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

October 28, 2024

Shionogi & Co., Ltd.

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Agenda

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

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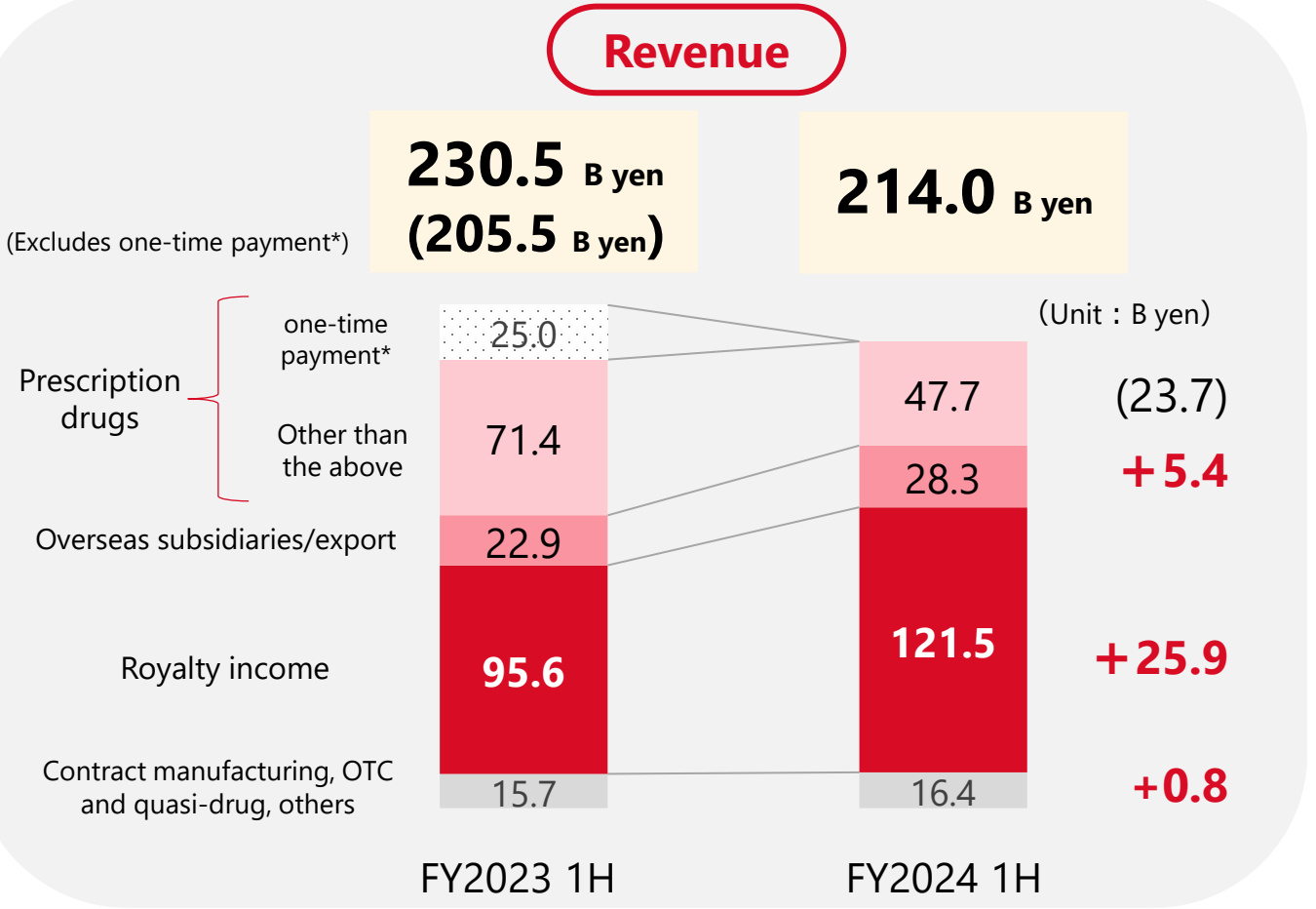
Overview of 1st Half (Interim period)
FY2024 Financial Results

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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**

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



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

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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	
	Forecasts		1H results	Achievement (%)	1H results	Change (%)	Change
	Full year	1H					
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)**
Profit before tax	200.0	82.5	**93.8**	**113.7%**	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)**
EBITDA*	-	-	**86.7**	**-**	114.2	**(24.1)**	**(27.5)**

Exchange Rate (Average)

	FY2024 Forecast	FY2024 1H Results
USD($) – JPY(¥)	145	152.78
GBP(£) – JPY(¥)	178	195.57
EUR(€) – JPY(¥)	155	166.06

* Earnings Before Interest, Taxes, Depreciation, and Amortization: Operating profit added depreciation and adjusted for one-time factors (impairment losses, gain on sale of property, plant and equipment, etc.)

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Statement of Profit or Loss

(Unit：B yen)

	Forecast		FY2024		FY2023	Y on Y	
	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
- 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 ※

※ Factors that occurred last fiscal year

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Revenue by Segment

(Unit：B yen)

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

Royalty income

Increase

- Strong sales of ViiV's HIV franchise

※ Factors that occurred last fiscal year

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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

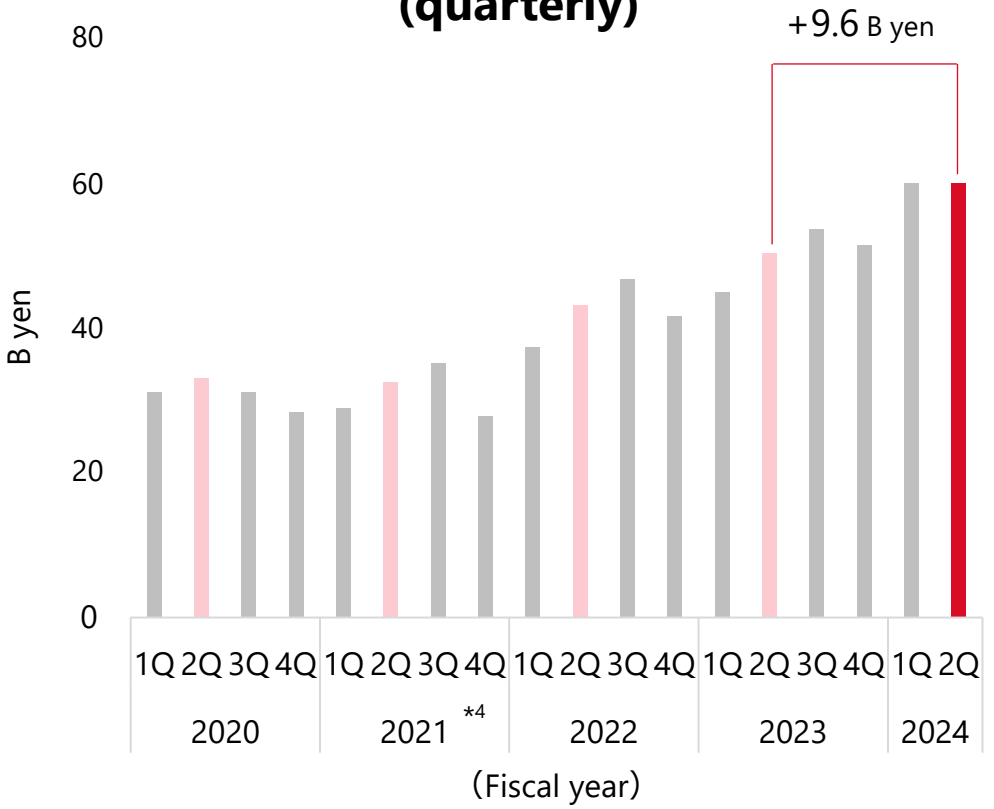
* Including temporary income from transfer of ADHD drugs

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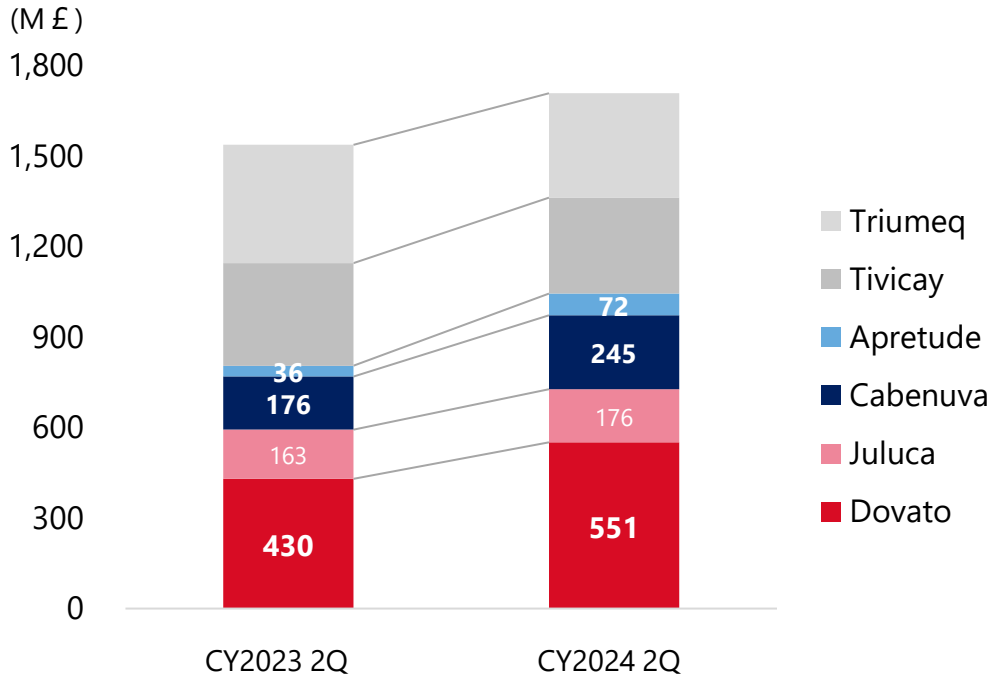
Expansion of the HIV Business

Continued stable growth each quarter, centered on the growth of oral two drug regimens* and LA formulations*2

Transition of SHIONOGI's HIV royalty income (quarterly)



Sales of ViiV's dolutegravir and cabotegravir products*3



LA formulations: Continued strong growth (YoY +49.5%)

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

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

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Expansion of Overseas Business

Steady growth in overseas business, centered on Cefiderocol

Sales revenue of overseas subsidiaries/exports (quarterly)



・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

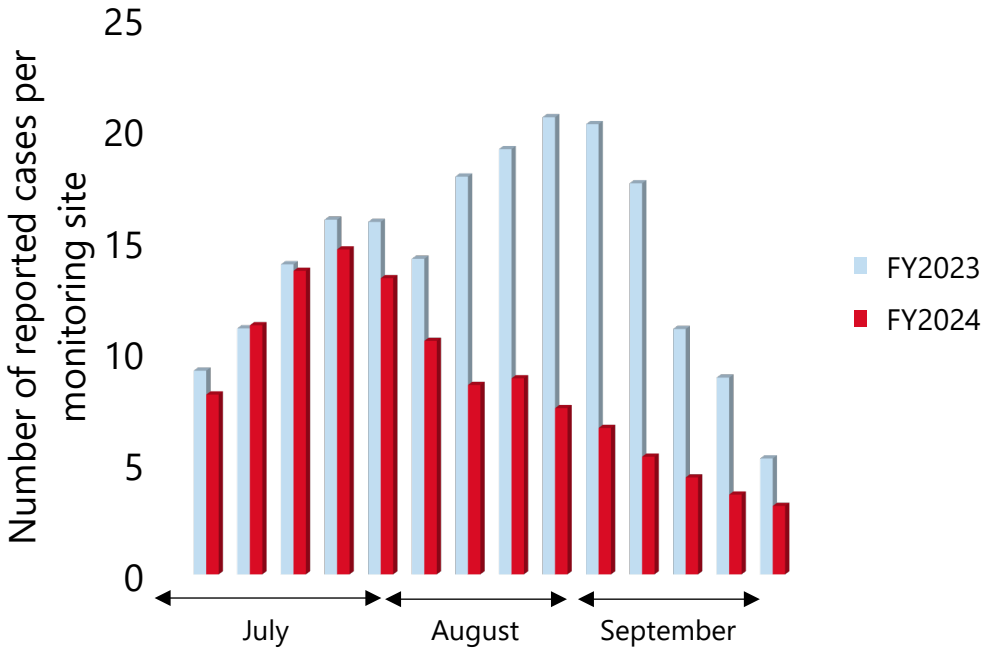
* PROVE Study (Infectious Disease Week 2024)

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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

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Summary 1H FY2024 Financial Results

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

HIV and overseas 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, overseas business and domestic business**

- **Increase in HIV royalty income**
  - Strong sales of HIV franchise by ViiV
  - Assuming an increase in the 2H based on 1H performance
- **Increse 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**

* For details, please refer to P. 21-23

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	Forecasts	Revised	Revised amount
Revenue	4,550	4,600	**50**	435.1	**5.7%**	**24.9**
Operating profit	1,600	1,650	**50**	153.3	**7.6%**	**11.7**
Profit before tax	2,000	2,060	**60**	198.3	**3.9%**	**7.7**
Profit attributable to owners of parent	1,630	1,710	**80**	162.0	**5.5%**	**9.0**

FY2024 Exchange Rate (Average)

	Forecast	1H Results	Forecast Change
USD($) – JPY(¥)	145	152.78	**148**
GBP(£) – JPY(¥)	178	195.57	**190**
EUR(€) – JPY(¥)	155	166.06	**161**

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 66.0	14.6 **67.0**	**1.0**	37.5	**36.9**	**(0.6)**	13.2 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	49.8 226.5	48.9 **225.0**	**(1.5)**	115.5	**118.3**	**2.8**	47.4 206.0	9.2	19.0
Selling, general & administrative expenses	23.4 106.5	23.7 **109.0**	**2.5**	54.5	**59.1**	**4.6**	23.8 103.4	5.4	5.6
R&D expenses	26.4 120.0	25.2 **116.0**	**(4.0)**	61.0	**59.2**	**(1.8)**	23.6 102.6	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	35.2 160.0	35.9 **165.0**	**5.0**	91.0	**89.1**	**(1.9)**	35.2 153.3	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	44.0 200.0	44.8 **206.0**	**6.0**	117.5	**112.2**	**(5.3)**	45.6 198.3	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
Infectious disease drugs	91.2	**83.4**	**(7.8)**	**53.5**	**54.1**	**0.6**	82.9	**0.5**	**0.4**
COVID-19 related products + Influenza franchise	80.1	**72.3**	**(7.8)**	**47.4**	**47.4**	**0.1**	73.4	**(1.5)**	**(1.1)**
Symproic	6.5	**5.9**	**(0.6)**	**3.6**	**3.5**	**(0.1)**	4.5	**30.7**	**1.4**
OxyContin franchise	5.0	**5.0**	**-**	**2.7**	**2.9**	**0.3**	4.2	**20.4**	**0.8**
Actair	1.4	**1.3**	**(0.1)**	**0.9**	**0.9**	**0.0**	0.7	**86.1**	**0.6**
Cymbalta	3.3	**3.3**	**-**	**1.5**	**1.8**	**0.4**	3.8	**(13.7)**	**(0.5)**
Others	27.5	**25.8**	**(1.7)**	**14.8**	**13.7**	**(1.1)**	55.0*	**(53.0)**	**(29.1)**
QUVIVIQ	1.6	**3.0**	**1.4**	1.6	**3.0**	**1.4**	-	-	-
Prescription drugs	134.9	**124.7**	**(10.2)**	**76.9**	**77.0**	**0.1**	151.1	**(17.5)**	**(26.4)**

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

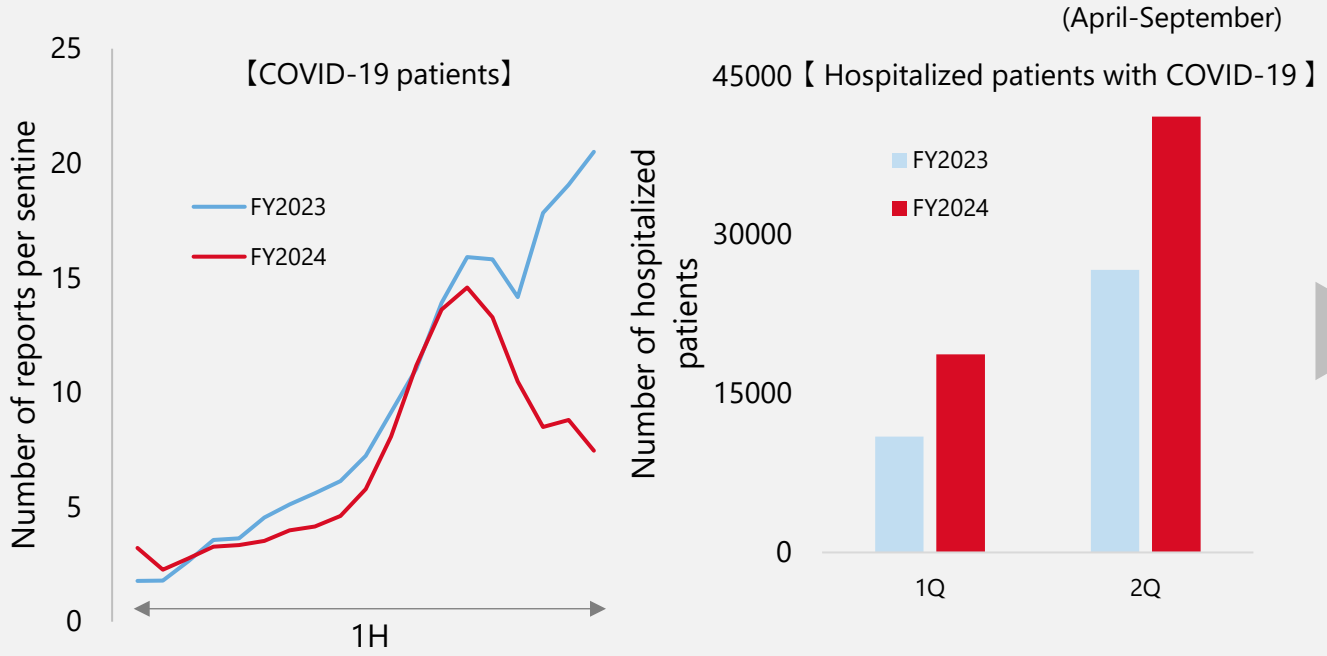
* Including temporary income from transfer of ADHD drugs

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

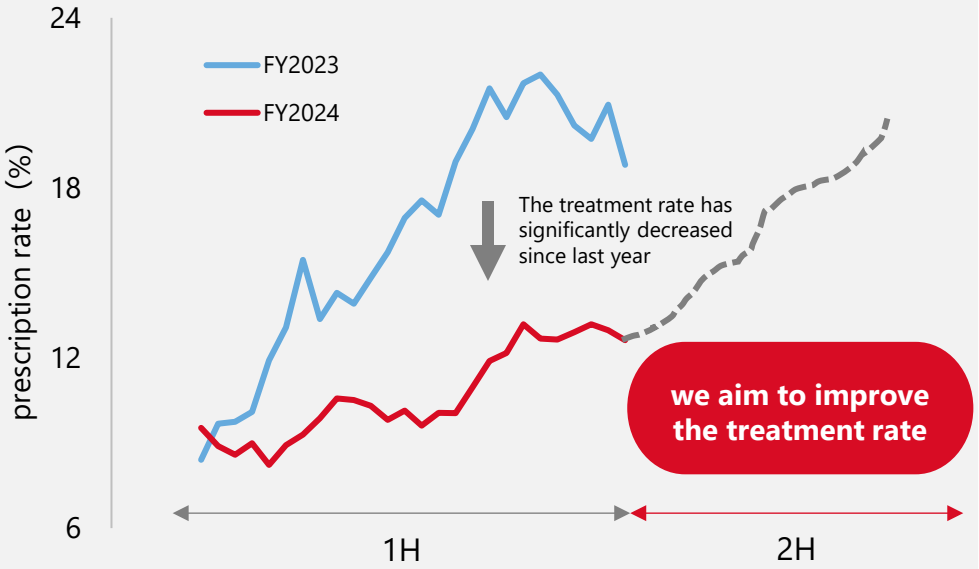
As a leading company in infectious diseases,
aiming to improve the treatment rate for people suffering from COVID-19

Trends in COVID-19 patients and hospitalized patients*



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

*2 Quoted from JAMDAS

* After changing the status of COVID-19 to Category 5 infectious disease Press materials about new-style coronavirus infectious disease |Ministry of Health, Labour and Welfare

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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

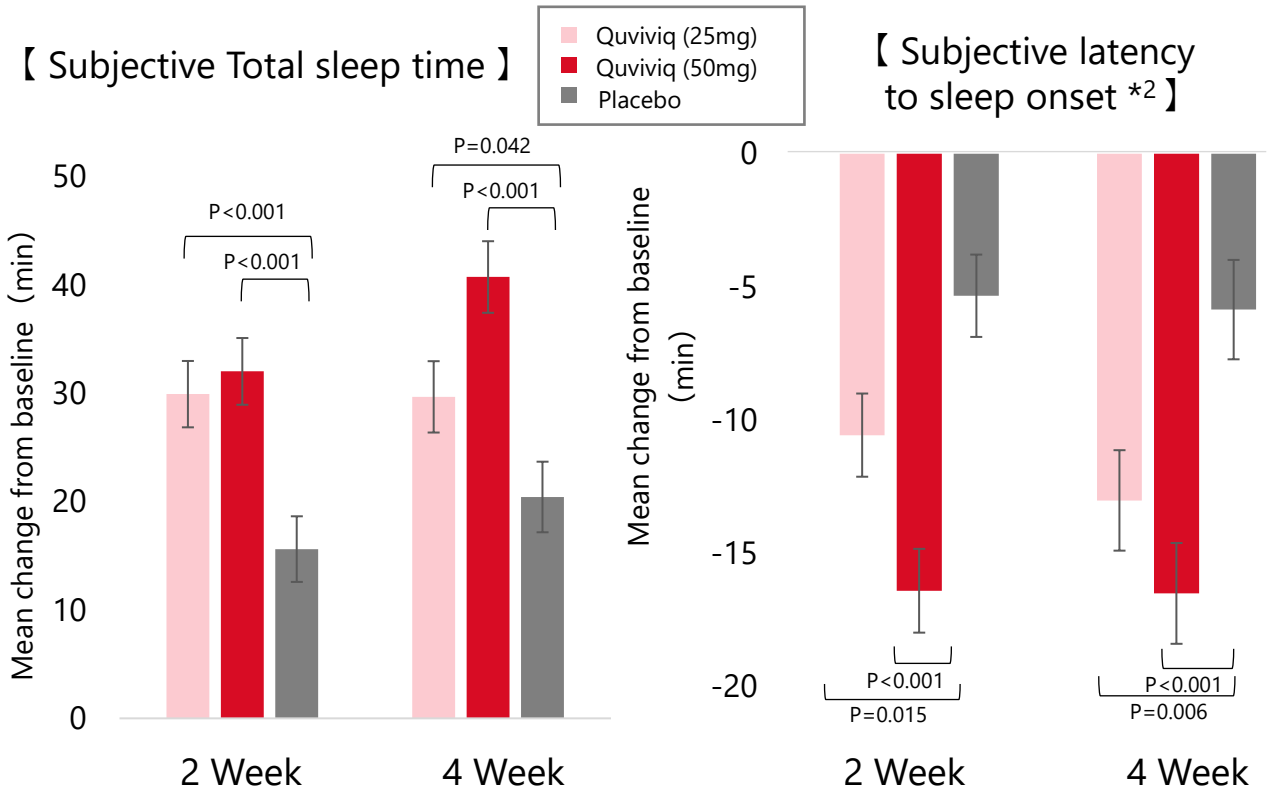
~ 2023		2024
Symproic OIC*	**Actair** House dust mite allergic rhinitis	**QUVIVIQ** Insomnia
OxyContin franchise Pain	**Cymbalta** Depression	Mechanism：DORA*2

* Opioid-induced constipation *2 DORA : Dual Orexin Receptor Antagonist

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

* Discovered by Idorsia *3 Time from lights out or bedtime to sleep onset

*2 Conducted by Nxera Pharma Japan and Mochida pharmaceutical: Data cited from the Articles (Sleep Medicine 122 (2024) 27-34) and created by SHIONOGI

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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*2

* ESRS Home | European Sleep Research Society *2 Lancet Neurol 2022; 21: 125–39.

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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

Nxera

MOCHIDA PHARMACEUTICAL CO., LTD.

SHIONOGI

Sold through Two Channels

New Sales Scheme

SHIONOGI

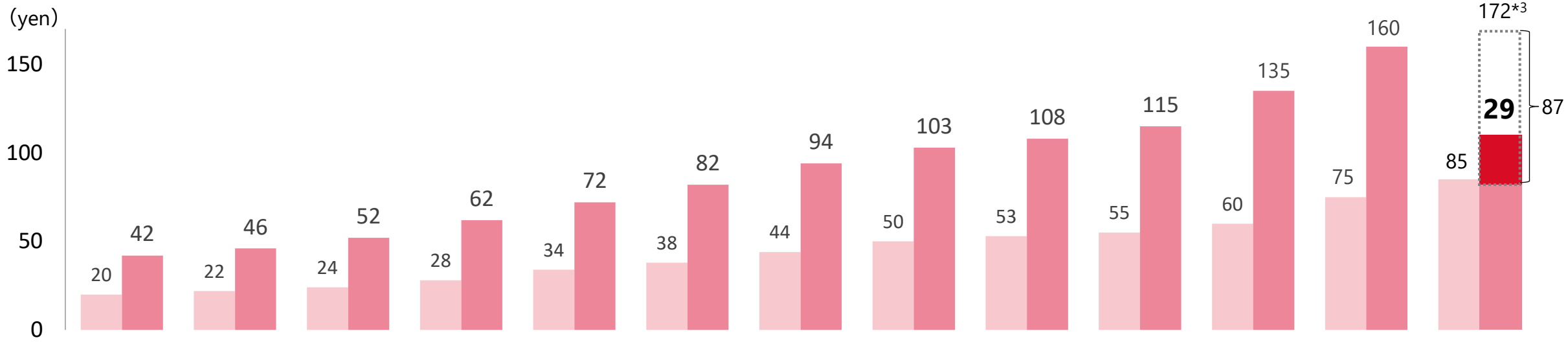
SHIONOGI to Exclusively Handle Distribution and Sales Activities in Japan

Shareholder Return

SHIONOGI

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



FY		12	13	14	15	16	17	18	19	20	21	22	23	24
Treasury stocks	Buyback	-	-	30 B yen	-	35 B yen	29.4 B yen	50 B yen	50 B yen	50 B yen	-	49.4 B yen	75 B yen	-
	Cancelation	-	-	-	-	22 M shares	5 M shares	7.35 M shares	5.2 M shares*	-	-	4.2 M shares	10.84 M Shares*2	-
DOE (%)		3.7	3.5	3.7	4.1	4.5	4.6	4.6	4.0	4.1	3.8	3.9	4.0	4.0 (expected)
ROE (%)		17.5	9.2	9.4	13.6	16.3	19.4	20.9	15.5	13.9	12.5	17.8	13.9	13.0 over (expected)

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

Values calculated based on IFRS after 2019

*2 Resolution passed on July 31, 2023, and treasure shares cancelled on April 17, 2024 *3 Providing figures that do not take stock splits into account

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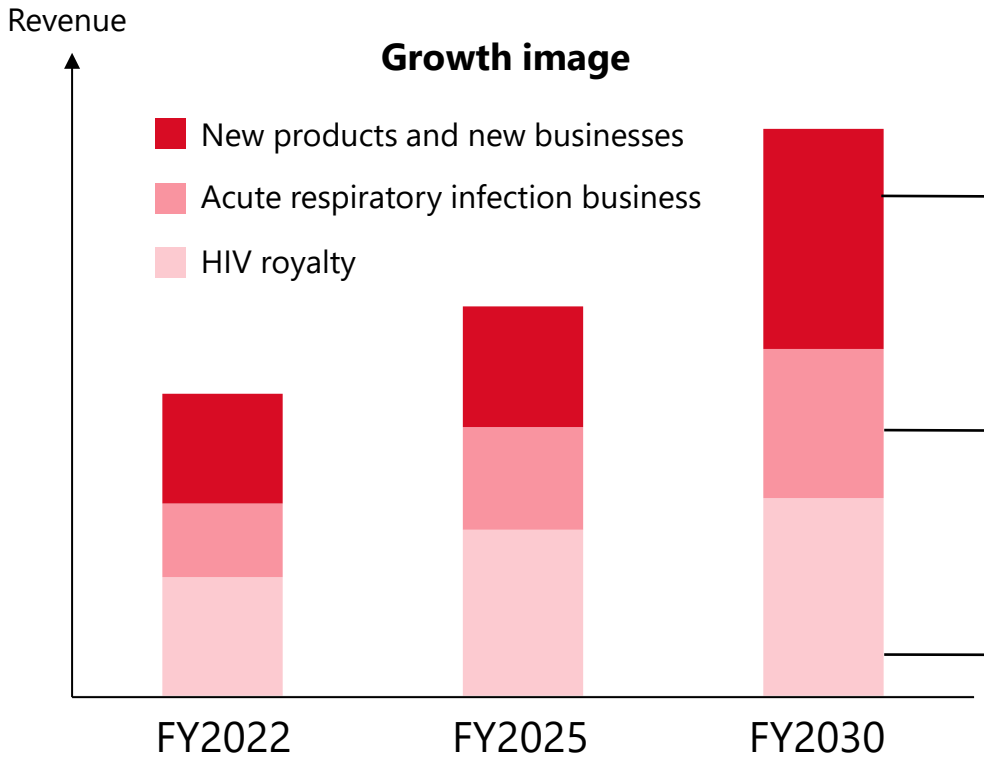
Towards the Realization of the 2030 Vision

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)**



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

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Towards the Realization of the 2030 Vision

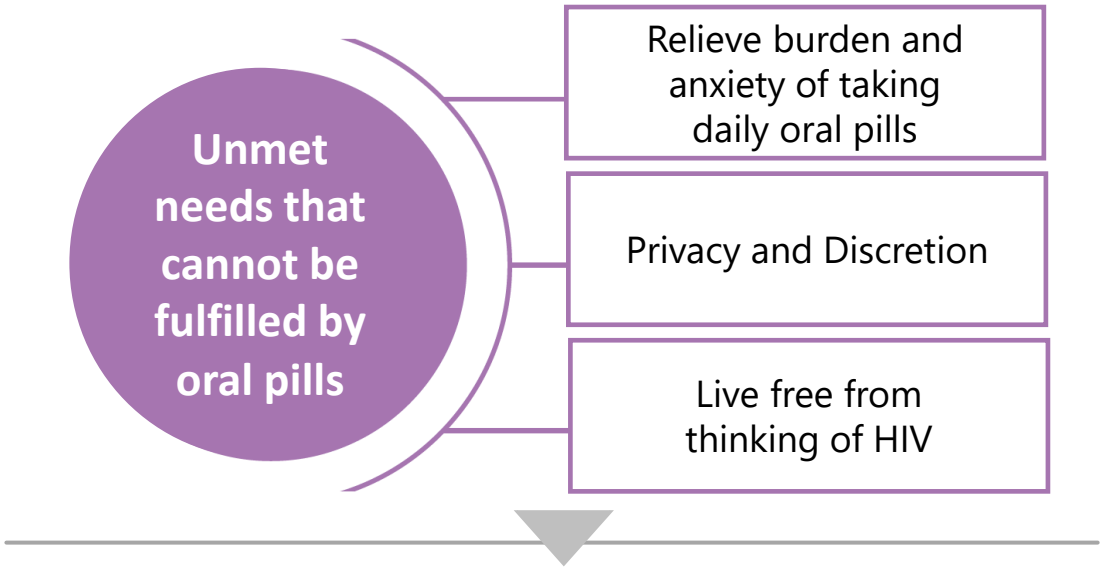
- Updates on HIV Business
- Updates on Acute Respiratory Infection Business
- Updates on New products and New businesses

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

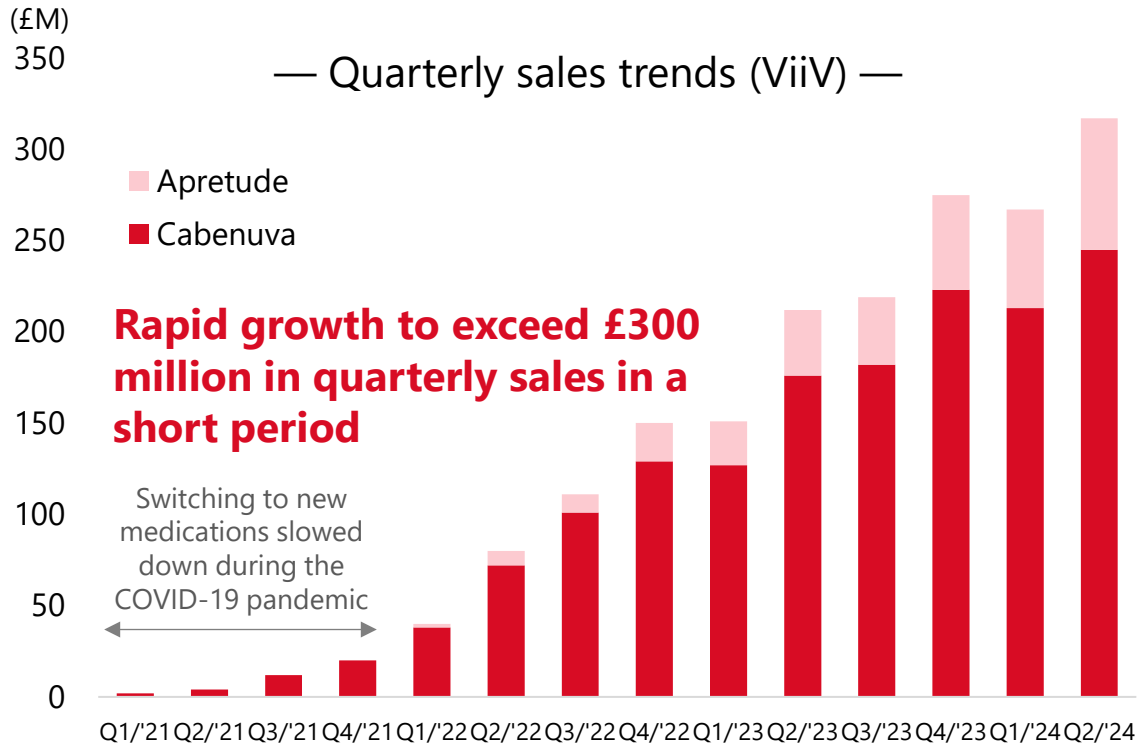
Addressing the unmet needs of people living with HIV (PLHIV) who aspire to achieve a quality of life comparable to healthy individuals

Unmet needs in HIV treatment and PrEP for LA formulations



- **65.8%** of PLHIV* are very interested in trying LA treatment*[2]
- **86.6%** of doctors are likely to suggest LA treatment*[2]

Rise of LA formulations since launch



* People Living With HIV *[2] Akinwunmi B et al. Sexually Transmitted Infections 2021;97:566-573
Apretude US launch: January 2022, Cabenuva US launch: February 2021

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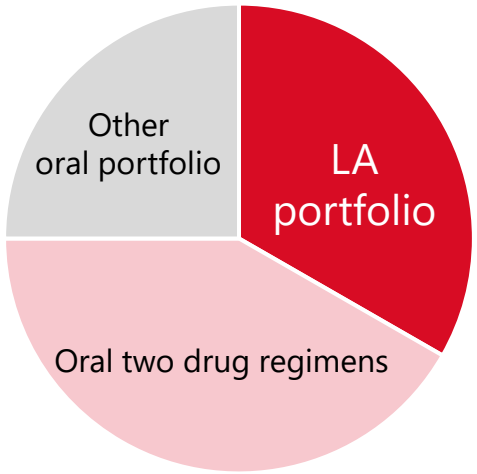
Sustainable Growth Strategy by SHIONOGI and ViiV*

Achieving short- to mid- to long-term growth through the expansion of existing LA formulations[2] and the launch of ULA formulations[3]

2021-2026	2026	2026-2031
Driving average annual growth rate of 6-8% for the entire HIV business	Expected sales of up to £7bn for the entire HIV business ⇒The sales ratio of LA formulations has reached one-third	Continue to introduce new products that contribute to further QOL improvement

Growth drivers

- **Cabenuva**
  LA formulation (Treatment)
- **Apretude**
  LA formulation (PrEP)
- **Dovato**
  Oral two drug regimen



Growth drivers

- **ULA (PrEP)**
- **ULA (Treatment)**
- **Self-injection**

Changes in the HIV business environment

Stronger-than-expected growth of LA formulations

Loss of the patent cliff for dolutegravir-related products

* Getting ahead of HIV with ViiV Healthcare management (September 28, 2023) *2 Long Acting: Administration once every 1-2 months
*3 Ultra Long Acting: Administration once every 4-6 months

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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*		**File and launch**		
	Q6M	S-365598*2 is candidate			Registrational study start	**File and launch**
ULA (Treatment)	Q4M	Cabotegravir*	Rilpivirine was selected		**File and launch**	
	Q6M	S-365598*2 is candidate	Candidates under consideration	Regimen selection and registrational study start		**File and launch**
Self-administered formulations (Treatment)	-	S-365598*2 is candidate	Candidates under consideration	Registrational study start		**File and launch**

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

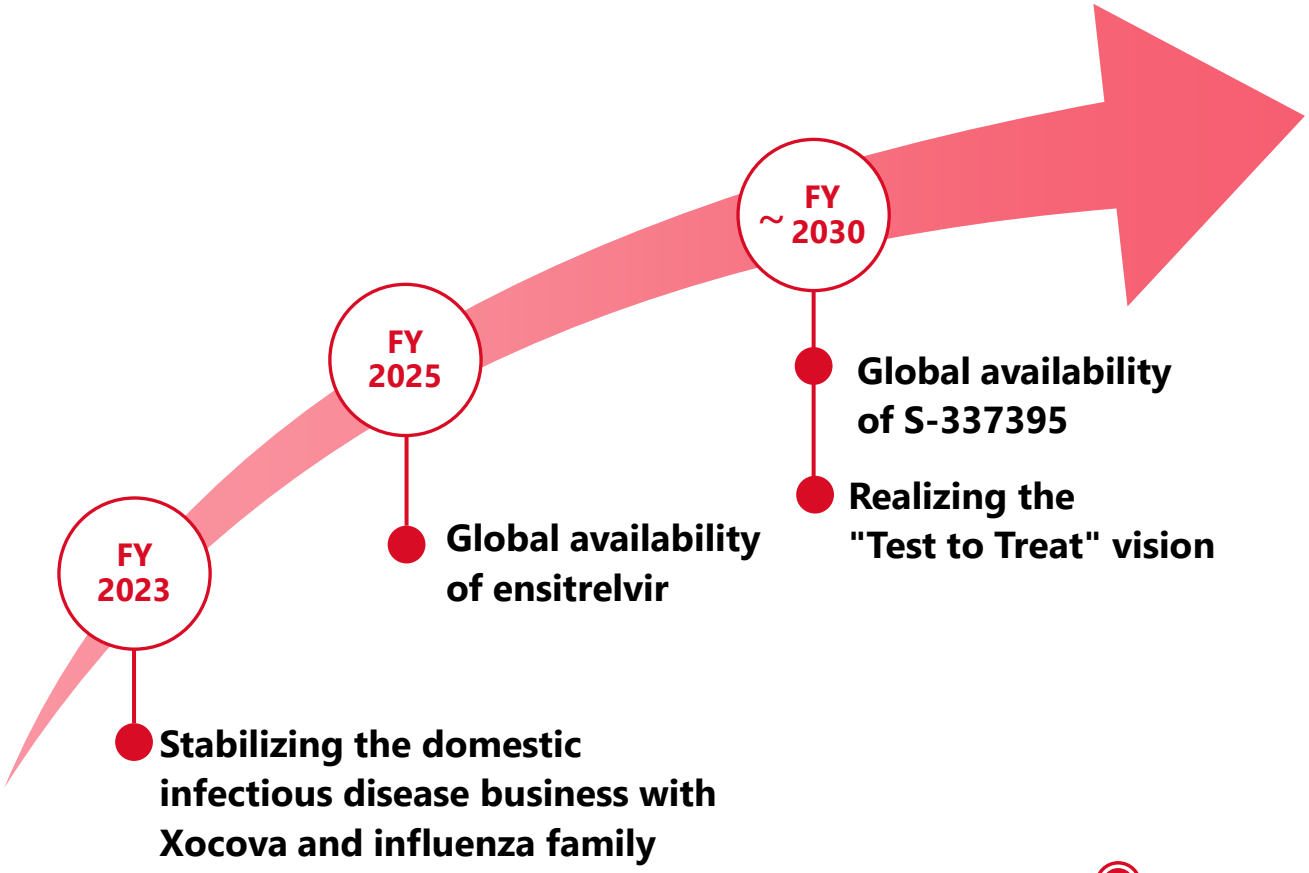
Promoting early diagnosis and early treatment

- 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



Growth vision for the acute respiratory infection business



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COVID-19: Development Status of Ensitrelvir

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

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

▶ Currentlyin 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

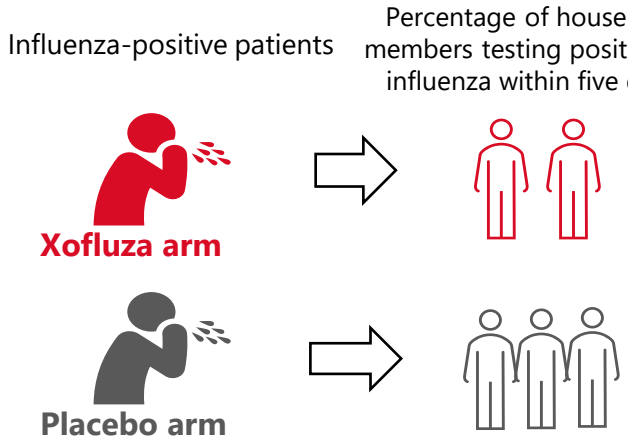
Significantly shortened the duration of infectious viral shedding compared to placebo, and reduced the time to symptom improvement by 'approximately one day'.



Transmission suppression*

Reduced risk of infection
by **29%**

Phase3 trial*3 (Transmission Suppression)

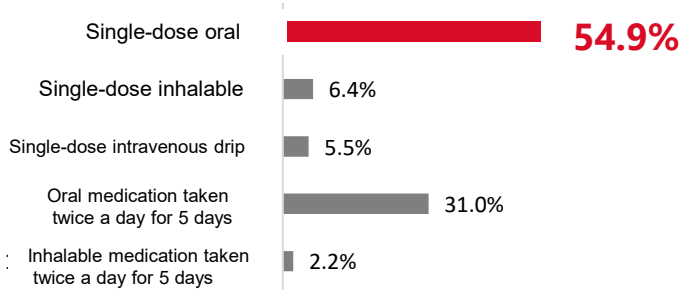


Complete treatment with a single oral dose

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

Survey Results for General Public*4

Q: "For influenza treatment, which type of medication would you choose?"



* 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

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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**	**Approval** (FY2024 1Q)	-
S-268023	**XBB1.5**	**Primary endpoint* not achieved** (FY2024 2Q)	Follow-up data currently being collected (evaluation of persistence of neutralizing antibody titers)
S-268024	**JN.1**	**Phase 3 in preparation** (FY2024 4Q)	We are currently conducting the manufacturing, process validation, and preclinical trials of the investigational drug
S-567123	**Sarbecovirus (Universal vaccine)**	**Phase 1 in preparation** (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

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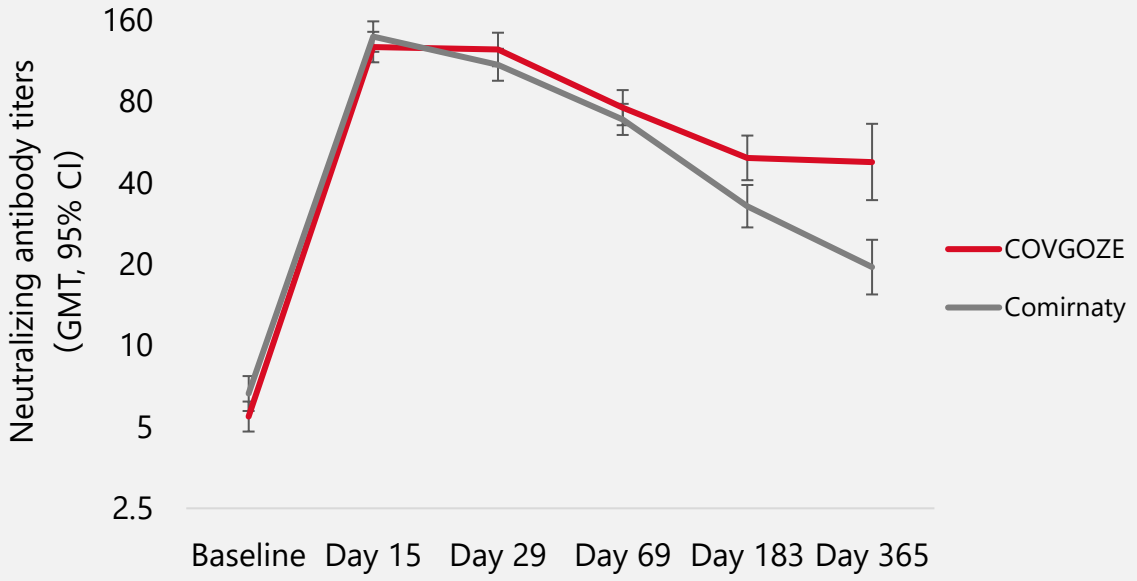
Towards the Realization of a Vaccine Platform

- 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

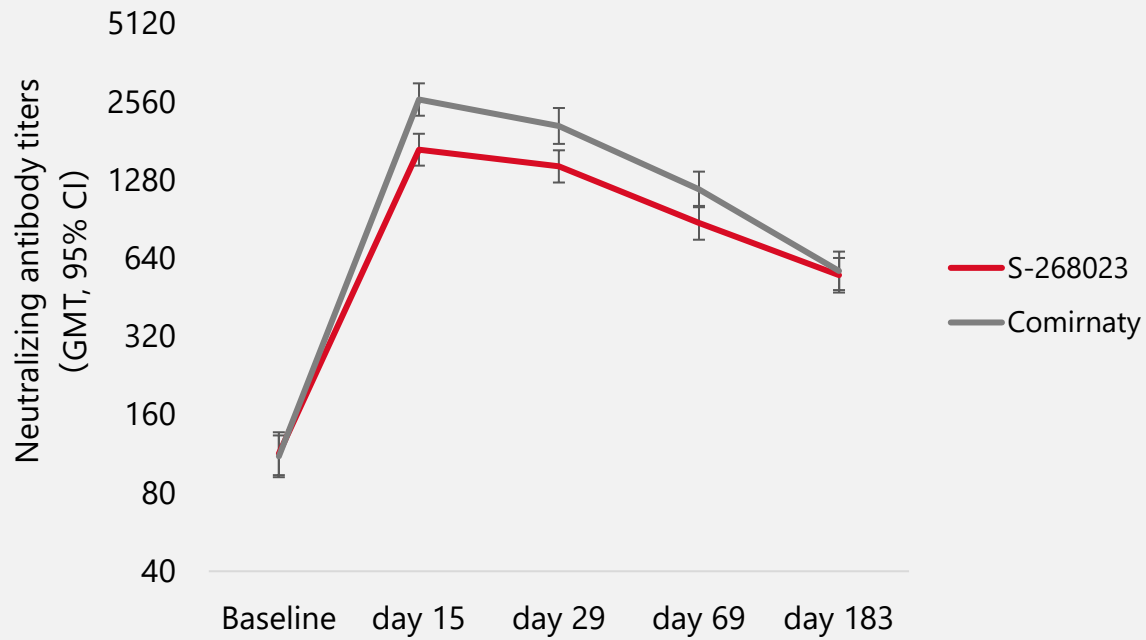
Clinical trial data

COVGOZE : Wuhan*



Clinical trial data

S-268023 : XBB1.5*2



* 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.

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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

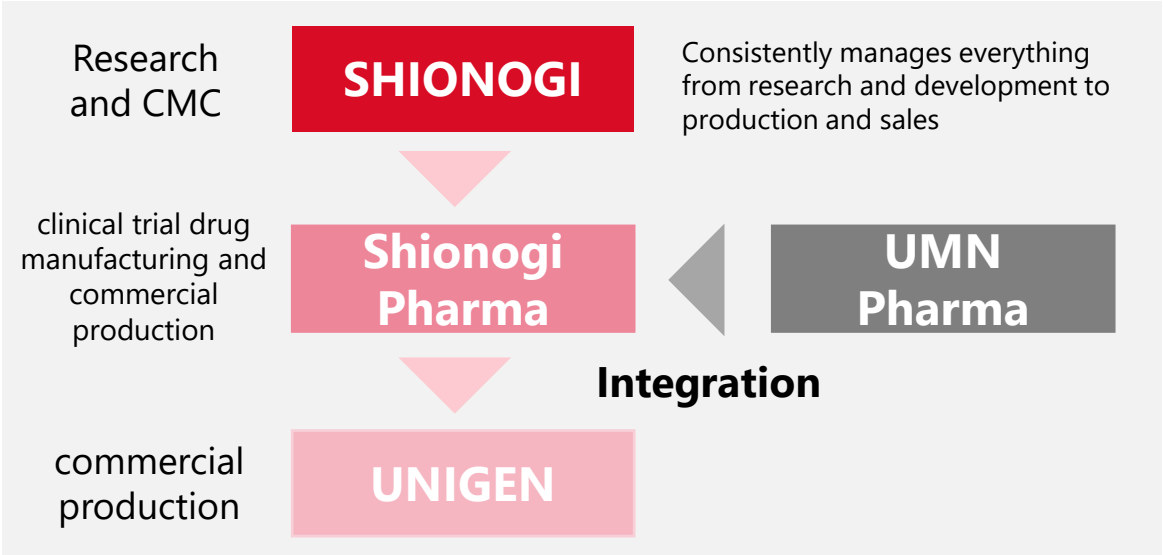
- Clinical trials of S-268023 (XBB1.5 strain).
  - Comparison with mRNA vaccines as control drugs*
- **Clinical trials of S-268024（JN.1 strain）**
  - Based on the principles stipulated in the guidelines, **the same modality vaccine will be selected as the control drug**

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

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)



Strengthening vaccine production capabilities and improving efficiency

* 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

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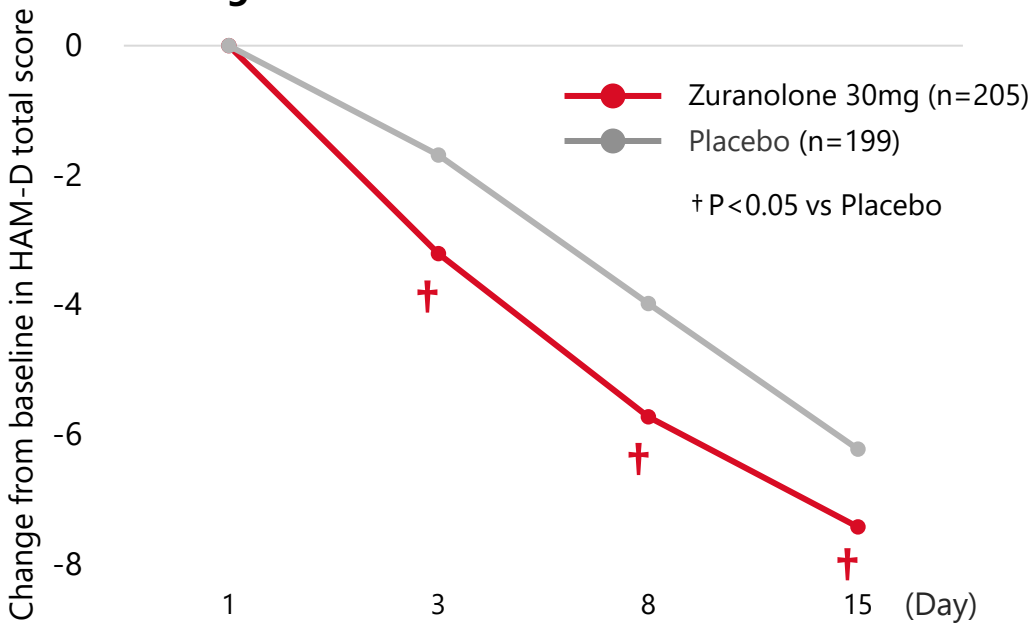
Zuranolone: New Drug Application (NDA) in Japan for Major Depressive Disorder

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

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

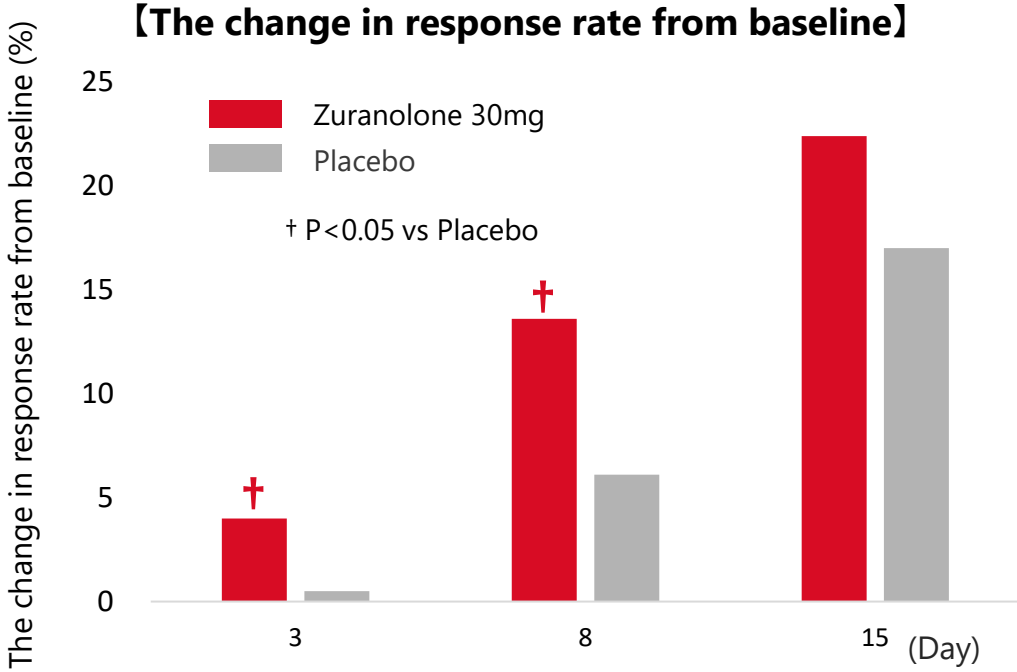
Results from Phase 3 validation study

【Change from baseline in HAM-D total score*2】



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

【The change in response rate from baseline】



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

* Press Release on September 27, 2024: Shionogi Submits New Drug Application in Japan for Zuranolone as a Treatment for Major Depressive Disorder
*2 17-item Hamilton Depression Rating Scale (The scale used to assess the severity of depression)

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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)*2

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)

*2 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 -

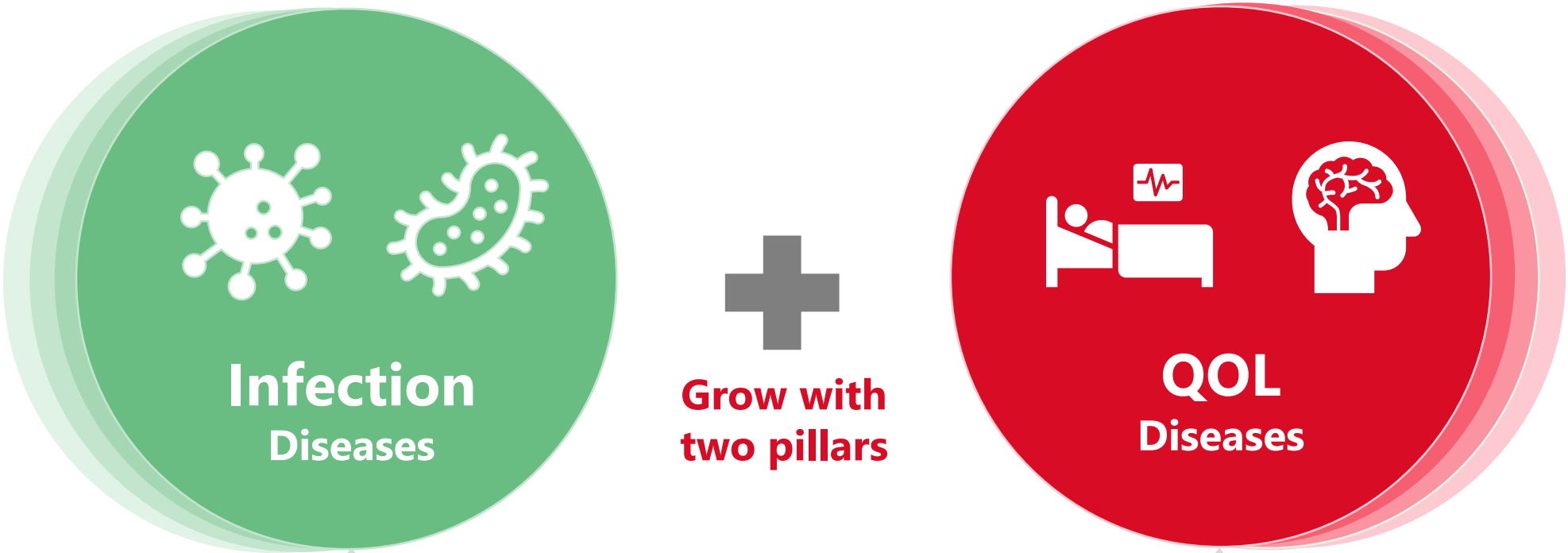
※ The bar starts from FPI and ends at CSR, Topline results: It is the timing of acquisition, and the timing of disclosure will be considered separately

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)	

* Investigational New Drug Application

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



The pillar of SHIONOGI's business

・Stabilization and further growth through the evolution of the business model.
・Evolve the infectious disease business by realizing "Test to Treat."

The new pillar of SHIONOGI

・Continuously introduce new products.
・Raise to the same level as the infectious disease business

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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

Infection diseases

~2024

- **Xofluza/Rapiacta** Influenza
- **Xocova** COVID-19
- **Fetroja** AMR

-From FY2024 onwards-

- **Vaccines** COVID-19, others
- **S-337395** RSV

Further strengthen the already stabilized infectious disease business

QOL Diseases

2024

- **QUVIVIQ** Insomnia

2025

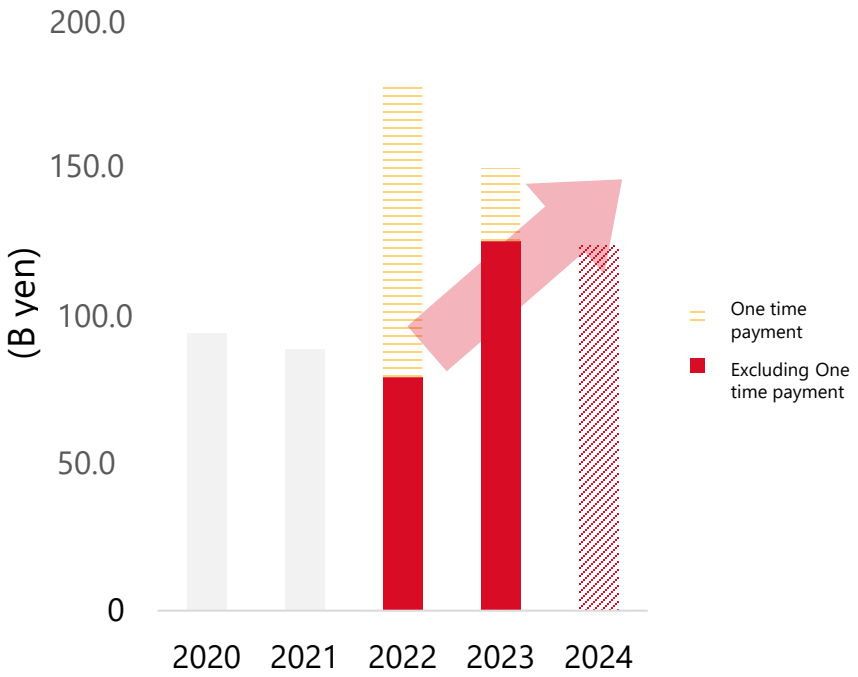
- **Zuranolone** Depression
- **SDT-001** ADHD app

2026-2027

- **Resiniferatoxin** Pain associated with knee osteoarthritis

We will continue to launch our highly anticipated new products in the domestic market

【Sales trends of domestic pharmaceutical products*】



domestic business will transition to a growth phase

* FY2024 numbers are based on forecasts

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Appendix

Pipeline: Infectious Disease

as of October 28

Preclinical	Phase 1	Phase 2	Phase 3		Submission
S-567123 COVID-19 Universal vaccine	**S-337395** RSV infections	**S-337395** RSV infections	**Cefiderocol** Aerobic Gram-negative bacterial infection (Pediatric)	**Ensitrelvir*** COVID-19 treatment	**Ensitrelvir*2** COVID-19 treatment
S-872600 Influenza nasal vaccine	**S-892216** COVID-19 treatment		**S-268023** COVID-19 vaccine (XBB 1.5)	**Ensitrelvir** COVID-19 prevention	**Baloxavir** Influenza virus infection (Granules, < 20kg)
S-875670 COVID-19 nasal vaccine	**S-743229** AMR (Complex urinary tract infection)		**S-268019** COVID-19 vaccine (Ages 5-19)	**Ensitrelvir** COVID-19 treatment (Ages 5-11)	**Cefiderocol** AMR (Gram-negative bacteria infection)
S-540956 Nucleic acid adjuvant	**S-649228** AMR (Gram-negative bacteria infection)		**Olorofim** Invasive Aspergillosis	**Cefiderocol** AMR (Gram-negative bacteria infection)	
S-554110 Nontuberculous mycobacterial infection		**Out license**			
S-268024 COVID-19 vaccine (JN.1)		**S-365598** HIV infection	**Baloxavir** Influenza virus infection (Transmission)		**Baloxavir** Influenza virus infection (Pediatric, < 1 year old)
S-917091 HIV infection					

Change from July 29 to October 28, 2024

- Cefiderocol (AMR): Submitted in China
- Cefiderocol (AMR): Phase 3 in China
- S-268024 (COVID-19 vaccine (JN.1)): The decision was made to proceed to preclinical development
- S-917091 (HIV infection): The decision was made to proceed to preclinical development

: Global development

: Progress from July 29 to October 28, 2024

* Phase 3 ongoing *2 Korea, Singapore

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Pipeline: QOL Diseases with High Social Impact

as of October 28

Preclinical	Phase 1	Phase 2		Phase 3	Submission
S-540956 Nucleic acid adjuvant	**S-151128** Chronic pain	**S-309309** Obesity	**Redasemtide*3** Acute ischemic stroke	**Resiniferatoxin [GRT7039]** Pain associated with knee osteoarthritis	**SDT-001** ADHD (pediatric)
S-109802 Post-stroke spasticity	**S-588210** Solid tumor	**S-531011*** Solid tumor	**Redasemtide** Epidermolysis bullosa	**Zatolmilast*5** Fragile X Syndrome	**Zuranolone** Depression
S-898270 Dementia	**S-740792** Gait disorders associated with multiple sclerosis	**Rizmoic*2** Opioid-induced Constipation (pediatric)	**Zatolmilast** Alzheimer's disease	**S-588410** Esophageal cancer	
	S-606001 Pompe disease	**S-588410** Bladder cancer	**ADR-001*4** Decompensated liver cirrhosis	**SR-0379** Cutaneous ulcer	
		S-488210 Head and neck squamous cell carcinoma	**S-222611 [Epertinib]** Malignant tumor	**Naldemedine** Opioid-induced Constipation	
			S-600918 + Drug X Sleep apnea syndrome		
			Out license **S-723595** Type 2 diabetes		

: Global development

Change from July 29 to October 28, 2024

- Zuranolone (Depression): Submitted in Japan
- S-600918 ＋Drug X (Sleep apnea syndrome): Phase 2 started in US
- S-740792 (Gait disorders associated with multiple sclerosis) Phase 1 in US
- S-606001 (Pompe disease): Phase 1 in Japan

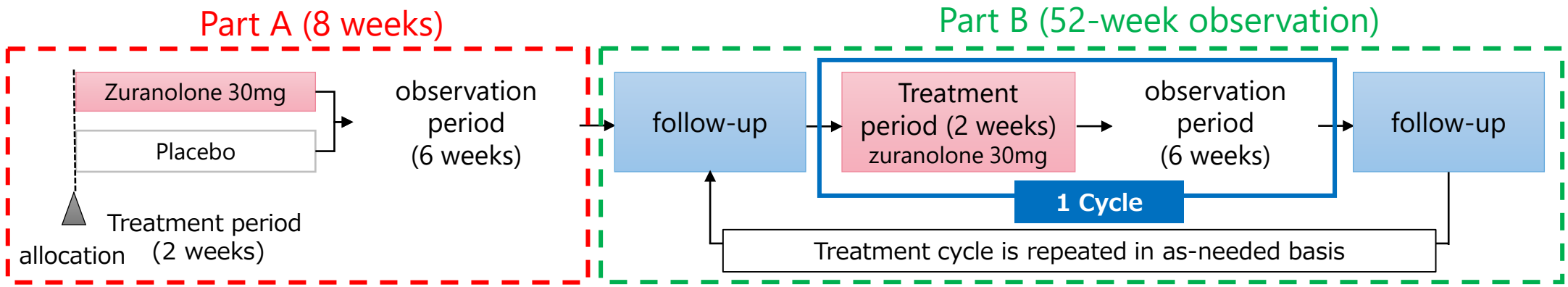
: Progress from July 29 to October 28, 2024

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

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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



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Anti-HIV drug released by ViiV

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

Other Major Progress*

- **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

* Progress from July 29 to October 27, 2024

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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- Risks and uncertainties include general industry and market conditions, and general domestic and international economic conditions such as interest rate and currency exchange fluctuations. Risks and uncertainties particularly apply with respect to product-related forward-looking statements. Product risks and uncertainties include, but are not limited to, technological advances and patents attained by competitors; challenges inherent in new product development, including completion of clinical trials; claims and concerns about product safety and efficacy; regulatory agency's examination period, obtaining regulatory approvals; domestic and foreign healthcare reforms; trend toward managed care and healthcare cost containment; and governmental laws and regulations affecting domestic and foreign operations.
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