority action

#### 4. Establishment of new business model for infectious diseases Difficulty of Infectious Disease Business



### **Profitability by medical property**



Many companies have withdrawn from antimicrobial R&D due to low profit predictability Venture companies developing infectious disease drugs also have gone bankrupt



### 4. Establishment of new business model for infectious diseases Establishment of a Sustainable Business Model



### To build a sustainable business model

No growing industries/markets

No attractive market

Negative spiral in the infectious disease business

No fire

in trouble if a fire breaks out

**Example: fire extinguisher model** 

Decrease in R&D investment

As a precaution, purchase a fire extinguisher

Build a model that will be supported by society in normal times\* and will make the maximum contribution in an emergency

⇒ Need for society as a whole to continue working on infectious disease control

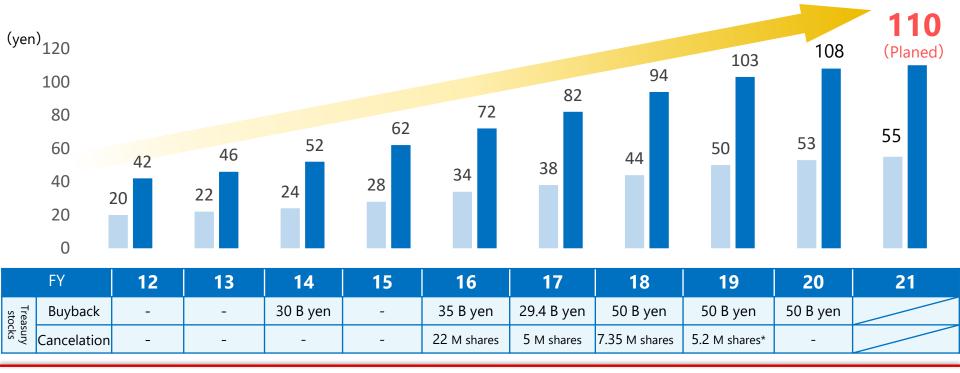


## 4. Shareholder Return



## **Shareholder Return Strategy**

- Shareholder return policy through which shareholders can feel our growth
  - Plan to increase dividend again for the tenth consecutive year in FY2021





Values calculated based on JGAAP until 2018 and IFRS after 2019

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45

\* Resolution passed on March 30, 2020, and treasure shares cancelled on April 6, 2020

## **Thank You for Your Attention**



## あしたの感染症と、 たたかっている。

感染症がこの世からなくなることはない。 パンデミックも、きっとまた起こる。 だからこそ、シオノギは逃げずに向き合い続けます。 その時私たちの創るワクチンが、治療薬が、 強く、強く、ひとつでも多くのいのちを守れるように。

薬ができることの、その先へ。

#### **SHIONOGI**



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Shionogi's official social media account

**Instagram** SHIONOGI/シオノギ @shionogi\_official



**YouTube** Shionogi/シオノギ

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**YouTube** シオノギカナデ /Shionogi Kanade

