1st Half (Interim period) of Fiscal 2025 Financial Results

October 27, 2025

Shionogi & Co., Ltd.

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Agenda

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Overview of 1st Half (Interim period) FY2025 Financial Results

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1st Half FY2025 Highlights

- **Maintain revenue and operating profit at the same level as the previous year**
  - Stable profit growth in the HIV business and overseas businesses
- **Profit before tax increased, and profit attributable to owners of parent increased slightly**
  - Increased dividend from ViiV reflecting solid progress in the HIV business
- **Progress on key initiatives driving medium to long term growth**
  - HIV business: Expansion of LAI*1 formulations
  - Acquisition of TORII PHARMACEUTICAL CO., LTD. as a wholly-owned subsidiary*2
  - Ensitrelvir NDA accepted in the US and Europe

*1 LAI: Long acting injectable *2 September 2025 Press Release

Financial Results

Revenue and operating profit declined year-on-year, but profit before tax and profit attributable to owners of parent exceeded the previous year

(Unit: B yen)

	FY2025				FY2024	Y on Y	
	Forecasts		1H results	Achievement (%)	1H results	Change (%)	Change
	Full year	1H					
Revenue	530.0	233.0	**213.0**	**91.4**	214.0	**(0.5)**	**(1.0)**
Operating profit	175.0	82.0	**74.8**	**91.2**	75.9	**(1.4)**	**(1.1)**
Profit before tax	222.0	102.0	**98.4**	**96.5**	93.8	**4.9**	**4.6**
Profit attributable to owners of parent	180.0	86.0	**83.5**	**97.1**	83.1	**0.5**	**0.4**
EBITDA*	196.0	93.0	**85.8**	**92.3**	86.7	**(1.0)**	**(0.8)**

* 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)

	FY2025 Forecast		FY2025		FY2024	Y on Y	
	Full year	1H	1H Results	Achievement (%)	1H Results	Change (%)	Change
Revenue	530.0	233.0	**213.0**	**91.4**	214.0	**(0.5)**	**(1.0)**
Cost of Sales	16.6 88.0	14.2 33.0	13.7 **29.3**	**88.7**	14.1 30.1	**(2.9)**	**(0.9)**
Gross profit	442.0	200.0	**183.7**	**91.9**	183.8	**(0.1)**	**(0.1)**
SG&A*1, R&D expenses total	49.6 263.0	49.8 116.0	50.1 **106.8**	**92.1**	49.9 106.7	**0.1**	**0.1**
SG&A*1	24.7 131.0	24.9 58.0	25.5 **54.3**	**93.7**	23.3 49.9	**8.9**	**4.4**
R&D expenses	24.9 132.0	24.9 58.0	24.6 **52.4**	**90.4**	26.6 56.8	**(7.7)**	**(4.4)**
Other income & expenses	(4.0)	(2.0)	**(2.2)**	**107.6**	(1.2)	**74.0**	**(0.9)**
Operating profit	33.0 175.0	35.2 82.0	35.1 **74.8**	**91.2**	35.5 75.9	**(1.4)**	**(1.1)**
Finance income & costs	47.0	20.0	**23.6**	**118.1**	18.0	**31.4**	**5.6**
Profit before tax	41.9 222.0	43.8 102.0	46.2 **98.4**	**96.5**	43.9 93.8	**4.9**	**4.6**
Profit attributable to owners of parent	180.0	86.0	**83.5**	**97.1**	83.1	**0.5**	**0.4**

Main variation factors (Y on Y)

Revenue

- Increase: Royalty income, Overseas subsidiaries /export
- Decrease: Prescription drugs

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- Increase: Selling-related expenses in US business, PMI costs

R&D expenses

- Decrease: Multiple large-scale clinical trials were conducted in FY2024
  - Ensitrelvir Phase 3 trial
  - S-309309 Phase 2 trial

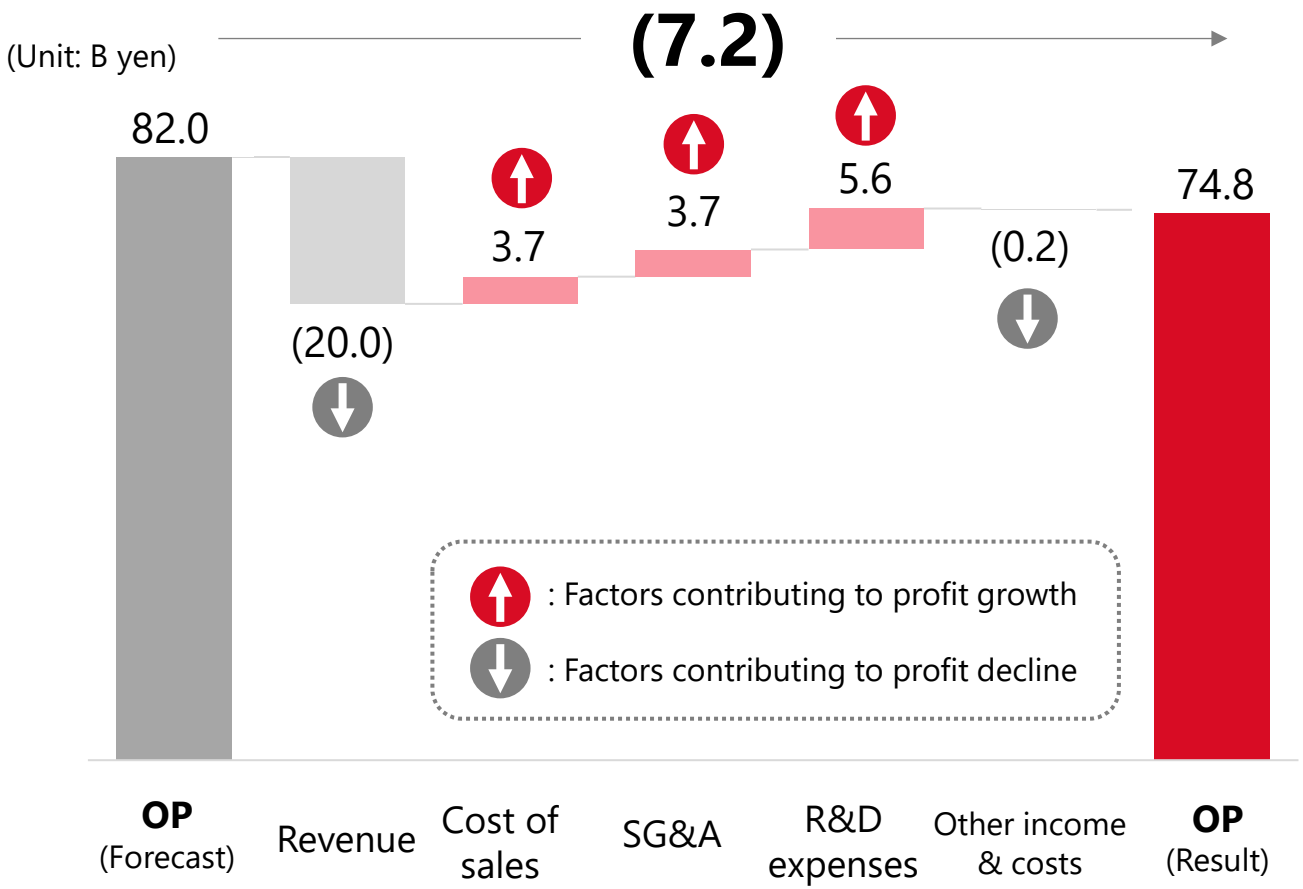
Finance income & costs

- Increase: Dividends from ViiV
  - Strong sales performance in the HIV franchise

*1 Selling, general & administrative expenses

Analysis of Operating Profit Factors (vs. 1H forecast)

Thorough cost management based on the epidemic situation reduces discrepancies with forecasts



Implemented thorough cost optimization across all divisions

- **SG&A**
  - Refined decision-making through strict prioritization
    - > Achieved cost reductions of JPY about 5 billion within two months
  - Maintained planned investments essential for growth
    - > Sales-related expenses for the U.S. business
- **R&D expenses**
  - Advanced prioritized R&D investments
    - > Clinical trials for key assets are progressing as planned

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Revenue by Segment

(Unit: B yen)

	Forecast		FY2025		FY2024	Y on Y	
	Full year	1H	1H Results	Achievement (%)	1H Results	Change(%)	Change
Prescription drugs	183.0	62.0	**36.8**	**59.4**	47.7	**(22.8)**	**(10.9)**
Overseas subsidiaries/export	54.9	25.7	**30.6**	**119.2**	28.3	**8.1**	**2.3**
Shionogi Inc. (US)	22.6	10.9	**13.6**	**124.5**	11.2	**21.0**	**2.4**
Fetroja	-	-	**13.0**	-	9.4	**39.3**	**3.7**
Shionogi B.V. (EU)	16.9	8.3	**9.8**	**118.4**	8.3	**18.3**	**1.5**
Fetcroja	-	-	**7.6**	-	6.4	**19.1**	**1.2**
Shionogi China	7.0	3.5	**3.0**	**84.9**	4.2	**(29.2)**	**(1.2)**
Others	8.4	3.0	**4.3**	**142.1**	4.6	**(7.6)**	**(0.4)**
Contract manufacturing	13.2	6.5	**7.1**	**109.5**	7.8	**(8.3)**	**(0.6)**
OTC and quasi-drug	18.5	8.9	**7.9**	**88.4**	8.2	**(3.6)**	**(0.3)**
Royalty income	257.9	128.7	**129.3**	**100.5**	121.5	**6.4**	**7.8**
HIV franchise	244.8	125.8	**125.8**	**100.0**	119.6	**5.2**	**6.2**
Others	13.1	2.9	**3.5**	**121.0**	1.9	**84.8**	**1.6**
Others	2.5	1.2	**1.2**	**101.6**	0.5	**135.4**	**0.7**
Total	530.0	233.0	**213.0**	**91.4**	214.0	**(0.5)**	**(1.0)**

Main variation factors (Y on Y)

Prescription drugs

- Increase: Torii Pharmaceutical*1
- Decrease: Sales of acute respiratory virus infection treatments
  - Sales of Xocova declined as the outbreak subsided

Overseas subsidiaries/export

- Increase: Sales of cefiderocol (US and Europe)
- Decrease: Sales of China business

Royalty income

- Increase:
  - HIV franchise: Sales generated by ViiV
  - Others: Royalty income from Roche
    - > Influenza outbreaks in China and US

*1 Connection with the full acquisition of the subsidiary, expenses for the month of September have been recognized

Prescription Drugs in Japan

(Unit: B yen)

	FY2025				FY2024	Y on Y	
	Forecast Full year	Forecast 1H	1H Results	Achievement (%)	1H Results	Change(%)	Change
Acute Respiratory Virus Infection Treatments	85.8	31.0	**8.7**	**28.0**	24.9	**(65.1)**	**(16.2)**
Quviviq	9.3	1.2	**0.4**	**35.6**	-	**-**	**0.4**
Symproic	8.1	3.9	**2.9**	**75.0**	2.4	**23.9**	**0.6**
OxyContin franchise	5.6	2.9	**2.3**	**78.8**	2.1	**10.7**	**0.2**
Others	74.2	23.0	**22.5**	**97.9**	18.4	**22.1**	**4.1**
TORII	33.0	3.0	**5.5**	**184.0**	-	**-**	**5.5**
Total	183.0	62.0	**36.8**	**59.4**	47.7	**(22.8)**	**(10.9)**

Acute respiratory virus infection treatments

- COVID-19 related product: Xocova
- Influenza franchise: Xofluza, Rapiacta

Results for the 1H of FY 2025 and Future Outlook

Accelerate efforts toward sustainable growth based on 1H results and challenges

	1H results	Challenges
Revenue	**Solid progress in the HIV business and overseas businesses** • Good progress as a medium to long-term revenue base	**Growth in domestic business** • Stabilization of acute respiratory infection business • Growth in the QOL disease area*1
Profit	**Profit before tax and profit attributable to owners of parent growth exceeded the previous year** • Actions to manage costs in line with sales	**Strengthening company-wide cost management** • Timely and effective decision-making

*1 High social impact QOL-related diseases: sleep disorders, hearing loss, rare pediatric diseases, Immunology/Allergy, etc.

FY2025 Financial Forecasts

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Revision of Earnings Forecast

Revenue and all profit items are expected to increase compared to the previous year

(Unit: B yen)

	FY2025			FY2024	Y on Y	
	Initial Forecast	Revised Forecast	Revised Amount	Result	Change (%)	Change
Revenue	530.0	**500.0**	**(30.0)**	438.3	**14.1**	**61.7**
Operating profit	175.0	**185.0**	**10.0**	156.6	**18.1**	**28.4**
Profit before tax	222.0	**232.0**	**10.0**	200.8	**15.6**	**31.2**
Profit attributable to owners of parent	180.0	**188.0**	**8.0**	170.4	**10.3**	**17.6**
EBITDA*1	196.0	**206.0**	**10.0**	179.3	**14.9**	**26.7**

* 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.)

Assumptions Underlying the Revised Forecast

Revenue forecast revised downward, while all profit metrics revised upward

― Topline ―

Upward revision

Royalty income and overseas subsidiaries/exports

- **Increase in royalty income**
  - Increase in other royalties
  - Strong sales performance of HIV franchise by ViiV
- **Increase in sales at Shionogi Inc., and Shionogi B.V.**
  - Steady sales growth of cefiderocol

Downward revision

Prescription drugs

Delay in progress of acute respiratory infection treatments

- Revision of forecasts for Xocova, Xofluza, and Quviviq

― Cost management ―

SG&A

- A zero-based review following the shortfall first-half revenue
- Continued investment in activities for new product launches

R&D

- Review of priorities including JT pharmaceutical pipeline
- Continued investment in key assets as planned

― New business opportunities ―

Upward revision

Growth in other income & Expenses

- Increase in other income

Consolidated Statement of Income

(Unit: B yen)

	FY2025 Forecast Full year			FY2025 Forecast 2H			FY2024	Y on Y	
	Initial Forecast	Revised Forecast	Revised Amount	Forecast (May. 12)	Revised Forecast	Revised Amount	Result	Change(%)	Change
Revenue	530.0	**500.0**	**(30.0)**	297.0	**287.0**	**(10.0)**	438.3	14.1	61.7
Cost of Sales	16.6 88.0	**16.4** **82.0**	**(6.0)**	18.5 55.0	**18.4** **52.7**	**(2.3)**	14.6 63.8	28.5	18.2
Gross profit	442.0	**418.0**	**(24.0)**	242.0	**234.3**	**(7.7)**	374.4	11.6	43.6
SG&A*1, R&D expenses total	49.6 263.0	**48.0** **240.0**	**(23.0)**	49.5 147.0	**46.4** **133.2**	**(13.8)**	49.0 214.7	11.8	25.3
SG&A*1	24.7 131.0	**24.0** **120.0**	**(11.0)**	24.6 73.0	**22.9** **65.7**	**(7.3)**	24.2 106.1	13.2	13.9
R&D expenses	24.9 132.0	**24.0** **120.0**	**(12.0)**	24.9 74.0	**23.5** **67.6**	**(6.4)**	24.8 108.6	10.5	11.4
Other income & Expenses	(4.0)	**7.0**	**11.0**	(2.0)	**9.2**	**11.2**	(3.2)	-	10.2
Operating profit	33.0 175.0	**37.0** **185.0**	**10.0**	31.3 93.0	**38.4** **110.2**	**17.2**	35.7 156.6	18.1	28.4
Finance income & costs	47.0	**47.0**	**-**	27.0	**23.4**	**(3.6)**	44.1	6.5	2.9
Profit before tax	41.9 222.0	**46.4** **232.0**	**10.0**	40.4 120.0	**46.6** **133.6**	**13.6**	45.8 200.8	15.6	31.2
Profit attributable to owners of parent	180.0	**188.0**	**8.0**	94.0	**104.5**	**10.5**	170.4	10.3	17.6

*1 Selling, general & administrative expenses

Revenue by Business Segment

(Unit: B yen)

	FY2025 Forecast Full year			FY2025 Forecast 2H			FY2024	Y on Y	
	Initial Forecast	Revised Forecast	Revised Amount	Forecast (May 12)	Revised Forecast	Revised Amount	Result	Change(%)	Change
Prescription drugs	183.0	**143.5**	**(39.5)**	121.0	**106.7**	**(14.3)**	98.8	45.3	44.7
Overseas subsidiaries/export	54.9	**61.0**	**6.1**	29.2	**30.4**	**1.2**	59.1	3.2	1.9
Shionogi Inc. (US)	22.6	**27.2**	**4.6**	11.7	**13.6**	**1.9**	23.4	16.2	3.8
Shionogi B.V. (EU)	16.9	**19.3**	**2.4**	8.6	**9.4**	**0.8**	16.8	14.5	2.4
Shionogi China	7.0	**5.9**	**(1.1)**	3.5	**3.0**	**(0.5)**	8.7	(31.5)	(2.7)
Others	8.4	**8.6**	**0.2**	5.4	**4.4**	**(1.0)**	10.2	(15.5)	(1.6)
Contract manufacturing	13.2	**14.0**	**0.8**	6.7	**6.9**	**0.2**	17.3	(18.9)	(3.3)
OTC and quasi-drug	18.5	**17.5**	**(1.0)**	9.6	**9.6**	**0.0**	16.8	4.1	0.7
Royalty income	257.9	**261.5**	**3.6**	129.2	**132.2**	**3.0**	244.7	6.9	16.8
HIV franchise	244.8	**245.0**	**0.2**	119.0	**119.2**	**0.2**	240.4	1.9	4.6
Others	13.1	**16.5**	**3.4**	10.2	**13.0**	**2.8**	4.3	286.9	12.2
Others	2.5	**2.5**	**-**	1.3	**1.3**	**0.0**	1.7	48.8	0.8
Total	530.0	**500.0**	**(30.0)**	297.0	**287.0**	**(10.0)**	438.3	14.1	61.7

Domestic Prescription Drug Revenue

(Unit: B yen)

	FY2025 Forecast Full year			FY2025 Forecast 2H			FY2024	Y on Y	
	Initial Forecast	Revised Forecast	Revised Amount	Forecast (May 12)	Revised Forecast	Revised Amount	Result	Change(%)	Change
Acute Respiratory Virus Infection Treatments	85.8	**56.0**	**(29.8)**	54.8	**47.3**	**(7.5)**	51.8	8.1	4.2
Quviviq	9.3	**2.5**	**(6.8)**	8.1	**2.1**	**(6.0)**	0.8	213.9	1.7
Symproic	8.1	**6.5**	**(1.6)**	4.2	**3.5**	**(0.7)**	5.0	28.7	1.4
OxyContin franchise	5.6	**5.3**	**(0.3)**	2.7	**3.0**	**0.3**	4.3	25.1	1.1
Others	74.2	**73.2**	**(1.0)**	51.2	**50.7**	**(0.5)**	36.9	98.4	36.3
Torii Pharmaceutical	33.0	**41.2**	**8.2**	30.0	**35.7**	**5.7**	-	-	41.2
Prescription drugs	183.0	**143.5**	**(39.5)**	121.0	**106.7**	**(14.3)**	98.8	45.3	44.7

Acute respiratory virus infection treatments

- COVID-19 related product: Xocova
- Influenza franchise: Xofluza, Rapiacta

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Domestic and Overseas Business Outlook

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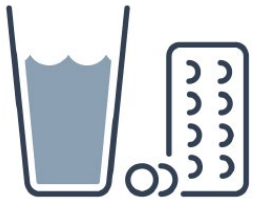
Strategic Directions for Infectious Diseases area

Ensuring social contribution and revenue stability through a diversified portfolio of infectious disease treatments

- COVID-19 treatment -

XOCOVA
(3CL protease inhibitor)

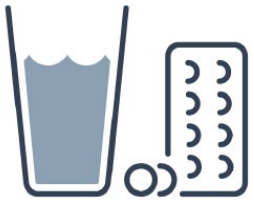


Oral medication recommended by academic societies, regardless of risk factors for severe illness*1

- Influenza treatments -

XOFLUZA
(Cap-dependent endonuclease inhibitor)

Granules formulation scheduled for launch within this calendar year



The only oral medication that can both treat and prevent Flu with a single dose

RAPIACTA
(Neuraminidase inhibitor)

Reliable administration can be ensured even when oral administration is limited

※Influenza: Trending in the 2025/2026 season (The second fastest in the past 20 years)

*1 2025 Guidelines for the Treatment of COVID-19 by Five Academic Societies

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Review of our Efforts against COVID-19

Modest overall treatment rate growth, significant increase among High-Risk[*1] patients

—Treatment rate and Xocova share among oral antivirals—

	FY2025 Target	FY2024 1H	FY2025 1H
Average Xocova share	>65%	Approximately 65%	Approximately 65%
Treatment rate[*2] Average value of the most prevalent month	>20%	13.1%	**13.9%**

- Maintains a strong market share in the oral antiviral market
- Despite efforts to raise disease awareness, the treatment rate did not reach our target

—Treatment rate by risk category—

HR patients

29.4 %[*3] (**7.1%** up Y on Y)

The risk of severe disease remains high, and the need for treatment is becoming increasingly recognized

SR[*4] patients

7.0 %[*3] (1.6% up Y on Y)

Lower need for treatment despite variant changes

[*1] HR (High Risk): Based on information from the Ministry of Health, Labour and Welfare and academic societies, HR is defined as having risk factors for severe disease such as advanced age or underlying conditions [*2] Created by our company based on JAMDAS data [*3] Created by our company based on JAMDAS data (2024) report [*4] SR(Standard Risk): Define non-HR cases as SR

Future Initiatives for COVID-19

Strengthening activities to prevent severe disease in HR patients requiring early diagnosis and treatment

—Need for Preventing Severe Disease in HR Patients—

The current treatment rate is insufficient, and the number of hospitalized patients remains high

Number of hospitalized patients*1

Approximately **50** K people

Early diagnosis and treatment at community clinics is critical

—New clinical guideline announced by the 5 Societies—

1. **Recommendation for early diagnosis and early treatment**
2. **Recommended Xocova as a treatment option for preventing severe illness**

※Published on October 16, 2025

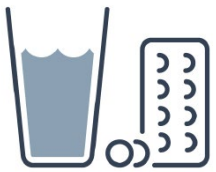
—Enhancing Xocova Information Provision Activities—

Strengthening activities for HR patients aimed at preventing severe disease

1 **Clinical Evidence**

Real-world evidence on reducing hospital admissions*3 and shortening hospital stays*4 in HR patients

2 **Economic & Pharmaceutical Value**



Communicate benefits of reducing severe cases and hospitalization

3 **Co-Promotion**

Collaborate with Trii flu clinics to reinforce early treatment initiatives

*1 Ministry of Health, Labour and Welfare: October 17, 2025 – Situation Report on Novel Coronavirus Infection (COVID-19) *2 https://nishakyo.or.jp/siryo/covid-sisin.pdf
*3 Takahiro Takazono et al.,Real-World Effectiveness of Ensitrelvir in Reducing Severe Outcomes in Outpatients at High Risk for COVID-19
*4 Ryohei Yoshida et al., Real-World Efficacy of Ensitrelvir in Hospitalized Patients With COVID-19 in Japan: A Retrospective Observational Study

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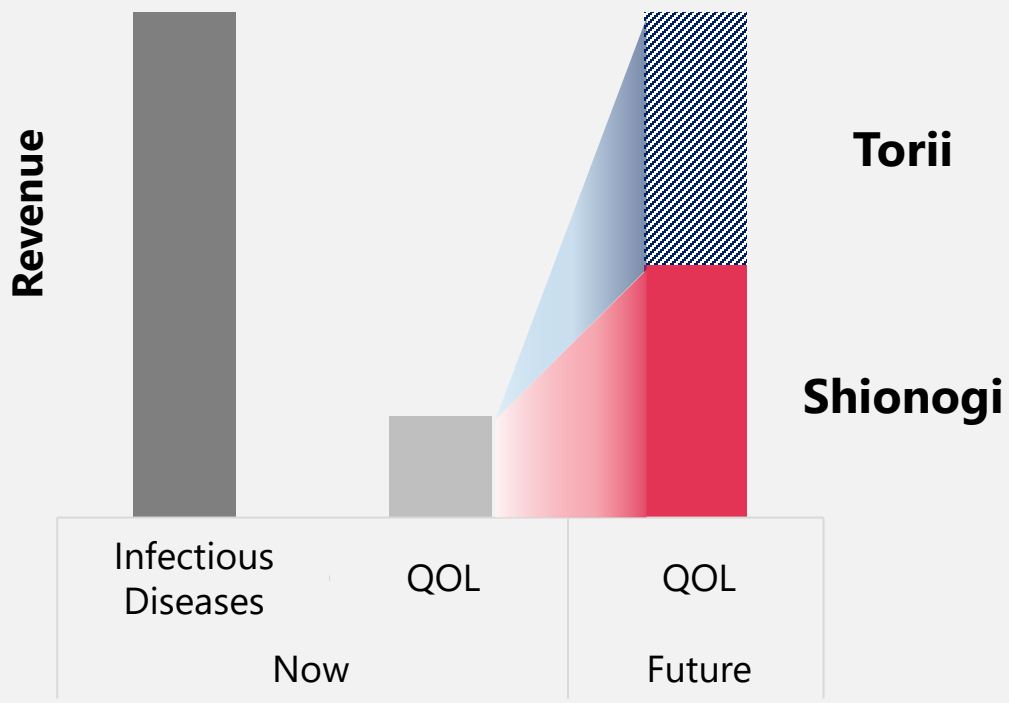
Strategic Directions for QOL Diseases area

Making QOL disease area a business pillar alongside infectious diseases area

Drive substantial growth in the QOL diseases area



Torii

Broad product portfolio delivering steady growth

- Allergen immunotherapy: Cedacure etc
- Dermatology: Corectim / Vtama etc

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- Growth of Quviviq*1 (after removal of prescription period restrictions)
  - Co-promotion with Torii Pharmaceutical is planned
- Launch of Zuranolone*2

*1 Quviviq: Insomnia treatment (dual orexin receptor antagonist, DORA)
*2 Zuranolone: Depression treatment (GABAA receptor (γ-aminobutyric acid-gated chloride ion channel) positive allosteric modulator)
For details on Zuranolone, refer to appendix p. 46 and 47

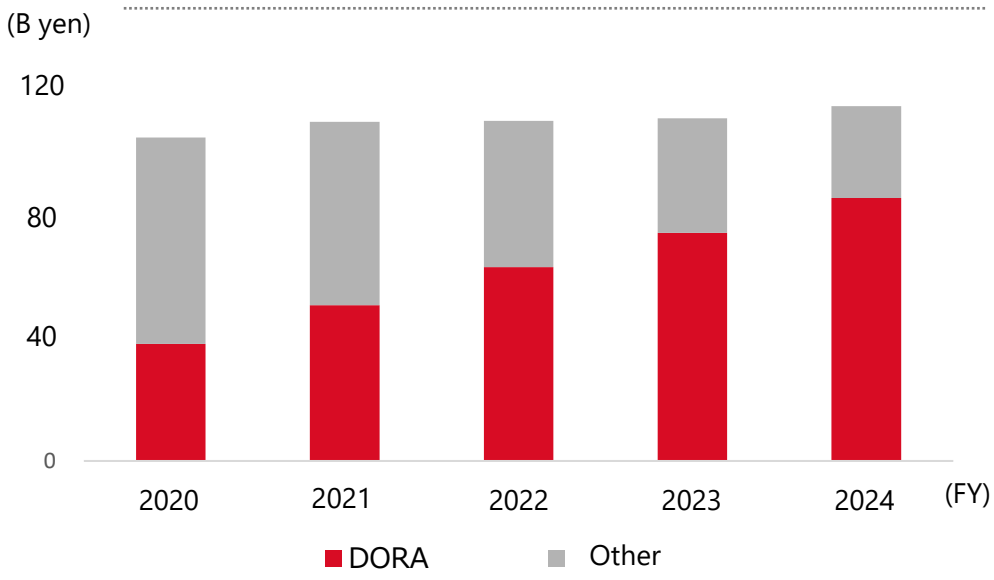
Driving Growth of Quviviq (Insomnia treatment)

Market penetration accelerated with the lifting of prescription period restrictions on December 1st.

Insomnia Market*1

Market size: Estimated at over ¥100 billion annually

- Growth of DORAs*2 driving market expansion



Current Status

- Limited prescription duration: Maximum of 14 days per fill*3

Results of Actions

- Maintained MR detailing rank within Top 3*4
- Number of adoptions expanded steadily
  - Accumulated prescription experience and confirmed positive feedback

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*2 Dual Orexin Receptor Antagonist *3 To ensure the safety and efficacy of new drugs, the prescription period is generally limited to a maximum of 14 days per prescription for one year starting from the month following their listing in the National Drug Price List *4 Source: Impact Track, INTAGE Healthcare Inc. (covering GP channels from December 2024 to August 2025)

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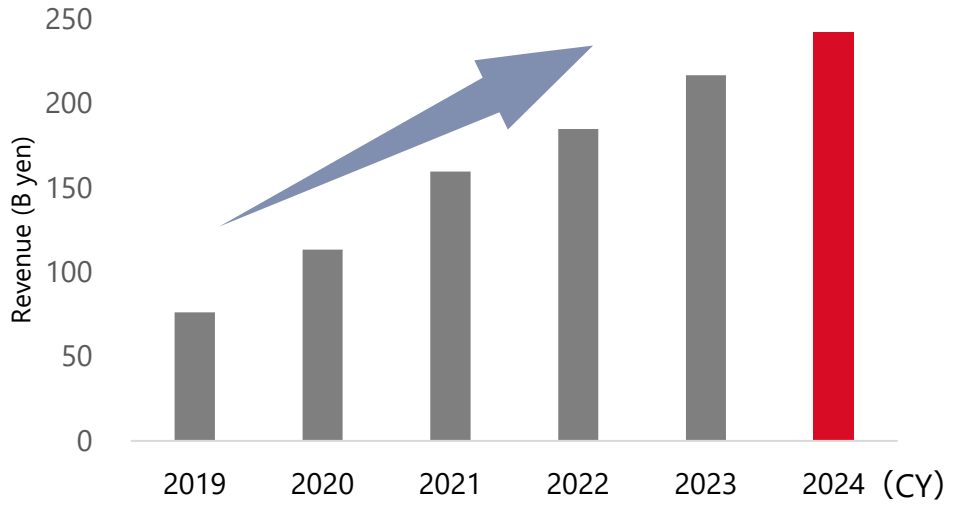
Strengthening QOL Disease Area by Full Acquisition of Torii Pharmaceutical

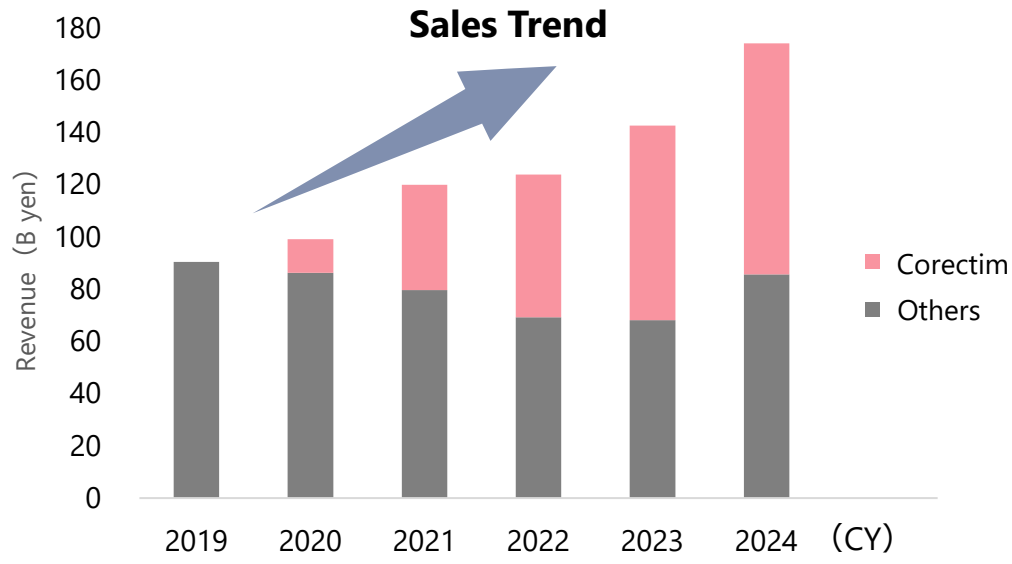
Achieving stable growth in both the allergen and dermatology segments

Allergens



- Operating of API Manufacturing Facility for Cedarcure
- Increasing Inventory in Preparation for Lifting of Shipping Restrictions

Dermatology



- Sustained Growth Driven by Expansion of Corectim
- Further Growth Through Early Market Penetration of Vtama*2

*1 SLIT: Sublingual Immunotherapy *2 Launch timing for Vtama: October 2024

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Further Growth of Overseas Business

Accelerate growth in Europe and U.S. business, and full-scale expansion of new drug business in China

China Business

Shift to new drug business

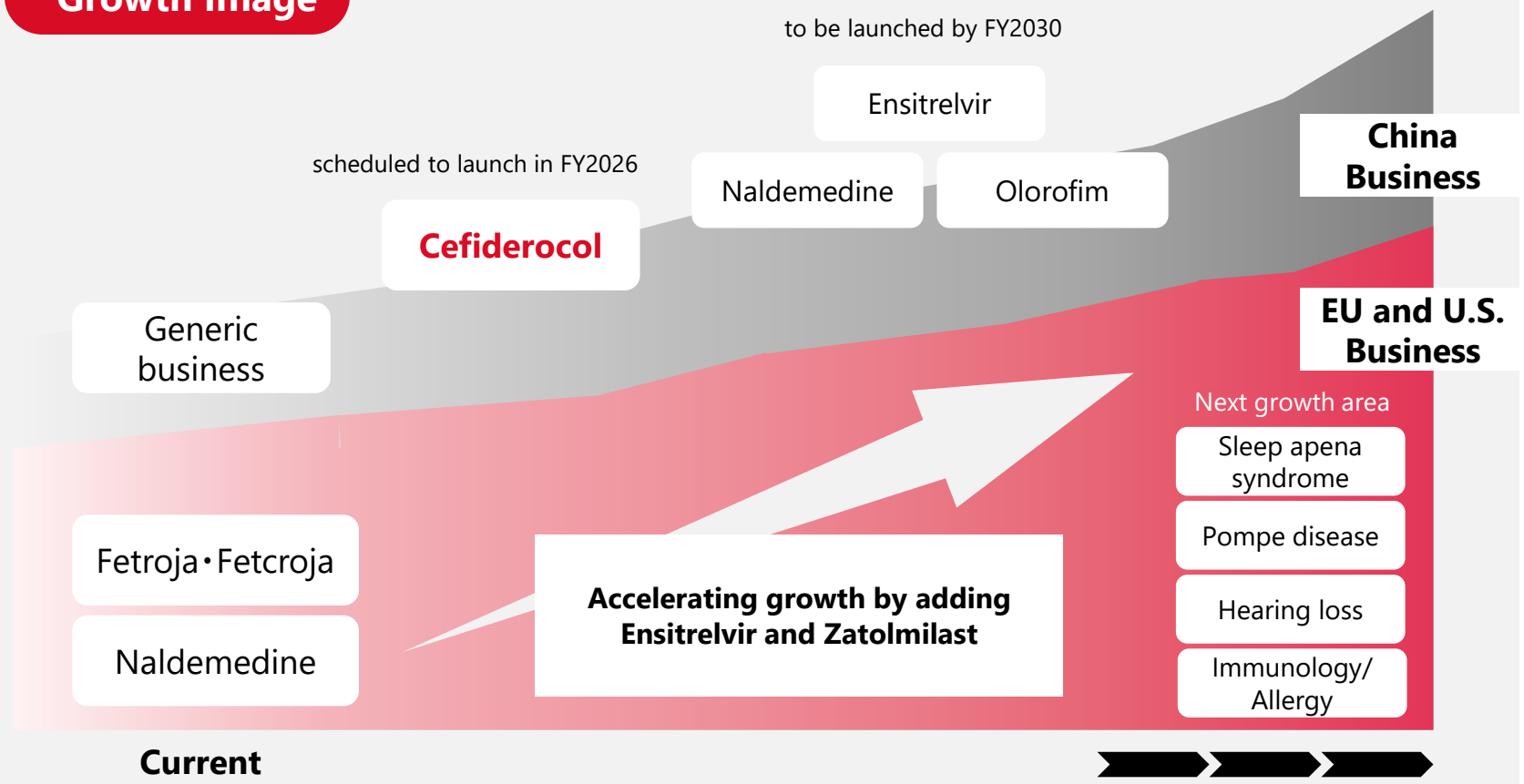
Rapid expansion into China based on successful experiences in Europe and the U.S

Europe and U.S. Business

Accelerating Growth

- Growth of cefiderocol
- Launch of products including QOL disease treatments

Growth Image



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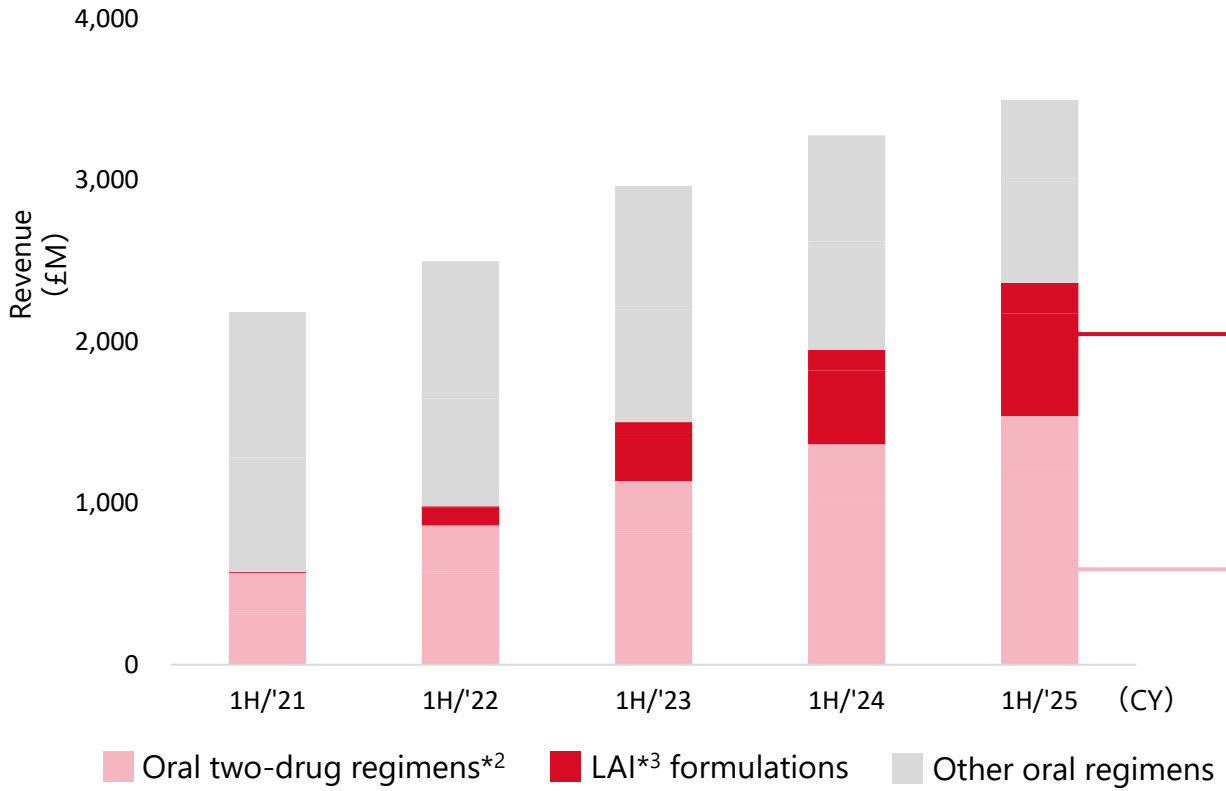
Toward the Realization of the 2030 Vision

SHIONOGI

HIV Business: Progress in ViiV's HIV Franchise (GSK's Q2 results as of July 30, 2025)

Driving overall growth of the HIV business through expansion of LAI formulations and oral two-drug regimens

ViiV's sales trends*1



YoY increase from the same period

Treatment

Cabenuva (cabotegravir + rilpivirine)

+ £**177**M (+42%) Q1 CY2025 result: £635M

Prevention

Apretude (cabotegravir)

+ £**64**M (+56%) Q1 CY2025 result: £190M

Treatment

Dovato (dolutegravir + lamivudine)

+ £**191**M (+21%) Q1 CY2025 result: £1,225M

*1 Created by SHIONOGI based on GSK's Q2 Quarterly Results *2 Oral two-drug regimens: Dovato, Juluca *3 Long Acting injectable: Cabenuva, Apretude

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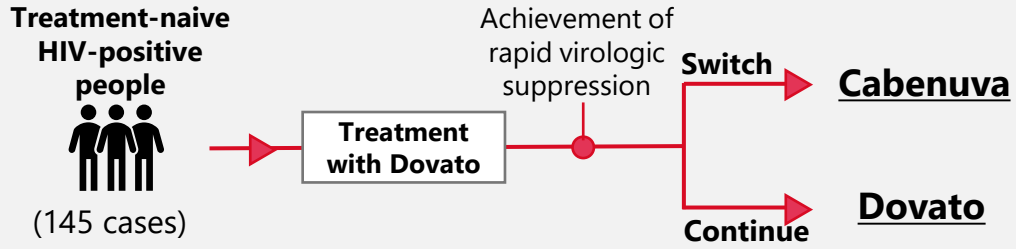
Various Clinical Data Supporting the Growth of LAI Products

Multiple reports suggest that cabotegravir formulations are preferred for treatment and prevention

Treatment VOLITION trial*1,2

A study investigating whether treatment-naïve people choose to switch to Cabenuva after achieving rapid viral suppression with Dovato

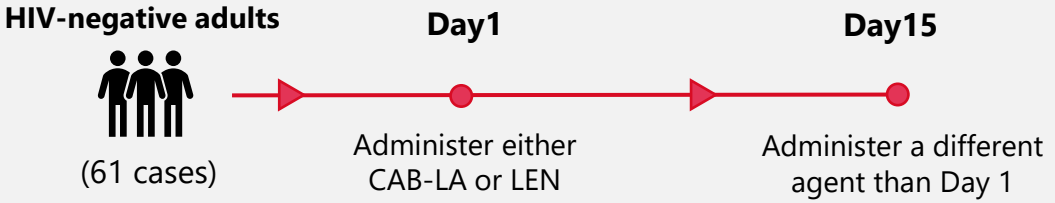


Evaluate the rates and drivers for switching from oral 2-drug regimens to LAI

Switching to Cabenuva	Switching drivers
Percentage of patients who chose to switch from oral medication to LAI formulations **89%**	Not having to worry about missing a dose each day **80%** Not having to carry medication **68%**

Prevention CLARITY trial*3,4

Phase1 study comparing acceptability and tolerability of single dose cabotegravir (CAB-LA) and lenacapavir (LEN) injections



Evaluate the acceptability of injection site reactions 7 days after administration of each drug.

Participants who answered "completely or very acceptable"		Percentage of people who preferred CAB-LA after single dose	
CAB-LA	LEN	HIV-negative adults	Healthcare providers
68%	**48%**	**90%**	**86%**

*1 Press release *2 NCT05917509 *3 Press release *4 NCT06970223

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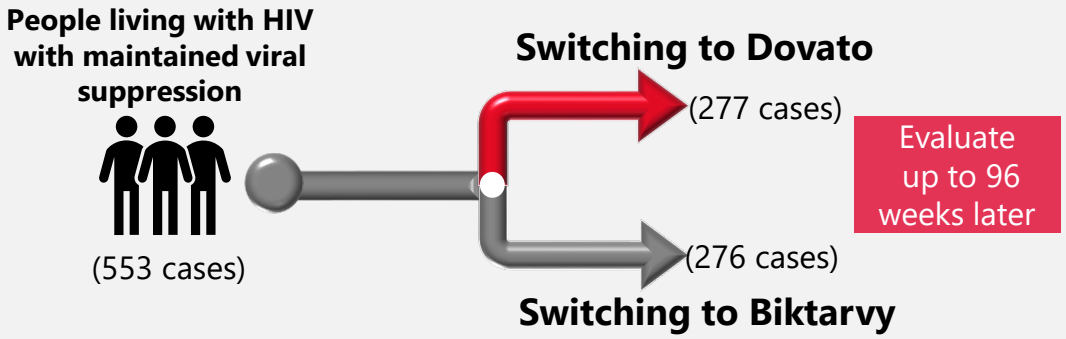
Clinical Evidence for Oral Two-Drug Regimens Uptake

Dovato as a promising option not only for its viral suppression effects but also for its impact on weight

PASO DOBLE trial*[1,2]

A head-to-head study comparing the two-drug regimen Dovato with Biktarvy (three-drug regimen)



Primary endpoint	Viral suppression after 96 weeks of treatment (Proportion of patients with HIV-1 RNA levels of ≥ 50 copies/mL, FDA snapshot method, non-inferiority margin 4%)
Key secondary endpoints	Weight gain, BMI change, percentage of subjects with weight gain of 5% or more, etc.

Results

Achieved primary and key secondary endpoints

- Viral load suppression effects after 96 weeks ---- **Non-inferiority**
- Weight gain side effect ---- **Significantly suppressed**

	Dovato	Biktarvy
Virologic failure	**0 case**	3 cases
Weight change after 96 wk	**0.84 kg**	2.35 kg
Percentage of participants gaining ≥5% of their body weight at wk 96	**20.1%**	34.8%
Drug-related adverse events	**7.6%**	13.4%

*[1] ViiV HEALTHCARE ANNOUNCES 96-WEEK DATA REAFFIRMING DOVATO IS AS EFFECTIVE AS BIKTARVY IN MAINTAINING VIROLOGICAL SUPPRESSION OF HIV-1 WITH SIGNIFICANTLY LESS WEIGHT GAIN *[2] NCT04884139

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Investment Strategy for Future Growth

Aiming to expand business in growth areas through aggressive investment, leveraging abundant cash flow

Business Investment

Proactive Promotion of Deals

JT Group Pharmaceutical Business M&A

Several other deals in progress

Prerequisites

- Further strengthen SHIONOGI's strengths
- Do not overinvest or buy at high prices

Capital Investment

Establishing a production system resilient to changes

Reintegration of Shionogi Pharma

Strengthen the global supply chain

Planned

- Update our own factories
- Establish overseas production capabilities

R&D Investment

Enhancing in-house drug discovery capabilities

Reorganization of research structure (integration with JT)

Progress in development pipeline

In progress

- Enhance speed and quality of drug discovery
- Focused investment in high-priority development pipeline

Reintegration of Shionogi Pharma*1

As a company striving to tackle infectious diseases,
we have reaffirmed the importance of building a production system resilient to environmental changes

- Factors behind the reintegration -

External Environment

- **Sudden fluctuations in demand**
  - Outbreaks of acute infectious diseases, shortages in medical pharmaceuticals supply
- **Rising geopolitical risks**
  - Risks in supply of raw materials and active pharmaceutical ingredients from overseas, rising costs
- **Declining labor population involved in production and quality**

Business Environment

- **Global business expansion, mainly for infectious disease drugs**
  - Cefiderocol, Ensitrelvir
- **JT Group pharmaceutical business M&A**
  - Torii and JT products, development pipeline

- Future Challenges and Countermeasures -

Accelerating the construction of a unified group production system

Shionogi & Co., Ltd.
(Parent company)

100%

Shionogi Pharma Co., Ltd.
(Subsidiary)

Scheduled for April 2027

Shionogi & Co., Ltd.

Reintegrate production functions within the company

- Building a production system for sudden fluctuations in demand
- Strengthening efforts in cost control and cost reduction
- Retaining and acquiring personnel responsible for production and quality control

*1 A wholly owned subsidiary of our company that manufactures and undertakes contract manufacturing of prescription pharmaceuticals, as well as contract manufacturing of investigational drugs, analytical testing, pharmaceutical engineering, etc.

Strengthening the Global Supply Chain

Establish manufacturing methods with superior quality and efficiency at in-house factories, and stably supply products globally under any circumstances

- Developing a self-led production network -

Centering on in-house factories and Expanding the range of control within the company

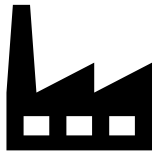
1

Review of manufacturing methods at in-house factories

Establish manufacturing methods with superior quality and efficiency

2

Expansion of production sites according to revenue growth



Based on established manufacturing methods, expand to 2nd and 3rd sites

- Key initiatives toward achieving our goals -

Update on our own factory

- Streamlining production and reducing manpower through advanced manufacturing technologies
  - Promotion of continuous manufacturing and DX*1 initiatives

Enhancement of overseas manufacturing capabilities

- Establishment of new overseas production sites
- Strengthening the global network with CMOs*2 and suppliers

S&OP*3 Function Reform

- **Strengthening collaboration among sales, supply, and production function**
  - Supplying medications in line with infectious disease trends
  - Ensuring a stable supply through highly accurate forecasting

*1 DX：Digital Transformation *2 CMO：Contract Manufacturing Organization *3 S&OP：Sales and Operation

Major Development Projects: Infectious Diseases

Project	Indication	Current stage*1	Update
Ensitrelvir	COVID-19 treatment	Submission	**Acceptance of New Drug Application by the EMA*2**
	COVID-19 treatment (age 6-11)	Submission	
	COVID-19 PEP	Submission	**Acceptance of New Drug Application by the FDA*3 and EMA**
S-268024	COVID-19 (JN.1 vaccine)	Phase 3	
Cefiderocol	AMR*4 (Pediatric・Gram-negative bacterial infection)	Phase 3	**Completed submission of all clinical trial reports to the FDA and EMA**
Olorofim	Invasive Aspergillosis	Phase 3	
S-337395	RSV infections	Phase 2b	**Initiated a phase 2b trial**
S-892216	COVID-19 treatment (Oral pill・ treatment)	Phase 2	**Primary endpoint achieved**
	COVID-19 (Long-acting injectable・ pre-exposure prophylaxis)	Phase 1	**Fast Track designation granted by the FDA**
S-743229	AMR (Complicated urinary tract infection)	Phase 1	
S-649228	AMR (Gram-negative bacterial infection)	Phase 1	
S-567123	COVID-19 Prevention(Injection)	non-clinical	

*1 The current stage indicated refers to the most advanced stage in any region, excluding countries or regions where the product has already been launched, and is not based on any specific region *2 EMA：European Medicines Agency *3 FDA：Food and Drug Administration *4 AMR：Antimicrobial Resistance

Major Development Projects: QOL Diseases with High Social Impact

Project	Indication	Current stage*1	Update
Zuranolone	Depression	Submission	
Resiniferatoxin	Pain associated with knee osteoarthritis	Phase 3	
Zatolmilast	Fragile X syndrome	Phase 2/3	**LPO*2 achieved**
	Jordan syndrome	Phase 2	
Redasemtide	Dystrophic epidermolysis bullosa	Phase 2	
	Acute ischemic stroke	Phase 2b	
SASS-001 (S-600918＋ Combination medicine)	Sleep apnea symdrome (central component)	Phase 2	
SASS-002 (Sulthiame)	Sleep apnea syndrome (obstructive)	Phase 2	**The results of the Phase 2 trial were published in the Lancet*3**
S-606001	Pompe disease	Phase 2	
S-309309	Obesity	Phase 2	
S-531011	Solid tumors	Phase 1b/2	**Obtained the results of Phase 1b parts**
S-151128	Chronic pain	Phase 1b	

*1 The current stage indicated refers to the most advanced stage in any region, excluding countries or regions where the product has already been launched, and is not based on any specific region
*2 LPO：Last Patient Out *3 The clinical trial conducted by Desitin prior to asset introduction to Shionogi-Apnimed Sleep Science, LLC: The Lancet

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S-892216 (COVID-19 Treatment, Oral): Phase 2 Trial Results

The Phase 2 trial conducted in Japan and US successfully achieved its primary endpoint

Trial design

Trial Design	Multicenter, Randomized, Double-blind, Placebo-controlled, Parallel-group trial
Subjects	Outpatients with COVID-19
Primary Endpoint	Change from baseline in SARS-CoV-2 viral RNA level by qRT-PCR testing (Nasopharyngeal swabs) on day 4
Secondary Endpoints	Safety, Pharmacokinetics, Time to sustained resolution of COVID-19 symptoms etc.
Dosing Regimen Sample Size	70 subjects each group • Placebo • S-892216: 3 groups

Preliminary trial results

- **Achieved primary endpoint**
  - Statistically significant reductions in viral load were confirmed in all S-892216 groups compared with placebo
- No new safety concerns were identified

Accelerating data analysis and study design planning in preparation for the upcoming Phase 3 trials

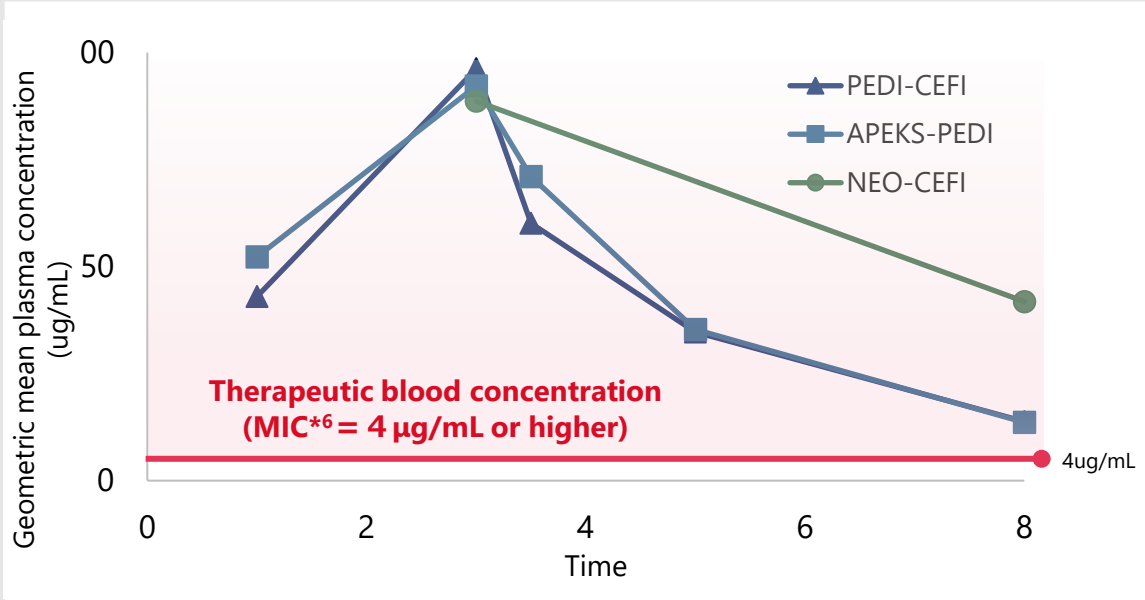
Cefiderocol Development Progress

Positive results confirmed in clinical trials on pediatric and neonates, application to be filed in Europe and the US within the fiscal year

Trial overview

Trial list	Pediatric*1: PEDI-CEFI*2, APEKS-PEDI*3 Neonate*4: NEO-CEFI*5
Study population	Hospitalized pediatric and neonatal patients with suspected or confirmed gram- negative bacterial infections
objective	Evaluate safety, tolerability, and pharmacokinetics in single and multiple doses

Results



- **Confirmed safety equivalent to that of adults**
- **Confirmed maintenance of plasma concentrations at therapeutically effective levels**

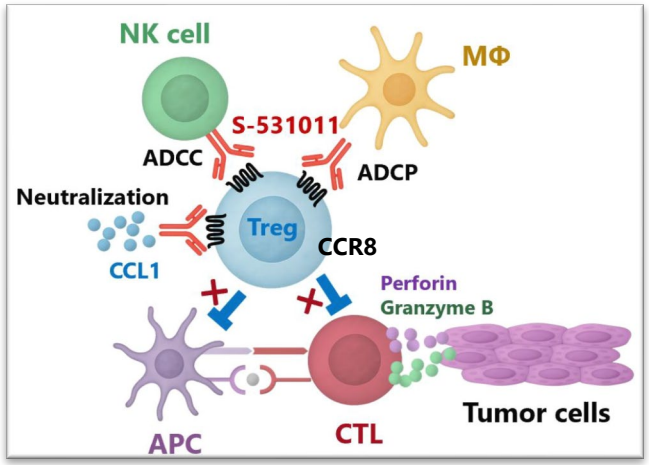
*1 Pediatric: 3 months to 18 years old *2 NCT04335539 *3 NCT04215991 *4 Neonate: 0-3 months *5 NCT06086626 *6 MIC：Minimum Inhibitory Concentration

S-531011 Mechanism and Future Schedule

Phase 1b trials showed positive results, and Phase 2 trials are currently underway

Concept and Mechanism

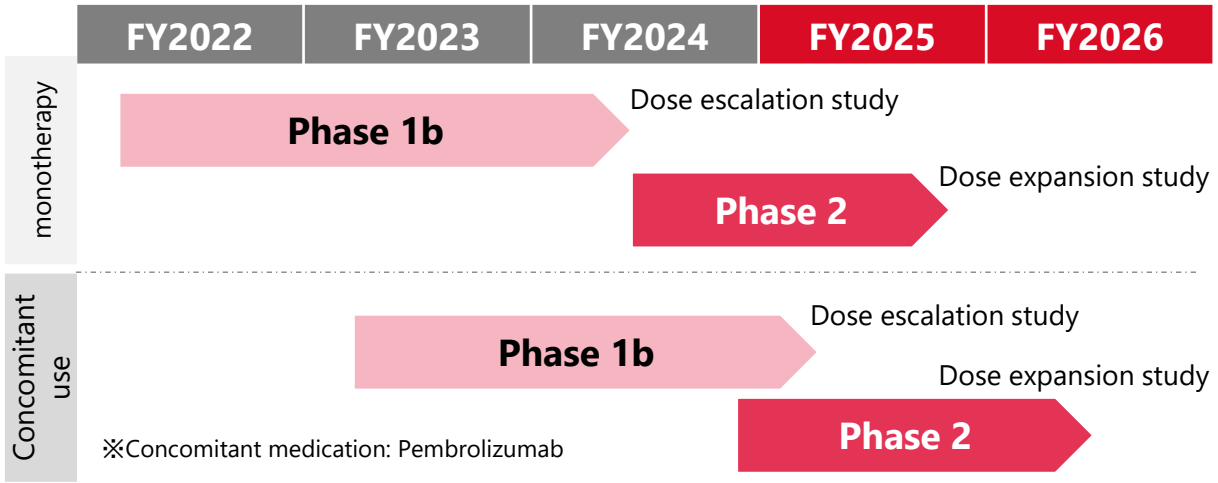
- 1995: Discovery of the existence of Treg*1
- 2014: Collaborative research with Osaka University on Treg begins
- 2018: CCR8*2, which is selectively highly expressed in intratumoral Tregs (patent pending) is discovered
- 2022: Clinical trials for S-531011 (a humanized antibody targeting CCR8) begins



1. S-531011 selectively binds to CCR8 expressed on tumor-infiltrating Tregs, exhibiting ADCC*3 activity, ADCP*4 activity, and neutralizing activity
2. Depletes tumor-infiltrating Tregs, thereby relieving immunosuppression
3. Restores tumor immunity and exerts antitumor effects

Phase 1b trial results*5 and future schedule

- Both monotherapy and combination therapy with pembrolizumab demonstrated **promising antitumor activity in advanced and metastatic colorectal cancer**
- All doses were **well tolerated**, both as monotherapy and in combination with Pembrolizumab



*1 CCR8: Chemokine (C-C motif) receptor 8 *2 Treg: Regulatory T cell *3 ADCC: Antibody-Dependent Cellular Cytotoxicity
*4 ADCP: Antibody-Dependent Cellular Phagocytosis *5 Presented at ASCO 2025 (American Society of Clinical Oncology Annual Meeting)

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Shareholder Return

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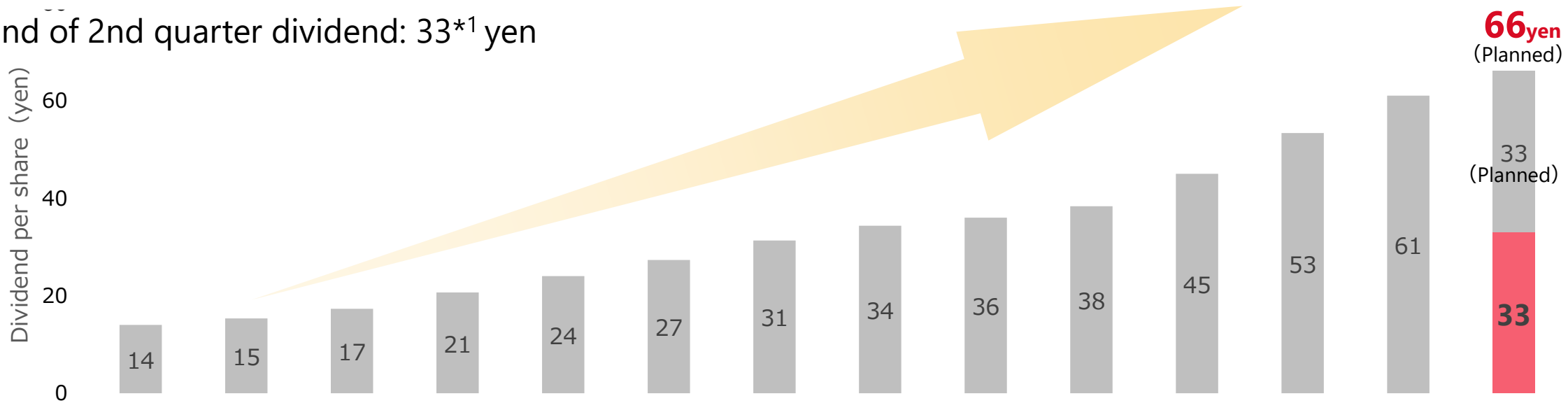
Shareholder Return

Shareholder return policy through which shareholders can feel our growth

- Considering flexible share buybacks based on the progress of growth investments
- Planning the **14th** consecutive annual dividend increase for FY2025
- End of 2nd quarter dividend: 33*1 yen



FY		12	13	14	15	16	17	18	19	20	21	22	23	24	25
Treasury stocks	Buyback (B yen)	-	-	30.0	-	35.0	29.4	50.0	50.0	50.0	-	49.4	75.0	-	-
	Cancelation*1 (M shares)	-	-	-	-	66.00	15.00	22.05	15.60*2	-	-	12.60	32.52*3	-	-

*1 Effective October 1, 2024, Shionogi has implemented a 3-for-1 stock split of its common stock. Dividends and Treasury stock's Cancelation are calculated based on the assumption that the stock split was implemented at the beginning of the FY2012 *2 Resolution passed on March 30, 2020, and treasure shares cancelled on April 6
*3 Resolution passed on July 31, 2023, and treasure shares cancelled on April 17, 2024

Appendix

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Shareholder Returns

Financial KPIs for the Medium-Term Management Plan STS2030 Revision Phase 2*1

Shareholder returns	FY2023 Results	FY2024 Results	FY2025 Target
EPS	181.17 yen	200.36 yen	200 yen or more
DOE	4.0 %	4.0 %	4 %
ROE	13.9 %	13.1 %	14 % or more

*1 Materials from the STS2030 Revision Medium-Term Management Plan briefing, announced in June 2023

FY2025 Exchange Rate

Exchange rate (average during the period)

	FY2025		
	Forecast (5/13)	Forecast (10/27)	Apr.-Sep. Results
USD($) – JPY(¥)	147 yen	146 yen	146.03 yen
GBP(£) – JPY(¥)	187 yen	197 yen	195.96 yen
EUR(€) – JPY(¥)	153 yen	171 yen	168.06 yen

Major Development Products

- Infection Diseases -

Pipeline	Indication	Current stage	Target Launch Timing*1
Ensitrelvir	COVID-19 treatment	Submission	- FY2027
	COVID-19 treatment (Pediatric Ages 6-11)	Submission	- FY2027
	COVID-19 PEP	Submission	- FY2027
S-268024	COVID-19 (JN.1Vaccine)	Phase3	- FY2027
Cefiderocol	Pediatric, Gram-negative bacterial infection	Phase 3	- FY2027
Olorofim	Invasive Aspergillosis	Phase 3	FY2028-2030
S-337395	RSV infections	Phase 2	FY2028-2030
S-743229	Complicated urinary tract infection	Phase 1	FY2028-2030
S-649228	Gram-negative bacterial infection	Phase 1	FY2028-2030
S-567123	COVID-19 (Universal vaccine)	Preclinical	FY2028-2030
S-892216	COVID-19 treatment (Oral))	Phase 2	FY2028-2030
	COVID-19 Prevention (Injection)	Phase 1	FY2031-

- QOL Diseases -

Pipeline	Indication	Current stage	Target Launch Timing*1
Zuranolone	Depression	Submission	FY2025
Resiniferatoxin	Pain associated with knee osteoarthritis	Phase 3	- FY2027
Zatolmilast	Fragile X syndrome	Phase 2/3	- FY2027
	Jordan syndrome	Phase 2	- FY2027
Redasemtide	Dystrophic epidermolysis bullosa	Phase 2	- FY2027
	Acute ischemic stroke	Phase 2b	FY2028-2030
SASS-001 (S-600918＋Combination medicine)	Sleep Apnea with a Central Component	Phase 2	FY2028-2030
S-531011	Solid tumor	Phase 1b/2	FY2028-2030
S-151128	Chronic pain	Phase 1b	FY2031-
S-606001	Pompe disease	Phase 2	FY2031-
S-309309	Obesity	Phase 2	Development Plan Under Consideration

*1 The listed launch timing refers to the earliest expected launch in any region and is not specific to any particular country or area

R&D Milestones Planned for FY2025

Red: Update from July 29, 2025, to October 28, 2025, ✓: Milestone-completed items

※Topline results: It is the timing of acquisition, and the timing of disclosure will be considered separately

Disease area	Pipeline	Indication	Current stage	FY2025 1H		FY2025 2H	
Infection Diseases	**Ensitrelvir**	COVID-19 treatment	Submission	Submission (EU)	✓		
		COVID-19 PEP	Submission	Submission (US, EU)	✓	Approval (Japan)	
		COVID-19 treatment (Pediatric Ages 6-11)	Submission	Submission (Japan)	✓		
	S-268024	COVID-19 (JN.1Vaccine)	Phase 3	Phase 3 Topline results	✓		
	Cefiderocol	Pediatric, Gram-negative bacterial infection	Phase 3	Phase 3 Topline results	✓	Submission (US, EU)	
	S-892216	COVID-19 treatment (Oral)	Phase 2			Phase 2 Topline results	✓
	S-743229	complicated urinary tract infection	Phase 1			Phase 1 Topline results	
	S-649228	Gram-negative bacterial infection	Phase 1			Phase 1 Topline results	
QOL Diseases with High Social Impact	**Zuranolone**	Depression	Submission			Approval (Japan)	
	Zatolmilast	Fragile X syndrome	Phase 2/3			Phase 2/3 Topline results	
	SASS-001 (S-600918 + Combination medicine)	Sleep Apnea with a Central Component	Phase 2			Phase 2 Topline results	
	S-531011	Solid tumor	Phase 1b/2			Phase 2 Topline results	
	S-606001	Pompe disease	Phase 2	Phase 1 Topline results	✓		
	S-740792	Gait disorders associated with multiple sclerosis	Phase 1			Phase 1Topline results	

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Pipeline: Infectious Diseases

as of October 27, 2025

Preclinical	Phase 1	Phase 2	Phase 3		Submission
S-567123 COVID-19 Universal vaccine	**S-743229** AMR (Complicated urinary tract infection)	**S-337395** RSV infections	**Cefiderocol** Gram-negative bacterial infection (Pediatric)	**Olorofim** Invasive Aspergillosis	**Ensitrelvir** COVID-19 treatment
S-872600 Influenza nasal vaccine	**S-649228** AMR (Gram-negative bacterial infection)	**S-892216** COVID-19 treatment (Oral pill・treatment)	**S-268023** COVID-19 vaccine (XBB 1.5)	**S-268024** COVID-19 vaccine (JN.1)	**Ensitrelvir** COVID-19 PEP
S-875670 COVID-19 nasal vaccine	**S-892216** COVID-19 (Long-acting injectable・pre-exposure prophylaxis)		**S-268019** COVID-19 vaccine (Ages 5-19)		**Cefiderocol** AMR (Gram-negative bacterial infection)
S-540956 Nucleic acid adjuvant					**Ensitrelvir** COVID-19 treatment (Ages 6-11)
S-554110 Nontuberculous mycobacterial infection					
S-917091 HIV infection					

Out license

S-365598 HIV infection	**Baloxavir** Influenza virus infection (Transmission)

Change from July 29, 2025, to October 27, 2025
• Baloxavir (Influenza virus infection Granules, < 20kg): Approval in Japan

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Pipeline: QOL Diseases with High Social Impact

as of October 27, 2025

Preclinical	Phase 1	Phase 2		Phase 3	Submission
S-540956 Nucleic acid adjuvan	**S-151128** Chronic pain	**S-309309** Obesity	**Redasemtide** Acute ischemic stroke	**Resiniferatoxin** **[GRT7039]** Pain associated with knee osteoarthritis	**Tapinarof** Atopic dermatitis in infants	**Zuranolone** Depression
S-109802 Post-stroke spasticity	**S-588210** Solid tumor	**S-531011** Solid tumor	**Redasemtide** Epidermolysis bullosa	**Zatolmilast** Fragile X Syndrome	**TO-210** Acne	**Naldemedine** Opioid-induced Constipation
	S-740792 Gait disorders associated with multiple sclerosis	**Naldemedine** Opioid-induced Constipation (pediatric)	**Zatolmilast** Alzheimer's disease	**S-588410** Esophageal cancer	**TO-209** Grass pollen-induced allergic rhinitis	**Tapinarof** Atopic dermatitisin Pediatric Patients
	S-898270 Alzheimer's disease	**S-588410** Bladder cancer	**ADR-001** Decompensated liver cirrhosi	**SR-0379** Cutaneous ulcer	**TO-203** House dust mite induced allergic asthma	
		S-488210 Head and neck squamous cell carcinoma	**S-222611** **[Epertinib]** Malignant tumor	**SDS-881** Dementia (AI program for cognitive function testing)		
		Zatolmilast Jordan syndrome	**SASS-001** (S-600918 ＋Combination medicine) Sleep Apnea with a Central Component			
		SASS-002 (Sulthiame) Obstructive Sleep Apnea	**Cantharidin*2** Common Warts			
		S-606001 Pompe disease	**S-723595** Type 2 diabetes			

Out license

Change from July 29, 2025, to October 27, 2025

- YCANTH*1: Approval in Japan
- Tapinarof *1 (Atopic dermatitisin Pediatric Patients): Submission in Japan
- Tapinarof *1 (Atopic dermatitis in infants): Phase 3
- TO-210*1: Phase 3
- TO-209*1: Phase 3
- TO-203*1: Phase 3
- Cantharidin*1: Phase 2*2

: Progress from to July 29 2025, to October 27, 2025

*1 Torii Pharmaceutical's Development Pipeline
*2 Conducted by Verrica in the US

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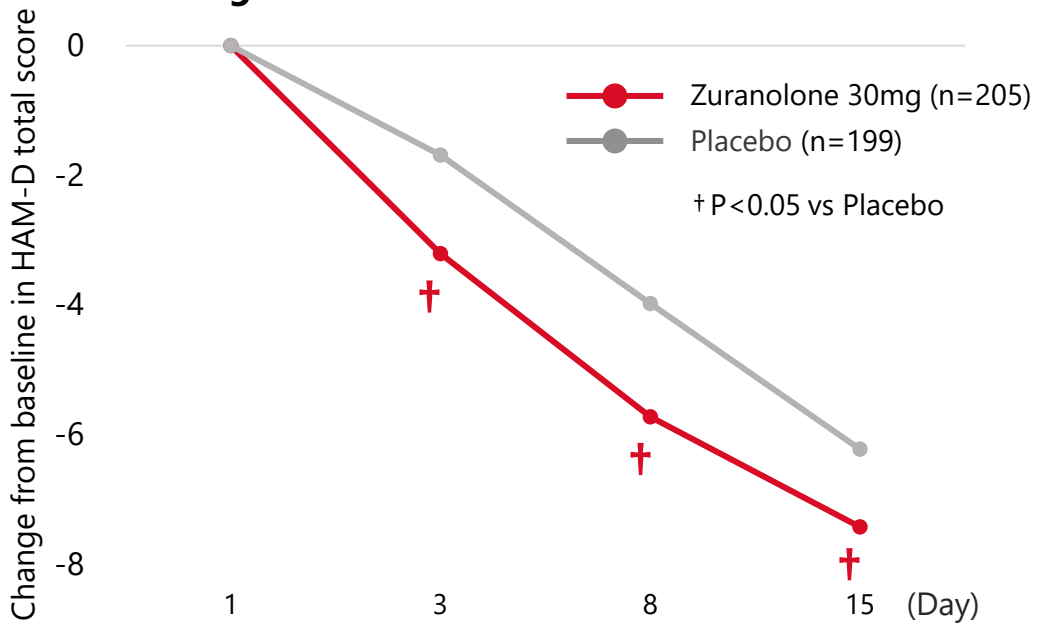
Zuranolone: New Drug Application (NDA) in Japan for Major Depressive Disorder

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.47

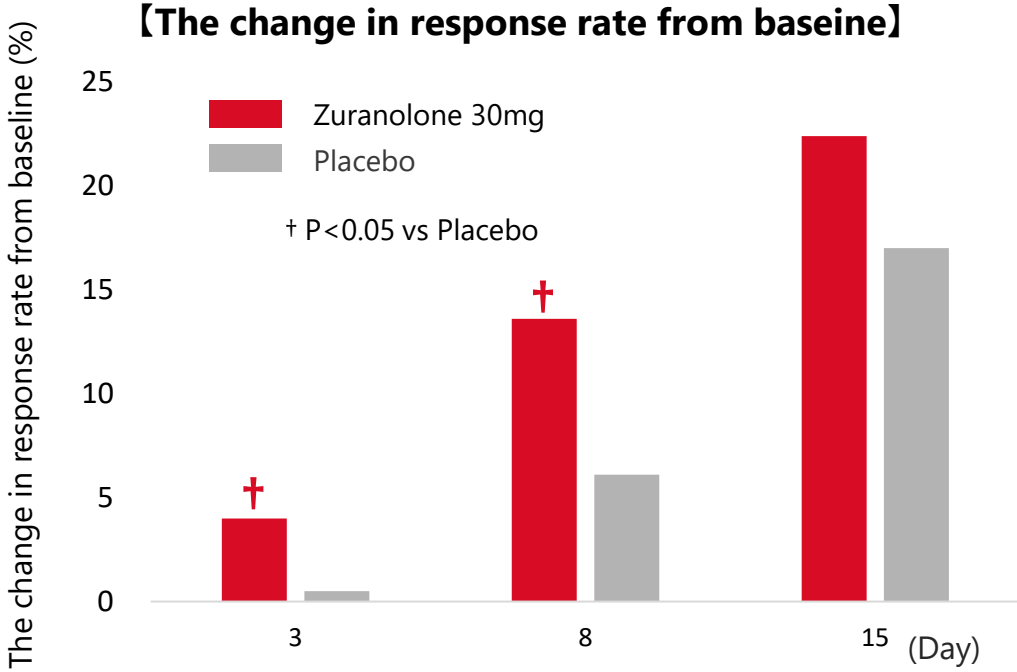
Results from Phase 3 validation study

【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 baseine】



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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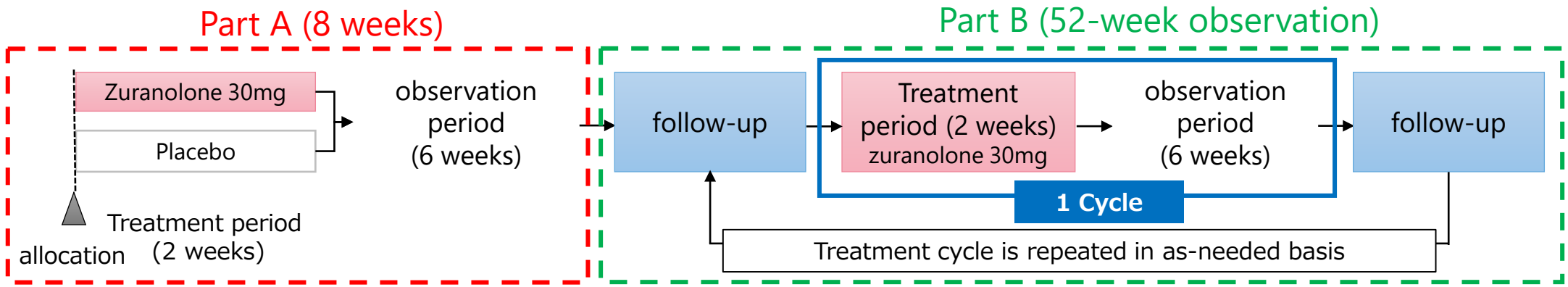
Zuranolone: Phase 3 Validation Study Design

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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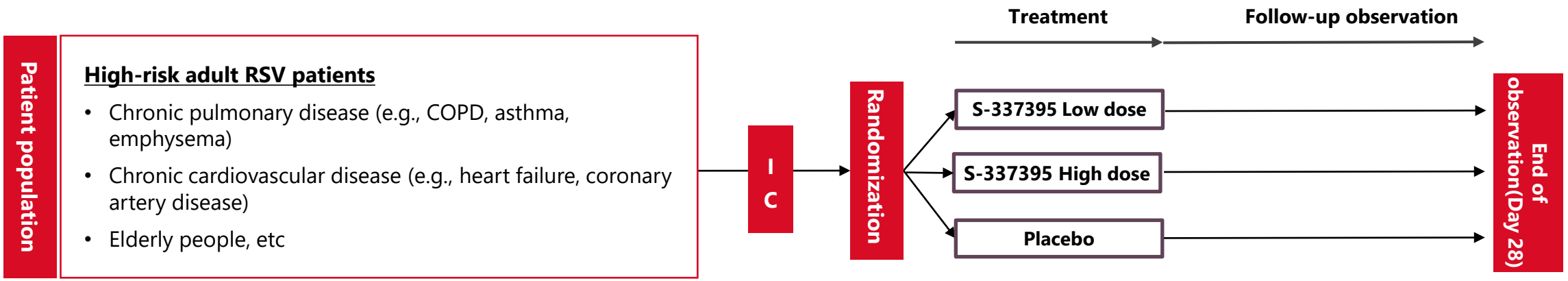
S-337395*1: Upcoming Development Plan (Phase 2b trial overview and design)

Initiated a Phase 2b study targeting high-risk patients, aiming to develop the world's first oral therapeutic

Primary Endpoint	Change from baseline in viral RNA load (qRT-PCR)
Secondary objectives	Efficacy assessment: time-course change from baseline in symptom severity score
Trial Design	Multicenter, randomized, double-blind, placebo-controlled, parallel-group design
Dosing Regimen Sample Size	• Randomization cohorts: placebo (n=64) • S-337395 low dose (n=64), high dose (n=64)



*1 Joint development with UBE Corporation

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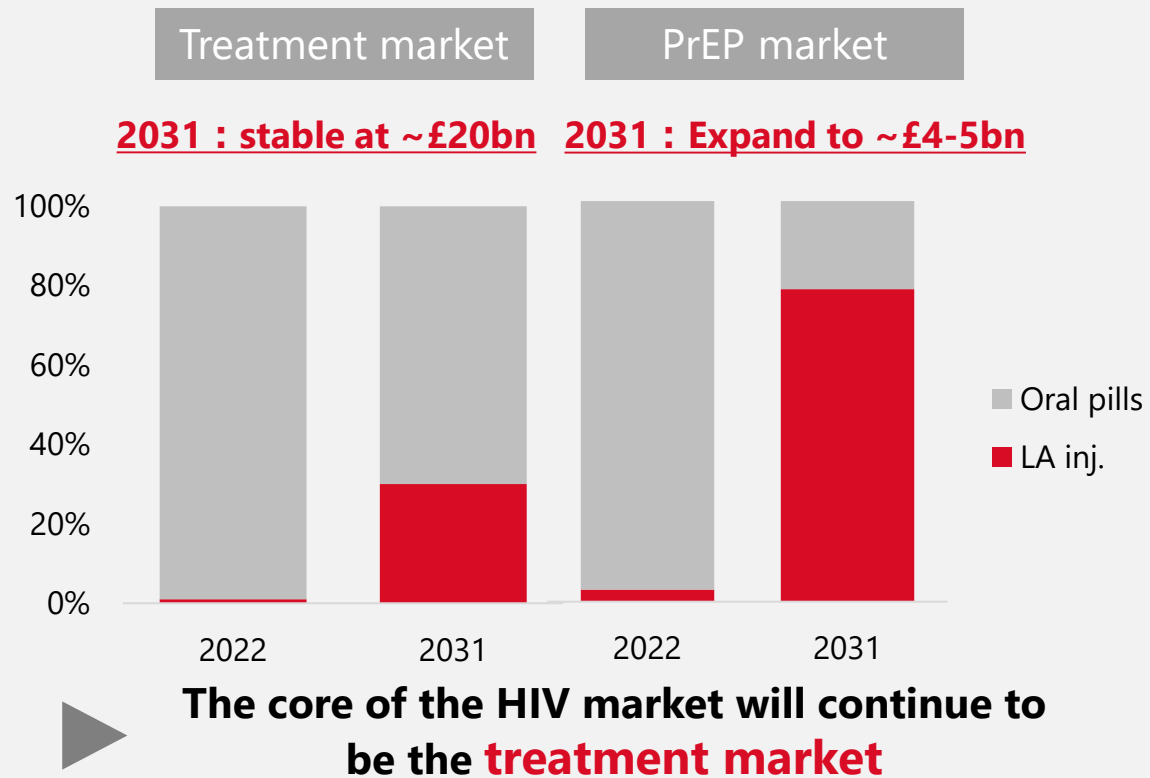
Anti-HIV Drug Released by ViiV

Product name	Formulations	Compounds	Administrations	Frequency	Indications	CY2024 Sales
Cabenuva	LAI formulations	CAB＋RPV	IM injection	Q2M (LA)	Treatment	£1,013M
Apretude		CAB	IM injection	Q2M (LA)	PrEP	£279M
Dovato	Oral two-drug regimens	DTG＋3TC	Oral	Every day	Treatment	£2,239M
Juluca		DTG＋RPV	Oral	Every day	Treatment	£685M
Tivicay	Oral single agent	DTG	Oral	Every day	Treatment	£1,350M
Triumeq	Oral three-drug regimen	DTG+ABC+3TC	Oral	Every day	Treatment	£1,325M

Growth Outlook for the HIV Market (Treatment + Prevention)

In the treatment and PrEP*1 market, LA formulations will continue to drive growth

Outlook for the HIV Market*2 (Treatment + PrEP)



The core of the HIV market will continue to be the treatment market

Treatment

- In the US, new infections have increased by approximately 2.5-3% in recent years*3
- The market size will be stable even after the launch of oral GE drugs
- **LA formulations, including integrase inhibitors**, will continue to be mainstream
  - LA injectables are expected to represent approximately **~30%** of the total by 2031

PrEP

- In the US, currently about one-third of potential candidates (approximately 1.2 million people) are receiving PrEP medications*4
- With the penetration of LA formulations, the overall PrEP market is expected to expand
  - LA injectables are expected to represent approximately **~80%** of the total by 2031
- LA integrase inhibitors are also expected to be an important option in the PrEP market, potentially taking over the substantial majority of the market if reimbursement is sufficient.

*1 PrEP: Pre-Exposure Prophylaxis *2 ViiV Healthcare Meet the Management *3 https://www.hiv.gov/hiv-basics/overview/data-and-trends/statistics
*4 https://www.cdc.gov/nchhstp/director-letters/expanding-prep-coverage

Other Major Progress[*1]

- August
  - Shionogi & Co., Ltd. Selected for METI's FY2024 Supplementary Budget Grant Program for Future-Oriented Co-Creation with the Global South – Feasibility Study on the Use of Digital Solutions to Promote Appropriate Use of Japan-Origin Antimicrobials and Hygiene Products in Kenyan Healthcare Facilities –

- September
  - Shionogi & Co., Ltd. and FRONTEO launch "Talk Lab KIBIT," a web application that uses AI analysis to assess mental health.
  - Shionogi & Co., Ltd. and FRONTEO have signed an absorption-type company split agreement to transfer Japan Tobacco Inc.'s pharmaceutical business to Shionogi.
  - Shionogi & Co., Ltd. and AirDog Japan have signed a basic business agreement to promote awareness of the current state and challenges of infectious diseases.

[*1] Only items with progress made between July 28 and October 20, 2025 are listed.

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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