

# **1st Half (Interim period) of Fiscal 2024 Financial Results**

October 28, 2024

Shionogi & Co., Ltd.



**SHIONOGI**

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- **Updates on Acute Respiratory Infection Business**
- **Updates on New products and New businesses**

# **Overview of 1st Half (Interim period) FY2024 Financial Results**

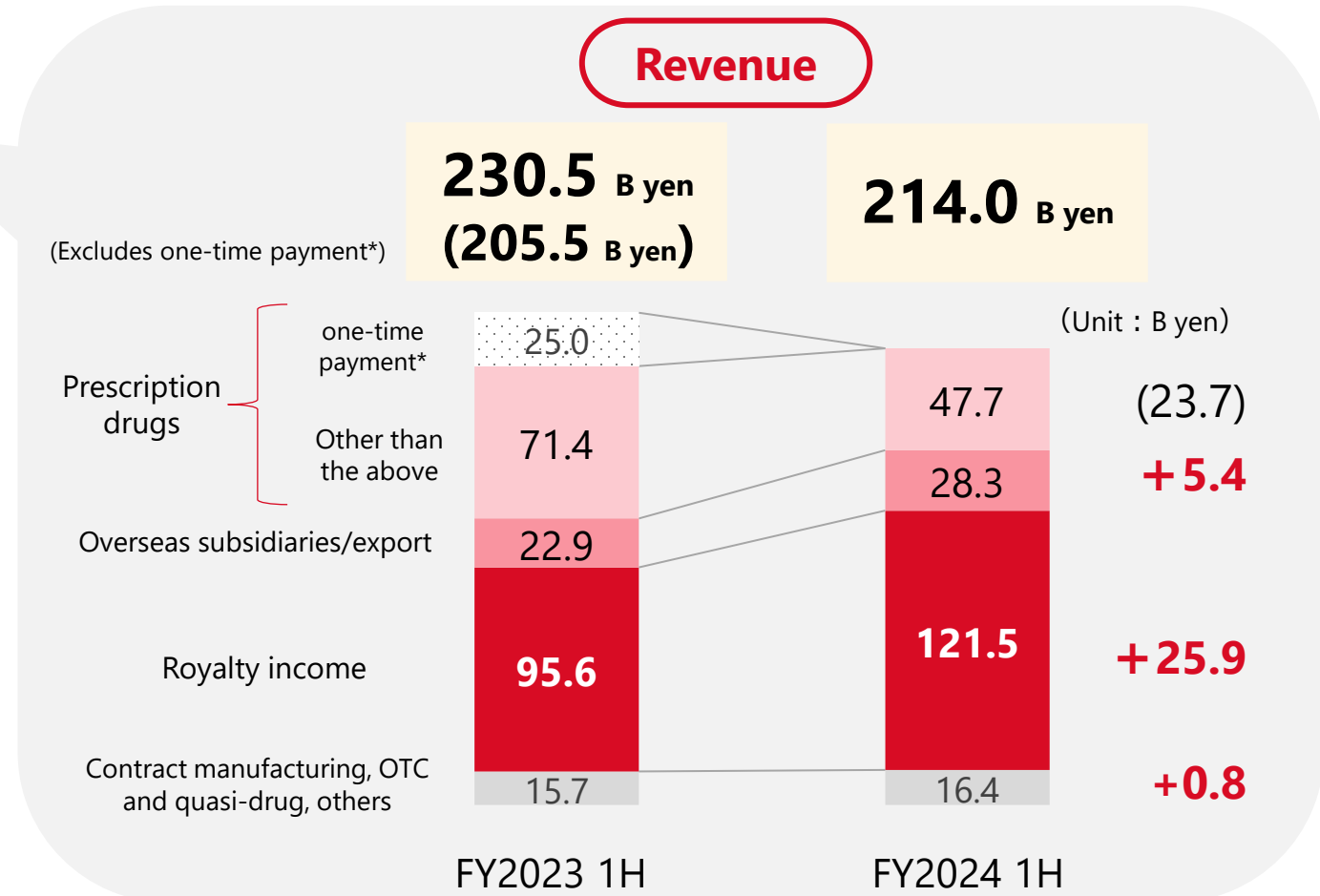


**SHIONOGI**

# Highlight

- The revenue and various profit items exceeded 1H plan
- Excluding the one-time payment\* from last year (25 billion yen), the top line has increased in revenue

<b>Revenue</b>	<b>214.0</b> B yen
1H Achievement (%)	<b>101.9</b>
<b>Operating profit</b>	<b>75.9</b> B yen
1H Achievement (%)	<b>110.0</b>
<b>Profit before tax</b>	<b>93.8</b> B yen
1H Achievement (%)	<b>113.7</b>
<b>Profit attributable to owners of parent</b>	<b>83.1</b> B yen
1H Achievement (%)	<b>125.0</b>



# Financial Results

## Summary

- The sales revenue and various profit items exceeded the first half plan
  - The HIV and overseas businesses strongly drove the growth
  - Costs were as expected, and the development products progressed steadily
- In the same period of the previous year, the one-time payment from last year affected the results, leading to a decrease in revenue and profit. However, excluding the one-time payment, there was an increase in both revenue and profit
  - In FY2023, a one-time payment of 25 billion yen was recorded due to the transfer of the license for ADHD treatment drug

(Unit : B yen)

	FY2024				FY2023	Y on Y		Exchange Rate (Average)		
	Forecasts Full year	1H	1H results	Achievement (%)	1H results	Change (%)	Change		FY2024 Forecast	FY2024 1H Results
Revenue	455.0	210.0	214.0	101.9%	230.5	(7.2)	(16.6)			
Operating profit	160.0	69.0	75.9	110.0%	98.1	(22.7)	(22.2)	USD(\$) <span> </span> – <span> </span> JPY(¥)	145	152.78
Profit before tax	200.0	82.5	93.8	113.7%	115.6	(18.8)	(21.8)	GBP(£) <span> </span> – <span> </span> JPY(¥)	178	195.57
Profit attributable to owners of parent	163.0	66.5	83.1	125.0%	90.6	(8.2)	(7.5)	EUR(€) <span> </span> – <span> </span> JPY(¥)	155	166.06
EBITDA*	-	-	86.7	-	114.2	(24.1)	(27.5)			

# Statement of Profit or Loss

(Unit : B yen)

	FY2024		FY2023		Y on Y	
	Forecast Full year	1H	1H Results Achievement (%)	1H Results	Change (%)	Change
Revenue	455.0	210.0	214.0	101.9	230.5	(7.2) (16.6)
Cost of Sales	14.5 66.0	13.6 28.5	14.1 30.1	105.7	12.1 27.9	8.1 2.3
Gross profit	389.0	181.5	183.8	101.3	202.7	(9.3) (18.8)
Selling, general & administrative expenses, R&D expenses total	49.8 226.5	52.9 111.0	49.9 106.7	96.2	41.8 96.5	10.7 10.3
Selling, general & administrative expenses	23.4 106.5	24.8 52.0	23.3 49.9	96.0	21.4 49.2	1.3 0.7
R&D expenses	26.4 120.0	28.1 59.0	26.6 56.8	96.3	20.5 47.2	20.4 9.6
Other income & expenses	(2.5)	(1.5)	(1.2)	82.4	(8.1)	- 6.9
Operating profit	35.2 160.0	32.9 69.0	35.5 75.9	110.0	42.6 98.1	(22.7) (22.2)
Finance income & costs	40.0	13.5	18.0	133.1	17.5	2.7 0.5
Profit before tax	44.0 200.0	39.3 82.5	43.9 93.8	113.7	50.1 115.6	(18.8) (21.8)
Profit attributable to owners of parent	163.0	66.5	83.1	125.0	90.6	(8.2) (7.5)

## Main variation Factors (Y on Y)

### Revenue

Increase

- Overseas subsidiaries /export
- Royalty income

Decrease

- Domestic sales

### 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)

	FY2024		FY2023		Y on Y	
	Forecast Full year	1H	1H Results Achievement (%)	1H Results	Change(%)	Change
<b>Prescription drugs</b>	134.9	58.0	<b>47.7</b>	<b>82.3</b>	96.4	(50.5) (48.6)
Excluding temporary income	-	-	<b>47.7</b>	-	71.4	(33.1) (23.6)
<b>Overseas subsidiaries/export</b>	53.7	24.7	<b>28.3</b>	<b>114.7</b>	22.9	23.5 5.4
Shionogi Inc. (US)	20.6	10.0	<b>11.2</b>	<b>112.1</b>	8.1	37.9 3.1
Fetroja	-	-	<b>9.4</b>	-	6.5	44.3 2.9
Shionogi B.V. (EU)	14.4	6.8	<b>8.3</b>	<b>122.1</b>	6.1	35.7 2.2
Fetroja	-	-	<b>6.4</b>	-	4.6	38.7 1.8
Ping An Shionogi/C&O	11.2	4.7	<b>4.2</b>	<b>89.3</b>	5.2	(20.0) (1.0)
Others	7.5	3.2	<b>4.6</b>	<b>144.2</b>	3.4	34.3 1.2
<b>Contract manufacturing</b>	15.5	6.5	<b>7.8</b>	<b>119.4</b>	7.9	(2.1) (0.2)
<b>OTC and quasi-drug</b>	16.6	8.0	<b>8.2</b>	<b>101.9</b>	7.1	15.1 1.1
<b>Royalty income</b>	232.5	112.2	<b>121.5</b>	<b>108.3</b>	95.6	27.1 25.9
HIV franchise	224.6	111.2	<b>119.6</b>	<b>107.6</b>	94.5	26.6 25.1
Others	7.9	1.0	<b>1.9</b>	<b>189.9</b>	1.1	70.1 0.8
<b>Others</b>	1.8	0.6	<b>0.5</b>	<b>86.3</b>	0.6	(19.8) (0.1)
<b>Total</b>	<b>455.0</b>	<b>210.0</b>	<b>214.0</b>	<b>101.9</b>	230.5	(7.2) (16.6)

## 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, Fetroja)
- Sales of Taiwan Shionogi

### Royalty income

Increase

- Strong sales of ViiV's HIV franchise

# Prescription Drugs in Japan

(Unit : B yen)

	FY2024				FY2023	Y on Y	
	Full year	1H	1H Results	Achievement (%)	1H Results	Change(%)	Change
Infectious disease drugs	91.2	37.6	29.2	77.7	49.0	(40.4)	(19.8)
COVID-19 related products + Influenza franchise	80.1	32.7	24.9	76.0	44.4	(44.0)	(19.6)
Symproic	6.5	2.9	2.4	81.5	2.1	12.9	0.3
OxyContin franchise	5.0	2.3	2.1	88.5	2.2	(5.6)	(0.1)
Actair	1.4	0.5	0.4	75.1	0.3	33.4	0.1
Cymbalta	3.3	1.8	1.5	80.5	2.1	(29.7)	(0.6)
Others	27.5	12.8	12.2	95.4	40.6*	(70.0)	(28.5)
Prescription drugs	134.9	58.0	47.7	82.3	96.4	(50.5)	(48.6)

COVID-19 related products

- Xocova
- COVID-19 vaccines

Influenza franchise

- Xofluza
- Rapiacta
- BrightpocFlu•Neo

Infectious disease drugs

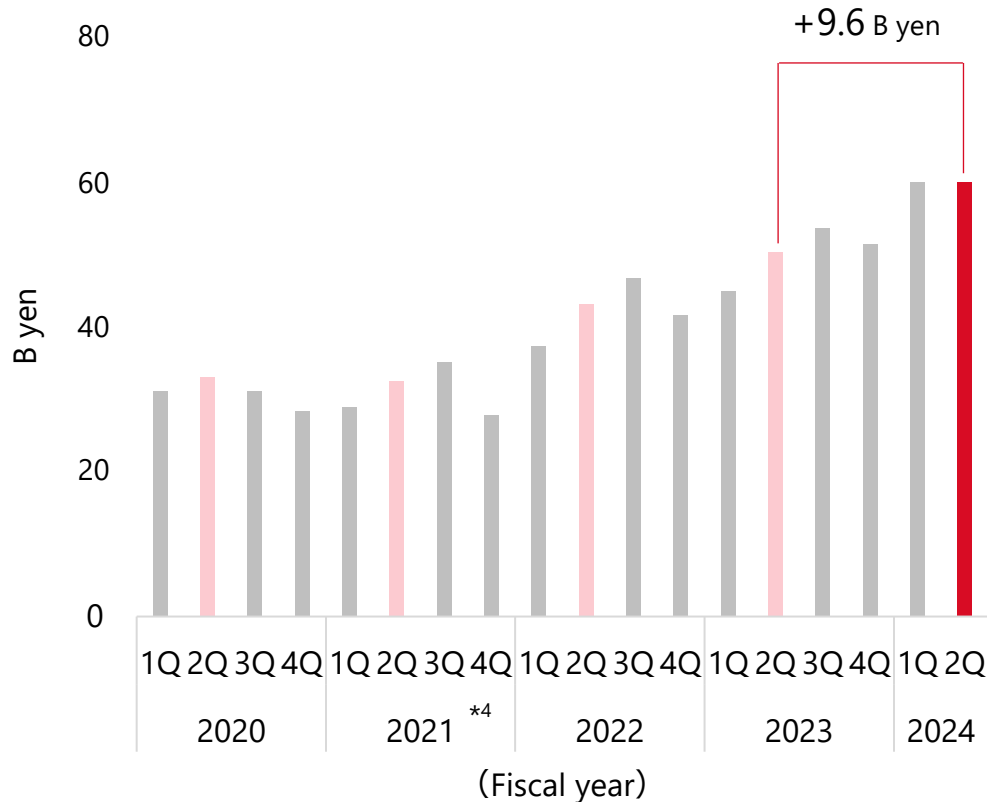
- FINIBAX
- Flumarin
- Flomox
- Shiomarin
- Baktar
- Flagyl
- ISODINE
- Fetroja



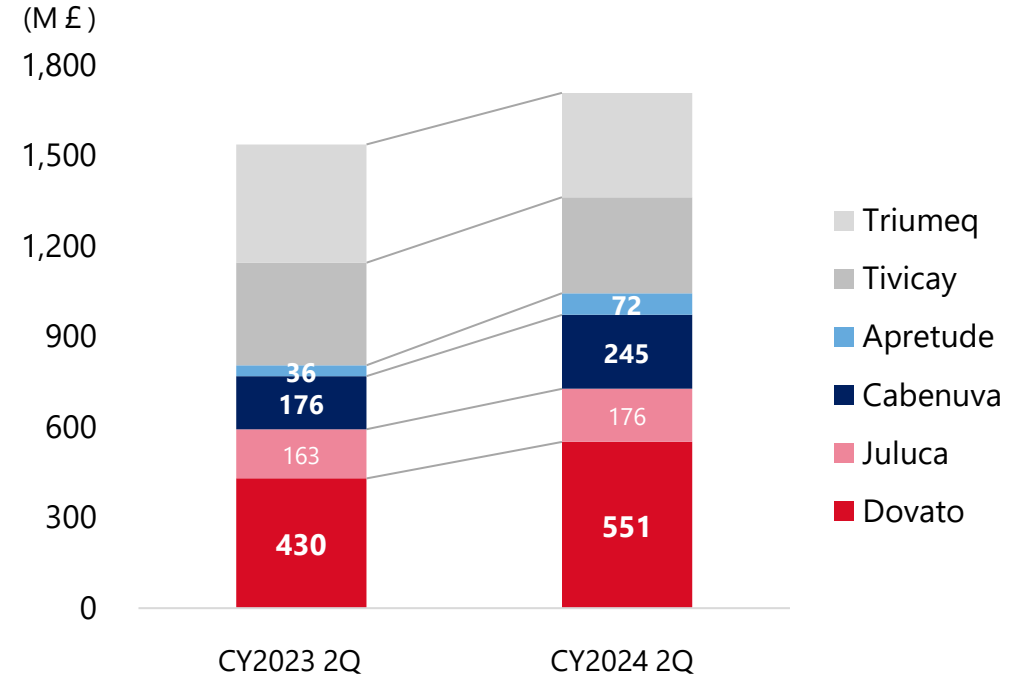
# Expansion of the HIV Business

**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



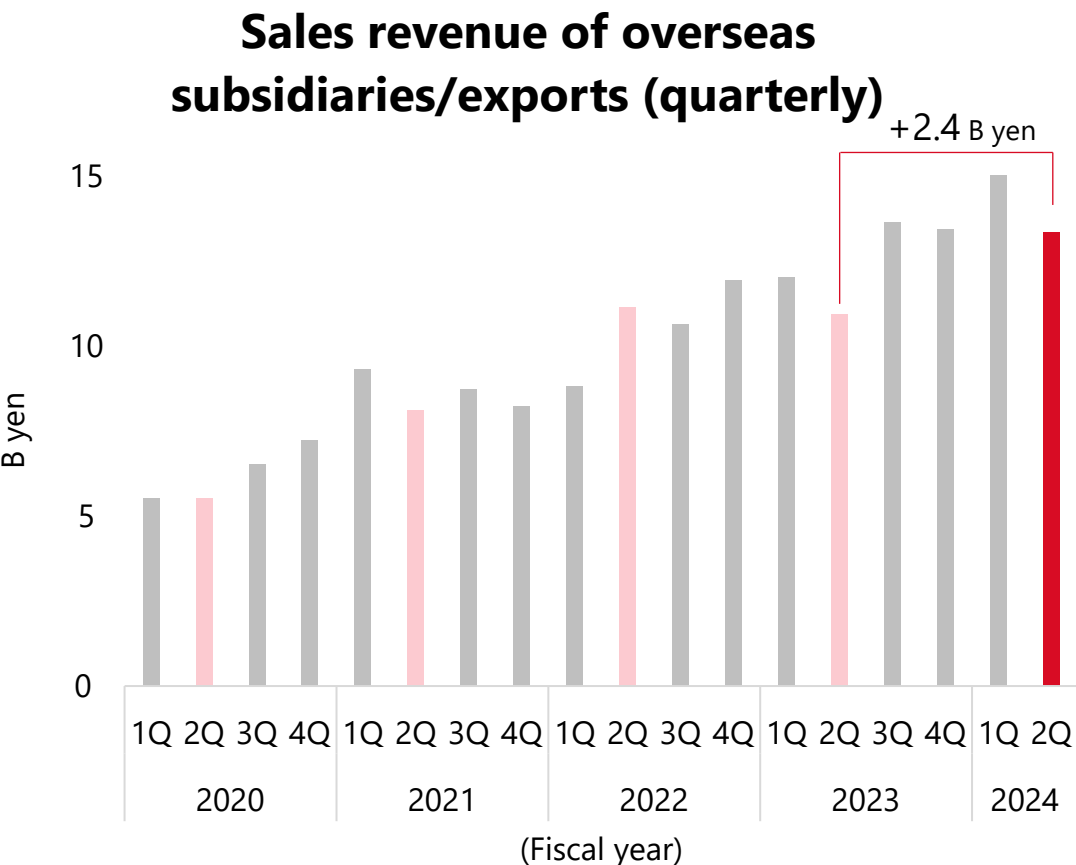
## Sales of ViiV's dolutegravir and cabotegravir products\*<sup>3</sup>



- **LA formulations: Continued strong growth (YoY +49.5%)**
- **Dovato: Achieved top market share in Europe**

# Expansion of Overseas Business

## Steady growth in overseas business, centered on Cefiderocol



•US  
•EU

### Strong YoY growth in cefiderocol sales

- U.S.: +1.3 billion yen, 38.2% growth
- Europe: +0.8 billion yen, 32.6% growth

•China

### Approval application for cefiderocol accepted

- Regulatory application submitted in Q1 has been accepted by Chinese authorities
- Aiming for further growth as overseas business

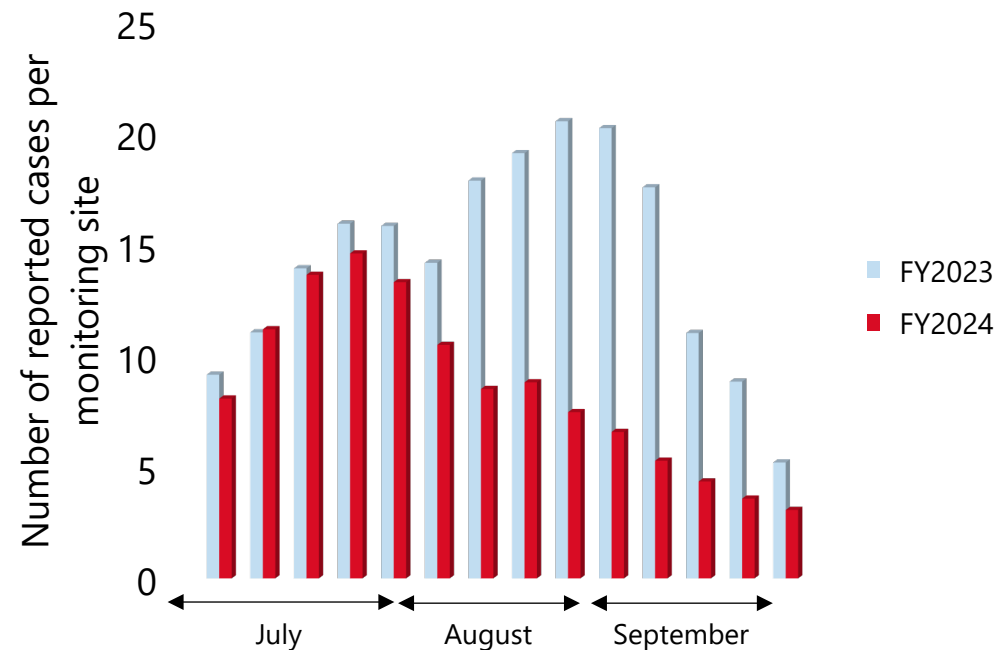
### Established real-world evidence of cefiderocol over four years\*

- Conducted on 1075 severe cases
  - Confirmed favorable clinical efficacy and safety

# Status of Domestic Business (COVID-19)

**Despite falling short of the first-half budget due to a decline in COVID-19 cases, steady sales were achieved through the expanded market share of Xocova**

COVID-19 patient trends\* (Q2)



- Initial rise in cases was similar to the previous year
- Significant decrease in the number of infections compared to the previous year from the second week of August

Treatment rate for COVID-19\*2

**13.4%** (Peak)

while the number of infections has decreased, there has been no significant drop in the treatment rate

▶ **Recognition of the importance of COVID-19 treatment is gradually increasing**

Xocova's market \*2

**70.2%** (Peak)

Significant increase in prescriptions, especially among patients with risk factors for severe illness

▶ **Growing recognition of Xocova as a COVID-19 treatment, regardless of the presence of risk factors for severe illness**

\*2 Data referenced from JAMDAS

\* 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

# Summary 1H FY2024 Financial Results

**While making aggressive investments, revenue and all profit items have grown beyond expectations**

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**HIV and international business segments robustly driving top-line growth**



- HIV Business: Continued growth driven by long-acting (LA) formulations
- Overseas subsidiaries Business: Sustained strong performance of cefiderocol in Europe and U.S

**Enhanced presence in the acute respiratory infection sector**



- Xocova: Improvement in COVID-19 treatment rates and expansion of market share
- Xofluza: Positive results from the transmission suppression trial

**Outperformed expectations across revenue and all profit compared to first-half plans**



- Controlled costs as planned in the first half
- Strategic investment in potential growth drivers

# **Revision of FY2024 Financial Forecasts**



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# Revision of Financial Forecasts

## Upward revision of revenue and all profit items based on strong 1H performance

### - Revenue -

Upward

#### HIV business and overseas business

- **Increase in HIV royalty income**
  - Strong sales of HIV franchise by ViiV
  - Assuming an increase in the 2H based on 1H performance
- **Increase in sales of Shionogi Inc., Shionogi B.V.**
  - Steady sales of cefiderocol
  - Conservative planning for the second half, taking into account exchange rate effects
- **Increase in sales of insomnia medication, QUVIVIQ\***  
(generic name: Daridorexant)
  - Expansion of sales facilities due to changes in the sales scheme

### - Revenue -

Downward

#### Domestic business

- **1H sales of COVID-19 related products and influenza family**
  - Downward revision of full-year forecast for unmet 1H targets
  - **2H plan remains unchanged**, assuming an outbreak of infectious diseases this winter

### - Cost -

#### Reduction of R&D expenses

- **Review of costs due to changes in the development schedule**

#### Increase in selling, general & administrative expenses

- **Strengthening of sales activities due to changes in the QUVIVIQ contract**
- **Active investment in sales activities for infectious disease drugs, etc**

# Financial Results

## Summary

- **Revenue and operating profit are expected to surpass previous record forecasts**
  - We are expected to achieve record highs for three consecutive terms
- **All profit items have also been revised upwards**
  - Steady increase in sales revenue and review of various expenses

(Unit : B yen)

	FY2024			FY2023		
	Forecasts	Revised	Revised amount	Results	Change (%)	Change
Revenue	455.0	<b>460.0</b>	<b>5.0</b>	435.1	<b>5.7</b>	<b>24.9</b>
Operating profit	160.0	<b>165.0</b>	<b>5.0</b>	153.3	<b>7.6</b>	<b>11.7</b>
Profit before tax	200.0	<b>206.0</b>	<b>6.0</b>	198.3	<b>3.9</b>	<b>7.7</b>
Profit attributable to owners of parent	163.0	<b>171.0</b>	<b>8.0</b>	162.0	<b>5.5</b>	<b>9.0</b>

FY2024 Exchange Rate (Average)			
	Forecast	1H Results	Forecast Change
USD(\$)-JPY(¥)	145	152.78	<b>148</b>
GBP(£)-JPY(¥)	178	195.57	<b>190</b>
EUR(€)-JPY(¥)	155	166.06	<b>161</b>

# Statement of Profit and Loss

(Unit : B yen)

	FY2024 Full year			FY2024 2H			FY2023	Y on Y	
	Forecasts	Revised	Revised amount	Forecasts	Revised	Revised amount	Results	Change (%)	Change
Revenue	455.0	460.0	5.0	245.0	246.0	1.0	435.1	5.7	24.9
Cost of Sales	14.5	14.6					13.2		
	66.0	67.0	1.0	37.5	36.9	(0.6)	57.6	16.3	9.4
Gross profit	389.0	393.0	4.0	207.5	209.2	1.7	377.5	4.1	15.5
Selling, general & administrative expenses, R&D expenses total	49.8	48.9					47.4		
	226.5	225.0	(1.5)	115.5	118.3	2.8	206.0	9.2	19.0
Selling, general & administrative expenses	23.4	23.7					23.8		
	106.5	109.0	2.5	54.5	59.1	4.6	103.4	5.4	5.6
R&D expenses	26.4	25.2					23.6		
	120.0	116.0	(4.0)	61.0	59.2	(1.8)	102.6	13.0	13.4
Other income & expenses	(2.5)	(3.0)	(0.5)	(1.0)	(1.8)	(0.8)	(18.1)	-	15.1
Operating profit	35.2	35.9					35.2		
	160.0	165.0	5.0	91.0	89.1	(1.9)	153.3	7.6	11.7
Finance income & costs	40.0	41.0	1.0	26.5	23.0	(3.5)	45.0	(8.8)	(4.0)
Profit before tax	44.0	44.8					45.6		
	200.0	206.0	6.0	117.5	112.2	(5.3)	198.3	3.9	7.7
Profit attributable to owners of parent	163.0	171.0	8.0	96.5	87.9	(8.6)	162.0	5.5	9.0



# Revenue by Segment

(Unit : B yen)

	FY2024 Full year			FY2024 2H			FY2023		Y on Y
	Forecasts	Revised	Revised amount	Forecasts	Revised	Revised amount	Results	Change (%)	Change
Prescription drugs	134.9	124.7	(10.2)	76.9	77.0	0.1	151.1	(17.5)	(26.4)
Overseas subsidiaries/export	53.7	57.6	3.9	29.0	29.3	0.3	49.9	15.4	7.7
Shionogi Inc. (US)	20.6	22.6	2.0	10.6	11.4	0.8	17.9	26.3	4.7
Shionogi B.V. (EU)	14.4	16.7	2.3	7.6	8.4	0.8	13.6	23.1	3.1
Ping An Shionogi/C&O	11.2	9.1	(2.1)	6.5	4.9	(1.6)	10.6	(14.3)	(1.5)
Others	7.5	9.2	1.7	4.3	4.6	0.3	7.8	17.5	1.4
Contract manufacturing	15.5	16.5	1.0	9.0	8.7	(0.3)	17.6	(6.3)	(1.1)
OTC and quasi-drug	16.6	16.6	-	8.6	8.4	(0.2)	14.6	13.3	2.0
Royalty income	232.5	242.8	10.3	120.3	121.3	1.0	200.4	21.2	42.4
HIV franchise	224.6	234.9	10.3	113.4	115.3	1.9	195.8	20.0	39.1
Others	7.9	7.9	-	6.9	6.0	(0.9)	4.6	72.6	3.3
Others	1.8	1.8	-	1.2	1.3	0.1	1.4	25.3	0.4
Total	455.0	460.0	5.0	245.0	246.0	1.0	435.1	5.7	24.9

# Prescription Drugs in Japan

(Unit : B yen)

	FY2024 Full year			FY2024 2H			FY2023		Y on Y
	Forecasts	Revised	Revised amount	Forecasts	Revised	Revised amount	Results	Change (%)	Change
<b>Infectious disease drugs</b>	91.2	<b>83.4</b>	<b>(7.8)</b>	<b>53.5</b>	<b>54.1</b>	<b>0.6</b>	82.9	<b>0.5</b>	<b>0.4</b>
COVID-19 related products + Influenza franchise	80.1	<b>72.3</b>	<b>(7.8)</b>	<b>47.4</b>	<b>47.4</b>	<b>0.1</b>	73.4	<b>(1.5)</b>	<b>(1.1)</b>
<b>Symproic</b>	6.5	<b>5.9</b>	<b>(0.6)</b>	<b>3.6</b>	<b>3.5</b>	<b>(0.1)</b>	4.5	<b>30.7</b>	<b>1.4</b>
<b>OxyContin franchise</b>	5.0	<b>5.0</b>	-	<b>2.7</b>	<b>2.9</b>	<b>0.3</b>	4.2	<b>20.4</b>	<b>0.8</b>
<b>Actair</b>	1.4	<b>1.3</b>	<b>(0.1)</b>	<b>0.9</b>	<b>0.9</b>	-	0.7	<b>86.1</b>	<b>0.6</b>
<b>Cymbalta</b>	3.3	<b>3.3</b>	-	<b>1.5</b>	<b>1.8</b>	<b>0.4</b>	3.8	<b>(13.7)</b>	<b>(0.5)</b>
<b>Others</b>	27.5	<b>25.8</b>	<b>(1.7)</b>	<b>14.8</b>	<b>13.7</b>	<b>(1.1)</b>	55.0	<b>(53.0)</b>	<b>(29.1)</b>
<b>QUVIVIQ</b>	1.6	<b>3.0</b>	<b>1.4</b>	1.6	<b>3.0</b>	<b>1.4</b>	-	-	-
<b>Prescription drugs</b>	134.9	<b>124.7</b>	<b>(10.2)</b>	<b>76.9</b>	<b>77.0</b>	<b>0.1</b>	151.1	<b>(17.5)</b>	<b>(26.4)</b>

COVID-19 related products

- Xocova
- COVID-19 vaccines

Influenza franchise

- Xofluza
- Rapiacta
- BrightpocFlu・Neo

Infectious disease drugs

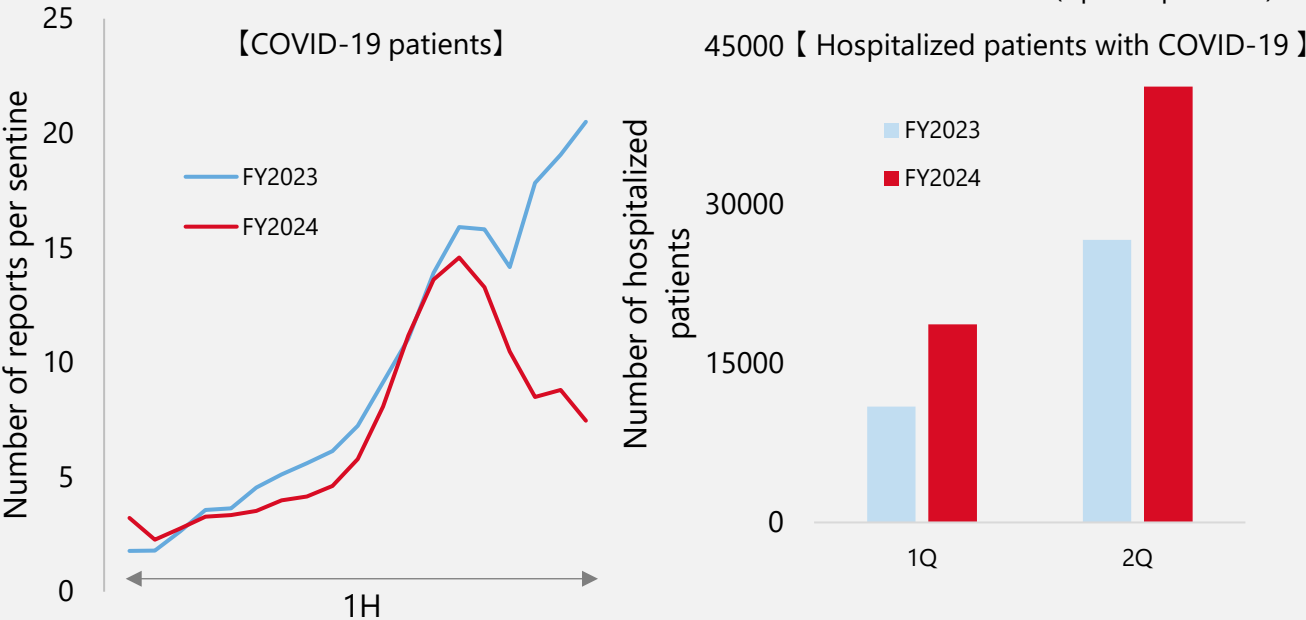
- FINIBAX
- Flumarin
- Flomox
- Shiomarin
- Baktar
- Flagyl
- ISODINE
- Fetroja

# Regarding the Acute Respiratory Infection Business in the 2H of the Year

**As a leading company in infectious diseases,  
aiming to improve the treatment rate for people suffering from COVID-19**

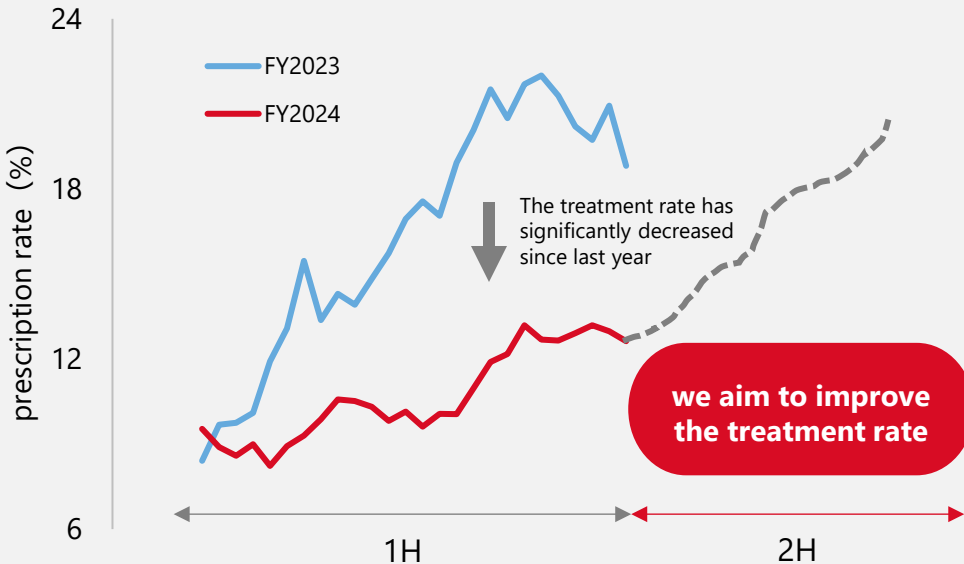
## Trends in COVID-19 patients and hospitalized patients\*

(April-September)



Despite a significant decrease in infected patients, the number of hospitalized patients has significantly increased

## Trends in COVID-19 treatment rates\*2




**Early treatment with antiviral drugs is extremely important**

We aim to improve the treatment rate and increase market share through various measures

# Make "QOL diseases" the Next Pillar of SHIONOGI

**Starting with the launch of QUVIVIQ, make the QOL disease area a new pillar of SHIONOGI**


Infectious diseases



By achieving a high market share,  
we have established a stable business pillar

Xocova COVID-19	Xofluza/Rapiacta Influenza
Cefiderocol AMR	Dovato, Cabenuva HIV treatment & PrEP

QOL diseases



Establishing QOL diseases, which are less affected by trends,  
as a new pillar alongside the infectious disease

~ 2023

Symproic  
OIC\*

OxyContin franchise  
Pain

Actair  
House dust mite allergic rhinitis

Cymbalta  
Depression

2024

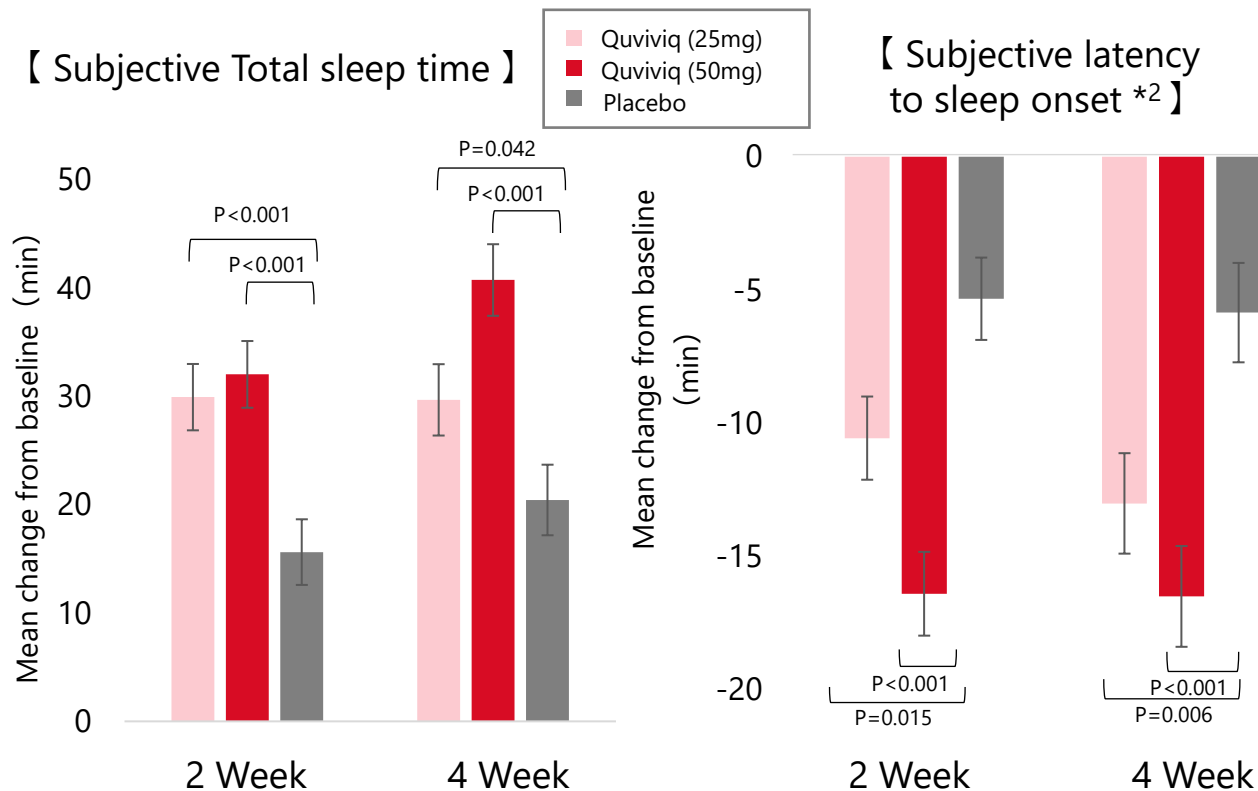
QUVIVIQ  
Insomnia

Mechanism : DORA\*2

# QUVIVIQ\*: Nxera Pharma Japan has Obtained Manufacturing and Marketing Approval

## All primary and secondary endpoints were achieved in Phase 3 trial in Japan

### Positive results from Phase 3 trial in Japan\*



**Primary Endpoint:** Comparison of changes from baseline to 4 weeks in subjective total sleep time and subjective sleep latency between the QUVIVIQ 50mg group and the placebo group.

**Secondary Endpoint:** Comparison of changes from baseline to 4 weeks in subjective total sleep time and subjective sleep latency between the QUVIVIQ 25mg group and the placebo group.

- QUVIVIQ significantly improved subjective Total Sleep Time, a primary endpoint defined as the change from baseline compared to placebo at 2 week ( $p < 0.001$  for 50mg)
- QUVIVIQ also significantly improved sleep onset as measured by a decrease in subjective Latency for Sleep Onset, a primary endpoint defined as the change from baseline compared to placebo at 2 week ( $p < 0.001$  for 50mg)
- No serious side effects have been reported due to the administration of QUVIVIQ

# QUVIVIQ: Unmet Needs in Insomnia Treatment and Features of QUVIVIQ

## Potential to Become the Best-in-Class Treatment in the Expanding Insomnia Field by Meeting Unmet Needs

### Important Unmet Needs in Insomnia Treatment

**Nocturnal awakenings**

**Rapid sleep onset**

**Carry-over effects to the next day after medication**

### Features of the New Insomnia Treatment, QUVIVIQ

#### Dual Orexin Receptor Antagonist

- Alleviates excessive wakefulness through strong inhibition of orexin receptors

- **Recommended in the 2023 European Insomnia Guidelines**

- In the pharmacological treatment of short-term and long-term insomnia, it is recommended as the only orexin receptor antagonist that can be used\*

#### Outstanding pharmacokinetic profile

**Tmax** ▶ about **0.5-1.4 hour**

**T 1/2** ▶ about **6-9 hour**

- Significant improvement in next-day sleepiness and daytime functioning confirmed in global trials\*<sup>2</sup>

# QUVIVIQ: Change in Sales Scheme

QUVIVIQ, which has excellent efficacy and plays a central role in the QOL disease area, will be sold exclusively in Japan

## Change in Sales Scheme

### Previous Sales Scheme



MOCHIDA PHARMACEUTICAL CO., LTD.



SHIONOGI

Sold through Two Channels



### New Sales Scheme



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**SHIONOGI to Exclusively Handle  
Distribution and Sales Activities in Japan**

# Shareholder Return

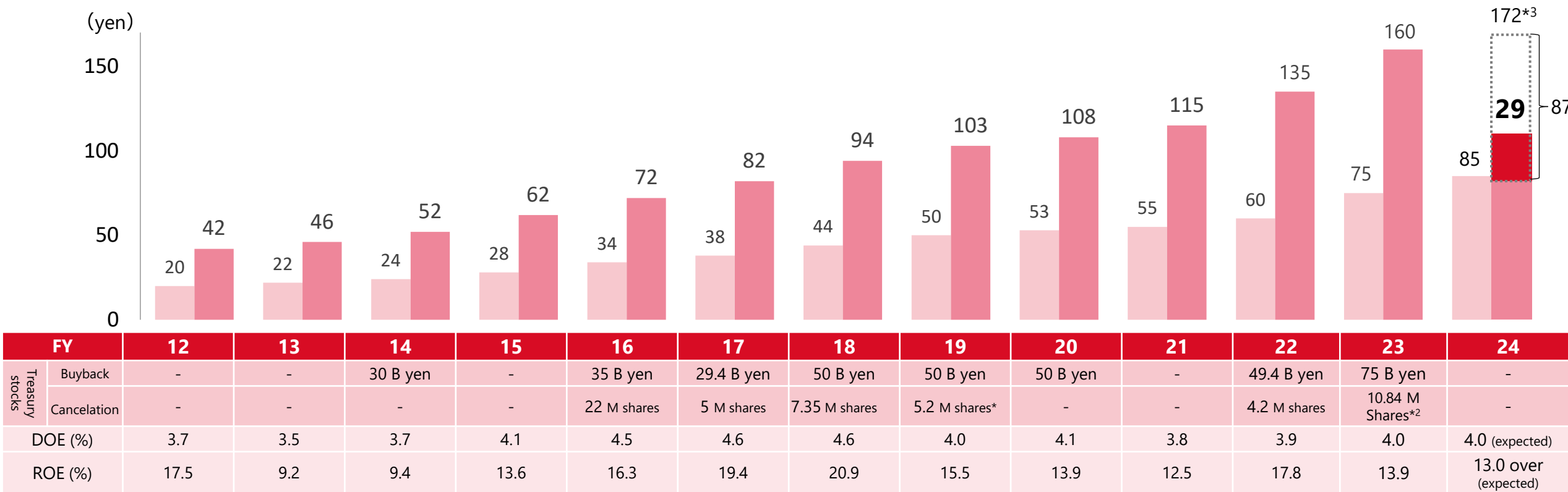


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# Shareholder Return Policy through which Shareholders can Feel Our Growth

- Implemented a stock split to enhance stock liquidity and broaden the investor base (effective date: October 1, 2024)
  - Split each share into three shares and revised the forecasted dividend per share to 29 yen
  - Pre-split equivalent year-end dividend: 87 yen (effectively an increase)
- Planning for the 13th consecutive year of dividend increases** in FY2024
- Aiming to improve capital efficiency through share buybacks and cancellations, as well as reducing cross-shareholdings



# **Towards the Realization of the 2030 Vision**

Growth Strategy Based on Three Pillars



**SHIONOGI**

# Update of STS2030 Revision Based on Current Growth Rate

- HIV business has revised its 2025 and 2030 revenue forecast upwards due to growth exceeding expectations for LA formulations and oral two-drug regimens
- Further growth in acute respiratory infections business by combining COVID-19 treatment with influenza treatment, leveraging the strengths of having both drugs
- Growth toward realizing the 2030 Vision through active investment (R&D, business investment) (until 2030)

Revenue

## Growth image

- New products and new businesses
- Acute respiratory infection business
- HIV royalty

FY2022

FY2025

FY2030

### Expansion of new products and new businesses

- Approval and launch of products under development
- Expansion of portfolio
  - Investment in drug discovery for unmet needs and growth drivers
- Growth of vaccine business

### Establishment of acute respiratory infection business

- Expansion of the domestic market and global expansion of COVID19 treatment drugs
- Expansion of the domestic market for influenza family
- Pursuit of the importance of testing to treat

### Changes in HIV royalty outlook

- LA formulations grow beyond initial expectations

# Towards the Realization of the 2030 Vision

- Updates on HIV Business
- Updates on Acute Respiratory Infection Business
- Updates on New products and New businesses

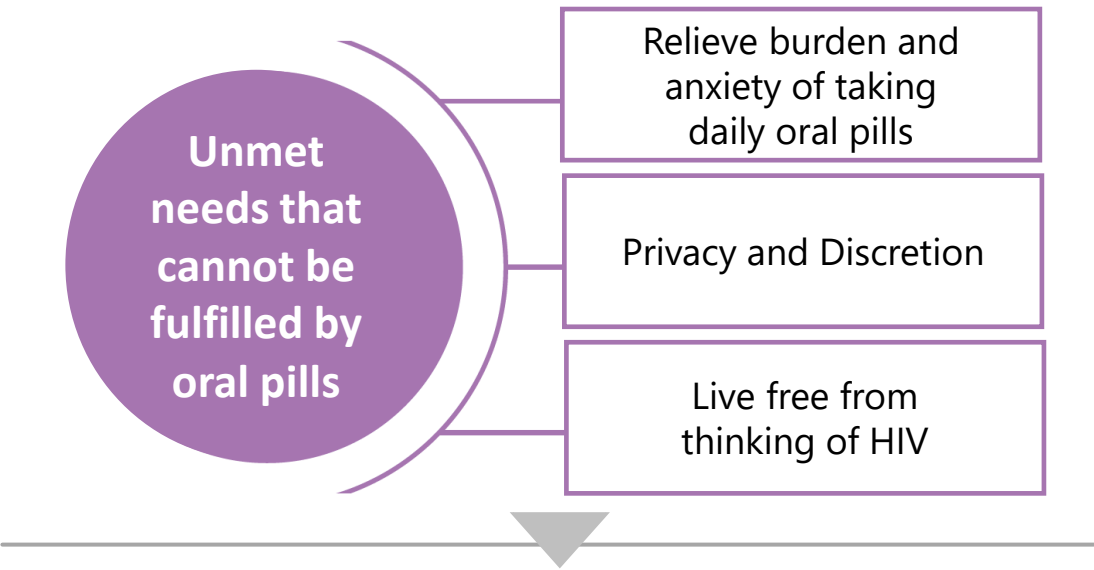


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# Progress of the Paradigm Shift of Anti-HIV Therapy: From Oral pills to the Era of Long-Acting Formulations

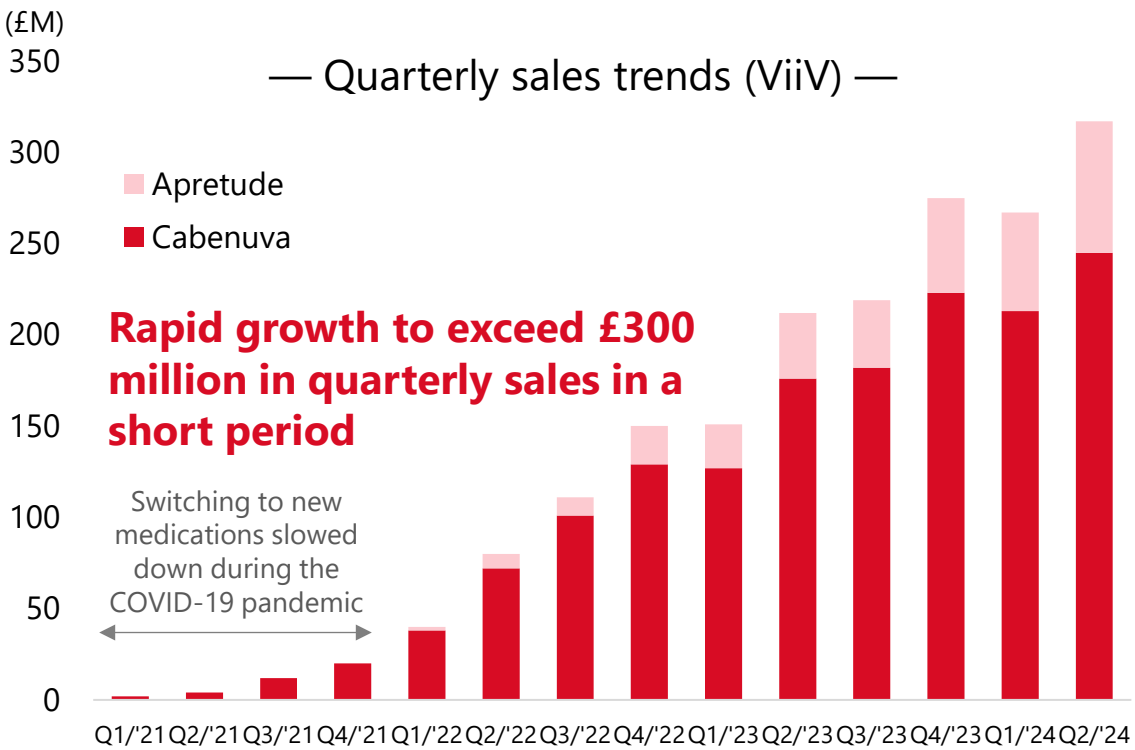
Addressing the unmet needs of people living with HIV (PLHIV) who aspire to achieve a quality of life comparable to healthy individuals

## Unmet needs in HIV treatment and PrEP for LA formulations



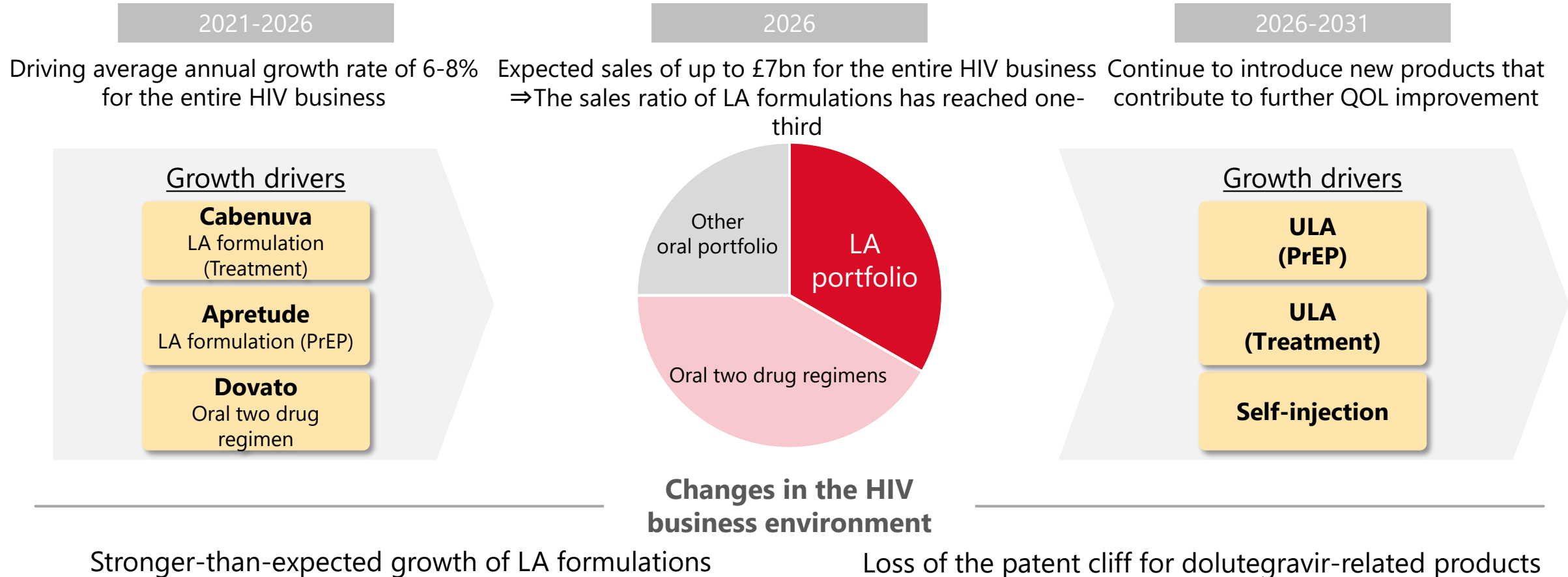
- **65.8%** of PLHIV\* are very interested in trying LA treatment\*<sup>2</sup>
- **86.6%** of doctors are likely to suggest LA treatment\*<sup>2</sup>

## Rise of LA formulations since launch



# Sustainable Growth Strategy by SHIONOGI and ViiV\*

**Achieving short- to mid- to long-term growth through the expansion of existing LA formulations<sup>2</sup> and the launch of ULA formulations<sup>3</sup>**



\* [Getting ahead of HIV with ViiV Healthcare management \(September 28, 2023\)](#) \*<sup>2</sup> Long Acting: Administration once every 1-2 months

\*<sup>3</sup> Ultra Long Acting: Administration once every 4-6 months

# Sustainable Growth Strategy by SHIONOGI and ViiV: Growth Strategy for 2026-2031

Drive further expansion of the LA formulation market through the launch of new products that meet diverse unmet needs

## Promising compounds (licensed from SHIONOGI to ViiV) and key milestones

### Cabotegravir\* (Integrase inhibitor)

- Developed the current LA formulation market
- Positive data on efficacy and safety in real-world clinical evidence has been accumulated

### S-365598\*2 (Novel integrase inhibitor)

- High potency
- Demonstrated an excellent resistance barrier and has a resistance profile different from existing drugs

	Duration	Key drugs	Combination candidates	CY2026	CY2027	CY2028-2030
ULA (PrEP)	Q4M	Cabotegravir*		<b>File and launch</b>		
	Q6M	S-365598*2 is candidate			Registrational study start	<b>File and launch</b>
ULA (Treatment)	Q4M	Cabotegravir*	Rilpivirine was selected		<b>File and launch</b>	
	Q6M	S-365598*2 is candidate	Candidates under consideration	Regimen selection and registrational study start		<b>File and launch</b>
Self-administered formulations (Treatment)	-	S-365598*2 is candidate	Candidates under consideration	Registrational study start		<b>File and launch</b>

Q4M: ULA formulation administered once every 4 months, Q6M: ULA formulation administered once every 6 months

\* Successful development of ULA formulations may extend patent protection period for cabotegravir for new LA medicines, formulations and regimens

\*2 [The third-generation integrase inhibitor \(development code: VH4524184\) licensed out by Shionogi to ViiV](#)

# Towards the Realization of the 2030 Vision

- Updates on HIV Business
- Updates on Acute Respiratory Infection Business
- Updates on New products and New businesses



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# Outlook for the Acute Respiratory Infection Business

**Strengthening the business model through “establishing a disease portfolio” and  
“promoting early diagnosis and early treatment”**

## Providing solutions for multiple diseases (Establishing a disease portfolio)

- COVID-19: Global expansion of ensitrelvir  
Accelerating the development of S-892216
- RSV infection: Accelerating the development of S-337395
- Influenza: enhancing the presence of the influenza family

## Promoting early diagnosis and early treatment

- Emphasizing the importance of early treatment with antiviral drugs
- Developing and providing convenient, affordable, and accurate diagnostic tests

SHIONOGI's Vision for Test to Treat

**Anywhere**



Not only in hospitals and clinics, but also at home, nursing homes, etc.

**Anytime**



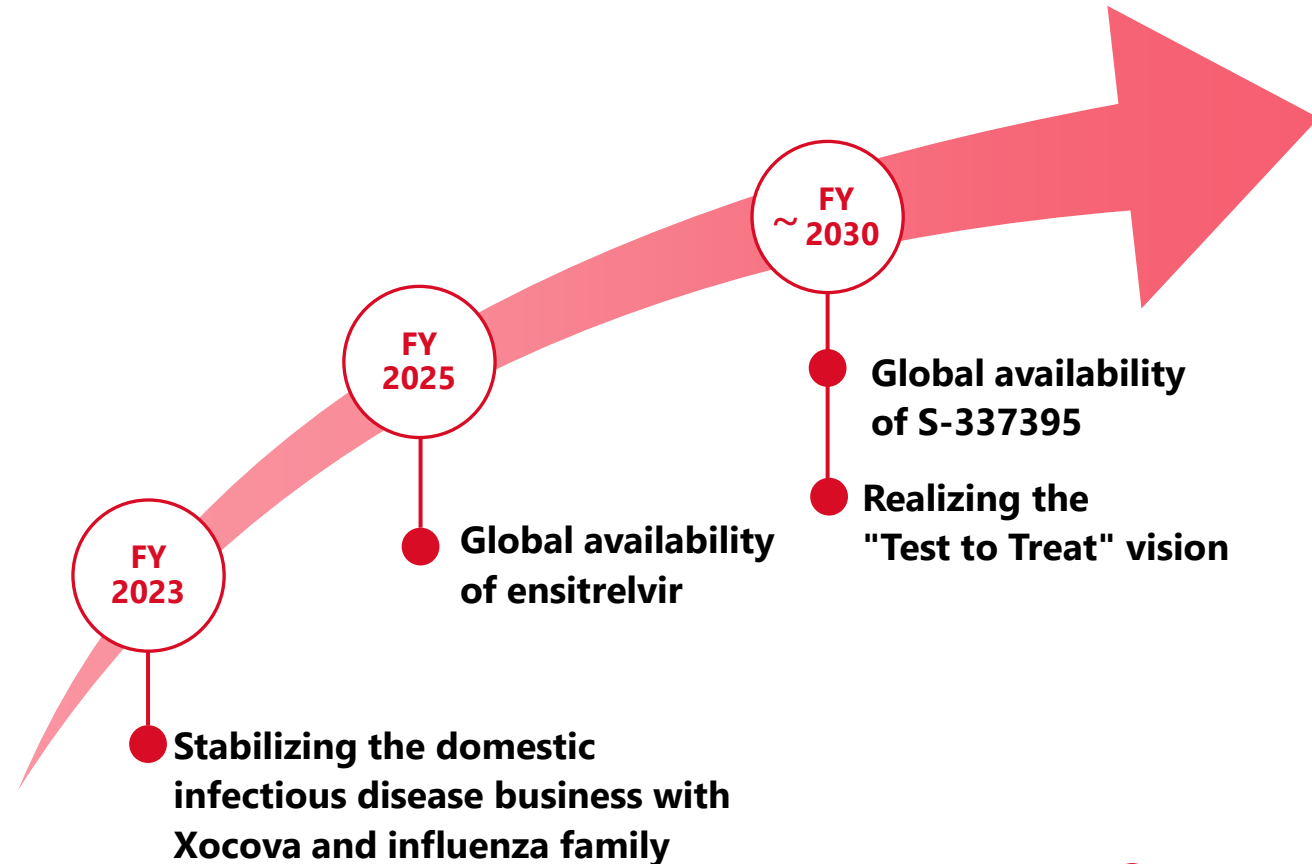
Take action immediately when you feel unwell

**Anyone**



Not limited to healthcare workers

Growth vision for the acute respiratory infection business



# COVID-19: Development Status of Ensitrelvir

**Conducting various clinical trials to drive further growth of ensitrelvir,  
including indications expansion and global development**

<b>SCORPIO-HR</b> (Global : Phase 3)	Assessment of efficacy in outpatients, including those with risk factors for severe illness	<b>Ongoing 6-month follow-up analysis for Long COVID</b>
<b>Pediatric trial</b> (Japan : Phase 3)	Safety and pharmacokinetics assessment in children	<b>Expected completion of enrollment by October 2024</b>
<b>SCORPIO-PEP</b> (Global : Phase 3)	Assessment of preventive effect of symptomatic SARS-CoV-2 infection in close contacts	<b>Ongoing analysis following enrollment completion</b>
<b>STRIVE trial</b> (Global : Phase 3)	Assessment of efficacy, including mortality prevention effect in hospitalized patients (conducted by NIH)	<b>Enrollment is scheduled to be completed in the first half of FY2025</b>
<b>Long COVID</b> (Investigator-initiated trials )	Assessment of preventive efficacy for Long COVID and safety	<b>Collaborative research in progress with Osaka University</b>

▶ Currently in discussions with regulatory authorities, including the FDA and EMA, to apply for approval

# Influenza: Enhancing the Presence of Xofluza

Providing a new value of antiviral drugs, 'transmission suppression\*  
as a 'single-dose oral medication' that many patients desire.



Rapid virus elimination

Time to virus elimination  
**24 hours (median)**

**Time to cessation of virus shedding\*2**

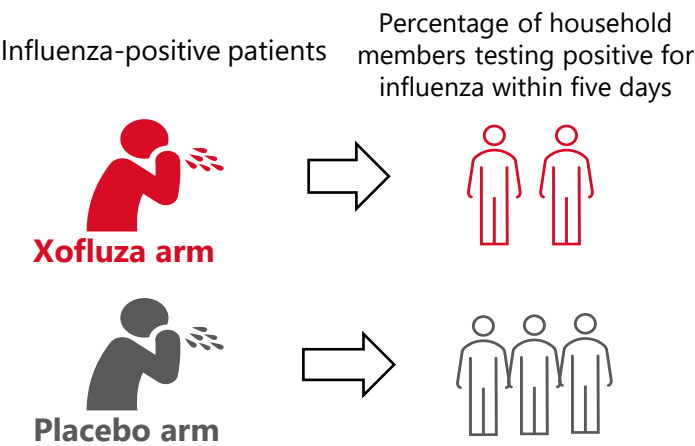
Significantly shortened the duration of infectious viral shedding compared to placebo, and reduced the time to symptom improvement by 'approximately one day'.



Transmission suppression\*

Reduced risk of infection  
by **29%**

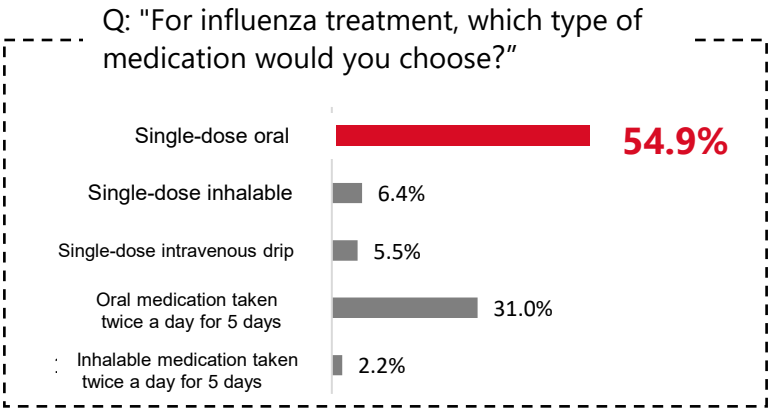
**Phase3 trial\*3 (Transmission Suppression)**



Complete treatment with  
a single oral dose

Chose single-dose oral medication  
more than **50%**

**Survey Results for General Public\*4**



\* Transmission suppression: Preventing the spread of the virus to others \*2 Based on CAPSTONE-1 trial results \*3 CENTERSTONE study  
\*4 iBRIDGE Corporation. 「Survey about your health : Conducted in May 2024

# Towards the Realization of the 2030 Vision

- Updates on HIV Business
- Updates on Acute Respiratory Infection Business
- Updates on New products and New businesses



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# SHIONOGI's COVID-19 Vaccine Portfolio

**Promoting the vaccine business through both platform establishment※ and universal vaccine development**

Project	Antigen	Status	Remarks
COVGOZE	Wuhan	<b>Approval</b> (FY2024 1Q )	-
S-268023	XBB1.5	<b>Primary endpoint* not achieved</b> (FY2024 2Q)	Follow-up data currently being collected (evaluation of persistence of neutralizing antibody titers)
S-268024	JN.1	<b>Phase 3 in preparation</b> (FY2024 4Q)	We are currently conducting the manufacturing, process validation, and preclinical trials of the investigational drug
S-567123	Sarbecovirus (Universal vaccine)	<b>Phase 1 in preparation</b> (FY2024 4Q)	We are currently conducting clinical trial design under consideration and preclinical trials of the investigational drug

※ Platform

For vaccines that have been established as a platform, if there is a commitment to obtain data on quality, efficacy, safety, and immunogenicity after marketing, it is possible to apply for a complete change to the current recommended strain with the latest quality and preclinical test results

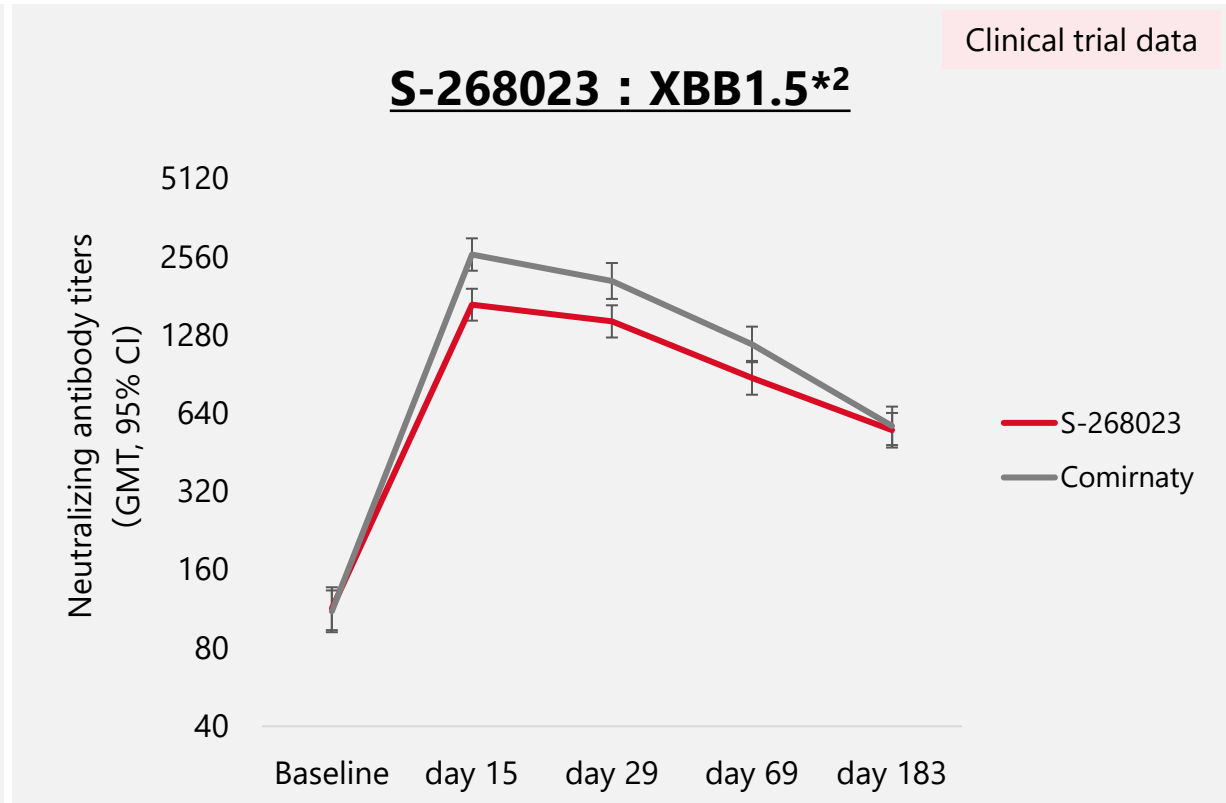
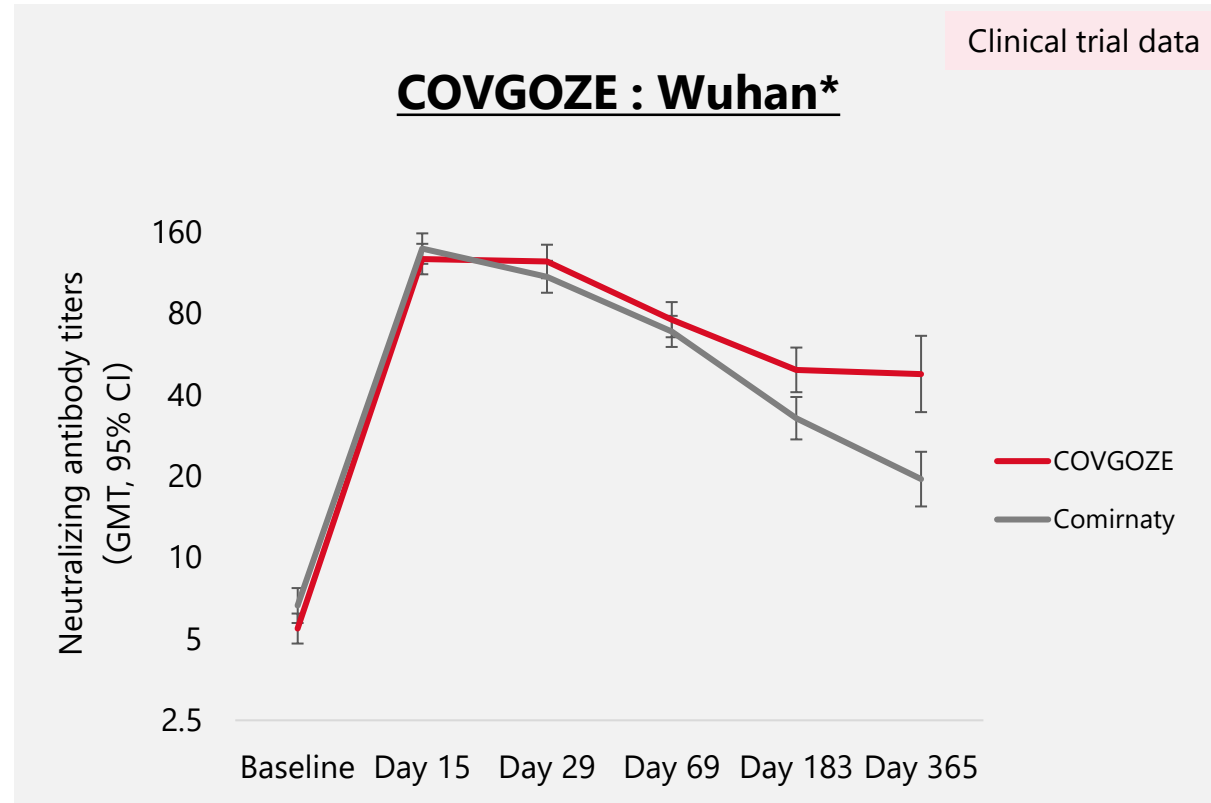
\* Geometric mean titer of neutralizing activity and antibody response rate against the XBB.1.5 strain on Day 29 after vaccination



# Towards the Realization of a Vaccine Platform

## - Characteristics of SHIONOGI's First Vaccine -

**Over a period of six months to one year, the neutralizing antibody titers remained high compared to pre-vaccination levels**



\* The S-268019 additional immunization comparative trial for individuals who have received two doses of Comirnaty intramuscular injection (Data presented at the joint conference of the 97th Annual Meeting of the Japanese Society of Infectious Diseases, the Academic Lecture Meeting, and the 71st Academic Meeting of the Japanese Society of Chemotherapy in 2023). Additionally, this study is supported by AMED under the project number JP21nf0101626 and by the Ministry of Health, Labour and Welfare / Regarding additional immunization, COVGOZE is not yet approved

\*2 Evaluation of the safety and clinical efficacy of S-268023 in subjects aged 20 years and older who have completed initial immunization, and verification of non-inferiority to Comirnaty RTU intramuscular injection (monovalent: XBB.1.5). This study is supported by AMED under project number JP21nf0101626, as well as by the Ministry of Health, Labour and Welfare.

# Towards the Realization of a Vaccine Platform: Future Strategies

Aiming to establish a platform as a vaccine expected to induce neutralizing antibodies over the course of one year

**Clinical trials using the JN.1 strain will commence**  
(scheduled for FY2024 4Q)

## Considering the design of clinical trials

- Clinical trials of S-268023 (XBB1.5 strain).
  - Comparison with mRNA vaccines as control drugs\*
- **Clinical trials of S-268024 (JN.1 strain)**
  - Based on the principles stipulated in the guidelines, **the same modality vaccine will be selected as the control drug**

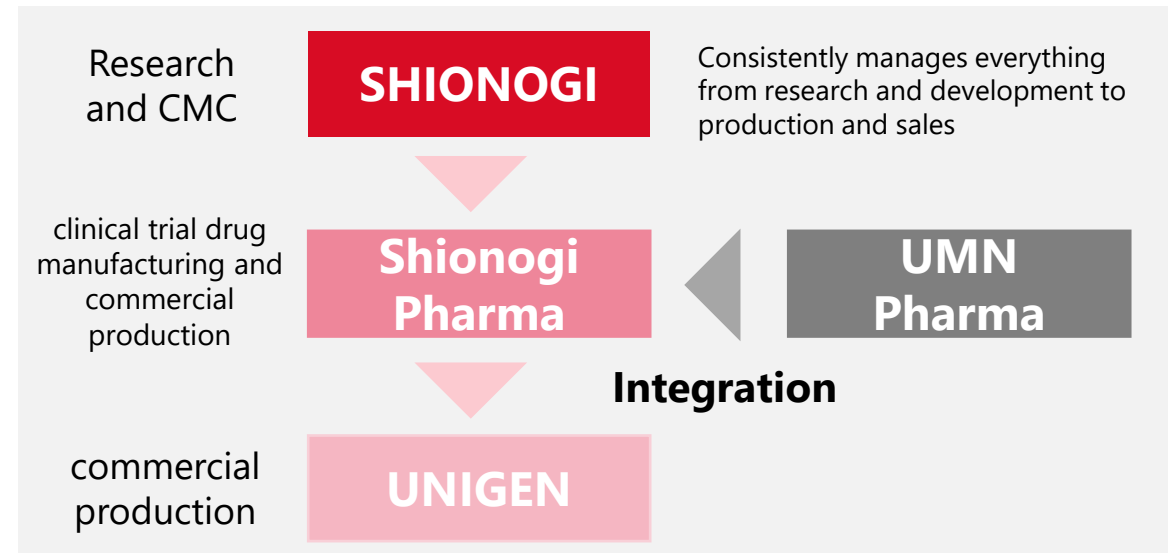
## Expectation of sustained neutralizing antibody titers

- Given that the regular vaccination interval for the COVID-19 vaccine is one year, the trend of neutralizing antibody titers over one year is important

\* In clinical trials of S-268023, no vaccines of this modality have been approved in Japan, so mRNA was used as a control drug for comparison

## Centralizing vaccine production functions

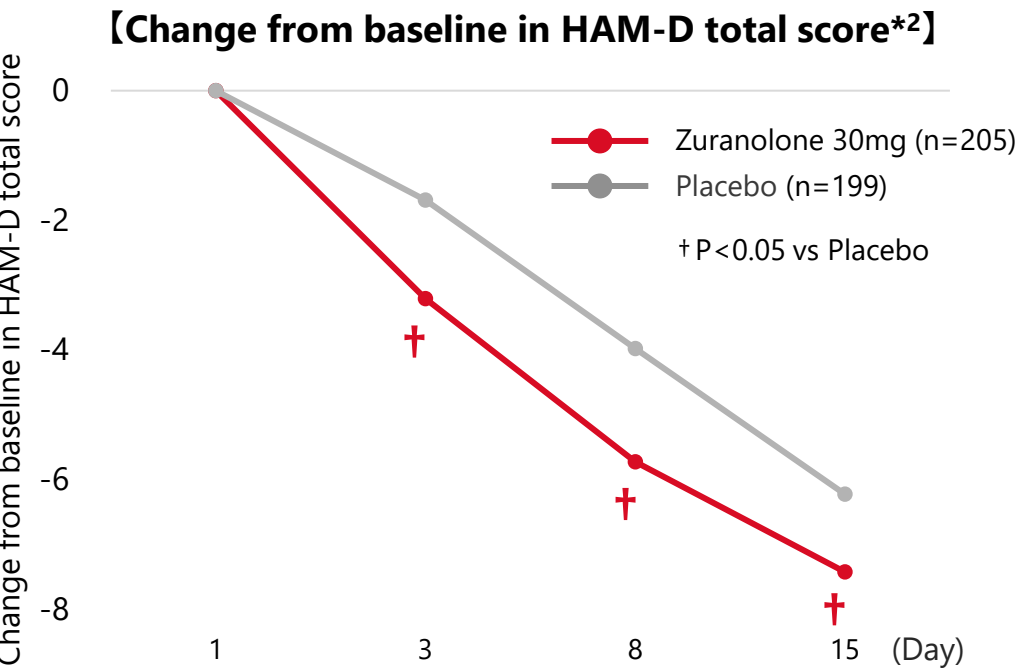
- Establish new Vaccine Business Division (from April 2024)
- UMN Pharma's production functions will be integrated into Shionogi Pharma (scheduled April 2025 )



# Zuranolone: New Drug Application (NDA) in Japan for Major Depressive Disorder

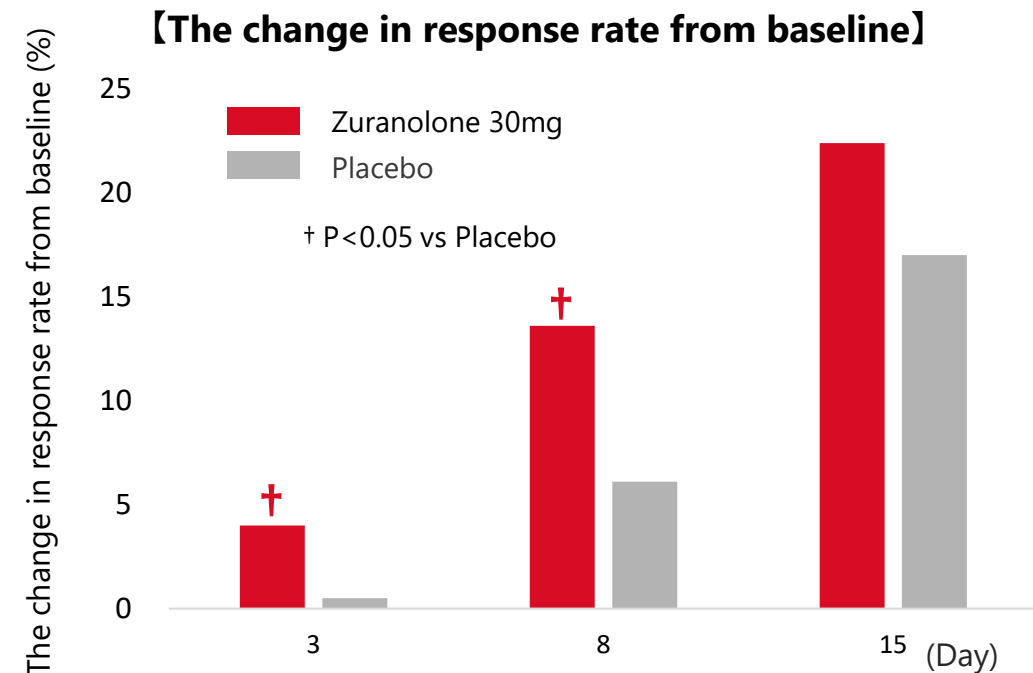
Based on favorable clinical trial results, submitted NDA in Japan\*

## Results from Phase 3 validation study



**Achieved the primary endpoint and confirmed the rapid onset of action of zuranolone**

Primary endpoint: Change from baseline in the total HAM-D17 score\*<sup>2</sup> on Day 15  
Response rate: The percentage of patients whose total HAM-D score\*<sup>2</sup> improved by 50% or more from baseline  
Overview of the Phase 3 validation study design: [Please refer to appendix p.49](#)



**Observed favorable results in the response rate, a measure of antidepressant efficacy**



# Zuranolone: Unmet Needs in Antidepressant Treatment and Characteristics of Zuranolone

**As a new treatment option, aim to become "a novel therapy, rapid acting therapy for the acute treatment\* of depression"**

## Key unmet needs in antidepressant treatment

### The onset of effect can be slow

- Many antidepressants take 6 to 8 weeks to show effects

### Low pharmacotherapy response rate

- Discontinuation of administration due to insufficient efficacy or the occurrence of side effects



## Characteristics of the novel antidepressant zuranolone



### Rapid onset

- Start to show its effects from Day 3 (after taking the medication twice)



### Ease of use

- No dose adjustment required, and administration is completed in two weeks
- Post-treatment management can be flexibly determined based on symptoms and shared decision-making (SDM)\*<sup>2</sup>



### Safety

- Demonstrated good tolerability
- Results from the observation period of up to 52 weeks showed no dependency

\* Acute phase of depression: From the start of treatment after diagnosis to remission (disappearance of depressive symptoms) (Source: Depression Treatment Guidelines, Key Points of Depression Treatment-10)

<sup>\*2</sup> The process in which healthcare professionals and patients share scientific evidence and, while considering the patient's preferences and values, determine the best treatment method

# 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			Analyzing the 6-month follow-up for Long COVID
	Ensitrelvir	COVID-19 (Pediatric)	Phase 3	Complete enrollment (FY24 2Q) → Phase 3 topline results (FY24 4Q)		Registration expected to be completed: October 2024
	Ensitrelvir	COVID-19 (prevention)	Phase 3	Complete enrollment (FY24 2Q) → Phase 3 topline results (FY24 3Q)		Recruitment completed and under analysis
	S-892216	COVID-19	Phase 1	Phase 2 start (FY24 4Q) → Topline results (FY25 3Q)		
COVID-19 vaccines	COVGOZE (S-268019)	COVID-19 (Wuhan, Vaccine)	Approval			
	S-268023	COVID-19 (XBB1.5,Vaccine)	Phase 3			Phase 3 interim analysis completed
	S-268024	COVID-19 (JN.1, Vaccine)	Preclinical	Phase 2 start (FY24 4Q) → Topline results (FY25 2Q)		
	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)		Received Fast Track designation from the FDA: October 2024
	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)		Achieved FPI for Combination Phase 1: September 2024

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

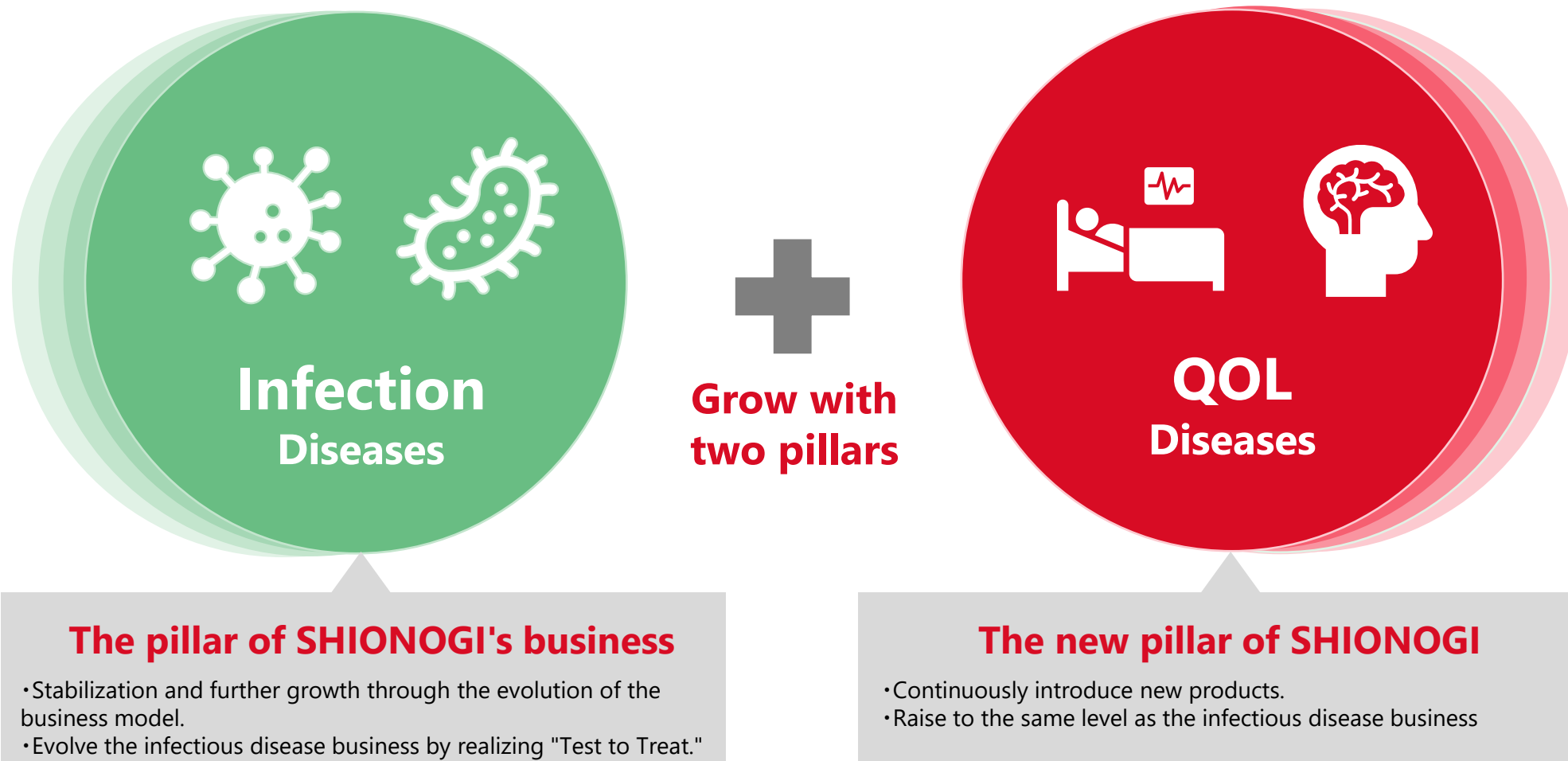
※ The bar starts from FPI and ends at CSR, Topline results: It is the timing of acquisition, and the timing of disclosure will be considered separately

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)	Submitted in Japan : September 2024
	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)	
	Redasemtide	Acute ischemic stroke	Phase 2b			
		Dystrophic epidermolysis bullosa	Phase 2			
	S-309309	Obesity	Phase 2	Considering future development strategies		
	S-600918 + Drug X	Sleep apnea syndrome	Phase 2	Phase 2 start (FY24 3Q)	Phase 2 topline (FY25 3Q)	IND application* in US : October 2024
	S-531011	Solid tumor	Phase 1b/2	Phase 2 part start (FY24 2Q)		Achieved FPI in Phase 2 part : September 2024
	S-151128	Chronic pain	Phase 1b	Phase 1b topline (FY24 2Q)		
	S-606001	Pompe	Phase 1		Phase 2 start (FY25 1Q)	

# SHIONOGI will Grow with the Two Pillars of Infectious Diseases and QOL Diseases

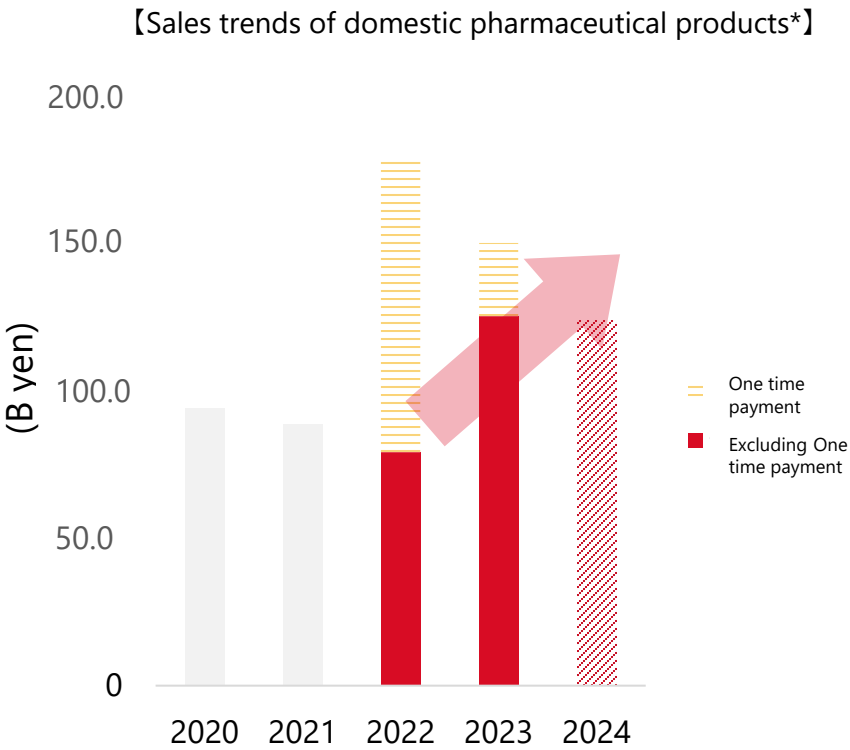
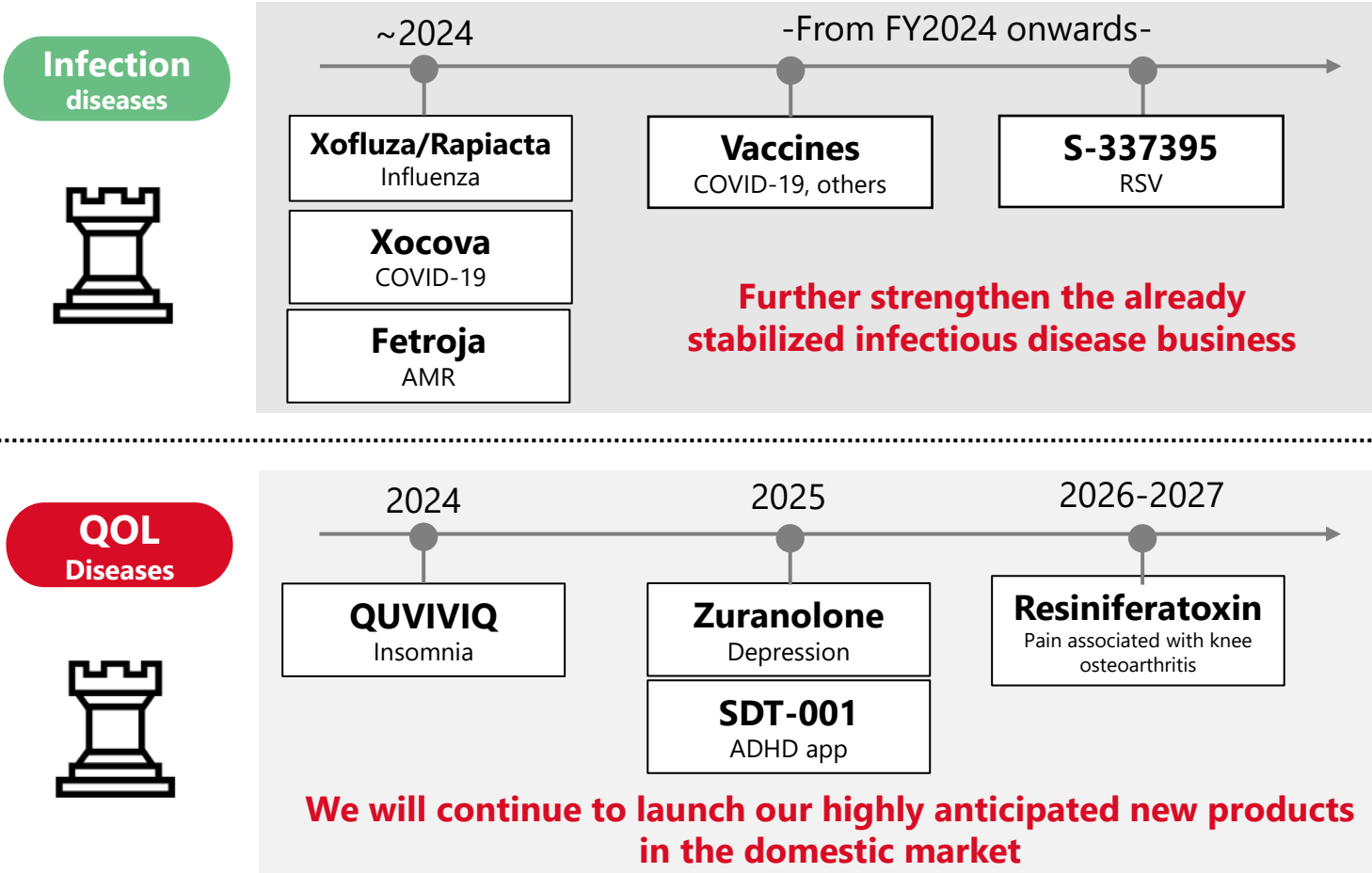
**In addition to the stable growth of its infectious disease business, SHIONOGI is seriously committed to tackling QOL diseases**

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# Future of Prescription Drugs in Japan

By establishing the two pillars of "infectious diseases" and "QOL diseases,"  
the domestic business will transition to a growth phase

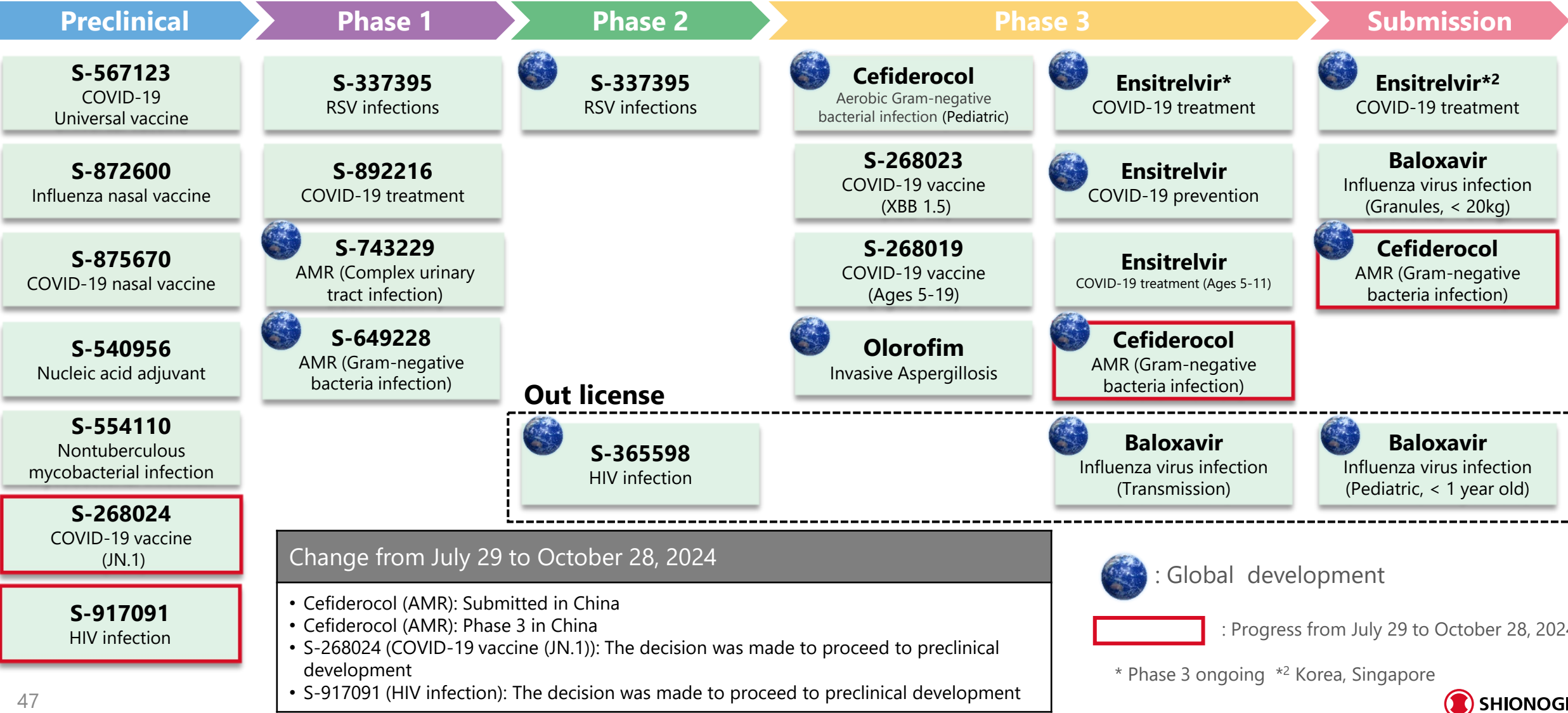


domestic business will transition to a growth phase

# Appendix

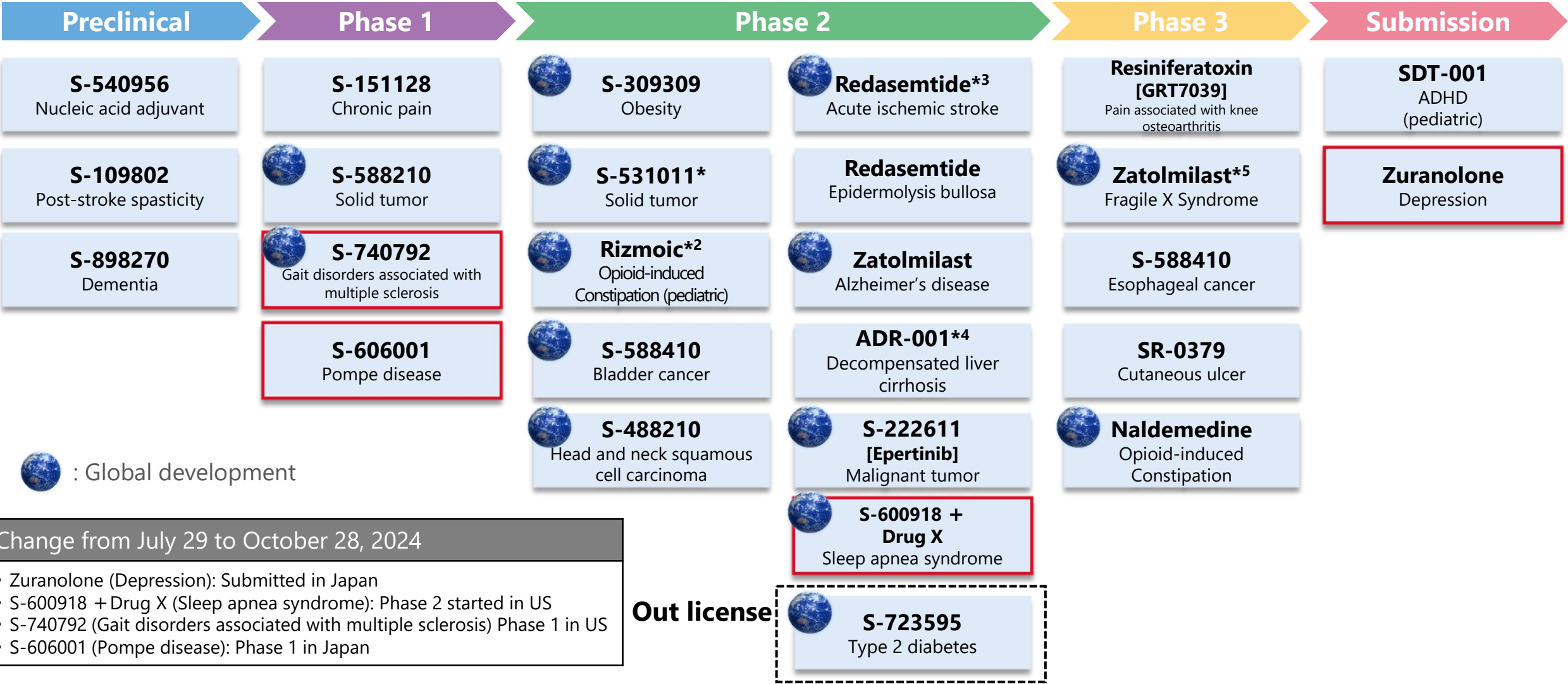
# Pipeline: Infectious Disease

as of October 28



# Pipeline: QOL Diseases with High Social Impact

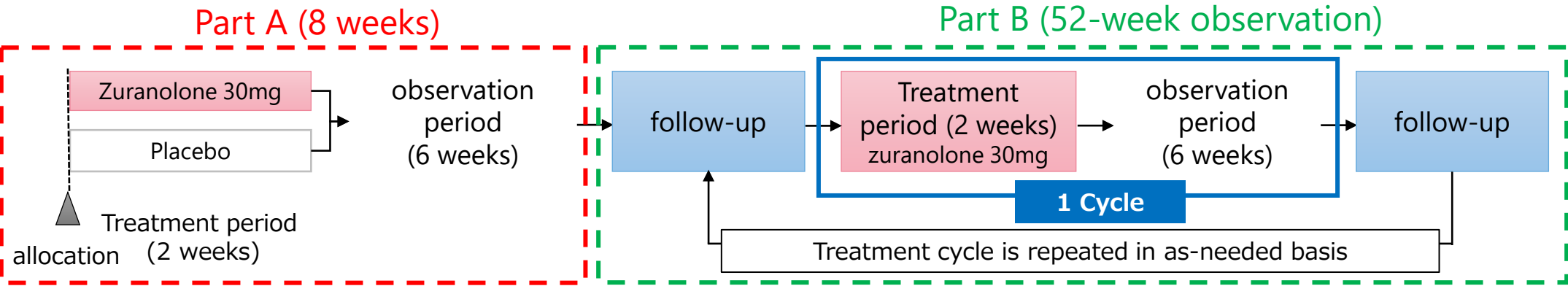
as of October 28





# Phase 3 Validation Study Design

Subject	Patients with moderate to severe major depressive disorder
Purpose	[Part A] Examination of superiority of Zuranolone over placebo [Part B] Examination of safety and tolerability of re-administration when necessary
Primary endpoint	Change from baseline in the total HAM-D17 score on Day 15
Dosing group	[Part A] A multicenter, randomized, double-blind, placebo-controlled, parallel-group trial [Part B] Multicenter, open label
Sample size	Zuranolone 30mg group, placebo group
Dose administration	[Targets] 200 in each group, 400 in total, [Result] 412



# 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<sup>\*</sup>

- **July**
  - Conclusion of a comprehensive collaboration agreement with Deloitte Tohmatsu Cyber LLC in the field of cybersecurity
- **September**
  - Published the Integrated Report 2024
- **October**
  - Signed a basic agreement with OKUSHIN SYSTEM Co., Ltd., Kaien Co., Ltd., and Daikin Sunrise Settsu Co., Ltd. aimed at enhancing initiatives to understand disabilities in the workplace

# 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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