

# 3<sup>rd</sup> Quarter of Fiscal 2024 Financial Results

January 31, 2025

Shionogi & Co., Ltd.



SHIONOGI

# Agenda

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## **Overview of Q3 FY2024 Financial Results (P.3-12)**

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## **Towards the Realization of the 2030 Vision (P.13-26)**

- Transformation of Chinese Business
- Pipeline Progress

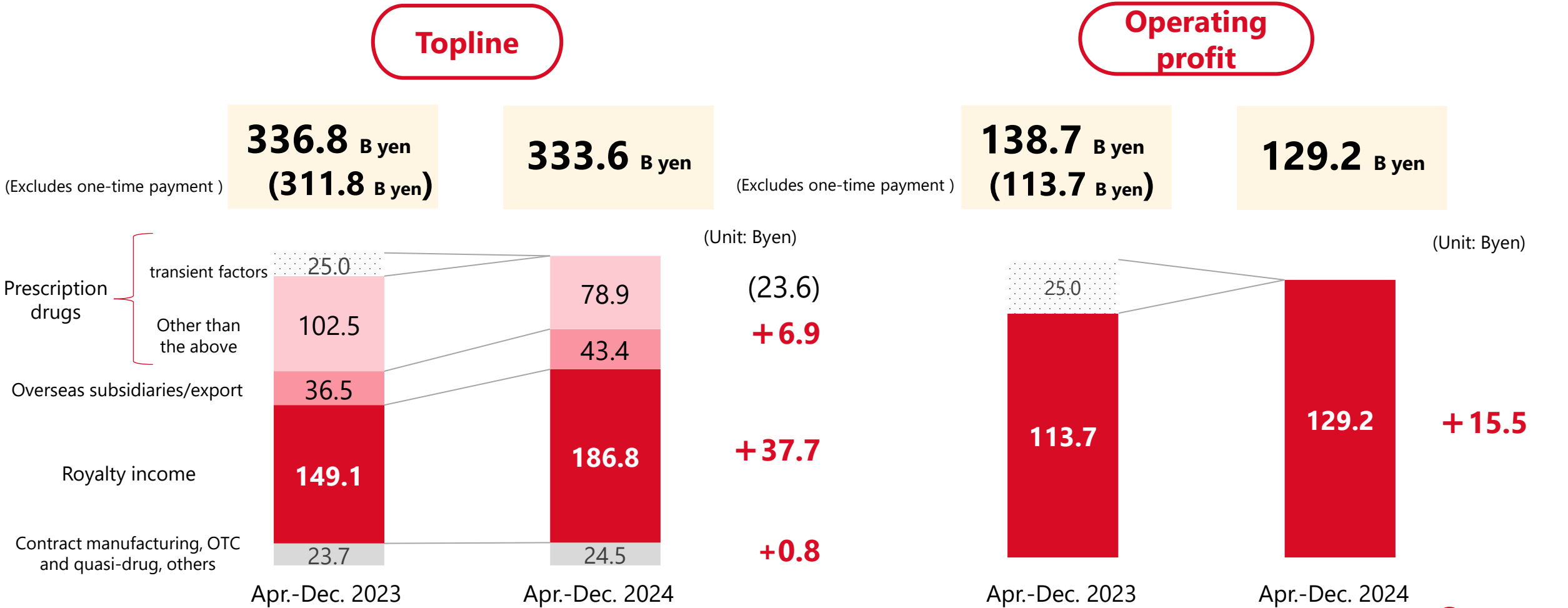
# Overview of Q3 FY2024 Financial Results



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# Highlight

Excluding the one-time payment\* from last year, both the top line and operating profit have increased



\* one-time payment from transfer of ADHD drugs in FY2023 (25B yen)

# Financial Results

## Summary

- **Sales revenue and various profit items landed almost as expected against the full-year forecast**
  - The HIV business and overseas business continue to grow strongly
  - Domestic business is making steady progress due to the stabilization of the infectious disease business.
- **Compared to the same period last year, revenue and profit increased, excluding one-time payments**

(Unit : B yen)

	FY2024			FY2023		Y on Y		Exchange Rate (Average)		
	Forecasts Full year	Apr.-Dec. Results	Achievement (%)	Apr.-Dec. Results	Change (%)	Change		FY2024 Forecast	FY2024 Apr.-Dec. Results	
Revenue	460.0	333.6	72.5	336.8	(1.0)	(3.2)				
Operating profit	165.0	129.2	78.3	138.7	(6.9)	(9.5)	USD(\$)-JPY(¥)	148	152.64	
Profit before tax	206.0	155.9	75.7	164.5	(5.2)	(8.6)				
Profit attributable to owners of parent	171.0	133.8	78.2	127.2	5.2	6.6	GBP(£)-JPY(¥)	190	195.50	
EBITDA*	-	146.4	-	160.2	(8.6)	(13.8)	EUR(€)-JPY(¥)	161	164.89	

# Statement of Profit or Loss

(Unit : B yen)

	FY2024			FY2023		Y on Y	
	Forecast Full year	Apr.-Dec. Results	Achievement (%)	Apr.-Dec. Results	Change (%)	Change	
Revenue	460.0	333.6	72.5	336.8	(1.0)	(3.2)	
Cost of Sales	14.6	13.8		12.6			
	67.0	46.0	68.7	42.4	8.6	3.6	
Gross profit	393.0	287.6	73.2	294.4	(2.3)	(6.9)	
Selling, general & administrative expenses, R&D expenses total	48.9	46.7		43.6			
	225.0	155.9	69.3	146.9	6.1	9.0	
Selling, general & administrative expenses	23.7	22.9		22.1			
	109.0	76.4	70.1	74.3	2.9	2.2	
R&D expenses	25.2	23.8		21.6			
	116.0	79.4	68.5	72.6	9.4	6.8	
Other income & expenses	(3.0)	(2.5)	81.7	(8.8)	(72.0)	6.3	
Operating profit	35.9	38.7		41.2			
	165.0	129.2	78.3	138.7	(6.9)	(9.5)	
Finance income & costs	41.0	26.7	65.0	25.7	3.5	0.9	
Profit before tax	44.8	46.7		48.8			
	206.0	155.9	75.7	164.5	(5.2)	(8.6)	
Profit attributable to owners of parent	171.0	133.8	78.2	127.2	5.2	6.6	

## Main Variation Factors (Y on Y)

### Revenue

Increase

- Overseas subsidiaries /export
- Royalty income

Decrease

- Prescription drugs

### Cost of Sales

Increase in expense

- Changes in product mix

### R&D expenses

Increase in expense

- Active investment in high-priority development products

### Other income & expenses

Decrease in expense

- Costs related to implementation of early retirement program ※

# Revenue by Segment

(Unit : B yen)

	Forecast Full year	FY2024		FY2023	Y on Y	
		Apr.-Dec. Results	Achievement (%)	Apr.-Dec. Results	Change (%)	Change
Prescription drugs	124.7	78.9	63.3	127.5	(38.1)	(48.6)
Excluding temporary income	-	78.9	-	102.5	(23.0)	(23.6)
Overseas subsidiaries/export	57.6	43.4	75.3	36.5	18.8	6.9
Shionogi Inc. (US)	22.6	17.5	77.4	13.1	33.6	4.4
Fetroja	-	14.7	-	10.6	39.6	4.2
Shionogi B.V. (EU)	16.7	12.9	77.5	10.1	28.5	2.9
Fetcroja	-	9.9	-	7.9	25.6	2.0
Ping An Shionogi/C&O	9.1	6.3	68.9	8.3	(24.4)	(2.0)
Others	9.2	6.7	72.5	5.1	32.1	1.6
Contract manufacturing	16.5	10.7	64.8	11.7	(8.9)	(1.0)
OTC and quasi-drug	16.6	12.7	76.5	10.6	20.0	2.1
Royalty income	242.8	186.8	76.9	149.1	25.3	37.7
HIV franchise	234.9	183.5	78.1	146.1	25.6	37.4
Others	7.9	3.3	41.2	3.0	7.7	0.2
Others	1.8	1.1	62.1	1.4	(18.2)	(0.2)
Total	460.0	333.6	72.5	336.8	(1.0)	(3.2)

## Main variation Factors (Y on Y)

### Prescription drugs

Decrease

- Sales of Infectious disease drugs
- A one-time payment for the transfer of the ADHD treatment drug license※

### Overseas subsidiaries/export

Increase

- Sales of cefiderocol (Fetroja, Fetcroja)

### OTC and quasi-drug

Increase

- Strong sales of Rinderon and Mucodyne

### Royalty income

Increase

- Strong sales of ViiV's HIV franchise

# Prescription Drugs in Japan

(Unit : B yen)

	Forecast Full year	FY2024		FY2023	Y on Y	
		Apr.-Dec. Results	Achievement (%)	Apr.-Dec. Results	Change (%)	Change
Infectious disease drugs	83.4	50.0	60.0	69.0	(27.5)	(19.0)
COVID-19 related products + Influenza franchise	72.3	43.3	59.9	62.0	(30.2)	(18.7)
Symproic	5.9	3.8	65.0	3.3	15.5	0.5
OxyContin franchise	5.0	3.3	66.2	3.3	(0.4)	(0.0)
Actair	1.3	0.7	51.1	0.5	27.6	0.1
Cymbalta	3.3	1.9	56.4	3.1	(40.3)	(1.3)
Others	25.8	19.2	74.4	48.2*	(60.1)	(29.0)
Quviviq	3.0	0.5	16.5	-	-	0.5
Prescription drugs	124.7	78.9	63.3	127.5	(38.1)	(48.6)

## Infectious disease drugs

- FINIBAX
- Flumarin
- Flomox
- Shiomarin
- Baktar
- Flagyl
- ISODINE
- Fetroja

## COVID-19 related products

- Xocova

## Influenza franchise

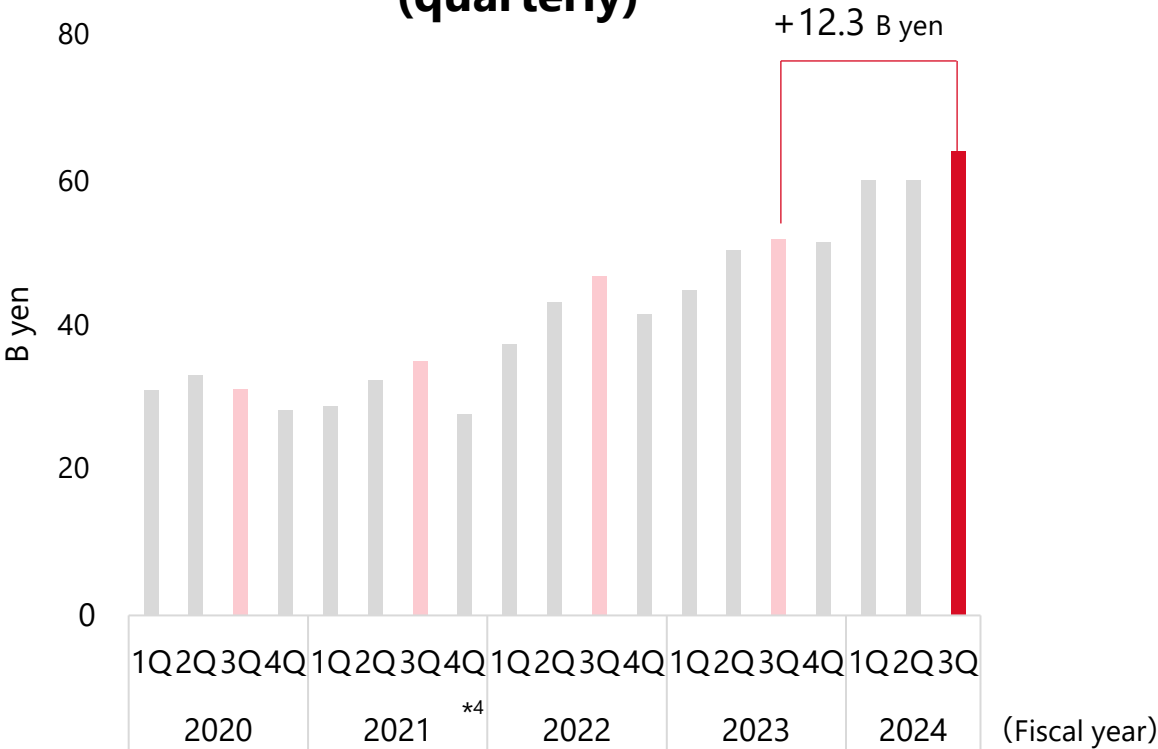
- Xofluza
- BrightpocFlu•Neo\*<sup>2</sup>
- Rapiacta



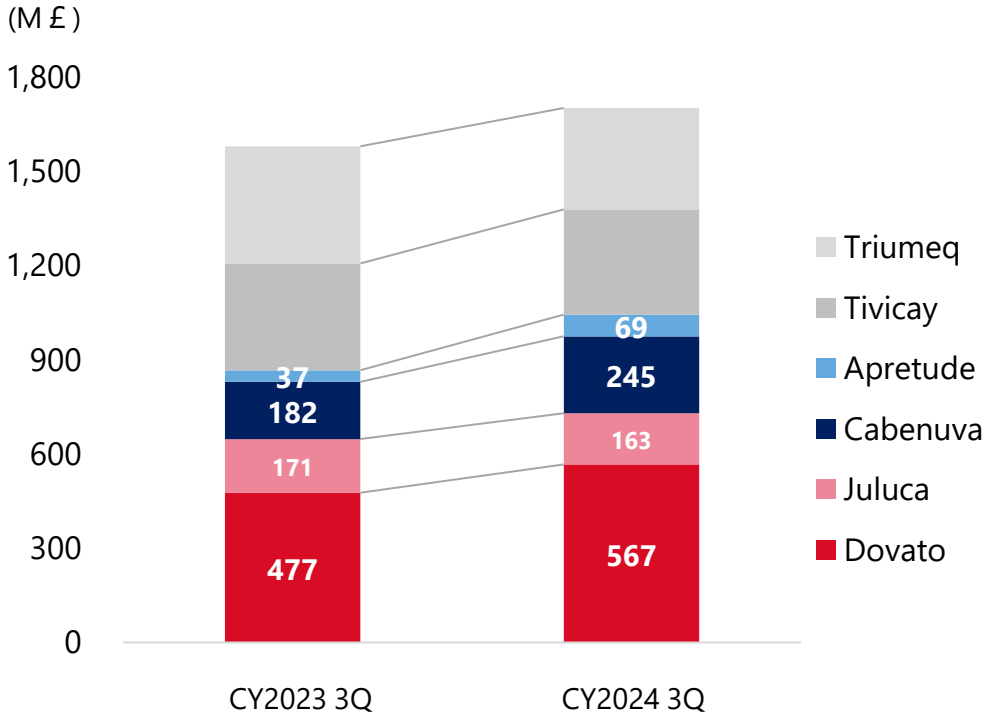
# Expansion of the HIV Business

Continued stable growth each quarter, centered on the growth of oral two drug regimens\* and LA formulations\*<sup>2</sup>

Transition of SHIONOGI's HIV royalty income (quarterly)



Sales of ViiV's dolutegravir and cabotegravir products\*<sup>3</sup>



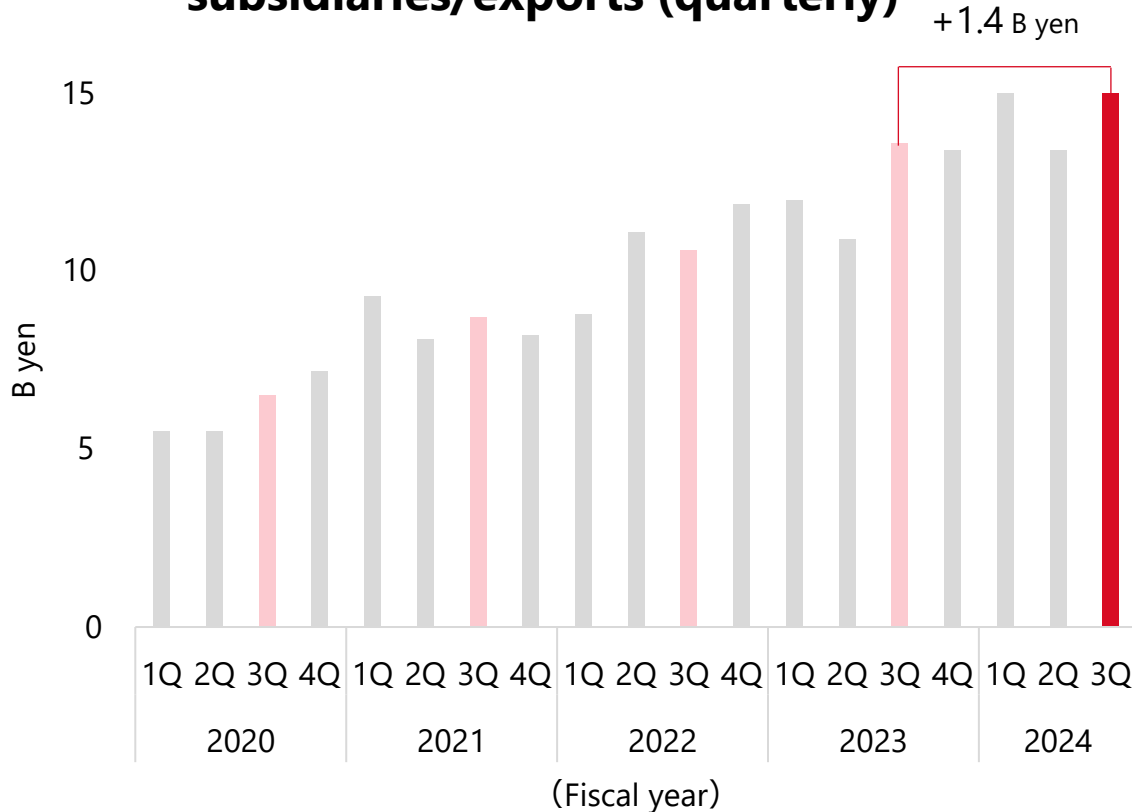
\* Oral two drug regimens: Dovato, Juluca \*<sup>2</sup> Long Acting: Cabenuva, Apretude \*<sup>3</sup> Source: Prepared by SHIONOGI based on GSK financial statements

\*<sup>4</sup> The additional royalties from the settlement between ViiV Healthcare, GSK, Shionogi and Gilead in Q4 2021 are not included

# Expansion of Overseas Business

**With the stable growth of Cefiderocol in Europe and the United States and the expansion of the countries where it is sold, the overseas business is poised for further growth**

**Sales revenue of overseas subsidiaries/exports (quarterly)**



## Strong YoY growth in cefiderocol sales

- US : +1.31 B yen, 32.1% growth
- EU : +0.25 B yen, 7.6% growth

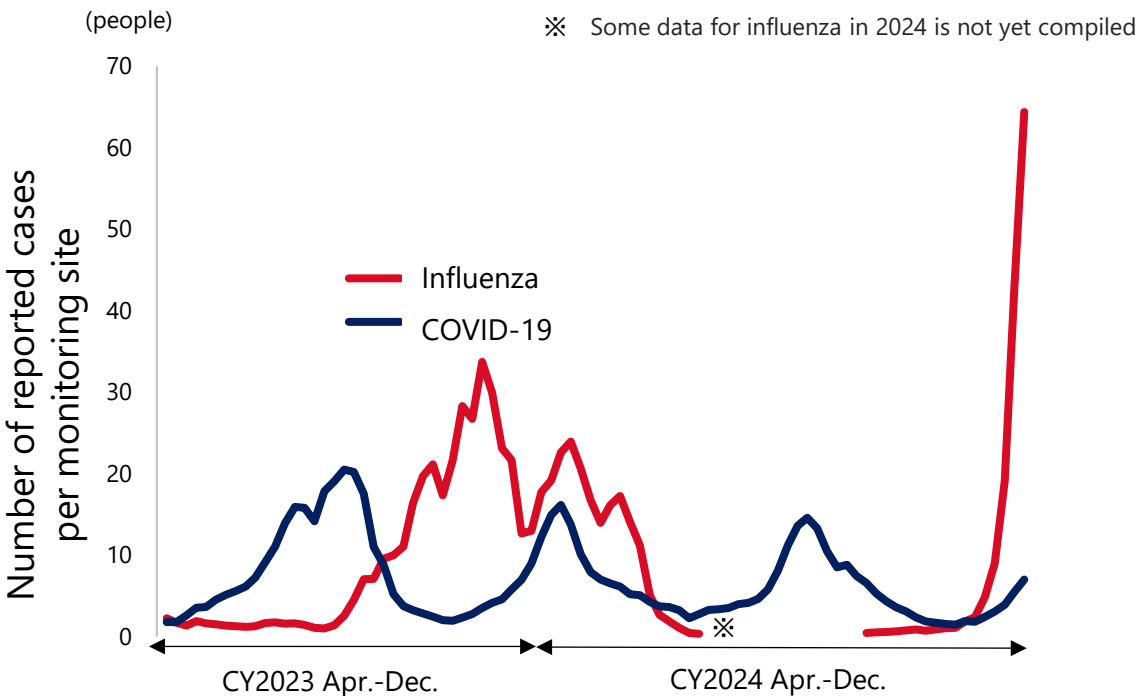
## Expansion of countries where Cefiderocol is sold (Sold in 25 countries)

- Latest application updates
  - Australia: Approval application accepted, FY2024 3Q **new**
  - China: Approval application accepted, FY2024 2Q

# Status of Domestic Business (Influenza and COVID-19)

**In the market for influenza and COVID-19 treatments, we aim to expand our market share and contribute to stable performance in response to the epidemics**

Patient trends\* (From Apr. 4<sup>th</sup> week of 2023)



Over the past two years, at any given time, influenza or COVID-19 has been prevalent

## Influenza Family\*<sup>2</sup> (Influenza treatment)

With the spread of infections, the prescription of Xofluza has surged since December

Treatment rate\*<sup>3</sup>

Consistently maintaining around **90%**

Market Share\*<sup>4</sup>

It has **further expanded** since last year

## Xocova (COVID-19 treatment)

Promoting awareness activities in preparation for the spread of infections in 4Q

Treatment rate\*<sup>3</sup>

3Q has consistently been around **12-14%**

Market Share\*<sup>4</sup>

It has been consistently around **65%**

\*<sup>3</sup> JAMDA (COVID-19: Usage rate of oral antiviral drugs for COVID-19 patients, Influenza: Usage rate of antiviral drugs for influenza patients, Weekly data)

\* Status updated following the reclassification of COVID-19 as a Category 5 infectious disease. Source: COVID-19 press releases by the Ministry of Health, Labour and Welfare \*<sup>2</sup> Xofluza and Rapiacta

# Results for Q3 of FY2024

**The growth of the HIV business and overseas business, along with the stabilization of the domestic business, is expected to achieve the full-year forecast**

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**The HIV business and overseas business have grown significantly**

- HIV business: **+37.4 billion yen** (Y on Y)
- Overseas business: **+6.9 billion yen** (Y on Y)

**In the domestic business, we aim to stabilize the infectious disease business and build a new revenue base**

- Both Xocova and the influenza family have secured a high market share and recorded stable sales during the spread of infections
  - Sales of influenza family expanded
- Launch of QUVIVIQ

**All items landed as expected against the full-year plan**

- Cost management is practiced in line with sales revenue
- Research and development are vigorously promoted with prioritized focus

# Towards the Realization of the 2030 Vision

- Transformation of the China Business
- Pipeline Progress



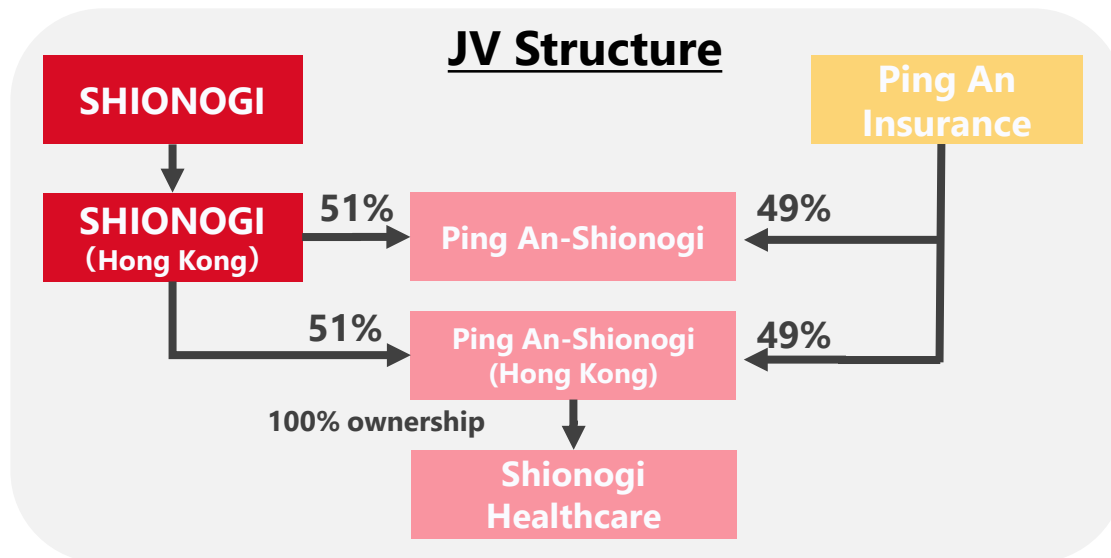
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# Dissolution of Joint Venture With Ping An Insurance

**SHIONOGI will independently expand its business in China and the broader Asia region**

## Achievements of the joint venture and the structure

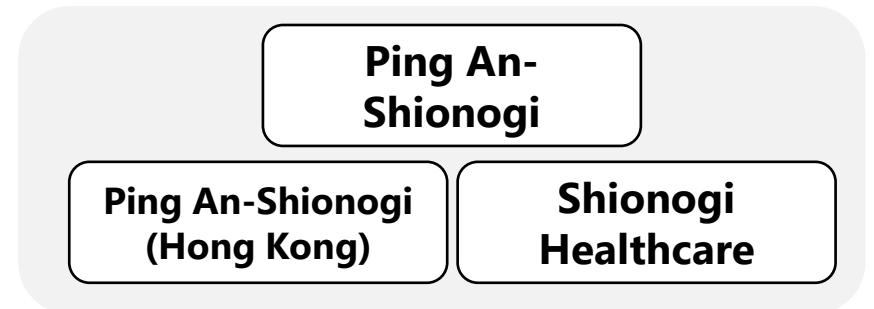
- Submission for approval of cefiderocol in China and its early use in designated medical zones
- Approval of Ensitrelvir and Cefiderocol in Singapore's SAR\*
- Leveraging AI-driven drug discovery expertise and acquisition of candidate compounds



Evolutionary  
Dissolution

## Future Framework

- SHIONOGI will fully acquire the following three subsidiaries
- Leveraging the expertise and know-how accumulated over the years, the company will expand its pharmaceutical development, manufacturing, and sales operations



**Further details on the business plan will be disclosed in the full-year financial results for FY2024**

# Future Outlook for the China Business

## Achieving growth in China by focusing on the new drug business

- Accelerating the launch of SHIONOGI products and advancing new drug discovery in China
- Driving top-line growth through the continuous launch of new drugs starting in FY2025

### Launch of SHIONOGI Products

<b>Cefiderocol</b> (AMR:Gram-negativebacteria infection)	<b>Naldemedine</b> (Opioid-inducedConstipation )
Already Submitted <b>Approval expected in 2025</b>	<b>Phase 3 Milestone Achieved</b> <b>Submission planned for 2025</b>
<b>Ensitrelvir</b> (COVID-19)	<b>Ololofim</b> (Invasive Aspergillosis)
Under Preparation for Submission	Global Phase 3 Trials Ongoing



### New Drug Discovery in China

- Continued Drug Discovery Utilizing AI Technology
- Clinical validation is underway for new drug candidates independently developed by SHIONOGI

<b>Candidate Compounds</b> (IPF)
Ongoing Investigator-Initiated Clinical Trials

# Towards the Realization of the 2030 Vision

- Transformation of the China Business
- Pipeline Progress

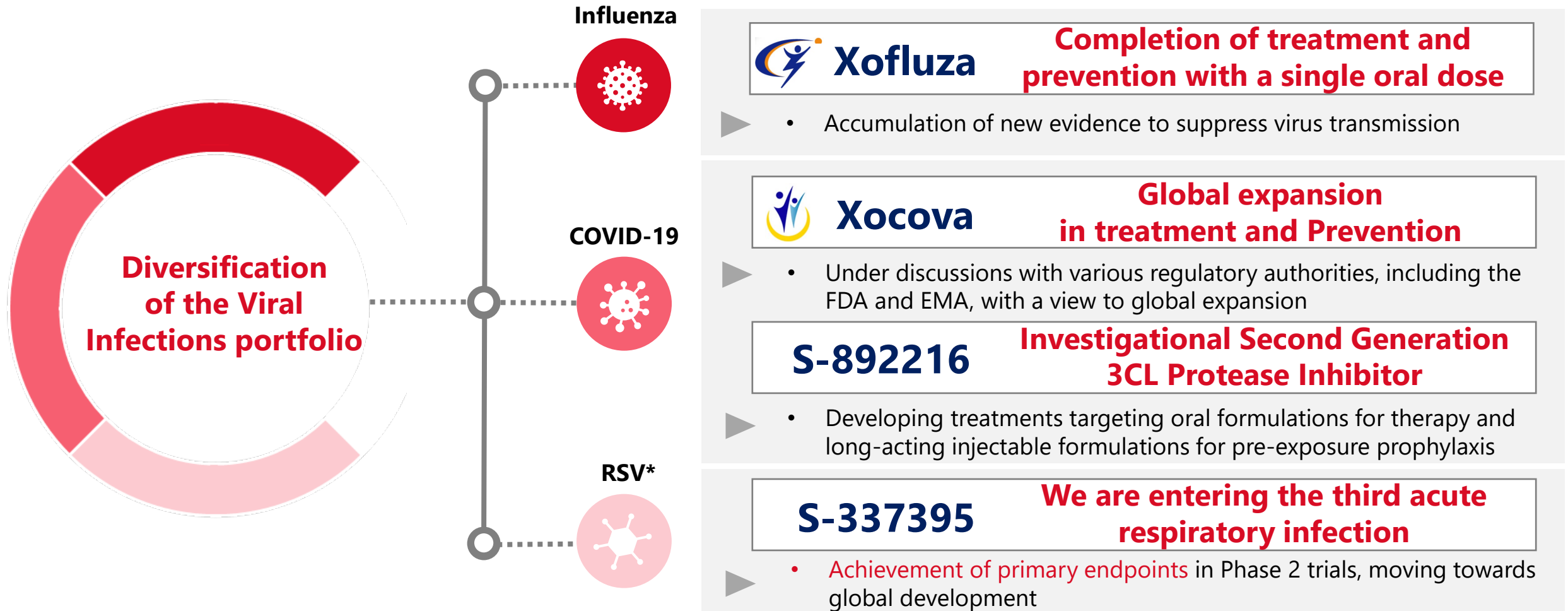


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# Acute Respiratory Infections Business : Diversification of Portfolio

**Expansion of the disease portfolio and globalization of each drug, moving from "stabilization" to "growth"**



# COVID-19: Global Market Potential

**COVID-19 continues to mutate and affects the health and lives of many people around the world**

## Estimated number of patients in US\*

from September 29, 2024, to January 4, 2025

—COVID-19 illnesses—  
**3.9 million - 7.0 million**

—COVID-19 outpatient visits—  
940,000 - 1.9 million

—COVID-19 hospitalizations—  
110,000 - 190,000

—COVID-19 deaths—  
13,000-22,000

## Total sales of two oral therapeutic products in US\*2

from January to September 2024

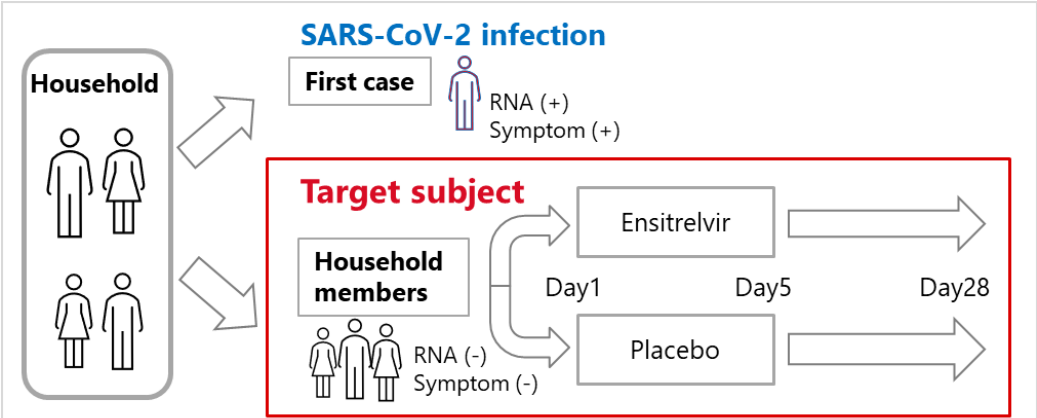
Approximately **4.3** billion dollars

# Ensirelvir: Positive Results From the SCORPIO-PEP\* Trial

Demonstrated the world's first preventive effect against the onset of COVID-19 with an oral antiviral drug\*2

## Trial design\*3

Country	US, South America, Africa, Asia including Japan
Trial Design	Multicenter, randomized, placebo-controlled, double-blind trial
Subjects	Family members or cohabitants of COVID-19 patients (approximately 2,400 cases)
Dosing Regimen Sample Size	<ul style="list-style-type: none"><li>Once daily for 5 days (Same as treatment indication)</li><li>Ensirelvir: 1,200 cases, placebo: 1,200 cases</li></ul>
Main purpose	Verification of the effect of suppressing the onset of COVID-19 symptoms for 10 days after starting ensirelvir administration



## Preliminary trial results

Results Summary	<p><b>—Achieved primary endpoints—</b></p> <p><b>&lt;Primary endpoint&gt;</b></p> <ul style="list-style-type: none"><li>Significantly reduced the proportion of subjects who became infected with SARS-CoV-2 and developed COVID-19 symptoms within 10 days of administration</li></ul> <p><b>&lt;Secondary endpoint&gt;</b></p> <ul style="list-style-type: none"><li>The proportion of subjects infected with SARS-CoV-2 also decreased</li><li>No new safety concerns</li><li>Pharmacokinetics similar to those in therapeutic trials</li></ul>
Detailed Report	Details will be announced at CROI*4 in March 2025 (Late-breaker)

\* PEP: Post-Exposure prophylactic  
\*2 [Press release dated October 29, 2024](#) \*3 jRCT: [2031230124](#)  
\*4 The Conference on Retroviruses and Opportunistic Infections

# Ensirelvir: Pediatric Trial Results in Japan

Promote development for expanded indications targeting pediatric patients aged 6 to under 12 years with limited treatment options

## Trial design\*

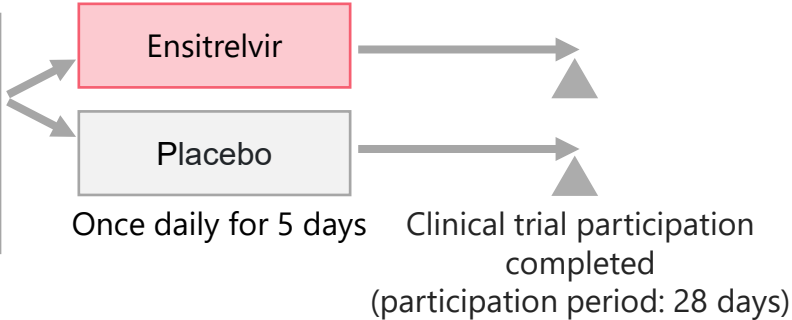
Country	Japan
Trial Design	Multicenter, randomized, double-blind, placebo-controlled trial
Subjects	Mild to moderate COVID-19 patients aged 6 to under 12 years (total of 120 cases)
Dosing Regimen Sample Size	<ul style="list-style-type: none"><li>Once daily for 5 days</li><li>Ensirelvir: 3 doses (total of 80 cases), placebo (40 cases)</li></ul>
Main purpose	Confirmation of safety, tolerability, and pharmacokinetics

## Preliminary trial results

Results Summary	<ul style="list-style-type: none"><li>Confirmed safety and tolerability</li><li>Good pharmacokinetics similar to adults</li></ul>
Detailed Report	The details of the trial results are scheduled to be reported at major conferences in Japan
Future Development Strategies	<b>Based on the trial results, we plan to submit an approval application in Japan</b>

**Key inclusion criteria**

- Participant who was diagnosed as SARS-CoV-2 positive within 72 hours
- Participant with body weight of >= 20 kg



# Ensitrelvir: Status of Global Development

Promoting various initiatives to maximize the value of ensitrelvir,  
including expanding indications and global deployment

## Development status

Clinical trial	Status
<b>SCORPIO-SR</b> (Asia: Phase 3)	<b>Achieved primary endpoints</b>
<b>SCORPIO-HR</b> (Global: Phase 3)	Primary endpoint not achieved
<b>Pediatric trial</b> (Japan: Phase 3)	<b>Confirmed preliminary trial results (safety and pharmacokinetics)</b>
<b>SCORPIO-PEP</b> (Global: Phase 3)	<b>Achieved primary endpoints</b>
<b>STRIVE trial</b> (Global: Phase 3)	Ongoing
<b>Long COVID</b> (Investigator-initiated trials)	Collaborative research in progress with Osaka University

## Status of applications to various countries/regions

Countries/region	Status
<b>US</b>	Pre-application consultation in progress
<b>Europe</b>	Pre-application consultation in progress
<b>Japan</b>	Normal approval obtained <b>Application in preparation for expansion of indications pediatric and PEP</b>
<b>China</b>	In discussion with regulators
<b>Singapore</b>	SAR approved Under review (Normal approval application completed)
<b>Taiwan</b>	<b>Application for approval was submitted / Government stockpiling contract was signed</b>
<b>Korea</b>	<b>Plans to add data from the SCORPIO-PEP trial and resubmit application</b>

# S-892216: Investigational Second Generation 3CL Protease Inhibitor

**Accelerating the development of new solutions to address significant public health challenges**

## S-892216 Profile



### Mechanism of action

- SARS-CoV-2 3CL protease inhibition



### Product Features

- Fewer drug interactions
- Strong antiviral effects
- No contraindications for pregnant women (no teratogenic effects observed in non-clinical studies)
- Different binding mode from other 3CL protease inhibitors, resulting in a distinct drug resistance profile

## S-892216 Development plan



### Oral pill\*

- Indications: COVID-19 Treatment
- Development Plan: Phase 2 scheduled to start in 4Q FY2024 (Japan, US)



### Long-acting injectable\*\*

- Indications: COVID-19 pre-exposure prophylaxis
- Development Plan: Investigational new drug application and initiation of Phase 1 trial planned within 2025 (US)



**\$375 million provided by the Biomedical Advanced Research and Development Authority (BARDA) through the Rapid Response Partnership Vehicle (RRPV) Consortium to support development.**



\* This research and development is supported by AMED under Grant Number 21fk0108584 and 22fk0108522h0001

22 \*\* Funded in whole or in part with federal funds from the Department of Health and Human Services; Administration for Strategic Preparedness and Response (ASPR); Biomedical Advanced Research and Development Authority (BARDA), under Other Transaction Number: 75A50123D00005.

# S-337395 : Market Potential and Mechanism (RSV virus infection)

**A market with significant unmet medical needs due to the lack of effective treatments despite a large number of potential patients**

## Potential Patient Numbers in the US\*<sup>1,2</sup>

Infants and young children  
(0–5 years)

Approximately  
**2.1 M People**

—Hospitalized patients—  
**58,000-80,000 People**

—Number of deaths—  
**100-500 People**

High-risk patients  
(65 years and older)

Approximately  
**1.2 M People**

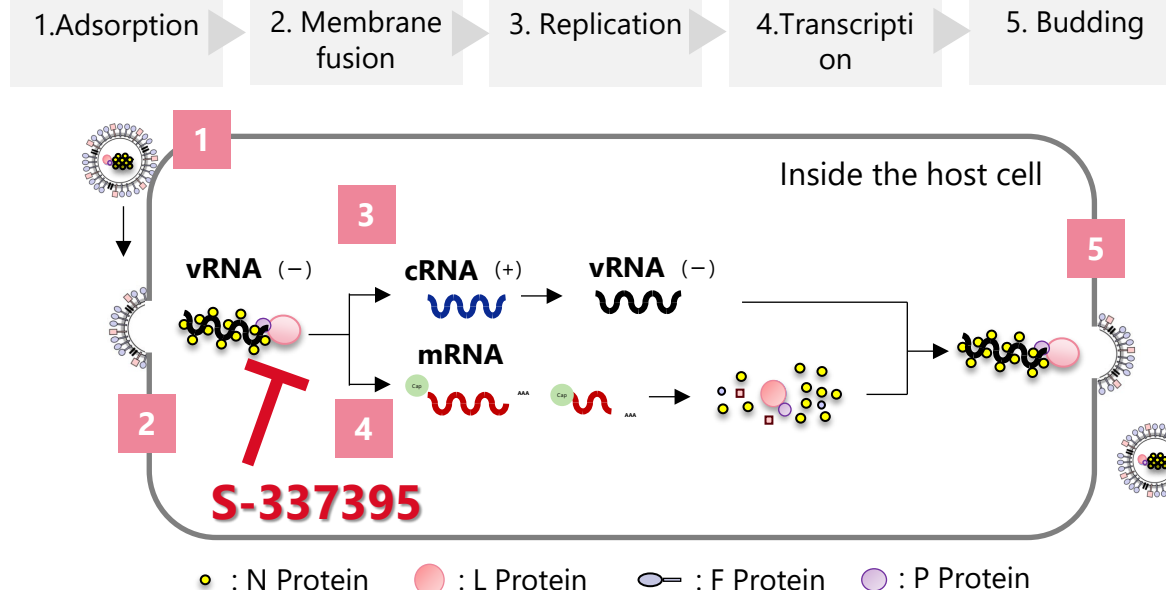
—Hospitalized patients—  
**-108,000 People**

—Number of deaths—  
**7,700 People**

**A large market with over 3 million potential patients annually**

## Mechanism of S-337395\*<sup>3</sup>

**Inhibits the L protein, which is involved in the transcription and replication of the RSV genome during the viral life cycle**



\*<sup>1</sup> Miloje Savic et al. "Respiratory syncytial virus disease burden in adults aged 60 years and older in high-income countries: A systematic literature review and meta-analysis"  
\*<sup>2</sup> Hall CB et al, "The Burden of Respiratory Syncytial Virus Infection in Young Children"

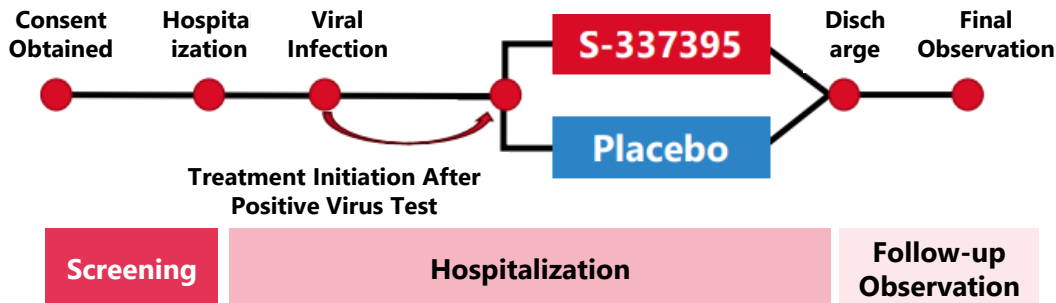
\*<sup>3</sup> A compound discovered through joint research with UBE Corporation

# S-337395 : Top-Line Result in Phase 2 Trial\*

**In the Phase 2 trial, a statistically significant reduction in viral load was confirmed**

## Trial Design

<b>Country</b>	United Kingdom
<b>Trial Design</b>	Randomized, placebo-controlled, double-blind comparative, Challenge Trial
<b>Subjects</b>	Healthy adults (Total: 114 participants)
<b>Dosing Regimen Sample Size</b>	<ul style="list-style-type: none"><li>Once-daily oral administration for 5 days</li><li>S-337395 : 4 dosage, Placebo: Minimum dose group 10 participants, Other groups: 26 participants</li></ul>
<b>Primary Endpoint</b>	AUC of RSV viral load measured by qRT-PCR



## Preliminary Trial Results

<b>Results Summary</b>	<p><b>-Achieved primary endpoints-</b></p> <ul style="list-style-type: none"><li>In the highest dose group, there was an 88.94% reduction in viral load (<math>P &lt; 0.0001</math>)</li><li>Dose-dependent reduction in viral load confirmed</li><li>Statistically significant improvement in clinical symptom scores</li><li>No concerns regarding tolerability and safety</li></ul>
<b>Detailed Report</b>	Detailed results of the trial will be reported at major international conferences
<b>Future Development Strategies</b>	Based on these trial results, we are considering development strategies to conduct late-stage global trials



# Progress of Major Development Products - Infection diseases -

※ The bar starts from FPI and ends at CSR, Topline results: It is the timing of acquisition, and the timing of disclosure will be considered separately

Disease area	Pipeline	Indication	Current stage	FY2024	FY2025	Note
COVID-19 treatments	Ensitrelvir	COVID-19	Preparation for global submission			
	Ensitrelvir	COVID-19 (Pediatric)	Phase 3	Complete enrollment (FY24 2Q)		Confirmed preliminary trial results: January 2025
	Ensitrelvir	COVID-19 PEP	Phase 3	Complete enrollment (FY24 2Q)		Primary endpoint achieved : October 2024
	S-892216	COVID-19	Phase 1	Phase 2 start (FY24 4Q)	Topline results (FY25 3Q)	
		COVID-19 PrEP	Preclinical			
COVID-19 vaccines	COVGOZE (S-268019)	COVID-19 (Wuhan, Vaccine)	Approval			
	S-268024	COVID-19 (JN.1, Vaccine)	Preclinical	Phase 2 start (FY24 4Q)	Topline results (FY25 2Q)	Preparing for Phase 3 trial
	S-567123	COVID-19 (Universal Vaccine )	Preclinical	Phase 1 start (FY24 4Q)	Topline results (FY25 2Q)	
Infection diseases	Olorofim	Invasive aspergillosis	Phase 3			
	S-337395	RSV infections	Phase 2	Topline results (FY24 3Q)	Adult Verification trial start (FY25)	Primary endpoint achieved : January 2025
	S-743229	AMR (Complex urinary tract infection)	Phase 1	Phase1 (combined use) topline (FY24 3Q)		
	S-649228	AMR (Gram-negative bacteria infection)	Phase 1	Phase1 (combined use) start (FY24 2Q)	Topline results (FY24 3Q)	

# Progress of Major Development Products - QOL Diseases with High Social Impact -

※ The bar starts from FPI and ends at CSR, Topline results: It is the timing of acquisition, and the timing of disclosure will be considered separately

Disease area	Pipeline	Indication	Current stage	FY2024	FY2025	Note
QOL Diseases with High Social Impact	SDT-001	ADHD	Submission	Approval (FY24 4Q)		
	Zuranolone	Depression	Submission	Submission (FY24 2Q)	Approval (FY25 2Q)	
	Resiniferatoxin	Pain associated with knee osteoarthritis	Phase 3		Submission (FY25 3Q)	
	Zatolmilast	Fragile X Syndrome	Phase 2/3	Phase 2/3 topline (FY25 1Q)	Submission (FY25 3Q)	
		Jordan syndrome	Phase 2	Phase 2 start (FY24 3Q)		Phase 2 started (IND application*): November 2024
	Redasemtide	Acute ischemic stroke	Phase 2b			
		Dystrophic epidermolysis bullosa	Phase 2			
	S-309309	Obesity	Phase 2	Additional non-clinical trials underway		
	SASS-001 (S-600918 + Drug X)	Sleep apnea syndrome	Phase 2	Phase 2 start (FY24 3Q)	Phase 2 topline (FY25 4Q)	
	S-531011	Solid tumor	Phase 1b/2	Phase 2 part start (FY24 2Q)		
	S-151128	Chronic pain	Phase 1b	Phase 1b topline (FY24 2Q)		
	S-606001	Pompe	Phase 1		Phase 2 start (FY25 1Q)	Rare pediatric disease Designation granted by the FDA

# Appendix

# Zatolmilast: Development Targeting Jordan Syndrome

**Initiating clinical trials targeting Jordan syndrome, aiming to develop the world's first treatment**

## What is Jordan Syndrome?



**A rare genetic disorder characterized by developmental delays**



**Estimated 250,000–300,000 potential patients globally**



**No approved treatments currently available**



**Significant unmet medical needs related to cognitive impairments**

## Features and Development Plan of Zatolmilast

**The world's first treatment to address existing unmet medical needs**

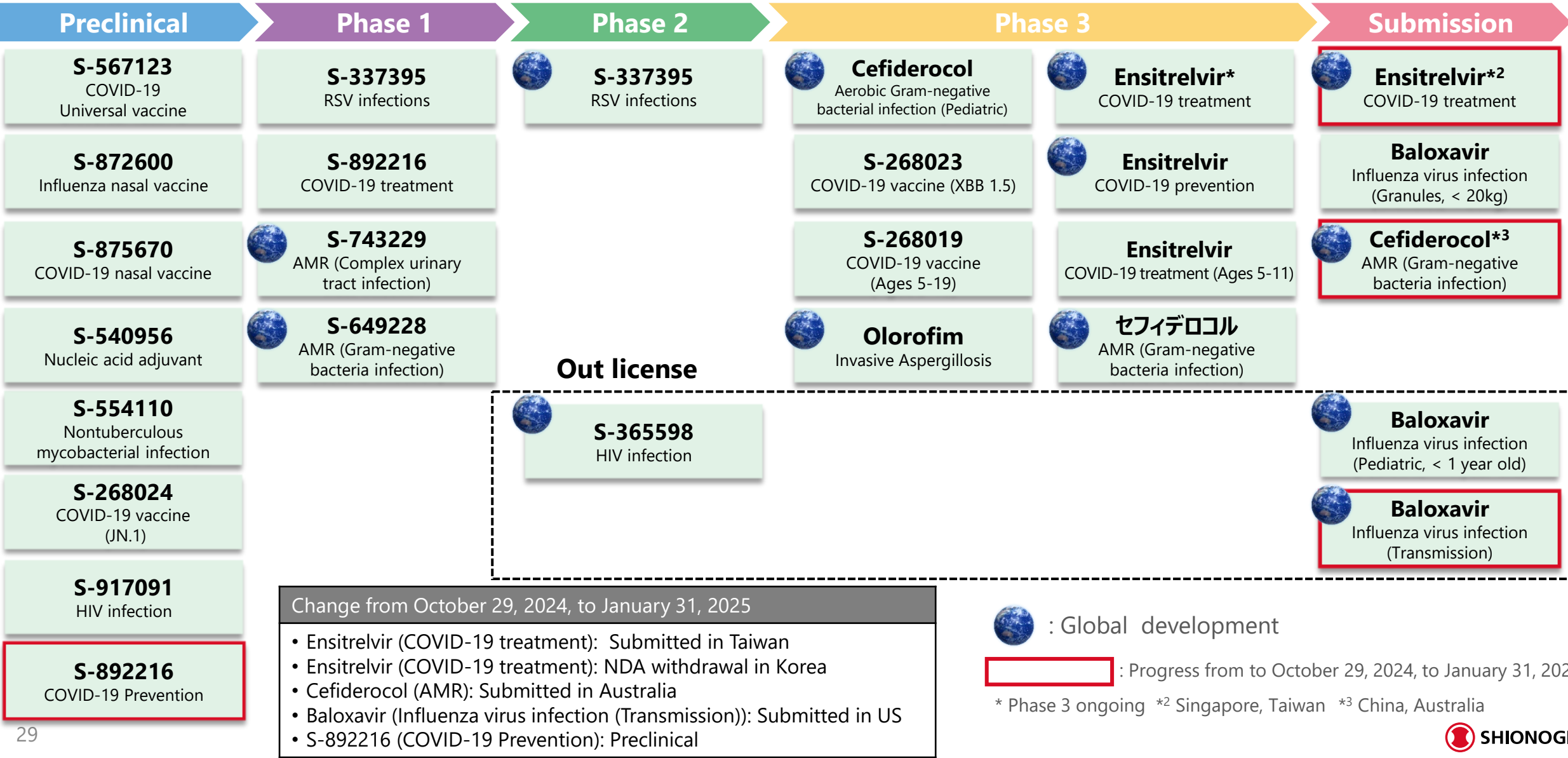
- Mechanism of Action: Selective allosteric inhibition of PDE4D
  - Enhances cognitive function by regulating intracellular signaling pathways in neurons
- Designated as a rare pediatric disease in the US

**Initiated Phase 2 trials, aiming for approval in 2026**

- Conducting development in parallel with fragile X syndrome studies

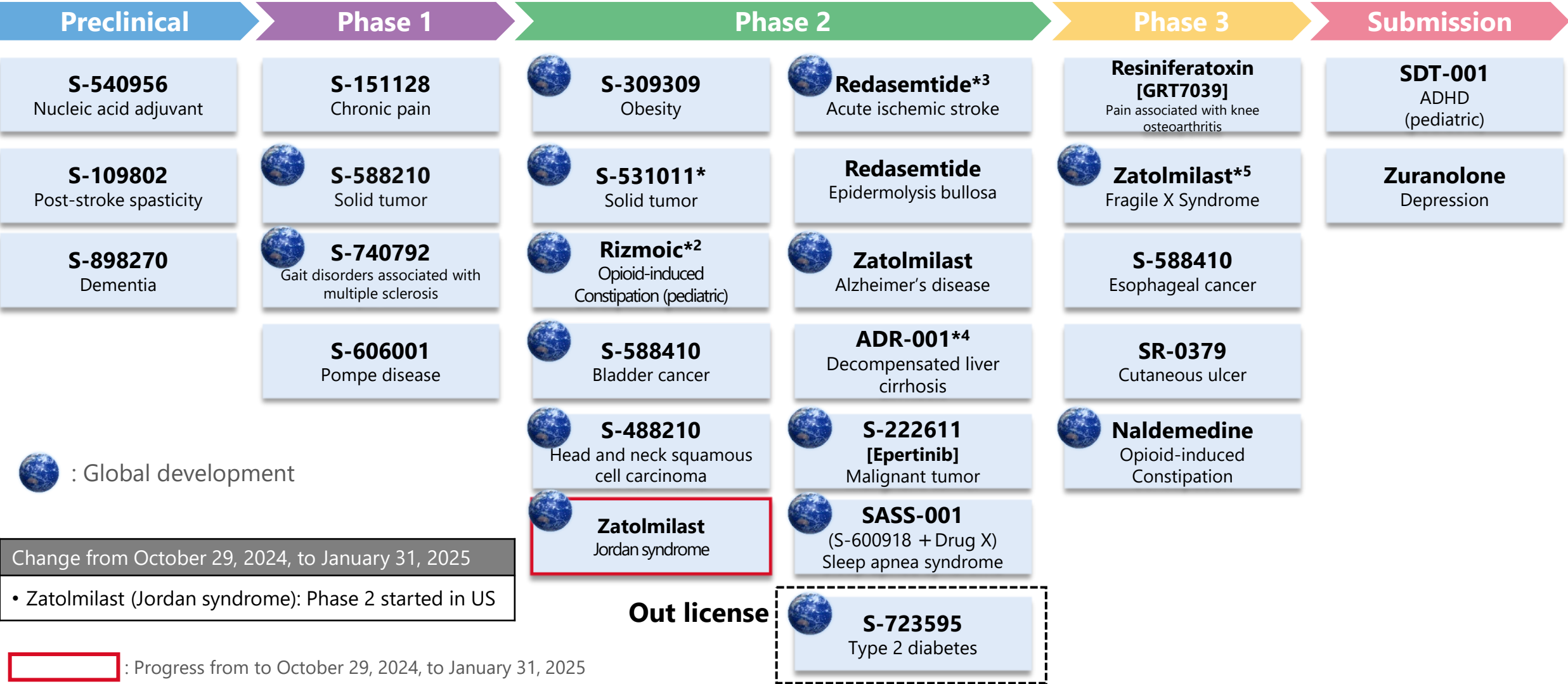
# Pipeline: Infectious Disease

as of January 31, 2025



# Pipeline: QOL Diseases with High Social Impact

as of January 31, 2025



\* Phase 1b/2 ongoing \*2,4 Phase 1/2 ongoing \*3 Global Phase 2b ongoing \*5 Phase 2/3 ongoing

# Anti-HIV drug released by ViiV

Product name	Formulations	Compounds	Administrations	Frequency	Indications	CY2023 Sales (M £)
<b>Cabenuva</b>	Long Acting	CAB + RPV	IM injection	Q2M (LA)	Treatment	708
<b>Apretude</b>		CAB	IM injection	Q2M (LA)	PrEP	149
<b>Dovato</b>	Two-drug regimens	DTG + 3TC	Oral	Every day	Treatment	1,819
<b>Juluca</b>		DTG + RPV	Oral	Every day	Treatment	661
<b>Tivicay</b>	Single agent	DTG	Oral	Every day	Treatment	1,386
<b>Triumeq</b>	Three-drug regimen	DTG+ABC+3TC	Oral	Every day	Treatment	1,542

# Other Major Progress\*

- **October**

- Disclosure of Materials on Measures to Achieve Management that Considers Capital Costs and Stock Prices

- **December**

- Integrated Report 2024 Wins Bronze Award (Honorable Mention) at the WICI Japan Integrated Report Awards 2024

- **January**

- AdvanSentinel Inc. has launched a joint research project with Tottori University and Kagoshima University to establish and utilize a highly sensitive detection method for highly pathogenic avian influenza viruses in the environment
- The "Resource Circulation Project", which aims for horizontal recycling of label backing paper, has won the World Star Awards 2025
- Shionogi & Co., Ltd. has entered into a business partnership with Hitachi, Ltd. to develop innovative services for the pharmaceutical and healthcare industries by leveraging data and generative AI
- Sponsorship for the New COVID-19 Treatment Insurance: "COVID-19 Treatment Benefit Insurance"



# Forward-Looking Statements

- Forecast or target figures in this material are neither official forecasts of earnings and dividends nor guarantee of target, achievement and forecasts, but present the midterm strategies, goals and visions. Official earnings guidance should be referred to in the disclosure of the annual financial report (*kessan tanshin*) in accordance with the rules set by Tokyo Stock Exchange.
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