1st Quarter of Fiscal 2025 Financial Results

July 28, 2025

Shionogi & Co., Ltd.

SHIONOGI

Agenda

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02 **Progress of HIV Business** **（P.9-11）**

03 **Toward the Realization of the 2030 Vision** **（P.12-23）**

- Integration with JT Pharmaceutical Division
- Advancement of the Pipeline

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Overview of Q1 FY2025 Financial Results

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Q1 FY2025 Highlights

Steady progress from both financial and non-financial perspectives

- **Achieved year-on-year growth in revenue and all profit metrics**
  - Expansion of the HIV franchise
- **Successful completion of the tender offer for TORII*1**
  - Significant progress toward the integration of JT Group's pharmaceutical business
- **Advancement of the development pipeline supporting medium- to long-term growth**
  - Submitted regulatory applications for ensitrelvir in the US and Europe

*1 Press release from June 2025: Scheduled to become a wholly owned subsidiary from September 2025

Financial Results

Achieved year-on-year increases in revenue and across all profit categories

(Unit: B yen)

	FY2025				FY2024	Y on Y	
	Forecast Full year	Forecast 1H	Apr.-Jun. Results	Achievement (%)	Apr.-Jun. Results	Change (%)	Change
Revenue	530.0	233.0	**99.8**	**42.8**	97.6	**2.2**	**2.2**
Operating profit	175.0	82.0	**35.1**	**42.8**	28.1	**24.9**	**7.0**
Profit before tax	222.0	102.0	**46.3**	**45.4**	36.5	**26.8**	**9.8**
Profit attributable to owners of parent	180.0	86.0	**39.4**	**45.8**	30.6	**28.5**	**8.7**
EBITDA*1	196.0	93.0	**40.6**	**43.7**	33.1	**22.8**	**7.5**

*1 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.)

Statement of Profit or Loss

(Unit: B yen)

	FY2025				FY2024	Y on Y	
	Forecast Full year	Forecast 1H	Apr.-Jun. Results	Achievement (%)	Apr.-Jun. Results	Change(%)	Change
Revenue	530.0	233.0	**99.8**	**42.8**	97.6	**2.2**	**2.2**
Cost of Sales	16.6 88.0	14.2 33.0	12.3 **12.3**	**37.3**	14.8 14.4	**(14.7)**	**(2.1)**
Gross profit	442.0	200.0	**87.5**	**43.7**	83.1	**5.2**	**4.3**
SG&A*1, R&D expenses total	49.6 263.0	49.8 116.0	51.3 **51.2**	**44.1**	55.9 54.6	**(6.2)**	**(3.4)**
SG&A*1	24.7 131.0	24.9 58.0	26.4 **26.3**	**45.4**	25.8 25.1	**4.6**	**1.2**
R&D expenses	24.9 132.0	24.9 58.0	24.9 **24.9**	**42.9**	30.2 29.4	**(15.4)**	**(4.5)**
Other income & Expenses	(4.0)	(2.0)	(1.2)	**58.6**	(0.5)	**152.8**	**(0.7)**
Operating profit	33.0 175.0	35.2 82.0	35.2 **35.1**	**42.8**	28.8 28.1	**24.9**	**7.0**
Finance income & costs	47.0	20.0	**11.2**	**56.2**	8.4	**33.5**	**2.8**
Profit before tax	41.9 222.0	43.8 102.0	46.4 **46.3**	**45.4**	37.4 36.5	**26.8**	**9.8**
Profit attributable to owners of parent	180.0	86.0	**39.4**	**45.8**	30.6	**28.5**	**8.7**

Main variation Factors (Y on Y)

Revenue

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

Cost of Sales

- Decrease: Changes in product mix

SG&A

- Increase: Selling-related expenses in US business

R&D expenses

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

Finance income & costs

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

*1 Selling, general & administrative

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Revenue by Segment

(Unit: B yen)

	FY2025				FY2024	Y on Y	
	Forecast Full year	Forecast 1H	Apr.-Jun. Results	Achievement (%)	Apr.-Jun. Results	Change(%)	Change
Prescription drugs	183.0	62.0	**14.1**	**22.8**	15.4	**(8.5)**	**(1.3)**
Overseas subsidiaries/export	54.9	25.7	**14.2**	**55.4**	15.0	**(4.9)**	**(0.7)**
Shionogi Inc. (US)	22.6	10.9	**6.2**	**56.8**	6.0	**3.7**	**0.2**
Fetroja	-	-	**5.9**	-	4.8	**23.2**	**1.1**
Shionogi B.V. (EU)	16.9	8.3	**4.7**	**56.7**	4.0	**17.4**	**0.7**
Fetcroja	-	-	**3.4**	-	3.1	**10.6**	**0.3**
Shionogi China	7.0	3.5	**1.5**	**42.8**	2.3	**(34.7)**	**(0.8)**
Others	8.4	3.0	**1.8**	**61.3**	2.7	**(31.6)**	**(0.9)**
Contract manufacturing	13.2	6.5	**4.5**	**68.5**	3.6	**24.1**	**0.9**
OTC and quasi-drug	18.5	8.9	**2.4**	**27.2**	2.4	**0.1**	**0.0**
Royalty income	257.9	128.7	**63.9**	**49.7**	61.0	**4.7**	**2.9**
HIV franchise	244.8	125.8	**61.2**	**48.6**	59.8	**2.3**	**1.4**
Others	13.1	2.9	**2.7**	**94.5**	1.2	**125.0**	**1.5**
Others	2.5	1.2	**0.6**	**52.7**	0.2	**282.1**	**0.5**
Total	530.0	233.0	**99.8**	**42.8**	97.6	**2.2**	**2.2**

Main variation Factors (Y on Y)

Prescription drugs

- Decrease: Sales of acute respiratory virus infection treatments

Overseas subsidiaries/export

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

Contract manufacturing

- Increase: Supply of APIs to ViiV and Roche

Royalty income

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

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Results for Q1 FY2025 and Future Outlooks

Driven by top-line growth and appropriate cost management, H1 forecast is expected to be achieved

	Results for Q1	Future outlooks
Top-line	• Expansion of the HIV franchise led by ViiV • Steady growth of cefiderocol	• Continued growth of the HIV franchise and cefiderocol • Increased sales of Xocova driven by the COVID-19 outbreak - Promotion of actions to improve treatment rates
cost management	• Implementation of cost management aligned with revenue • Progress in investments toward growth drivers was on track as planned	• Strengthening cost management with a view to M&A • Accelerating strategic R&D investments based on priorities

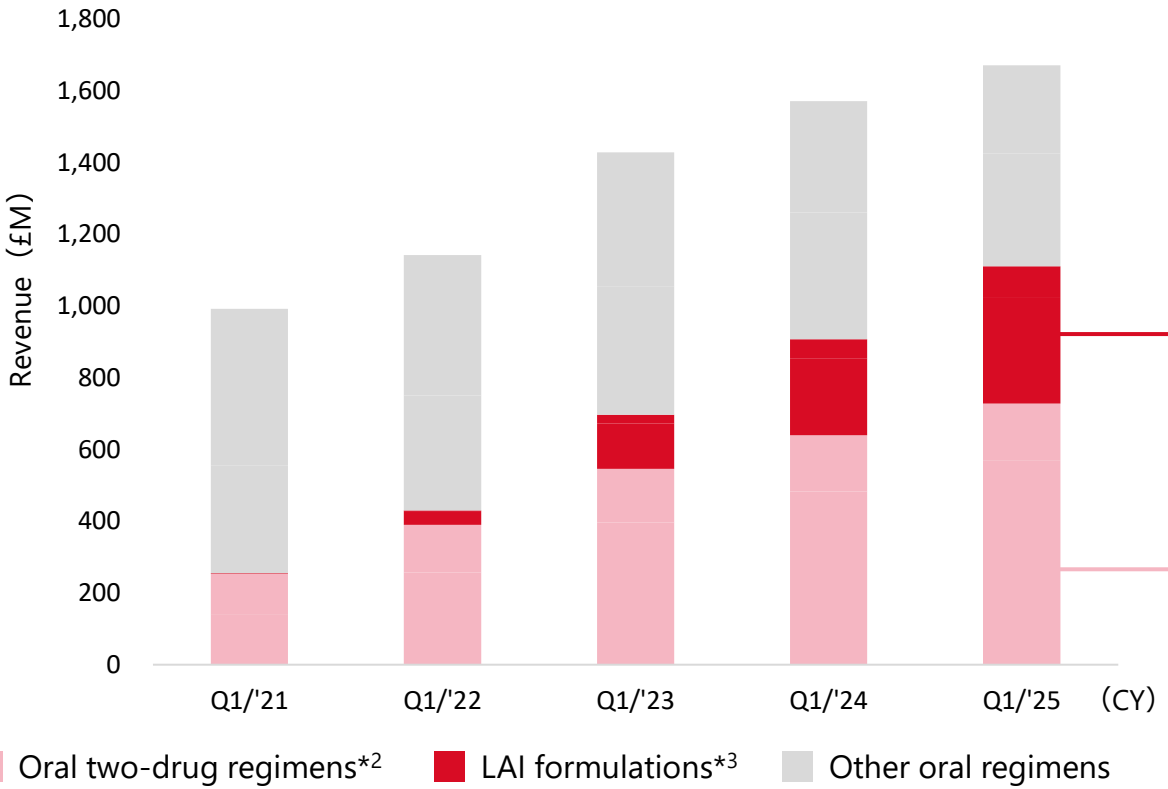
Progress of HIV Business

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Progress of HIV Business by ViiV Healthcare

The expansion of Long-Acting Injectables and oral two-drug regimens is accelerating, driving overall growth in the HIV business

ViiV's sales trends*1



YoY increase from the same period

Treatment

Cabenuva (cabotegravir + rilpivirine)

+ £**81**M (+38%) Q1 CY2025 result: £294M

PrEP

Apretude (cabotegravir)

+ £**35**M (+63%) Q1 CY2025 result: £89M

Treatment

Dovato (dolutegravir + lamivudine)

+ £**87**M (+19%) Q1 CY2025 result: £570M

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

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Development of ULA*1 formulation: S-365598/VH184*2 (Third-generation Integrase Inhibitor)

Candidate for multiple LAI formats, including Q6M, with potential to cover strains resistant to current INSTIs

Key features of S-365598/VH184

Distinct resistance profile compared with existing therapies

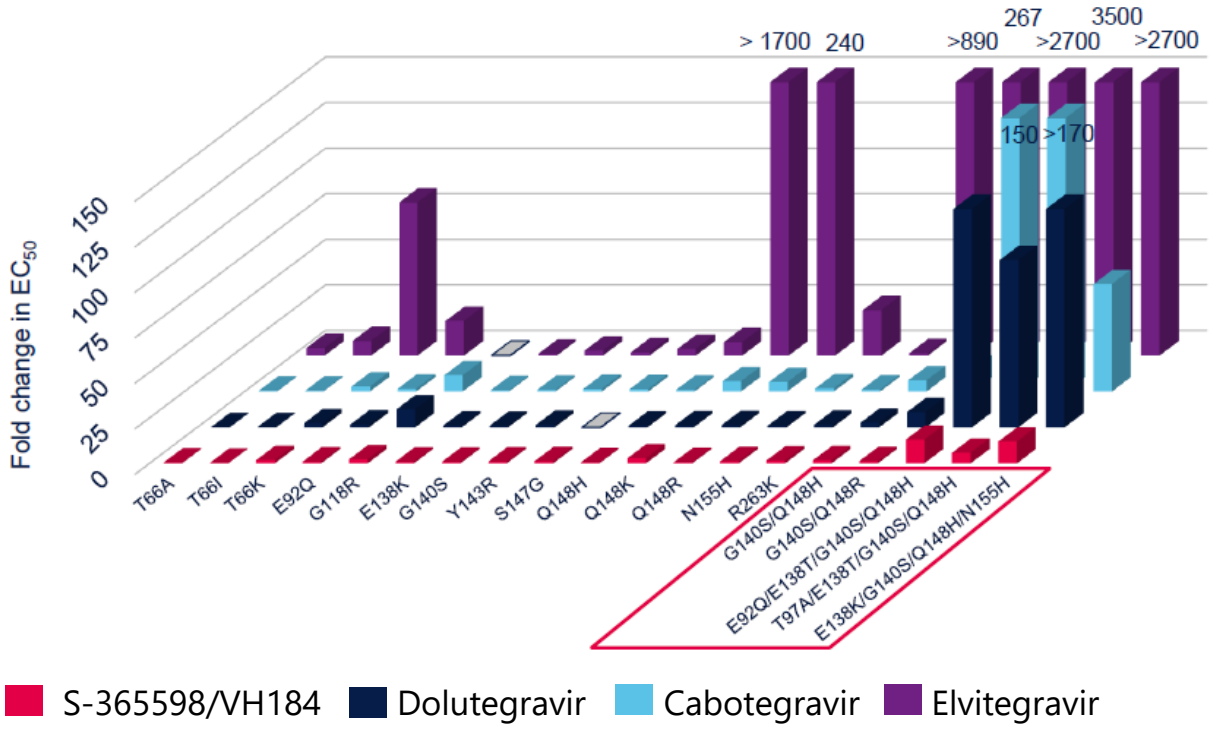
- Maintains antiviral activity against known resistance-associated mutations (highlighted in the red frame)

Development status

Q2M self-administration and Q6M formulation identified as a therapeutic candidates

- PoC*3 confirmed in an oral Phase 2 study
- Durability being evaluated in the Q6M formulation
  - Preliminary acquisition planned for CY2025

Antiviral activity of S-365598/VH-184 against a panel of HIV-1 molecular clones harboring INSTI resistance–associated mutations（In vitro)



*1 ULA: Ultra Long Acting *2 The third-generation integrase inhibitor (development code: VH4524184) licensed out by Shionogi to ViiV *3 PoC: Proof of Concept

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Toward the Realization of the 2030 Vision

- Integration with JT Pharmaceutical Division
- Advancement of the Pipeline

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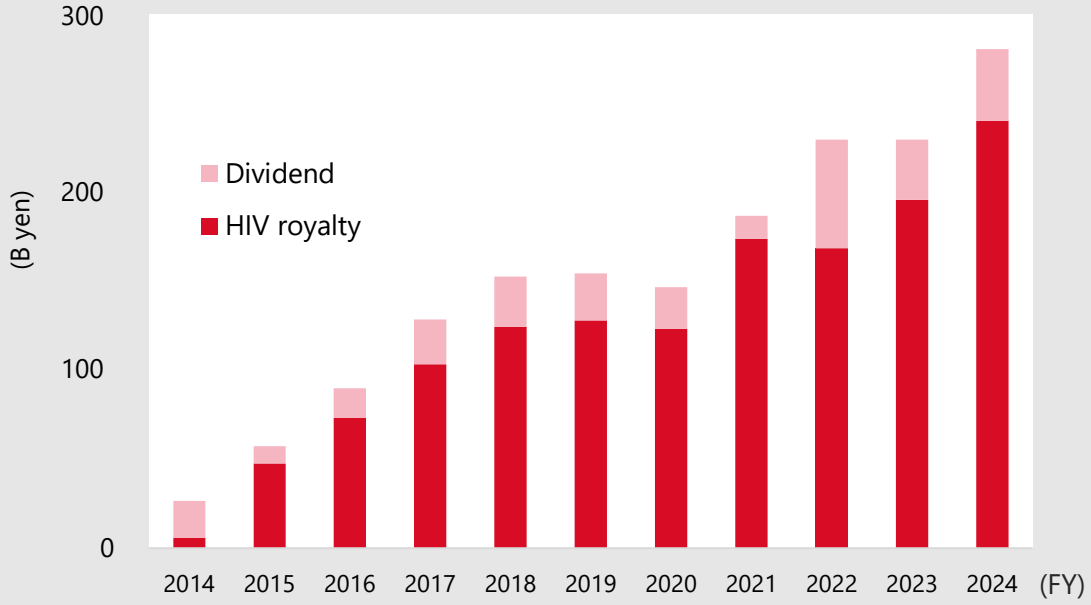
Premise for M&A: Outlook for Stable Management

The HIV business is expected to continue its steady growth

Growth of HIV business

Build a highly efficient and robust earnings base

[Trends of HIV royalty income and dividend from ViiV]



Mid- to long-term HIV business outlook

HIV business will remain the backbone of the business even after 2030

-Strong growth in LAI[*1] formulations-

Sustained growth of Cabenuva and Apretude

-Developing next-generation growth drivers-

Accelerating growth through the launch of new ULA[*2] formulations

[*1] Long Acting Injectable : Formulations administered once every two months [*2] Ultra Long Acting: Formulations administered once every 4 to 6 months

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Integration with JT Group's Pharmaceutical Business

M&A aligned with our management strategy reinforces our proprietary R&D and domestic commercial strength*1

SHIONOGI's Business Strategy*2: Delivering internally developed new drugs globally while pursuing

Creation of proprietary products

- Proportion of In-house drug discovery: **69**%*3

Royalty business

Our own commercialization

JT

Strengthening proprietary drug discovery capabilities

Establishing the world's leading small molecule drug discovery platform

TORII

Domestic commercial strength

Creating synergies in sales activities

*1 Agreement on the Absorption-Type Split of JT Pharmaceutical Division and Acquisition of Shares of Akros, and Commencement of Tender Offer for TORII in May 2025

*2 2030 Vision and Medium-Term Business Plan "Shionogi Transformation Strategy (STS2030)" in June 2020

*3 * The proportion of in-house origin compounds in the development pipeline as of May 2025 (including development candidates and results from joint research with partners)

Integration with JT Group's Pharmaceutical Business: M&A Prioritizing the Enhancement of In-House Drug Discovery Capabilities

Strengthening our proprietary pipeline through integration with JT

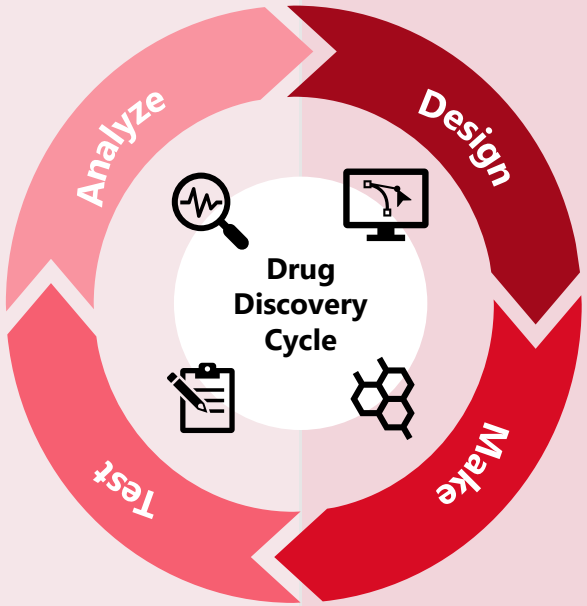
Accelerating and enhancing the quality of the drug discovery cycle

Pharmacology/ Safety and ADME Profiling

Streamlining the Drug Discovery Process

Prediction of Pharmacokinetics
(Advanced non-clinical evaluation systems)

A Platform Enabling Rapid and Thorough Evaluation
(JT's proprietary HTS*1 system that demonstrates strong capabilities in small molecule drug discovery)



Medicinal chemistry

Synthesis of High-Quality Compounds

Target Identification Based on JT's Unique Structural Insights
Combining protein structural analysis with strong capabilities in identifying high-quality targets, both augmented by AI

Expanded Team of Experienced Medicinal Chemists
Track record of generating numerous innovative drug candidates

Reinforcing our drug discovery foundation through advanced platforms

Data generation and utilization and compound profile prediction with advanced technology platforms (including AI and quantum computing)

*1 HTS: High Throughput Screening (A method for rapidly screening large-scale compound libraries to identify potential drug candidates)

Integration with JT Group's pharmaceutical business: Domestic commercial strength*1

Sales of both companies' products are expanding through co-promotion with TORII

Overview of the Co-promotion (Starting September 1): Product coverage will be expanded progressively

	Previous situation	Post-Co-promotion Landscape
Xocova **Xofluza** Acute Respiratory Virus Infection Treatments	Infectious diseases in internal medicine represent a core strength of Shionogi **Mainly focused on internal medicine** ※Also engaged in otolaryngology, but coverage remains limited	Leveraging TORII's strengths **to expand the sales network** Internal medicine + **Otolaryngology**
Corectim Medications for Atopic Dermatitis	TORII has strengths in otolaryngology and dermatology **Mainly focused on dermatology**	Leveraging Shionogi's strengths **to enhance outreach in internal medicine** **Internal medicine** + Dermatology

*1 In response to the request from the Japan Fair Trade Commission regarding information blocking related to Actair and Miticure, we are proceeding with careful measures in close coordination with TORII

Achieving the 2030 Vision

- Integration with JT Pharmaceutical Division
- Advancement of the Pipeline

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COVID-19 Anti-Viral Drugs: Development Update

Significant progress in the global expansion of ensitrelvir, with steady advancement of S-892216

Ensitrelvir

	Previous Status	Current Status
US	Initiated a rolling submission	Indication: prevention **Regulatory application submitted**
EU	Preparing for submission	**Indication: Treatment and post-exposure prophylaxis** **Regulatory application submitted**
Japan	Indication: Approved for treatment Indication: Additional application for post-exposure prophylaxis Pediatric indication in preparation	**Additional application for dosage and administration submitted** for pediatric patients aged 6 years and older and weighing at least 20 kg

S-892216

Antiviral Activity

Compared to existing therapies

App. **20** -Fold Higher Potency

DDI*1

No concerns against CYP3A inhibition

Use in Pregnant Women

No concerns In non-clinical studies

Demonstrates a superior profile as a next-generation COVID-19 anti-viral drug

	Update
Oral Treatment	Phase 2 ongoing: **FPI*2 achieved**
LAI*3 **PrEP*4**	Phase 1*5 initiated: April

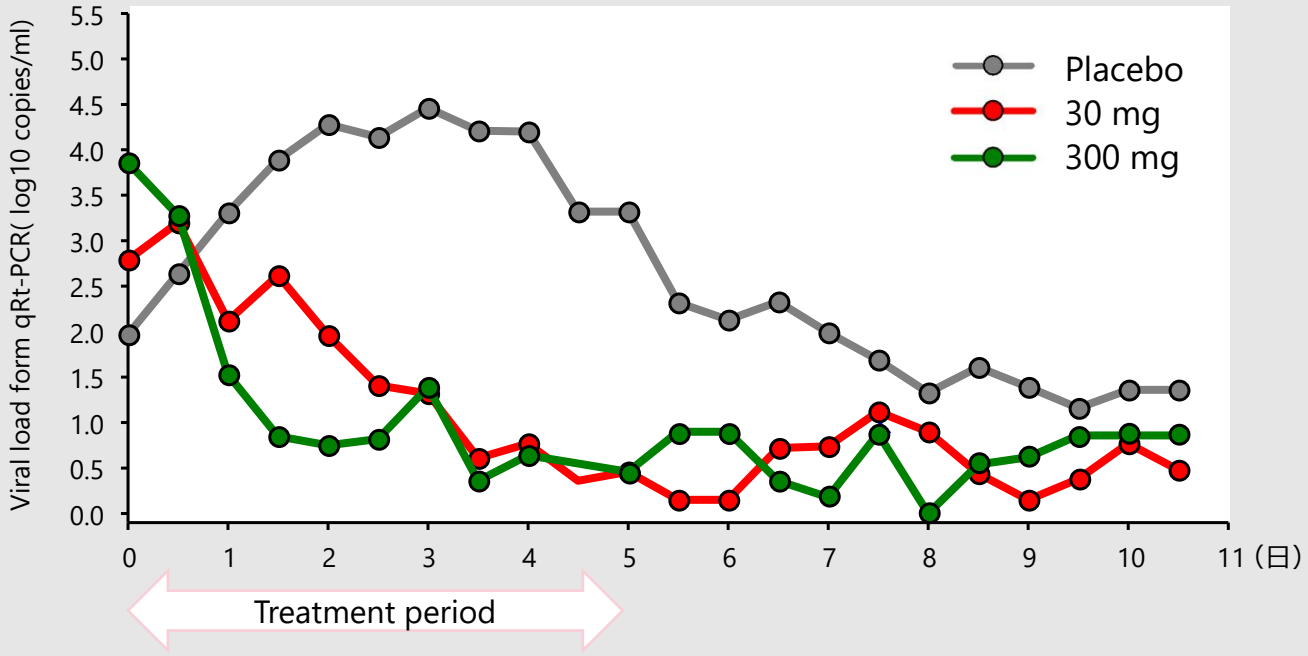
*1 Drug-Drug Interactions *2 First Patient In
*3 Long Acting Injectable *4 Pre-exposure prophylaxis

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

S-337395: Results from the Phase 2a Human Challenge Study[*1]

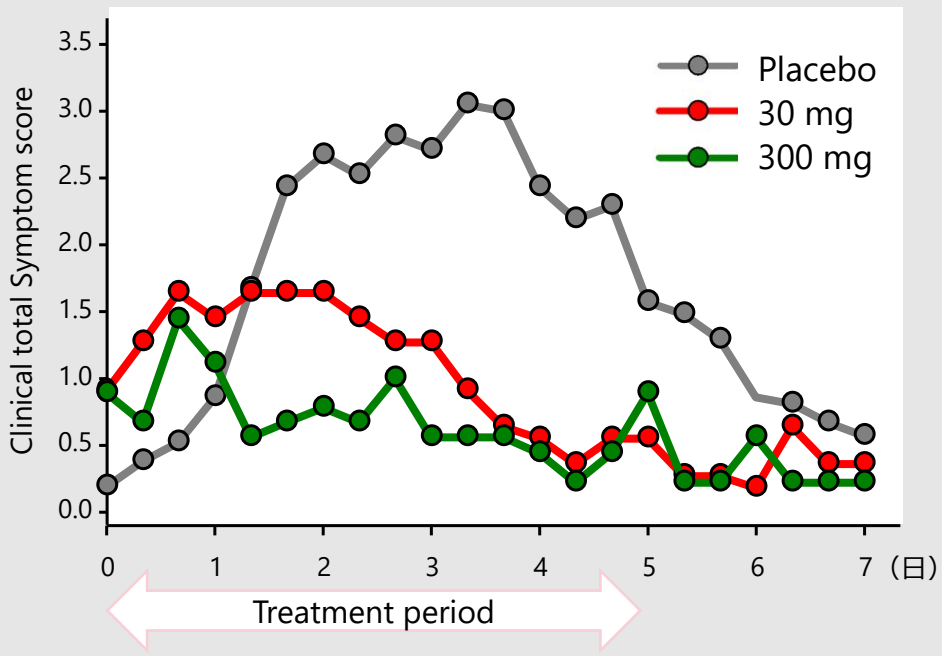
Demonstrated strong antiviral activity and a trend toward symptom improvement, supporting development as an RSV therapeutic

- Primary Endpoint: AUC of viral RNA load measured by qRT-PCR[*2] -



- **Dose-dependent reduction in viral load confirmed**
- **Statistically significant reduction in viral load compared with placebo (Viral AUC was reduced by approximately 89% versus placebo)**

- Secondary endpoint: Time course of symptom scores[*3]-



Statistically significant improvement in clinical symptom scores

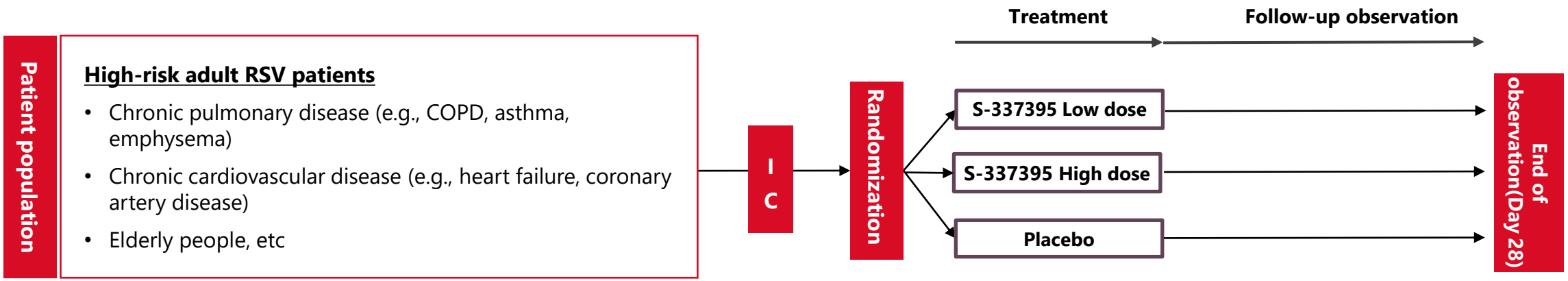
[*1] Joint development with UBE Corporation [*2] A method for the highly sensitive and quantitative measurement of specific RNA levels in viruses or cells
[*3] Participants self-evaluated 10 symptoms three times daily; analyses were based on scores at each time point

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

Initiate a Phase 2b trial in high-risk patients before year-end, accelerating development toward the world's first oral RSV therapy

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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COVID-19 Vaccine Portfolio

S-268024 achieved the primary endpoint, advancing the vaccine business to the next stage

Project	Antigen	Status	Remarks
COVGOZE	**Wuhan**	Approval (Q1 FY2024)	–
S-268023	**XBB1.5**	Phase 3 completed (Q2 FY2024)	・Primary endpoint*1 not achieved (Confirmation of neutralizing antibody induction against the XBB.1.5 variant) ・Favorable safety profile
S-268024	**JN.1**	Phase 3 in progress (Q1 FY2025)	**・Primary endpoint*1,2 achieved** **(Non-inferiority to intramuscular Nuvaxovid)** **・Favorable safety profile**
S-567123	**Sarbecovirus** **(Universal vaccine)**	Phase 1 in preparation (As of Q1 FY2025)	Clinical trial designs are under consideration, and preclinical studies are ongoing

*1 Geometric mean titer of neutralizing activity and antibody response rate against JN.1 variant on Day 29 after vaccination *2 JRCT

S-268024: Phase 3 Results

In the clinical trial, non-inferiority to vaccines of the same modality and favorable safety profile were confirmed

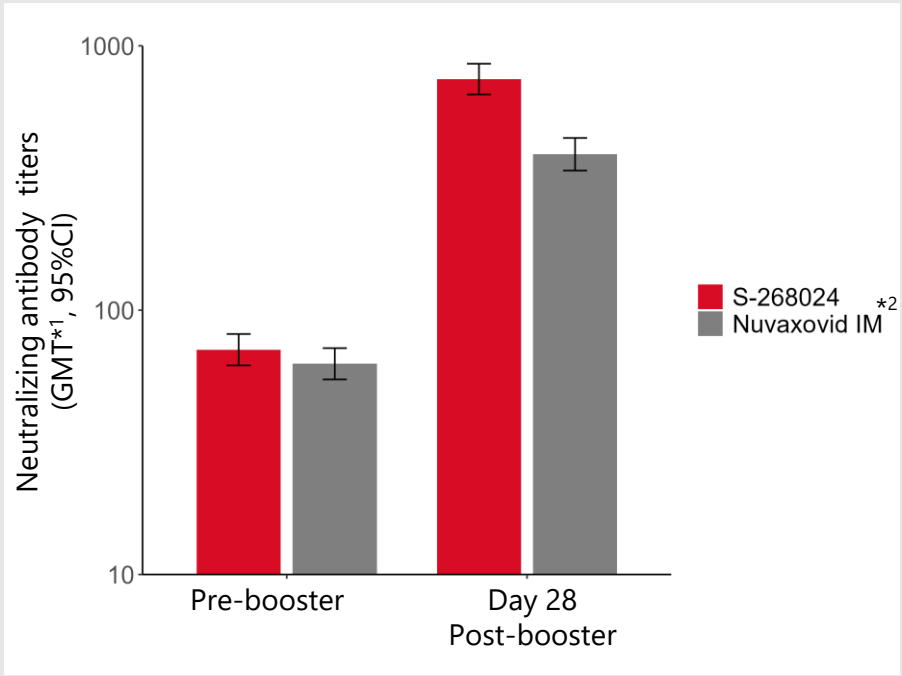
—Study objective and primary endpoint—

Purpose	Comparison of neutralizing antibody titers against the SARS-CoV-2 JN.1 variant following booster immunization with S-268024 versus intramuscular Nuvaxovid Participants: Individuals aged 18 years and older who have completed primary immunization
Primary endpoints	**Day 28 post-booster against SARS-COV-2 JN.1 variant:** • **Geometric mean neutralizing antibody titer (Non-Inferiority)** • **Seroconversion rate (Non-Inferiority)**

—Safety—

- S-268024 demonstrated **a favorable safety profile** comparable to COVGOZE and S-268023
- No new safety concerns were identified in this study

—Geometric mean neutralizing antibody titers (JN.1 variant)—



Non-inferiority to Nuvaxovid was demonstrated

*1 geometric mean titer *2 Intramuscular Injection

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Progress of Main Pipelines: QOL Diseases with High Social Impact

Steady progress toward establishing growth drivers in QOL indications

Pipeline	Indication	Update
Naldemedine	Opioid-induced constipation	**Completion of regulatory submission in China*1**
Redasemtide	Dystrophic epidermolysis bullosa	**Last Patient In (LPI) achieved for the additional Phase II clinical trial**
S-606001	Pompe disease	**Initiation of Phase 2**
S-898270	Alzheimer's Disease	**Initiation of Phase 1**
SASS-002 (Sulthiame)	Obstructive Sleep Apnea	**In-licensed to Joint Venture Shionogi-Apnimed Sleep Science*2 (Phase 2)**

*1 Press release (May 2025) *2 Press release (April 2025)

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Appendix

Prescription Drugs in Japan

(Unit: B yen)

	FY2025				FY2024	Y on Y	
	Forecast Full year	Forecast 1H	Apr.-Jun. Results	Achievement (%)	Apr.-Jun. Results	Change(%)	Change
Acute Respiratory Virus Infection Treatments	85.8	31.0	**2.9**	**9.3**	3.9	**(25.8)**	**(1.0)**
Quviviq	9.3	1.2	**0.1**	**9.8**	-	**-**	**0.1**
Symproic	8.1	3.9	**1.5**	**37.6**	1.1	**35.3**	**0.4**
OxyContin franchise	5.6	2.9	**1.1**	**38.9**	1.0	**8.3**	**0.1**
Others	74.2	23.0	**8.5**	**37.1**	9.4	**(9.4)**	**(0.9)**
Total	183.0	62.0	**14.1**	**22.8**	15.4	**(8.5)**	**(1.3)**

Acute Respiratory Virus Infection Treatments

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

FY2025 Exchange Rate

Exchange Rate (Average)		
	FY2025	
	Forecast	Apr.-Jun. Results
USD($) – JPY(¥)	147	144.60
GBP(£) – JPY(¥)	187	193.03
EUR(€) – JPY(¥)	153	163.83

COVID-19 Anti-Viral Drugs: Post-Marketing Large-Scale Clinical Studies

A reduced risk of developing post-COVID-19 conditions (Long COVID) was observed with antiviral treatment

Prospective observational study in COVID-19 patients at Tokushukai Group hospitals (ANCHOR studies)

- Study design -

Objective	Evaluate the frequency of post-COVID-19 conditions*1 with or without treatment with antiviral drug*2
Target patients	Inpatients and outpatients aged ≥12 years with confirmed SARS-CoV-2 infection and symptoms at Tokushukai Group hospitals
Endpoint	Incidence of post-COVID-19 conditions

- Interim report -

Compared to the absence of antiviral treatment, the administration of antiviral therapy

Antiviral treatment significantly reduced the risk of developing post-COVID-19 symptoms in a statistically meaningful manner

Detailed study results to be presented at a scientific conference

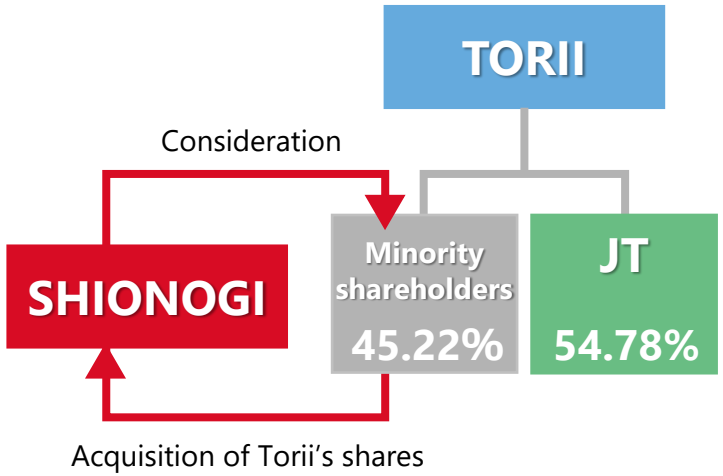
*1 At both 28 and 84 days after a positive diagnosis, the presence of any one of the following five symptoms was assessed: Fatigue, Dyspnea or respiratory distress, Olfactory (smell) dysfunction, Gustatory (taste) dysfunction, Cough (related to or unknown association with COVID-19)
*2 Treatment administered with one of the following: ensitrelvir, nirmatrelvir/ritonavir, or molnupiravir

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The M&A Process

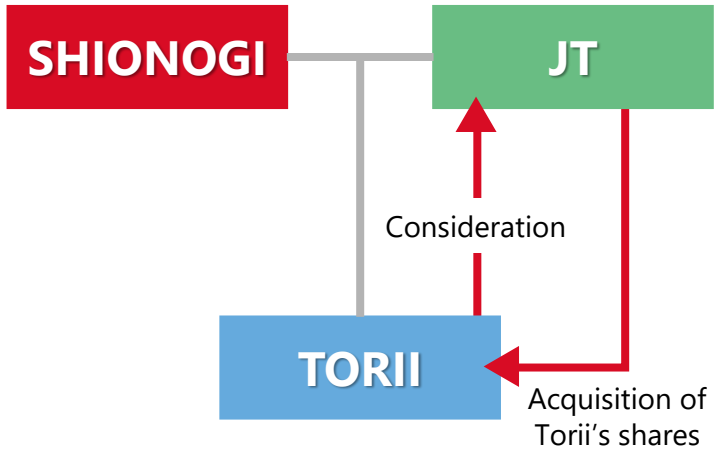
With the successful completion of the tender offer for Torii's shares, all of JT's Group Pharmaceutical Division will be transferred to SHIONOGI

Implementation of a tender offer for minority shareholders of Torii
⇒The TOB has been successfully concluded*1

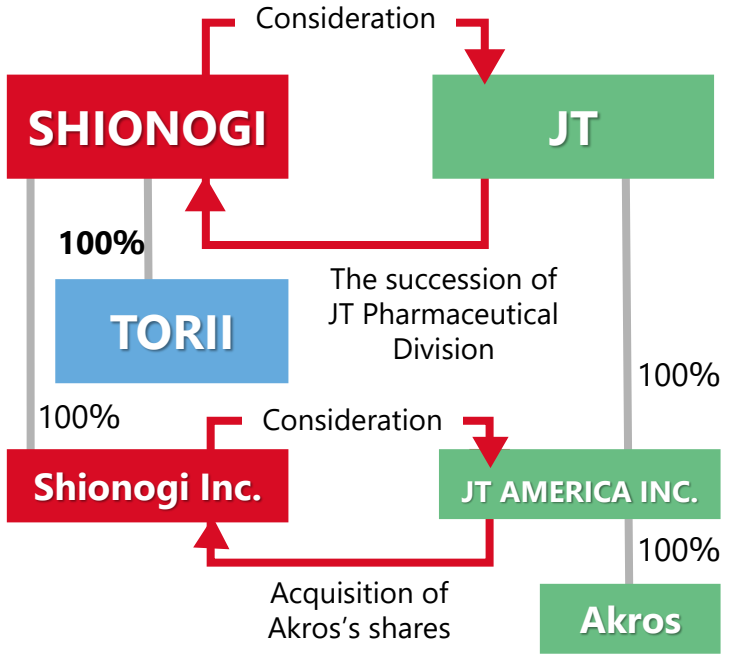


※ JT has agreed not to participate

- **Acquisition of own shares by Torii**
- **Complete subsidiary acquisition by SHIONOGI**



- **The succession of JT Pharmaceutical Division**
- **Acquisition of shares of Akros Pharma Inc.**



*1 Press release (June, 2025)

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Timeline of the M&A Transaction

Future planned actions

September 2025：The effectiveness of the stock consolidation and acquisition of own shares
⇒ Torii will become a wholly-owned subsidiary of SHIONOGI

December 2025：The effectiveness of the company split ⇒
- JT Pharmaceutical Division will be absorbed by SHIONOGI
- Akros will become a wholly-owned subsidiary of Shionogi inc.

- At the time of effectiveness for each of the above transactions, there will be no changes implemented in terms of business relationships, employee duties, workplaces, or working styles

CY2025							
May	June	July	August	September	October	November	December
The announcement of this transaction	**The TOB was successfully concluded*1**			The complete subsidiary acquisition of Torii		• JT Pharmaceutical Division will be absorbed by SHIONOGI • Akros will become a wholly-owned subsidiary of Shionogi inc.	

*1 Press release(June, 2025)

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R&D Milestones Planned for FY2025

Red: Update from May 13, 2025, to July 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, US)	
		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 bacteria infection	Phase 3	Phase 3 Topline results		Submission (US, EU)	
	S-892216	COVID-19 treatment (Oral)	Phase 2			Phase 2 Topline results	
	S-743229	Complex urinary tract infection	Phase 1			Phase 1 Topline results	
	S-649228	Gram-negative bacteria infection	Phase 1			Phase 1 Topline results	
QOL Diseases with High Social Impact	**Zuranolone**	Depression	申請			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 1b/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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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 bacteria 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 bacteria 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

Pipeline: Infectious Disease

as of July 28, 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** Aerobic Gram-negative bacterial infection (Pediatric)	**Olorofim** Invasive Aspergillosis	**Ensitrelvir** COVID-19 treatment
S-872600 Influenza nasal vaccine	**S-649228** AMR (Gram-negative bacteria 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)		**Baloxavir** Influenza virus infection (Granules, < 20kg)
S-540956 Nucleic acid adjuvant					**Cefiderocol** AMR (Gram-negative bacteria infection)
S-554110 Nontuberculous mycobacterial infection					**Ensitrelvir** COVID-19 treatment (Ages 6-11)
S-917091 HIV infection					

Out license

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

Change from May 13, 2025, to July 28, 2025
• Baloxavir (Influenza virus infection, Pediatric, < 1 year old): Aprpoval in EU • Ensitrelvir (COVID-19 treatment): Submitted in EU • Ensitrelvir (COVID-19 PEP): Submitted in US and EU • S-892216 (COVID-19 treatment Ages 6-11): Submitted in Japan

: Progress from to May 13 2025, to July 28, 2025

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Pipeline: QOL Diseases with High Social Impact

as of July 28, 2025

Preclinical	Phase 1	Phase 2		Phase 3	Submission
S-540956 Nucleic acid adjuvant	**S-151128** Chronic pain	**S-309309** Obesity	**Redasemtide** Acute ischemic stroke	**Resiniferatoxin [GRT7039]** Pain associated with knee osteoarthritis	**Zuranolone** Depression
S-109802 Post-stroke spasticity	**S-588210** Solid tumor	**S-531011** Solid tumor	**Redasemtide** Epidermolysis bullosa	**Zatolmilast** Fragile X Syndrome	**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	
	S-898270 Alzheimer's disease	**S-588410** Bladder cancer	**ADR-001** Decompensated liver cirrhosis	**SR-0379** Cutaneous ulcer	
		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	**S-723595** Type 2 diabetes	**Out license**	
		S-606001 Pompe disease			

Change from May 13, 2025, to July 28, 2025

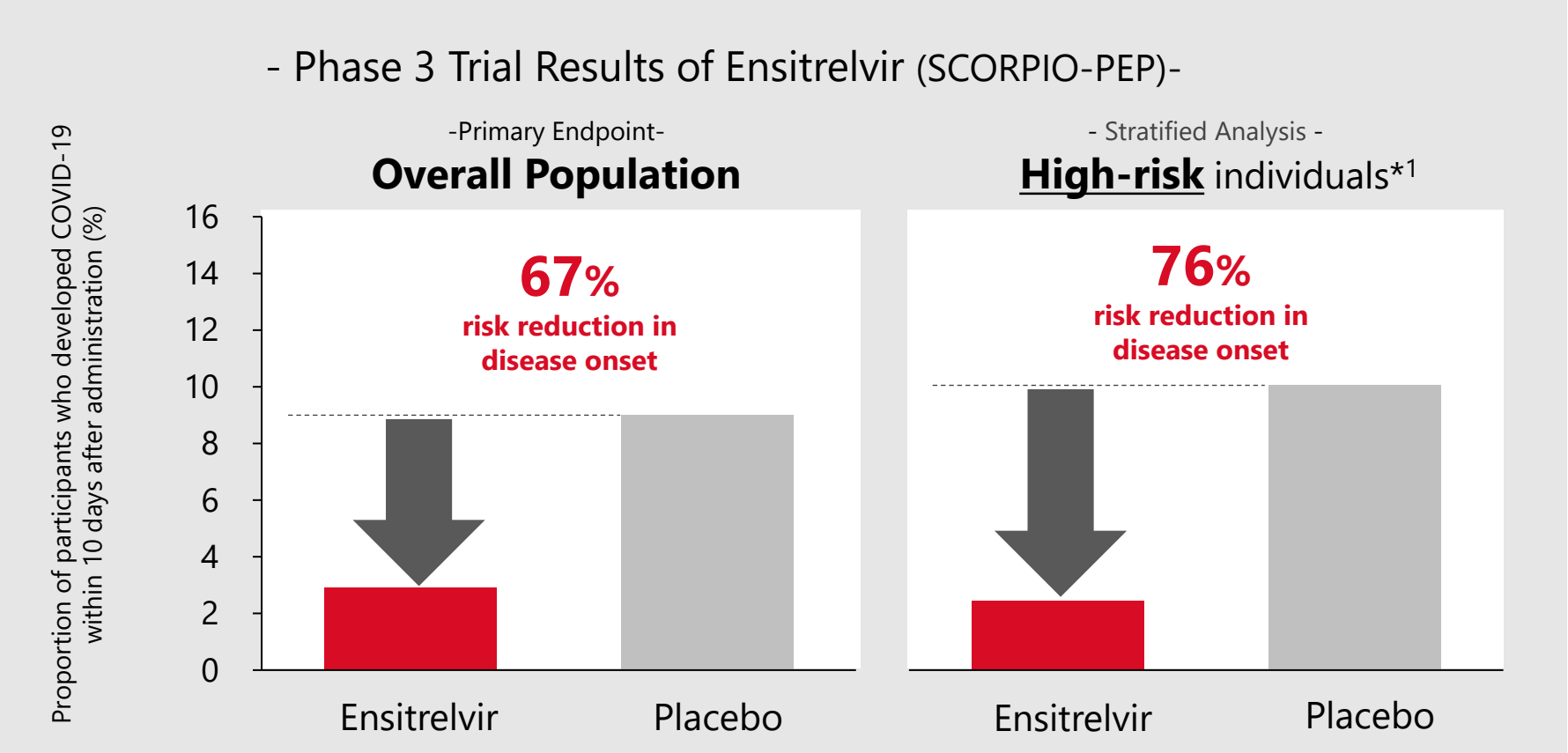
- Naldemedine: Submitted in China
- SASS-002(Sulthiame): In-licensed to Joint Venture Shionogi-Apnimed Sleep Science (Phase 2)
- S-606001: Phase 2 started
- S-898270: Phase 1 started

: Progress from to May 13 2025, to July 28, 2025

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Ensitrelvir: Results of SCORPIO-PEP Study

The world's first results demonstrating the preventive effect of an oral antiviral drug against the onset of COVID-19



*1 Key representative high-risk factors: BMI ≥30 kg/m2, smoking (current or former), age (≥65 years), heart disease, diabetes (type 1 or type 2); high risk is ≥1 risk factor

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S-337395
Indications: RSV Infection

Product Features:

- Antiviral drug with a new mechanism of action (L protein inhibitor)
  - Compound discovered through joint research with UBE
- Easy to use oral medication
- Potent antiviral effect

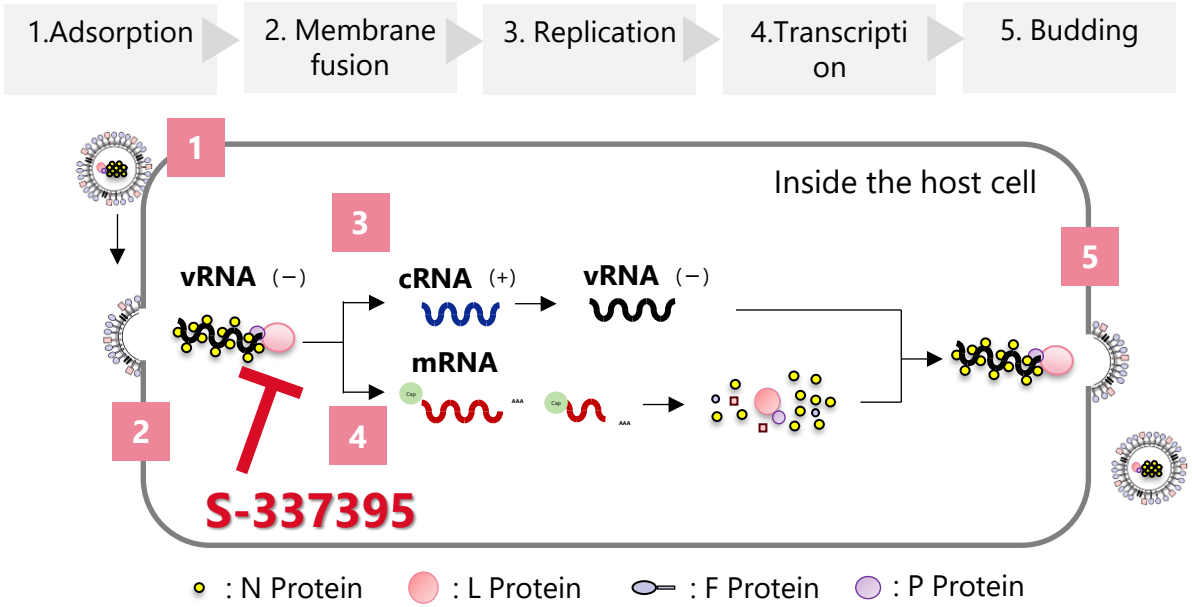
Market: Potential Patient Numbers in the US*1,2

A large market with over 3 million potential patients annually

Infants and young children (0–5 years)	High-risk patients (65 years and older)
Approximately **2.1** M People	Approximately **1.2** M People
—Hospitalized patients— 58,000-80,000 People	—Hospitalized patients— -108,000 People
—Number of deaths— 100-500 People	—Number of deaths— 7,700 People

Mechanism of action:

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



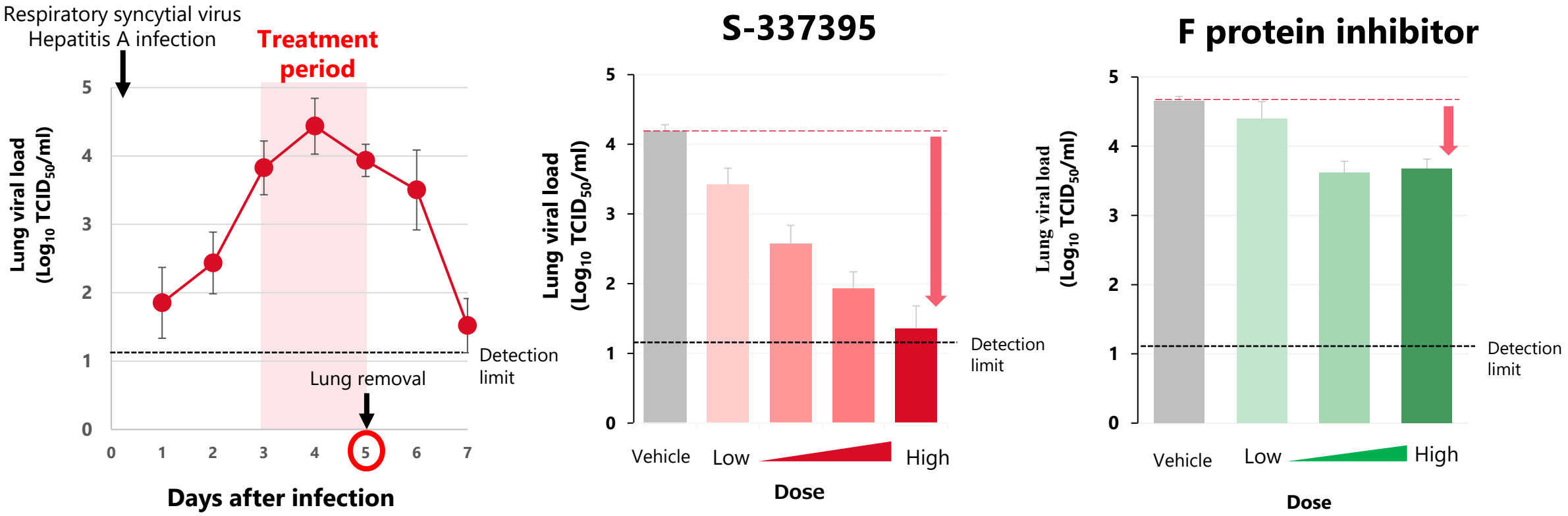
*1 Miloje Savic et al. "Respiratory syncytial virus disease burden in adults aged 60 years and older in high-income countries: A systematic literature review and meta-analysis"
*2 Hall CB et al, "The Burden of Respiratory Syncytial Virus Infection in Young Children"

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S-337395: Non-clinical data

Compared to F protein inhibitors, this drug shows a clear virus reduction effect even when administered near the peak of viral replication

RSV-infected mouse treatment model



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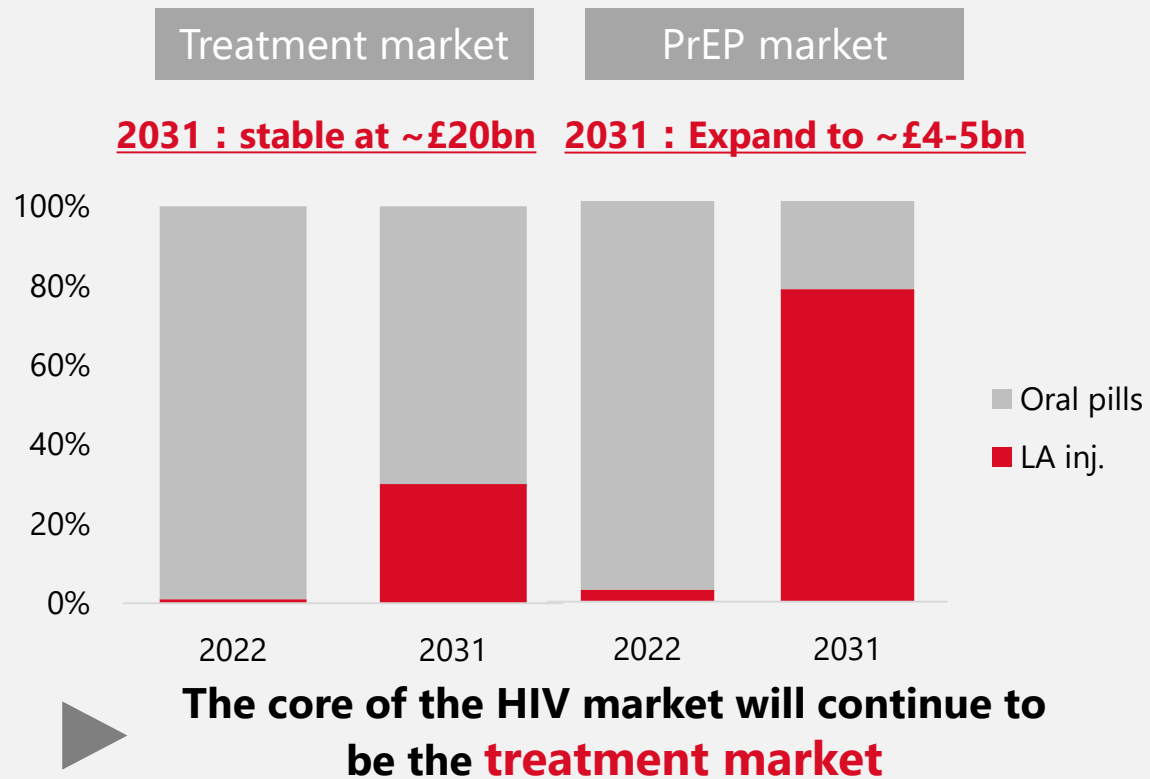
Anti-HIV Drug Released by ViiV

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

- **May**
  - A basic agreement was signed among three companies for the development and operation of a DTx distribution platform
- **June**
  - The "Resource Circulation Project," which aims for horizontal recycling of bell mount paperboard, received the Silver Award in the Special Award Sustainability category at the WorldStar Global Packaging Awards 2025
- **July**
  - Transition of promotional activities for allergen immunotherapy drug ACTAIR® in Japan
  - Conclusion of Investment Agreement with Japan Hydrogen Fund, L.P.
  - Completion of Disposal of Treasury Shares as Restricted Stock Compensation Plan

*1 Progress from May 13, 2025 to July 25, 2025

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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