

# **Medium-Term Business Plan**

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

### **Revision**

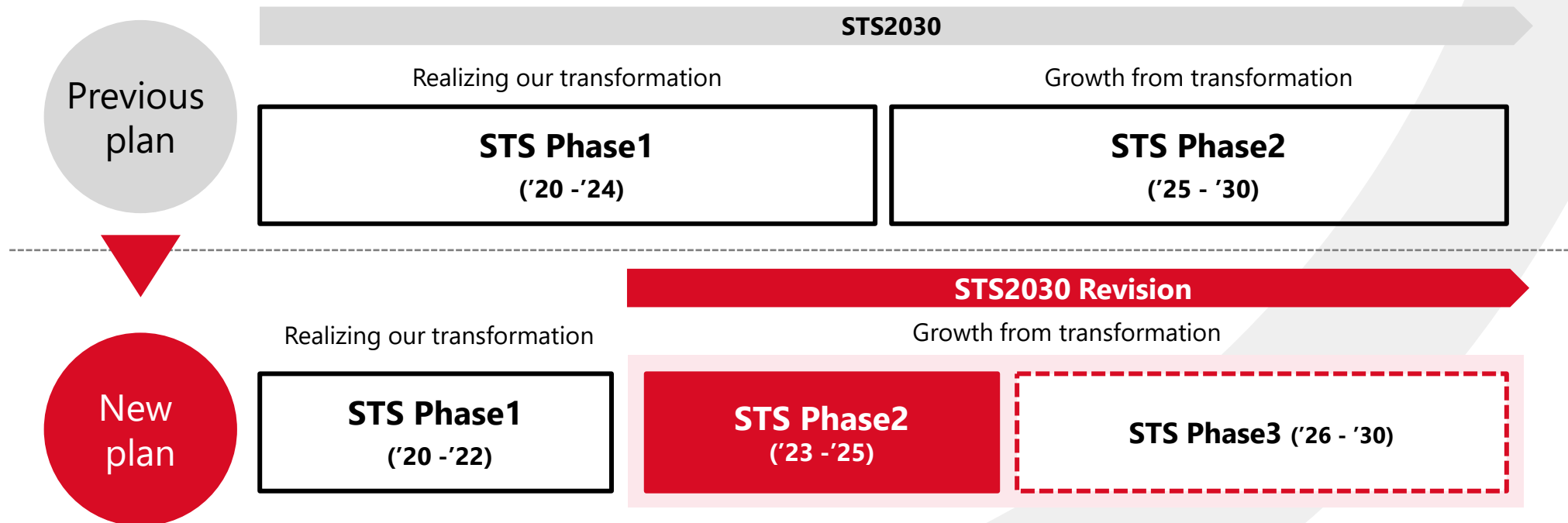
June 1, 2023  
Shionogi & Co., Ltd.



**SHIONOGI**

# Agenda

1. Reflections on STS Phase 1
2. Road to Realizing STS2030
3. STS Phase 2



# **1. Reflections on STS Phase 1**

## Building Innovation Platforms to Shape the Future of Healthcare

### SHIONOGI Group Vision (2030 Vision)

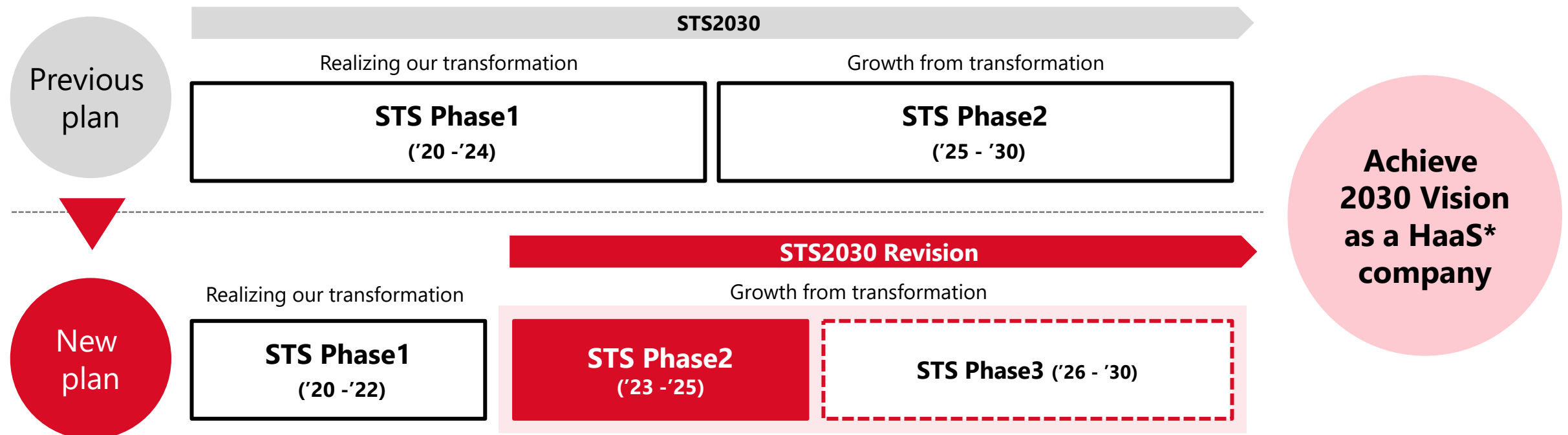
- What we want to achieve by 2030 -

Appearance after Vision is realized

- **Continuously creating innovative products/services, with a well-established and rapidly-growing global business**
  - Expansion of business model
  - Maintenance of high profit margins and growth after overcoming the patent cliff
- **Continuing to offer solutions to health issues facing society**
  - Freedom from the threat of infectious diseases, better QOL, extension of healthy lifespans, contribution to sustainable social security, and contribution to achieving SDGs
- **Excellent business persons who never take a break from building their expertise and capabilities, leveraging their individual strengths and creating new value**

# Purpose of the STS Revision

- **Significant progress toward achieving the 2030 Vision was made over the first three years of STS Phase 1**  
⇒ **The road to achieving the 2030 Vision has become clearer**
- **Initiating a new growth phase in STS Phase 2, raising financial targets**



# Reflections on STS Phase 1: Main Achievements

## Expansion of products discovered internally

- **Obtained domestic approval of ensitrelvir for COVID-19 treatment**
- **Strengthened overseas business**
  - Growth of cefiderocol; GARDP\*/CHAI\*<sup>2</sup> framework with MPP\*<sup>3</sup>
- **Achieved growth of the HIV franchise**

## Launch of products and services other than prescription drugs

- **Filed application for domestic approval of COVID-19 vaccine**
- **Provided new products and services in the infectious disease and CNS areas**
  - Wastewater surveillance service (AdvanSentinel), educational support (Yui Connection), brain activation by sound stimulus (kikippa), insomnia treatment app (SUSMED Med CBT-i®)

## Governance enhancement

- **Implemented new internal decision-making process**
- **Continued manager education**

## Achievement of major KPIs

(STS2030 target value in parenthesis)

KPI		FY2020	FY2021	FY2022
Growth	Revenue	297.2 B yen	335.1 B yen	426.7 B yen (400.0 B yen)
	Core operating profit* <sup>4</sup>	94.0 Byen	110.6 B yen	158.5 B yen (120.0 B yen)
	Core operating Profit margin	31.6%	33.0%	37.1% (over 30%)
	Overseas sales ratio	16.2%	22.3%	16.9% (over 25%)
	Original pipeline ratio	71%	73%	61% (over 60%)
Shareholder return	EPS	365 yen	378 yen	619 yen (over 370 yen)
	DOE	4.1%	3.8%	3.9% (over 4%)
	ROE	13.9%	12.5%	17.8% (over 13%)

\* The Global Antibiotic Research and Development Partnership \*2 Clinton Health Access Initiative \*3 The Medicines Patent Pool

\*4 Operating profit adjusted for one-time factors (impairment losses, gain on sale of property, plant and equipment, etc.)

# Reflections on STS Phase 1: Learnings and Points to Strengthen toward Transformation

## Lessons from the COVID-19 experience

### Renewed recognition of the threat of infectious diseases

- The impact of COVID-19 on the world

### Importance of the discovery of drugs for unmet needs

- Therapeutic and vaccine R&D efforts for COVID-19 were supported by many stakeholders

### Lack of ability to deliver globally

- Lack of global sales and supply capabilities

### Importance of business speed

- The speed of COVID-19 drug discovery will become the standard

**Recognition of the lack of capability to respond quickly to changes in the business environment**

## Points to strengthen toward transformation

### Marketing capabilities –Ability to deliver globally–

- Develop a global marketing system; strengthen supply chains
- Develop sales routes for products and services other than prescription drugs

### Pipeline –Investment in unmet needs–

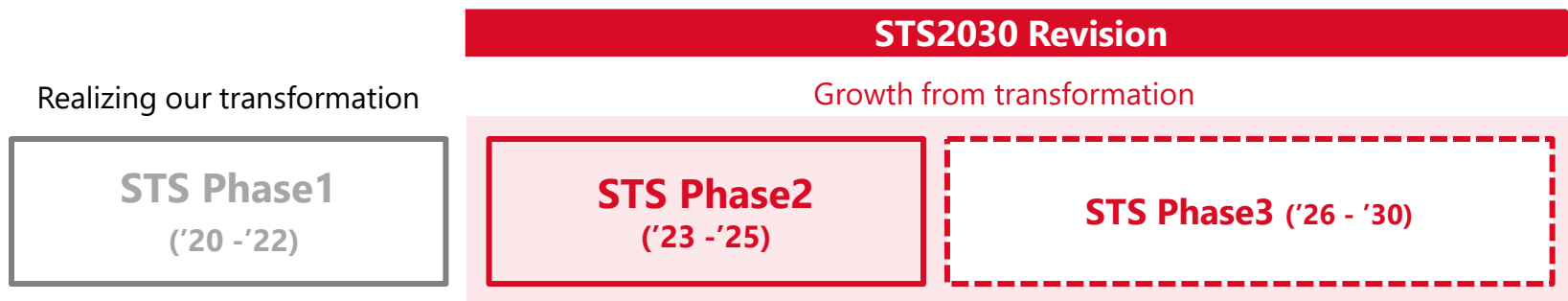
- Invest in R&D, shifting resources flexibly to highest priorities/best opportunities
- Invest aggressively to acquire growth drivers

### Strengthen company platform –Improve business speed; strengthen human resources–

- Making and implementing decisions: Improve speed in all aspects
- Revise/reinforce the necessary capabilities
  - Develop current human resources; hire outside personnel

## 2. Road to Realizing the 2030 Vision

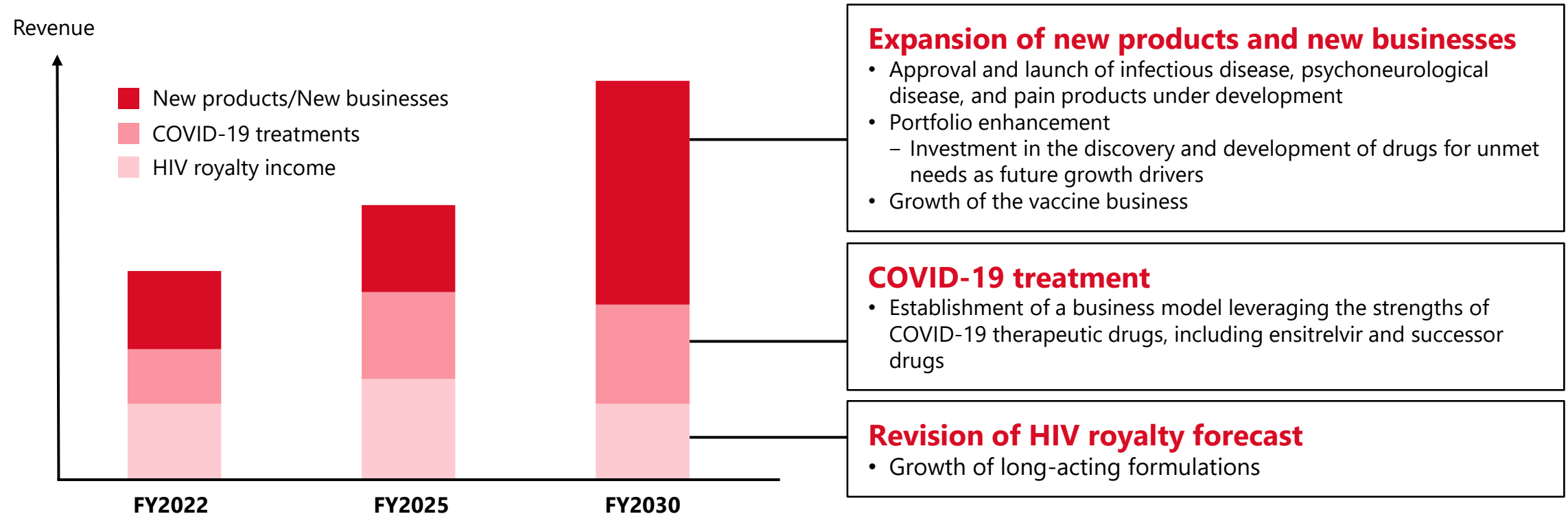
### - Three Pillars of STS2030 Revision -





# STS2030 Revision: New Growth to Realize the 2030 Vision

- **Continued growth of HIV franchise**
- **Growth centered around ensitrelvir (STS Phase 2: 2023-25)**
- **Growth toward realizing the 2030 Vision through aggressive investment (R&D, business investments) (-2030)**



# Current State and Future Outlook of the HIV Business

**Continued growth will be achieved through the continuous introduction of products that meet patients' needs**

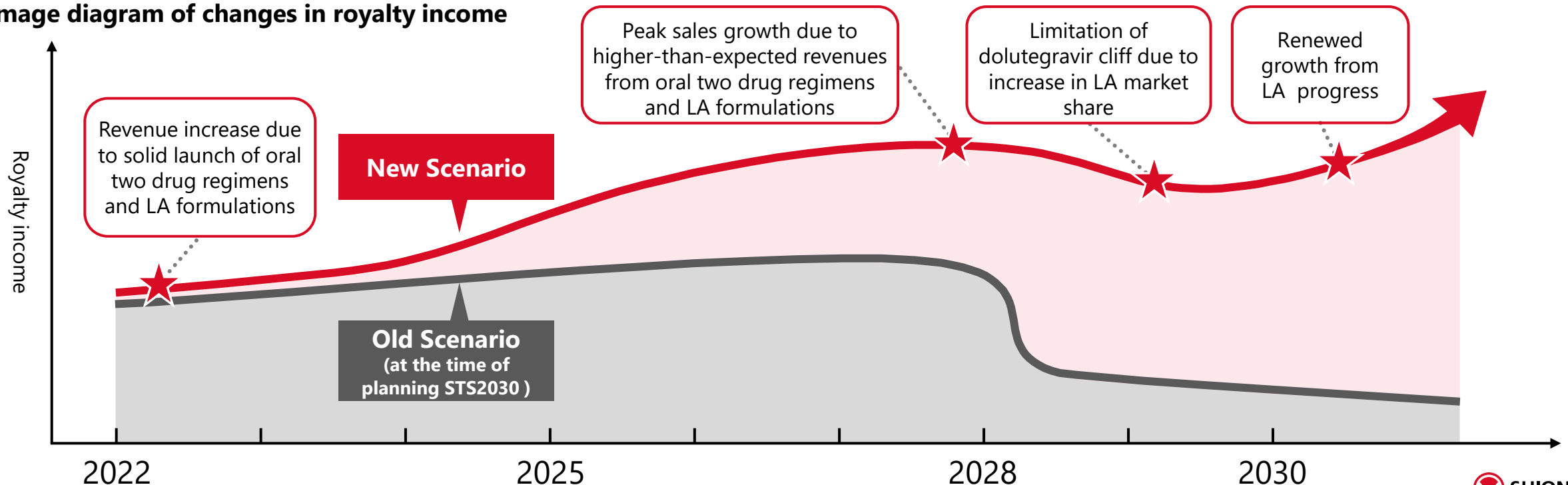
## Growth of Current Products

- Strong growth of oral two drug regimens (Dovato, etc.) and smooth launch of long acting (LA) formulations (Cabenuva, Apretude)

## Growth for Future HIV Products

- Growth of LA formulations and creation of new products to meet future unmet needs in the HIV area
- In-house drug discovery research for combination drugs for ultra-long-acting formulations

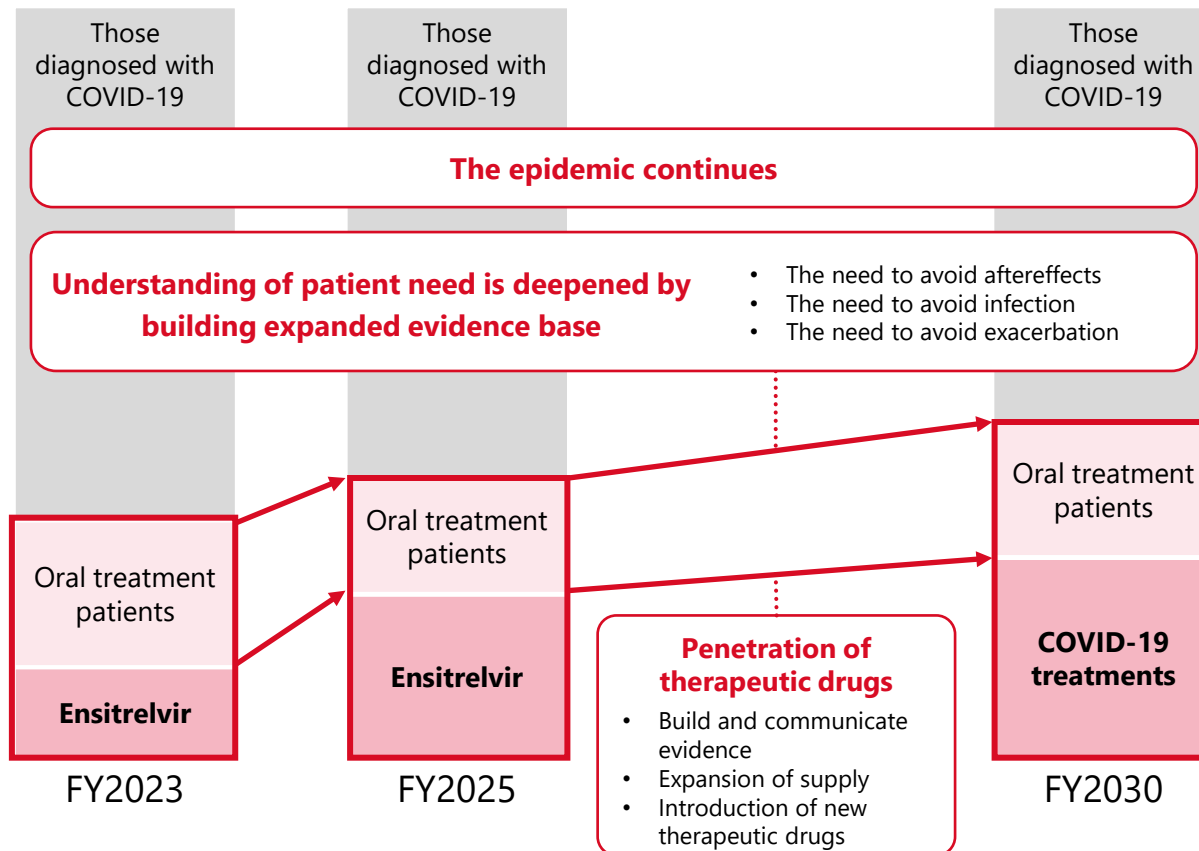
**Image diagram of changes in royalty income**



# Actions and Outlook for COVID-19 treatments

## Prediction and direction for COVID-19

- Our prediction: The epidemic continues as the virus evades immunity while continuing to mutate
- Our direction: Establish a position as the global standard COVID-19 drug based on clinical evidence



## Actions for continuous growth of COVID-19 treatments

- **Offer new evidence of ensitrelvir's value**
  - High-risk outpatients, in-patients
  - Evidence of disease prevention, reduce risk of long COVID, etc.
- **Provide ensitrelvir globally**
  - Asia: File application for approval in East Asian countries and expand to ASEAN\* countries
  - U.S., Europe: Approval and launch from FY2024
  - Other areas: Swift supply planned through partnering
- **Discover even more convenient new therapeutic drugs such as S-892216**

# Expansion Centered Around New Products and New Business

Achieve growth by expanding existing asset and development portfolios and new business (vaccine business)

## Growth of new products (prescription drugs)

### Pipeline

#### To be launched by FY2025

- Resiniferatoxin (Pain associated with osteoarthritis)
- Zanolmilast (Fragile X syndrome\*)
- Daridorexant (Insomnia)
- Zuranolone (Depression)
- SUSMED Med CBT-i®\* (Insomnia treatment app)

#### To be launched in or after FY2026

- Olorofim (Invasive aspergillosis)
- S-337395 (RSV infections)
- S-309309 (Obesity)
- S-151128 (Pain)
- Redasemtide (Ischemic stroke)
- S-531011 (Solid tumor)

### Growth of existing assets

- Xofluza
- Cefiderocol
- Naldemedine and more

in-licensing

## Growth of the vaccine business



Expand globally from Asia and grow into a  
¥100 billion business

## Business development based on our strengths

OTC

CDMO\*\*

Platform  
service  
business

# Revise Major KPIs (key evaluation indicators)

- Revised revenue forecast for FY2030 (600.0 B yen  $\Rightarrow$  800.0 B yen) due to business growth through expansion of global sales of ensitrelvir and HIV pipeline/aggressive investment
- To promote aggressive strategic investment, adjusted one of the profit indicators from core operating profit to EBITDA\*
- Incorporate non-financial indicators centered on the environment, human rights, and human capital\*<sup>2</sup>

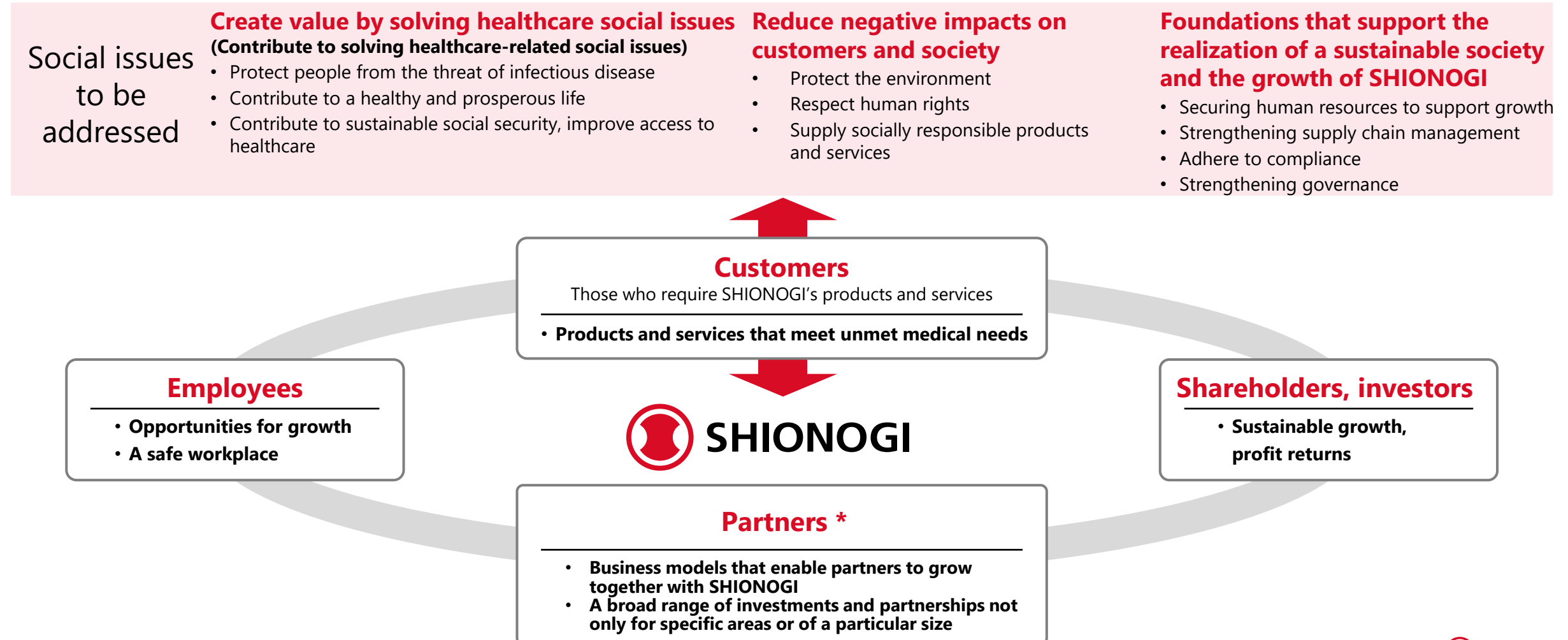
	STS Phase1	STS Phase2		STS Phase3
	FY2022	FY2023	FY2025	FY2030
Revenue	<b>426.7 B yen</b>	<b>450.0 B yen</b>	<b>550.0 B yen</b>	<b>800.0 B yen</b>
Overseas sales CAGR* <sup>3</sup>	—	—	<b>50%</b> Starting from FY2022	<b>15%</b> Starting from FY2025
EBITDA	<b>177.9 B yen</b>	<b>167.0 B yen</b>	<b>200.0 B yen</b>	—

### 3. STS Phase2



# Value Provided to Stakeholders

**As a HaaS company, collaborate with stakeholders to contribute to solving healthcare-related social issues**



# Overview of STS Phase2

Basic policy of the  
STS Phase2

**Achieve global top-line growth and establishment of growth drivers  
through aggressive investment, especially in the infectious disease area**

Materiality

**Create value by  
solving healthcare  
social issues**

①

**Protect people from the  
threat of infectious  
diseases**

②

**Contribute to a healthy  
and prosperous life**

③

**Improve access to  
healthcare**

**Strengthen the  
management base  
and  
contribute to a  
sustainable society**

④

**Key Strategic Priorities**  
Global strategy, investment and  
financial strategies

⑤

**Transformation  
actions**

⑥

**Strengthening  
management and  
ESG Focus**



# Healthcare-related Social Issues Addressed by SHIONOGI

**Work to address unmet needs to protect people from the threat of infectious diseases and “to contribute to a healthy and prosperous life**

<b>SHIONOGI's idea of unmet needs</b>	<ul style="list-style-type: none"><li>• Healthcare issues and diseases that are expected to remain unsolved and increase over the next 10–20 years</li><li>• Issues and diseases for which the best solutions can be realized by combining SHIONOGI's strengths and external networks</li></ul>
<b>Select focus needs</b>	<ul style="list-style-type: none"><li>• The needs to be addressed are decided by management and addressed by R&amp;D's high execution capability</li><li>• Break away from full in-house development to search for seeds and technologies and build networks worldwide</li></ul>
<b>Concentrate resources</b>	<ul style="list-style-type: none"><li>• Implement bold resource allocations learned from COVID-19</li></ul>

## Protect people from the threat of infectious diseases

**Diseases to be addressed: High-impact infectious diseases that threaten society**

Acute infectious diseases, incl. pandemic response

Exacerbation suppression and aftereffect suppression

Three major infectious diseases, incl. HIV

Antimicrobial resistance (AMR) infections

## Contribute to a healthy and prosperous life

**Diseases to be addressed: QOL diseases with high social impact**

(Realize children's growth and a vibrant and prosperous life)

Diseases  
being  
considered

Dementia

Obesity

Pediatric diseases

Sleeping  
disorder

Hearing  
impairment

Pediatric  
Indications/Formulations

Create value by solving social issues: ①Protect people from the threat of infectious diseases

# Strategies for the Infectious Disease Business

**Establish a business model for each area to achieve continuous growth**

**Contribute to global health and stable supply**

Build a sustainable business model

## Acute infectious diseases (COVID-19, influenza, etc.)

### Therapeutic drugs: Ensitrelvir, Xofluza

- Achieve growth of ensitrelvir in the global market

### Total care actions

- Achieve growth in the diagnosis, vaccine, and wastewater monitoring businesses

## Antimicrobial resistance (AMR)

### Work with society to create sustainable markets

- Roll out cefiderocol globally
- Introduce push and pull incentives
- Introduce rapid diagnosis that identifies antimicrobial-resistant bacteria and the mechanism of resistance

Build a stable business base by contributing to large numbers of patients

## Infectious diseases requiring a long period of treatment (three major infectious diseases, etc.)

### Cultivate new markets that address unmet needs

- Provide new solutions for HIV infection
- Develop a new drug (olorofim) against highly lethal fungal infections
- R&D of new treatments for infectious diseases with high unmet needs (tuberculosis, malaria, nontuberculous mycobacterial diseases)

## Total care, including vaccines

### Grow vaccines into the next earnings driver as a core business

- Launch COVID-19 and influenza vaccines
- Expand the business to Asia and across the world
- Establishment of new technologies that will be our strength (nasal, universal vaccines)

### Strengthen diagnostic capabilities

- Provide simple diagnostic solutions (home diagnosis kits, etc.)

Create value by solving social issues: ①Protect people from the threat of infectious diseases

# Global Rollout of Acute Infectious Disease Platforms

**Offer total care globally that goes beyond medicines building a sustainable business model**

**Build a business portfolio that is not affected by epidemics**

**Establish a total care platform for acute infectious diseases**

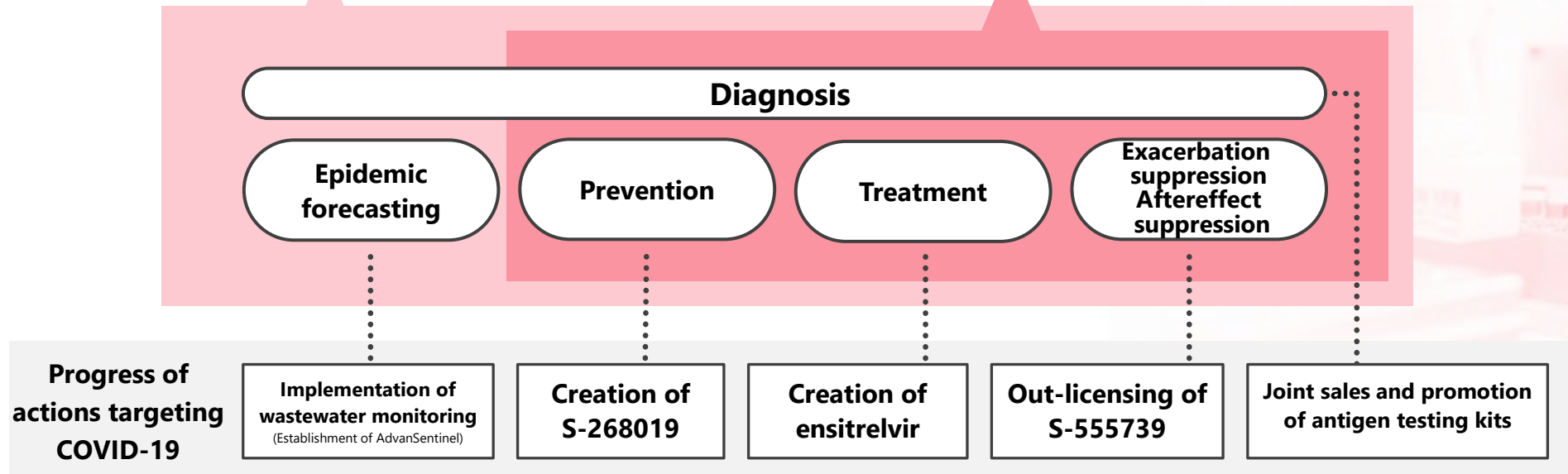
**Build a sustainable business model**

**Establish a purchase model in collaboration with government, etc.**

**Build a disease portfolio**

**Make wide-ranging efforts to tackle key upper respiratory tract infections**

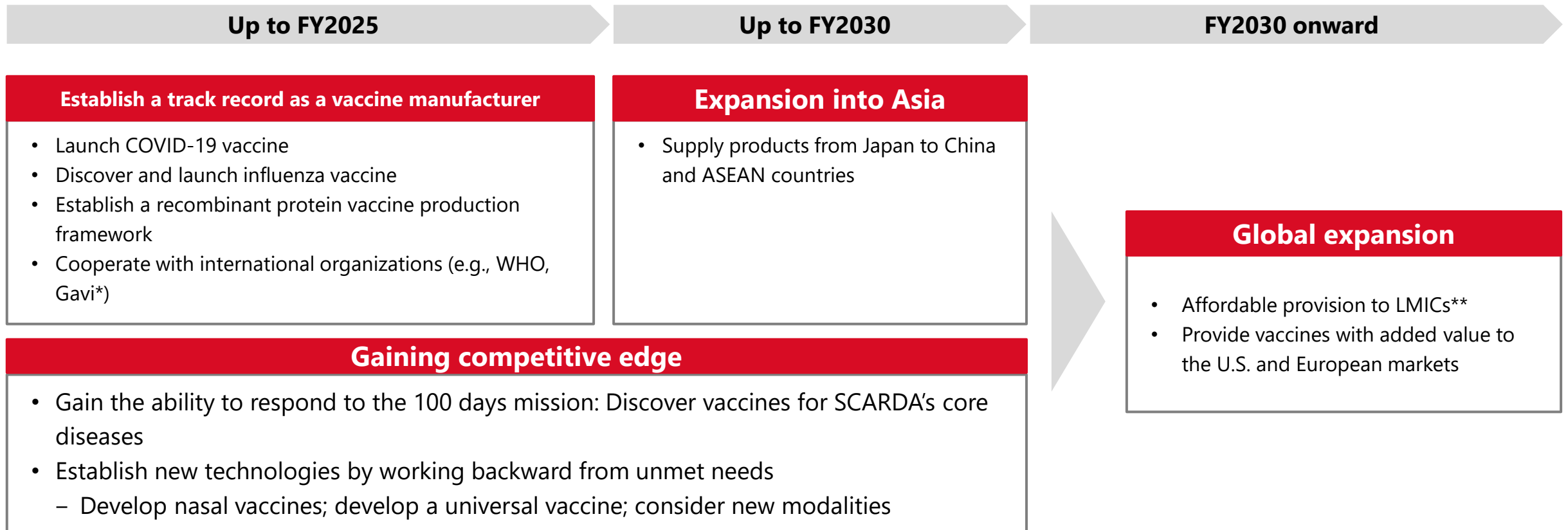
- COVID-19
- Influenza
- RSV and more



Create value by solving social issues: ①Protect people from the threat of infectious diseases

# Actions and Outlook for the Vaccine Business

**Aiming to grow the business into the next earnings driver, offering a steady business model less affected by patent cliffs**



Create value by solving social issues: ②Contribute to a healthy and prosperous life

# Main Pipeline Products for Diseases with High Social/QOL Impact: To be launched in STS Phase2

**Realize profit growth by delivering development pipeline products to patients/society**

## **Resiniferatoxin (GRT7039)**

- Indication: Pain associated with osteoarthritis
- A new painkiller option for patients with inadequate response to existing treatments

## **Zuranolone (S-812217)**

- Indication: Depression, depressive state
- A new option for antidepressants, which have a low drug treatment response rate

## **Zatolmilast (BPN14770)**

- Indication: Fragile X syndrome\*
- Number of symptomatic patients: Around one in 10,000
- There are no approved medicines.

## **Digital app & healthcare**

- SUSMED Med CBT-i® :Sleeping disorder treatment app
- SDT-001: Inattentive ADHD (pediatric)
- Kikippa: Brain activation by sound stimulus

## **Daridorexant**

- Indication: Insomnia
- A new option for sleep medication, for which various issues have been reported (interrupted sleep, safety, etc.)

## **Symproic/Rizmoic**

- Indication: Opioid-induced constipation
- A new treatment option for non-cancer OIC patients

Create value by solving social issues: ③Improve access to healthcare

## Actions to Improve Access to Healthcare

**Delivering the necessary solutions (drugs and services) at the necessary time through various initiatives to improve access to medical care**

### Actions to protect people from the threat of infectious diseases

#### Improve access to LMICs

- Collaboration with GARDP/CHAI
- Collaboration with Medicines Patent Pool
- Listing on WHO Model List of Essential Medicines\*

#### Promote and raise awareness of the proper use of infectious disease treatments

- In cooperation with and with support from ministries of health and experts in each country
- Holding educational seminars and practical classes for the general public

### Actions to contribute to a healthy and prosperous life

#### Address problems that cannot be solved with medicine

- Supporting children with developmental disorders in communities, schools, and workplaces
- Provision of educational support system (Yui-EN)
- Supporting mother and child public health in Africa
- Elimination of communication barriers due to individual characteristics

**Mother  
toMother**  
SHIONOGI Project

**COF コミュニケーション力アップ**  
気づきをカタチに、マイナスをプラスに

# Building a Foundation for Realizing New Value Creation

Basic policy for building  
the management base

**Create value by transforming our structure, changing the process that moves the structure, and developing human resources that can operate the process**

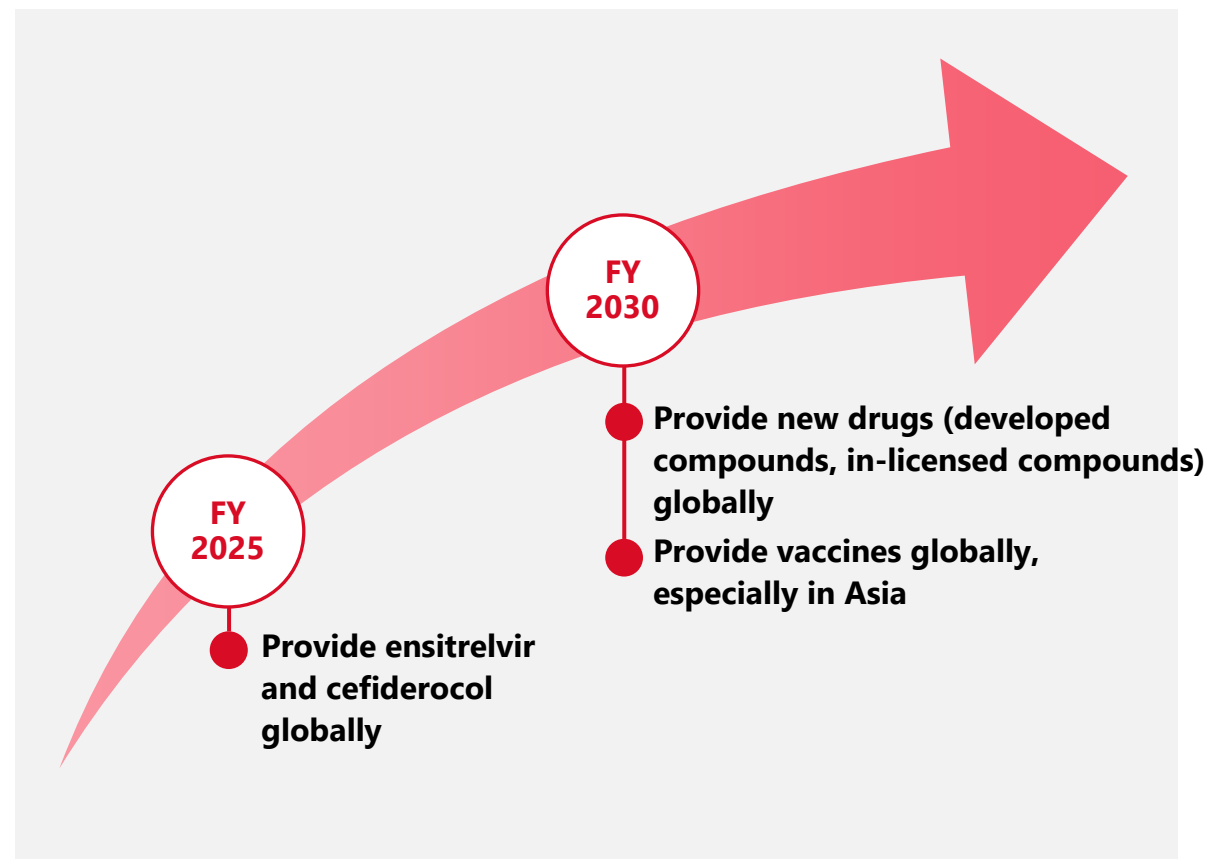
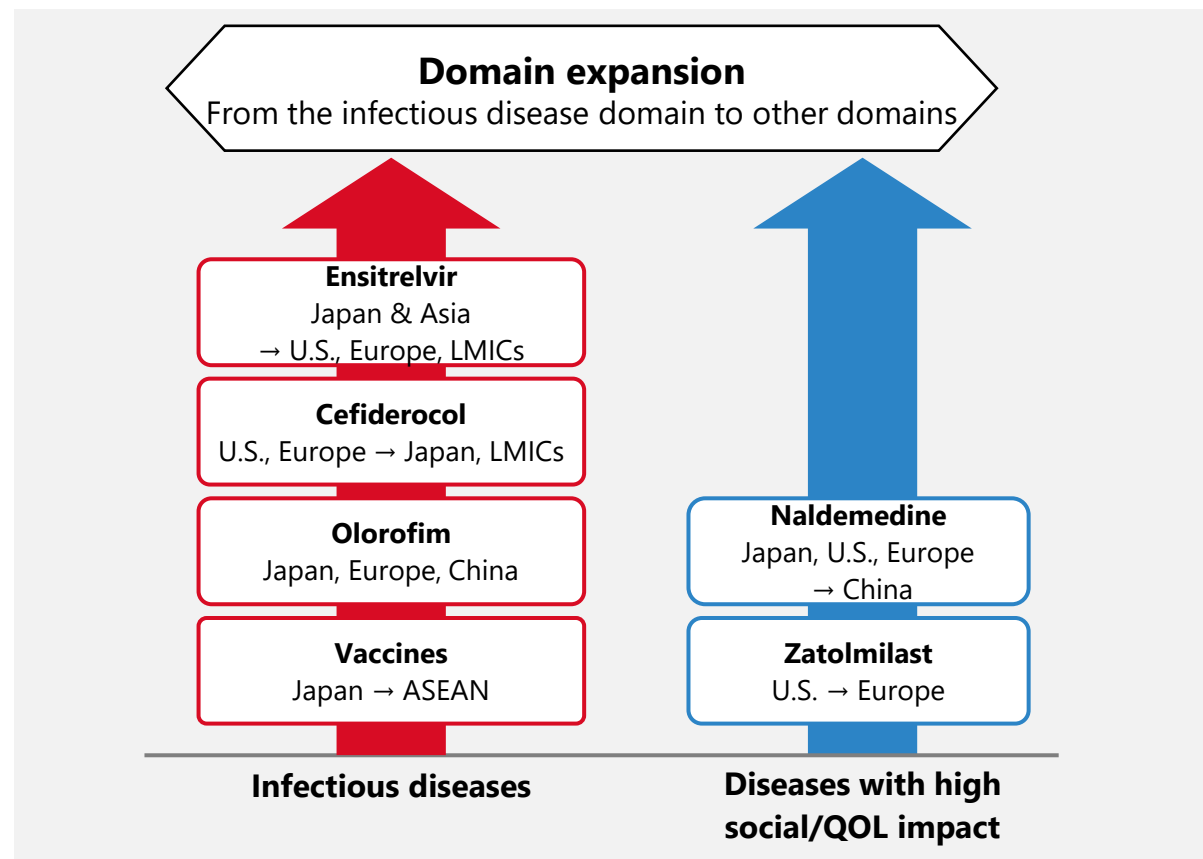


Strengthen the management base and Contribute to a sustainable society: ④Key Strategic Priorities

## Acceleration of Global Expansion

**“Supply the best and necessary medicine globally” based on the SHIONOGI Group Heritage  
(the company policy of SHIONOGI)**

Improve access to medical care, strengthen sales capabilities, and provide solutions (pharmaceuticals, etc.) globally



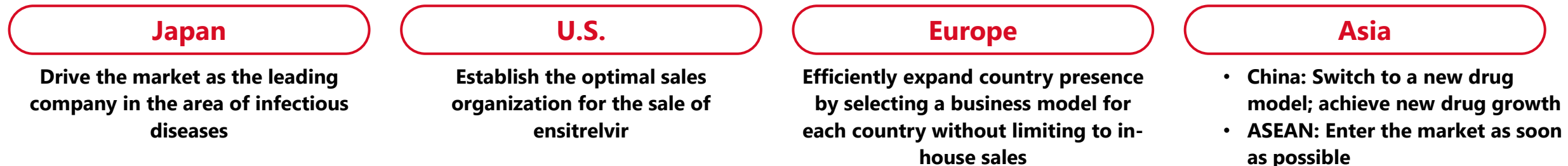


# Strengthening of Global Sales Capabilities

## Strengthening of global functions

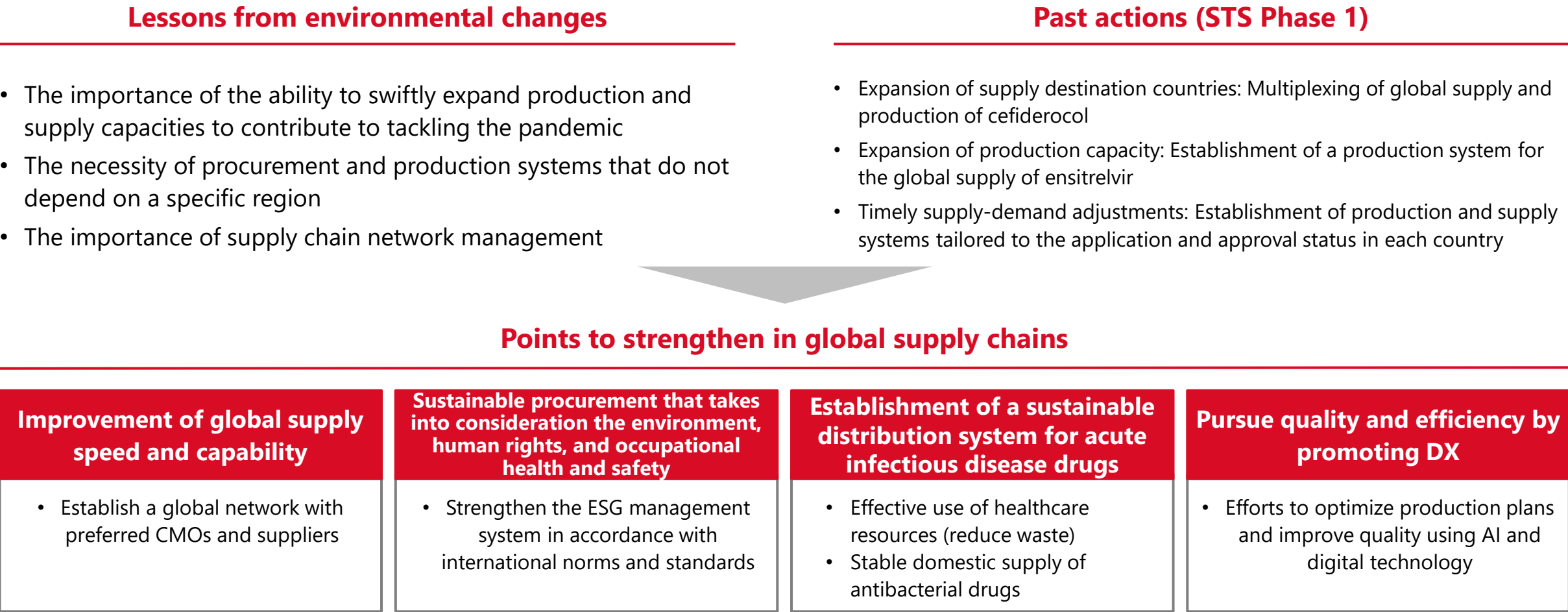


## Regional policies



# Building a Foundation for Realizing

## Improve the resilience of increasingly important supply chain management to strengthen global supply capabilities



# Investment and Financial Strategies



Strengthen the management base and Contribute to a sustainable society: ⑤Transformation actions

## Action to Increase Global Competitiveness

**Achieve operational transformation/value creation globally, leveraging our experience from COVID-19 drug discovery**

### Outcomes of STS Phase 1 improved speed, development of operational infrastructure

- New business processes learned from COVID-19 drug discovery
- Substantial revision the approval system
- Drastic business process improvement: Establishment of joint venture with Accenture for indirect operations
- Establishment of IT infrastructure: Global response to security and personal information protection

### Strengthen global corporate functions

- Redefining corporate functions in alignment with the globalization of business.
- Strengthening global strategy, global governance, and stakeholder engagement

### Realization of Dx transformation

- Business model & operation reforms: Improvement of drug discovery efficiency using AI, market inventory forecast, etc.
- Creating value by promoting data utilization: Creating value by developing SaMD\* and disease detection algorithms

Strengthen the management base and Contribute to a sustainable society: ⑥Strengthening management and ESG

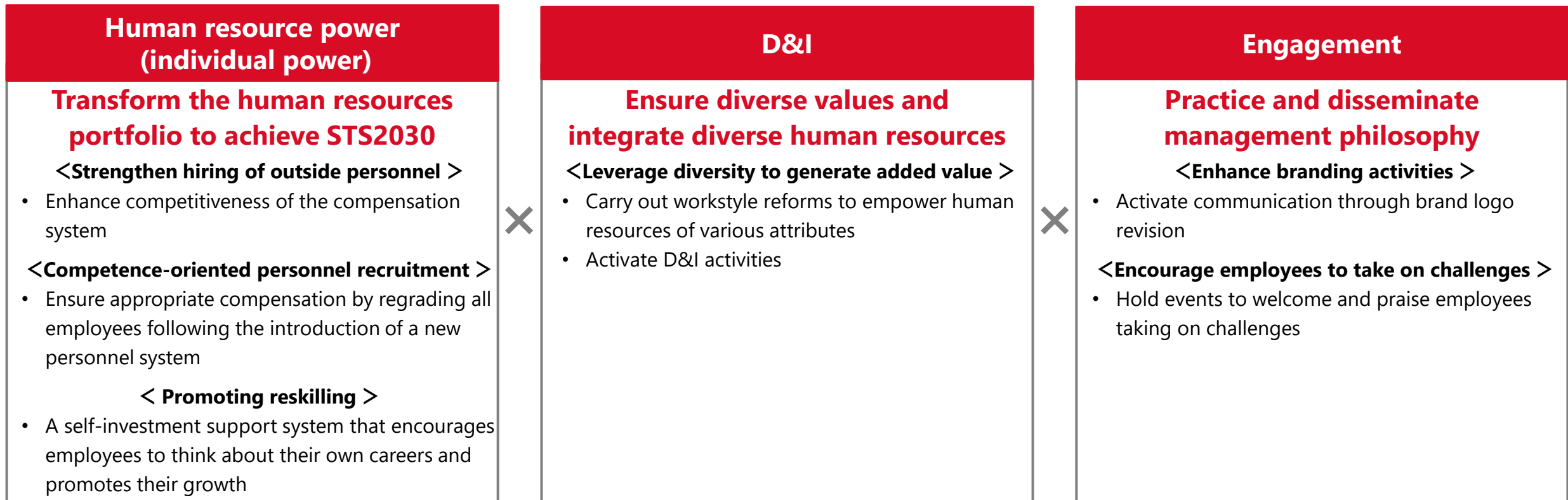
# Strengthen Human Capital to Achieve the 2030 Vision

## Acquire new Capabilities/Promote in-house integration and execute growth scenarios

Build on our existing strengths (business execution capabilities, expertise) to acquire and develop new strengths

Evaluate the progress of initiatives using KPIs and strengthen dialogue with stakeholders (Major KPIs: short-term – succession plan execution status, self-investment support utilization rate, etc., medium- to long-term – progress in talent management, etc.)

### Points to strengthen regarding human capital



Strengthen the management base and Contribute to a sustainable society: ⑥Strengthening management and ESG

## Addressing material issues impacting customers and society

Aiming to achieve both growth as a company and contribution to a sustainable society by strengthening our response to material sustainability issues through dialogue with stakeholders

### Environment

#### Implement the 2030 CO2 reduction plan to become carbon neutral

##### 【Medium-term target】

Scope1・2 : FY2030 : 46.2% reduction (compared to FY2019)  
Scope3 : FY2030 : Category 1 20% reduction (compared to FY2019)

### Society

#### Reinforcement of Consideration for Human Rights in Our Company and Partners

##### 【Medium-term target】

- Continuous implementation of human rights due diligence
- Risk assessment of important partners, on-site audits

### External evaluation results

- Became the first pharmaceutical company to be certified as an "Eco-First Company"



- FTSE : 3.6、MSCI : AA、DJSI : 63
- CDP Climate, Water Security: Double A List



# Summary: Overview of STS Phase 2 ('23 -'25)

## **Build on the results of Phase 1 to achieve global growth**

- Leverage business capability that was improved in all aspects during the COVID-19 pandemic
- Achieve significant global growth over three years, centered around ensitrelvir

## **A paradigm shift of the HIV franchise**

- The market environment changed drastically, including the growth of long-acting formulations
- Progress R&D for even more significant growth in the medium to long term

## **Acquire growth drivers**

- Enhance the pipeline through aggressive investment leveraging a robust financial base
- Concentrate investment in high-need, high value pipeline assets; shift resources flexibly, with approaches cultivated through COVID drug discovery

## **Strengthen the management base**

- Transform human resources and the organization
- Promote ESG management: Achieve growth in harmony with society

SHIONOGI Group Heritage

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

The three years of STS Phase 2 will be a period of global realization of the SHIONOGI Group Heritage (basic policy).

By creating social value, we will continue to grow sustainably together with our stakeholders.



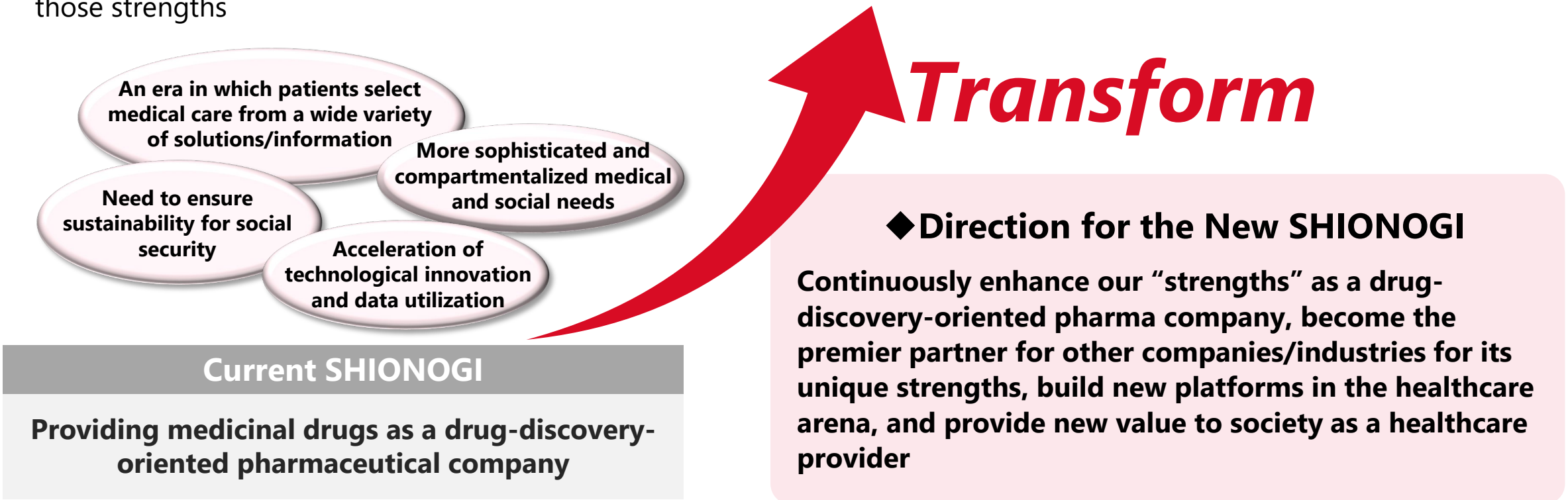
# Appendix

# Direction for the New SHIONOGI

## Delivering value by providing healthcare as a service

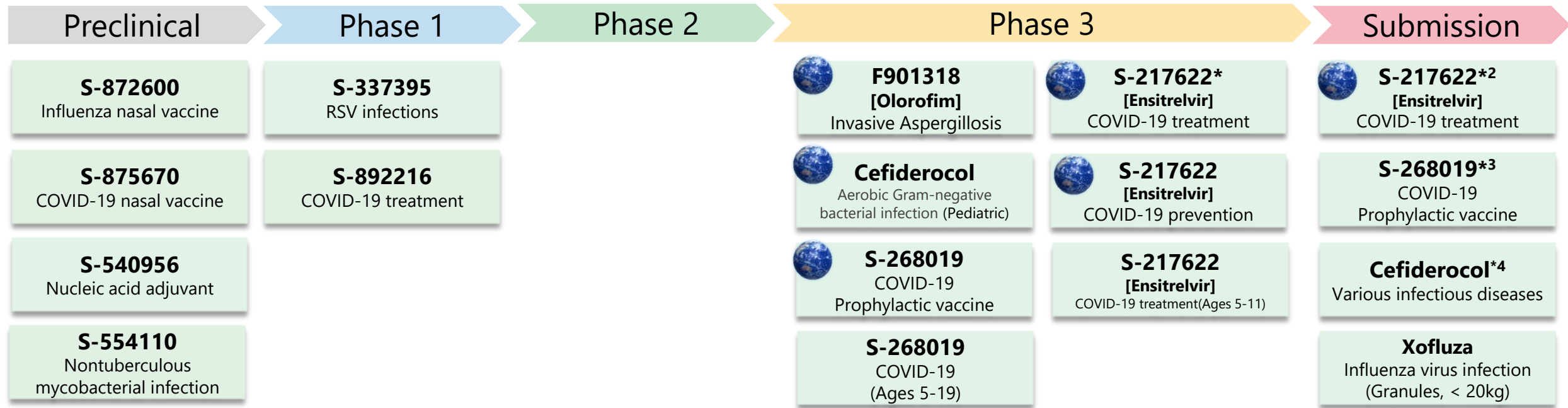
(Healthcare as a Service : HaaS)

- Generate new value and solve problems faced by patients and society through collaborative invention with a diverse range of partners
- Augment the strengths we have acquired through the discovery and development of “medicinal drugs,” and leverage those strengths



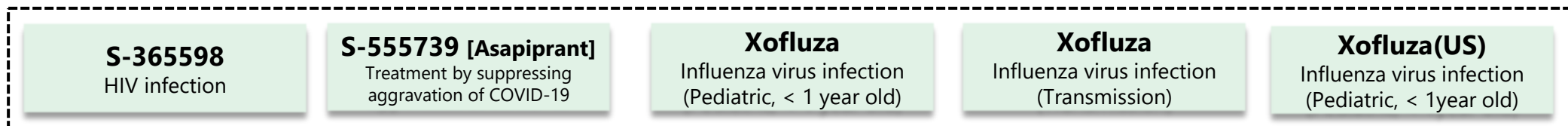
# Pipeline: Infectious Disease

as of June 1, 2023



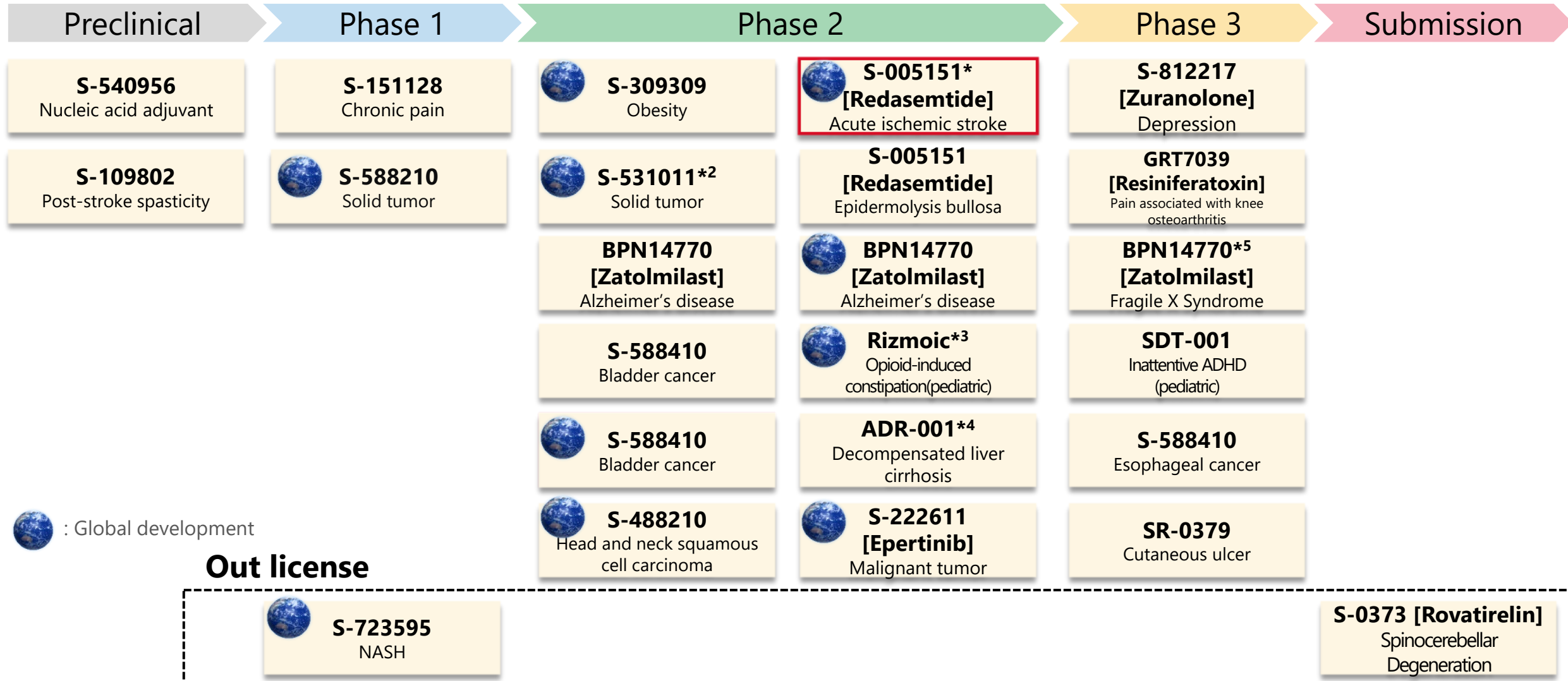
: Global development

## Out license



# Pipeline: QOL Diseases with High Social Impact

as of June 1, 2023



 : Global development