

3rd Quarter of Fiscal 2025 Financial Results

January 30, 2026

Shionogi & Co., Ltd.



SHIONOGI

Agenda

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Toward the Realization of the 2030 Vision

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- Business Investment Progress
- Development Pipeline Progress

Overview of Q3 FY2025 Financial Results



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Highlights of the Third Quarter

- **Revenue, operating profit, and profit attributable to owners of the parent for the cumulative third quarter reached record highs**
 - As a one-off factor boosting profit, a gain on negative goodwill gain associated with the acquisition of JT Group's pharmaceutical business was recorded*1
- **Revenue for the quarter amounted to 147.7 billion yen**
 - TORII's sales are beginning to be fully reflected in financial performance
- **Advancing business investments to accelerate medium- to long-term growth**
 - Conversion into an equity-method affiliate through additional investment in ViiV Healthcare*2
 - Acquisition of the edaravone business from Tanabe Pharma*3
 - Completion of succession of JT's pharmaceutical business and acquisition of shares in Akros Co., Ltd.*4

*1 Provisional accounting prior to the completion of Purchase Price Allocation

[*2 January 2026 Press release](#)

[*3 December 2025 Press release](#)

[*4 December 2025 Press release](#)

Financial Results

**Revenue and all profit items increased year-on-year,
showing steady progress toward achieving the full-year forecast**

(Unit: B yen)

	FY2025		FY2024		Y on Y	
	Forecasts Full year	Apr.-Dec. Results	Achievement (%)	Apr.-Dec. Results	Change (%)	Change
Revenue	500.0	360.7	72.1	333.6	8.1	27.1
Operating profit	185.0	148.7	80.4	129.2	15.1	19.5
Profit before tax	232.0	191.3	82.4	155.9	22.7	35.4
Profit attributable to owners of parent	188.0	158.2	84.2	133.8	18.3	24.4
EBITDA*1	206.0	147.8	71.7	146.4	1.0	1.4

Statement of Profit or Loss

(Unit : B yen)

	FY2025		FY2024		Y on Y	
	Forecasts Full year	Apr.-Dec. Results	Achievem ent (%)	Apr.-Dec. Results	Change (%)	Change
Revenue	500.0 16.4	360.7 15.1	72.1	333.6 13.8	8.1	27.1
Cost of Sales	82.0	54.3	66.3	46.0	18.1	8.3
Gross profit	418.0	306.3	73.3	287.6	6.5	18.8
SG&A*1, R&D expenses total	48.0	47.9		46.7		
	240.0	172.7	72.0	155.9	10.8	16.8
SG&A*1	24.0	25.1		22.9		
	120.0	90.4	75.3	76.4	18.3	14.0
R&D expenses	24.0	22.8		23.8		
	120.0	82.3	68.6	79.4	3.6	2.9
Other income & expenses	7.0	15.1	215.7	(2.5)	-	17.6
Operating profit	37.0	41.2		38.7		
	185.0	148.7	80.4	129.2	15.1	19.5
Finance income & costs	47.0	42.5	90.5	26.7	59.6	15.9
Profit before tax	46.4	53.0		46.7		
	232.0	191.3	82.4	155.9	22.7	35.4
Profit attributable to owners of parent	188.0	158.2	84.2	133.8	18.3	24.4

Main variation factors (Y on Y)

Revenue

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

Cost of Sales

Increase: Sales of TORII

SG&A

Increase: Selling-related expenses in US business
TORII's SG&A expenses, PMI costs

R&D expenses

Increase: Former JT Pharmaceuticals Business unit and TORII's R&D expenses

Other income & expenses

Increase: Negative goodwill gain arising from the M&A (provisional treatment before the completion of the PPA)

Finance income & costs

Increase: Dividends from ViiV

Revenue by Segment

(Unit : B yen)

	FY2025		FY2024		Y on Y		Main variation factors (Y on Y)
	Forecast Full year	Apr.-Dec. Results	Achieveme nt(%)	Apr.-Dec. Results	Change (%)	Change	
Prescription drugs	143.5	86.7	60.4	78.9	9.8	7.8	Prescription drugs
Overseas subsidiaries/export	61.0	48.9	80.2	43.4	12.8	5.6	
Shionogi Inc. (US)	27.2	22.1	81.3	17.5	26.3	4.6	
Fetroja	-	21.3	-	14.7	44.8	6.6	
Shionogi B.V. (EU)	19.3	15.6	81.0	12.9	20.6	2.7	
Fetcroja	-	12.1	-	9.9	21.9	2.2	
Shionogi China	5.9	4.5	76.1	6.3	(27.9)	(1.7)	
Others	8.6	6.7	78.0	6.7	0.9	0.1	
Contract manufacturing	14.0	10.2	73.0	10.7	(4.4)	(0.5)	
OTC and quasi-drug	17.5	11.7	66.7	12.7	(8.2)	(1.0)	
Royalty income	261.5	201.3	77.0	186.8	7.8	14.5	Royalty income
HIV franchise	245.0	193.4	79.0	183.5	5.4	9.9	
Others	16.5	7.8	47.5	3.3	140.8	4.6	
Others	2.5	1.9	75.4	1.1	68.6	0.8	
Total	500.0	360.7	72.1	333.6	8.1	27.1	

Prescription Drugs in Japan

(Unit: B yen)

	Forecast Full year	FY2025		FY2024		Y on Y	
		Apr.-Dec. Results	Achievement (%)	Apr.-Dec. Results	Change(%)	Change	
Acute Respiratory Virus Infection Treatments	56.0	27.3	48.7	43.3	(37.0)	(16.0)	
Quviviq	2.5	1.1	44.3	0.5	123.8	0.6	
Symproic	6.5	4.6	70.5	3.8	18.8	0.7	
OxyContin franchise	5.3	3.5	66.3	3.3	6.6	0.2	
Others	73.2	50.2	68.6	28.0	79.4	22.2	
TORII	41.2	24.1^{*1}	58.4	-	-	24.2	
Total	143.5	86.7	60.4	78.9	9.8	7.8	

Acute respiratory virus infection treatments

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

Results for the Third Quarter

Growth in core businesses led to record-high sales revenue, operating profit, and quarterly profit attributable to owners of the parent company



Stable performance in HIV and overseas businesses



- Strong growth of LAI*¹ products
- Steady growth of cefiderocol in the U.S. and Europe



Growth of the domestic business as a key challenge in the first half of the fiscal year



- Growth of TORII's products
- Stable contribution of Xofluza during the influenza season
- Sales expansion through co-promotion of priority products by Shionogi and Torii



Cost management aligned with sales



- Cost management of SG&A expenses, including those related to TORII
- Promotion of proactive R&D investment through prioritization

Toward the Realization of the 2030 Vision

- Business Investment Progress
- Development Pipeline Progress



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Business Investments Executed in FY2025

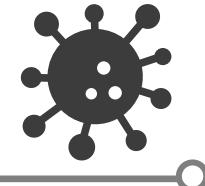
Active investing in business to realize the 2030 Vision

Executed a diverse range of strategic business investments

Additional investment in ViiV

Purpose:

- Strengthening the management foundation through further commitment to the HIV business



M&A involving JT Group's pharmaceutical business

Purpose:

- Strengthening in-house drug discovery capabilities
- Enhancing commercial capabilities in Japan



Acquisition of the edaravone business

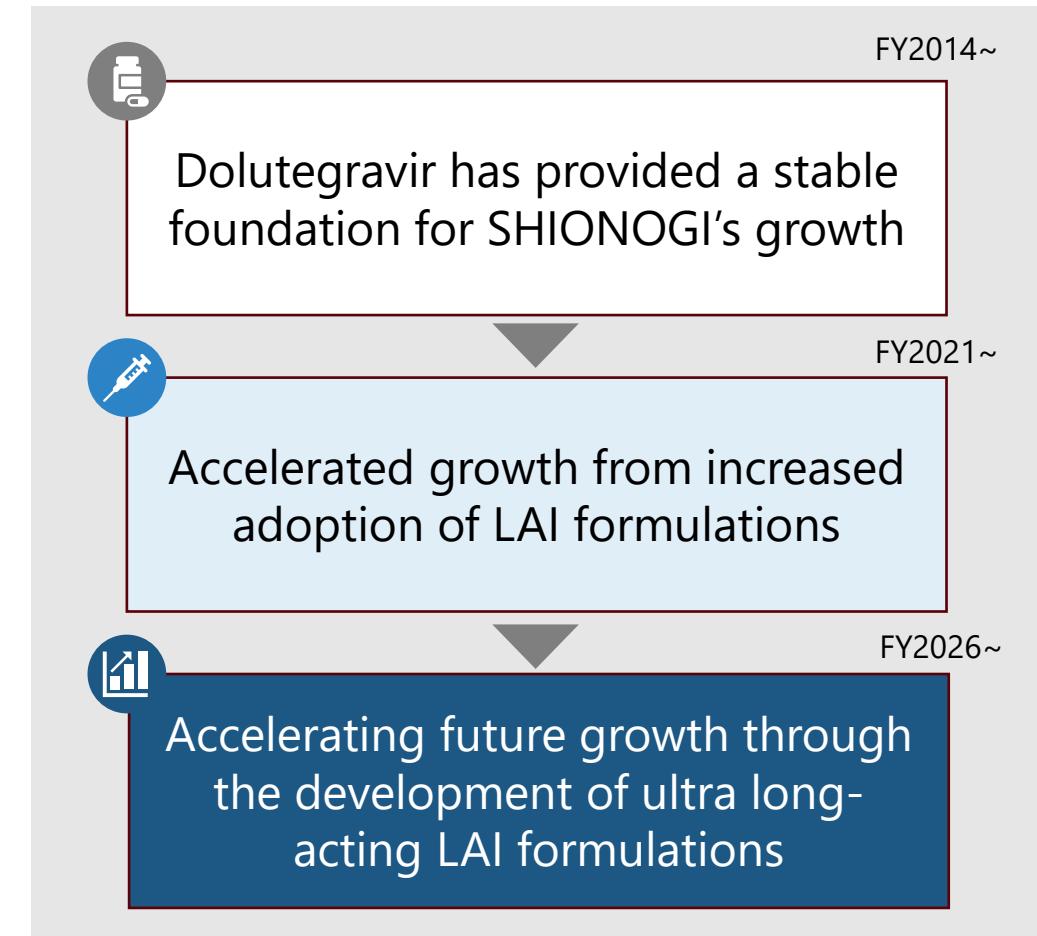
Purpose:

- Expanding U.S. business
- Establishing rare disease franchise



SHIONOGI's Growth Driven by HIV Business

Multiple integrase inhibitors discovered by SHIONOGI have significantly contributed to growth



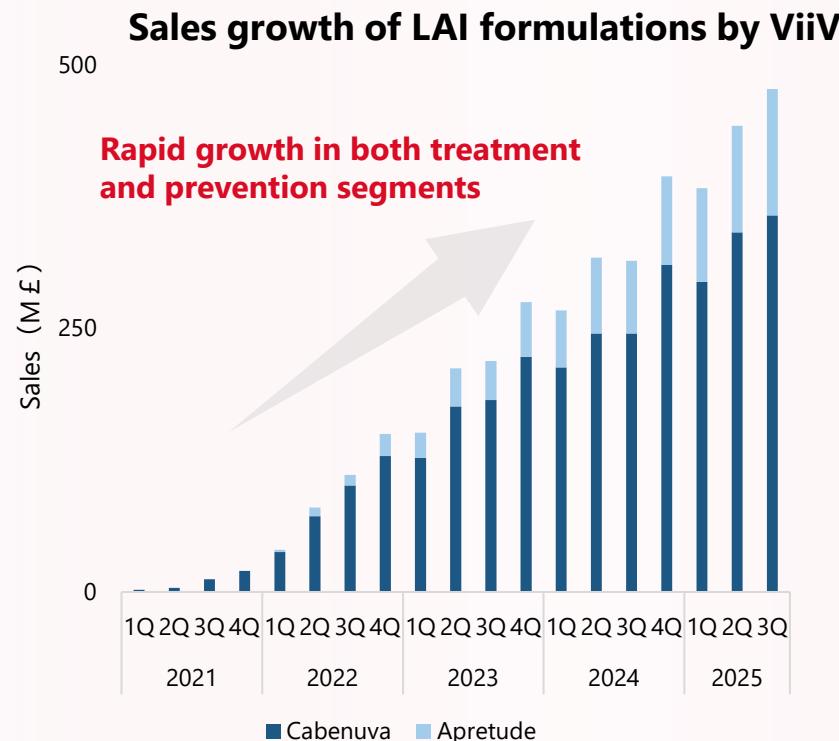
Long-acting Injectables Driving a Paradigm Shift in the HIV Market

Addressing unmet needs through innovative solutions to achieve sustained growth

2021~: Formulation administered once every month

2022~: Formulation administered once every two months

Growth of LAI Formulations



2021: Launch



2022: Launch



- From 2028 to 2030: Formulation administered once every six months -

Development and Launch of ULA*¹ Formulation (S-365598*²)

FY2021

Out-licensed to ViiV Healthcare

A distinct resistance profile compared to existing integrase inhibitors

FY2022

Start of clinical trials

FY2023

Clinical trial results obtained

(oral formulation: Phase 1 & 2)

- No concerns regarding tolerability or safety
- Potent efficacy as seen with best-in-class in similar studies

FY2025

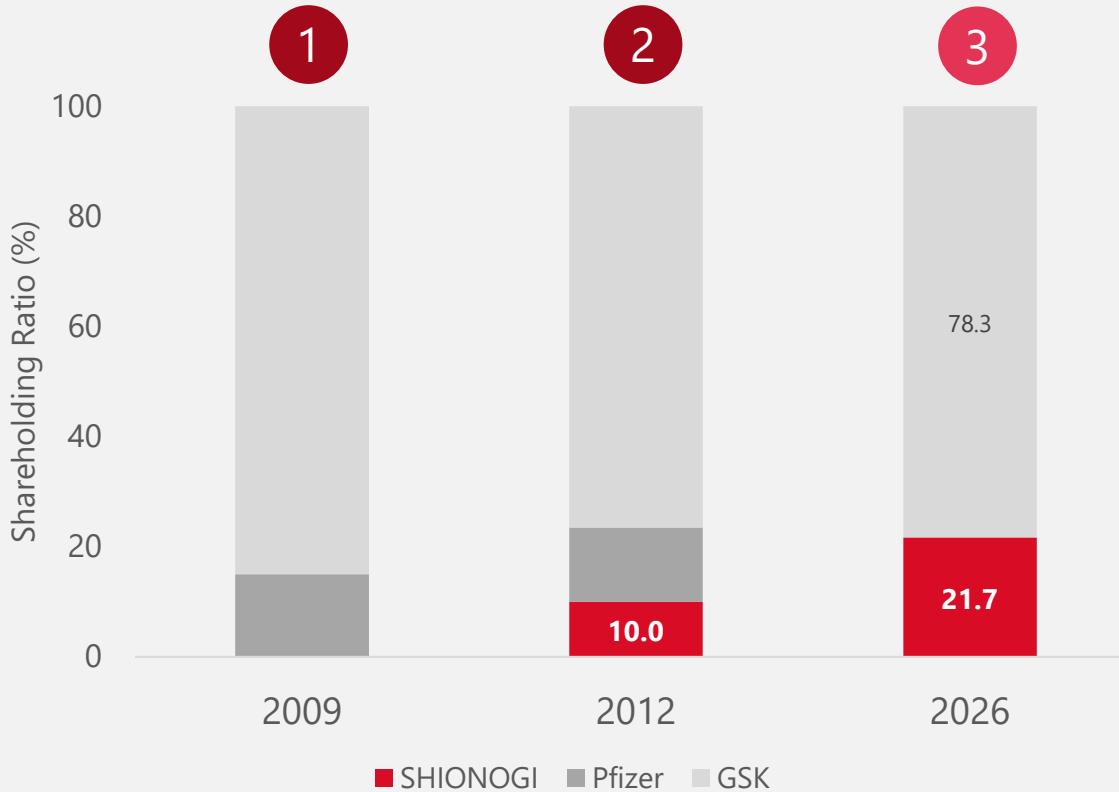
Expected results for injectable formulation
(injectable formulation: Phase 1)

Plan to obtain six-month PK data

Partnership with ViiV Healthcare

Strengthening partnership with ViiV Healthcare to ensure a stable earnings base and drive further growth

—Changes in shareholding ratio—



1 Establishment of ViiV Healthcare (by GSK and Pfizer)

2 Revision of contractual framework with ViiV Healthcare

- Transferred assets of Shionogi-ViiV Healthcare*¹ to ViiV Healthcare
- Acquired 10.0% of ViiV shares with the right to nominate one board member (one voting right)
- Received sales royalties from ViiV Healthcare

3 Equity-method affiliate status*²

- Shareholding ratio: **21.7%**
- The right to nominate one board member, with voting rights increased to **2**
- Became an equity-method affiliate

- Increased dividends
- Stronger commitment to HIV business

14 *¹ Shionogi-GSK Healthcare was established in September 2001 as a joint venture between GSK and SHIONOGI. Following GSK's transfer of its stake to ViiV Healthcare, the company name was changed to Shionogi-ViiV Healthcare

*² The transaction is subject to regulatory approvals, expected to occur during the end of March 2026

Integration of JT's Pharmaceutical Business

A new research and development framework has been launched to create innovative pharmaceuticals and deliver them globally

M&A background

Increasing difficulty in drug discovery

Increasing research resources needed to create new drugs

Strengthening the drug discovery technology platform

Acquired drug discovery platform

Approximately 670 researchers and related staff



Improve in-house drug discovery capabilities through a significant increase in resources*¹

X

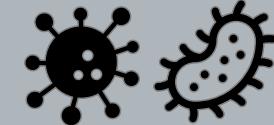
Advanced technology (AI, quantum computing and others)



Generation and utilization of data, and prediction of compound profiles

Strategic goals

Infectious Diseases



Maintaining a strong franchise

QOL Diseases



Establishing a second strong franchise

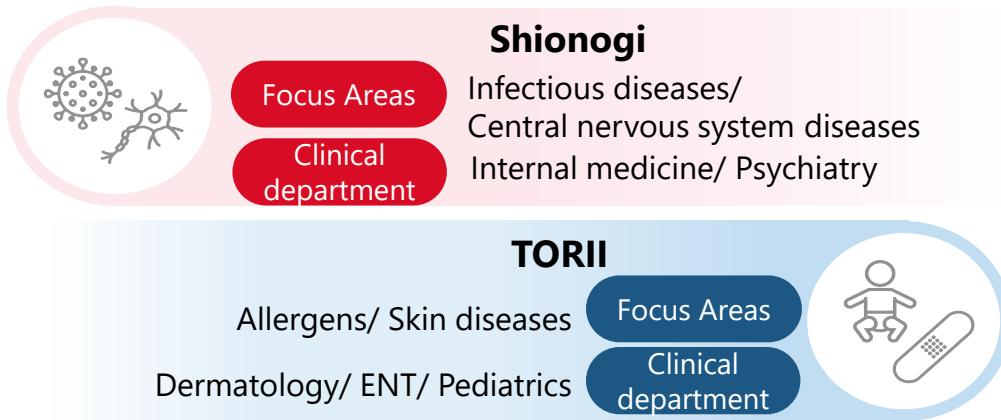
Expand small-molecule capabilities from infectious diseases to QOL diseases

*¹ Example: Doubling the number of medicinal chemists (drug discovery chemistry researchers)

Integration with TORII

Enhancing domestic sales by leveraging sales synergies and expanding our product lineup to meet market needs

- Strengthening domestic sales -



-Co-promotion leveraging the expertise of both companies-



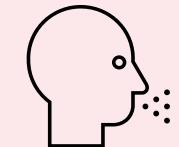
-Strengthening business that does not rely on patents-

-Sublingual immunotherapy (SLIT)-

Features

- A treatment in which allergen extracts are administered under the tongue to gradually desensitize the body
- Achieving long-term symptom relief rather than merely treating the symptoms

Expected effects



Improves sneezing,
runny nose, and nasal
congestion



Improves watery and
itchy eyes



Allergy
Reducing medication
dosage

High barriers to entry

- Difficulties in antigen extraction and quality control
- Need for long-term safety and efficacy evidence

Overview of the Edaravone Business Acquisition

Acquiring full rights to edaravone and a U.S. commercial platform to accelerate global growth beyond infectious disease areas

—Purpose of the business acquisition—



Expand our U.S. business to drive global growth



Establishing rare diseases as an important focus area

—Transaction overview—

- **Acquisition Target:** All global rights to edaravone
- **Economic Terms:**
 - ① Upfront payment: USD 2.5 billion
 - ② Royalty payment
- **U.S. Expansion:** Shionogi Inc. to acquire a new company to be established by Tanabe Pharma America, Inc. as a wholly owned subsidiary

Expected to make a sustained contribution to revenue and profit from FY2026 onward

Innovative Therapeutic Drugs Addressing Unmet Needs

A marketed product with established safety and efficacy, expected to deliver stable growth going forward

—Features of edaravone—

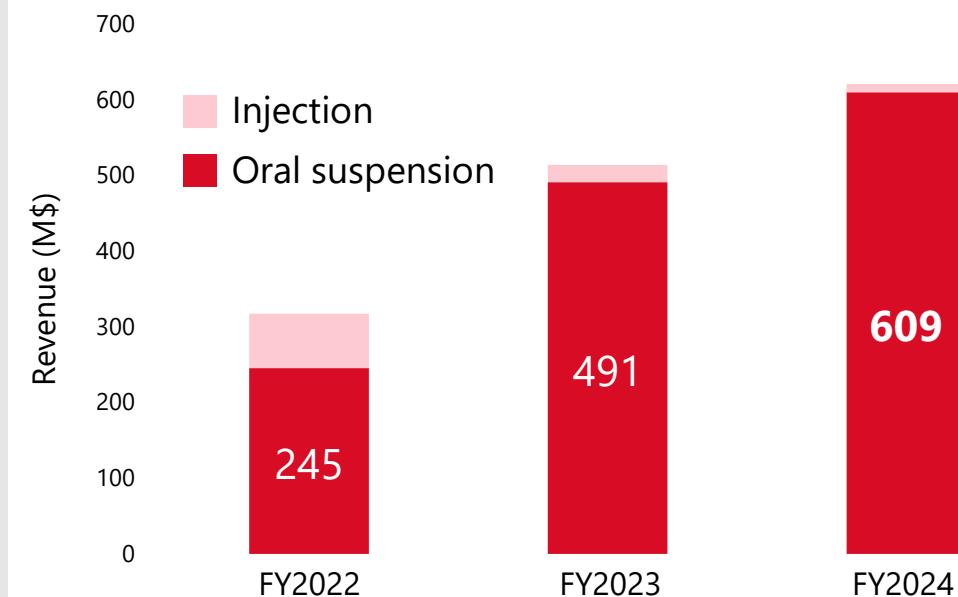
- **Indication:** Treatment of amyotrophic lateral sclerosis (ALS)
- **Modality:** Small-molecule drug
- **Formulations:**
 - Injection (U.S. launch: 2017)
 - Oral suspension (U.S. launch: 2022)



Enhancing QOL through the oral suspension

- ✓ Provides an option for patients with dysphagia
- ✓ Allows administration without requiring clinic visits
- ✓ Avoids injection-related pain

—U.S. Sales trend of edaravone (Radicava)*1—



Growth of the oral suspension is driving overall Radicava expansion

Toward Establishing a Rare Disease Business in the U.S.

Acquire a strong business foundation for expansion in the rare disease field

—Business foundations to be acquired—

1

Talent with deep expertise in rare diseases

2

Business operation know-how

3

Connections with established patient networks

—Expansion of our U.S. business over the mid- to long-term—

Build a commercial infrastructure in anticipation of rare disease pipeline launches

Aim for rapid market expansion following launch

Rare disease pipeline aiming for commercialization

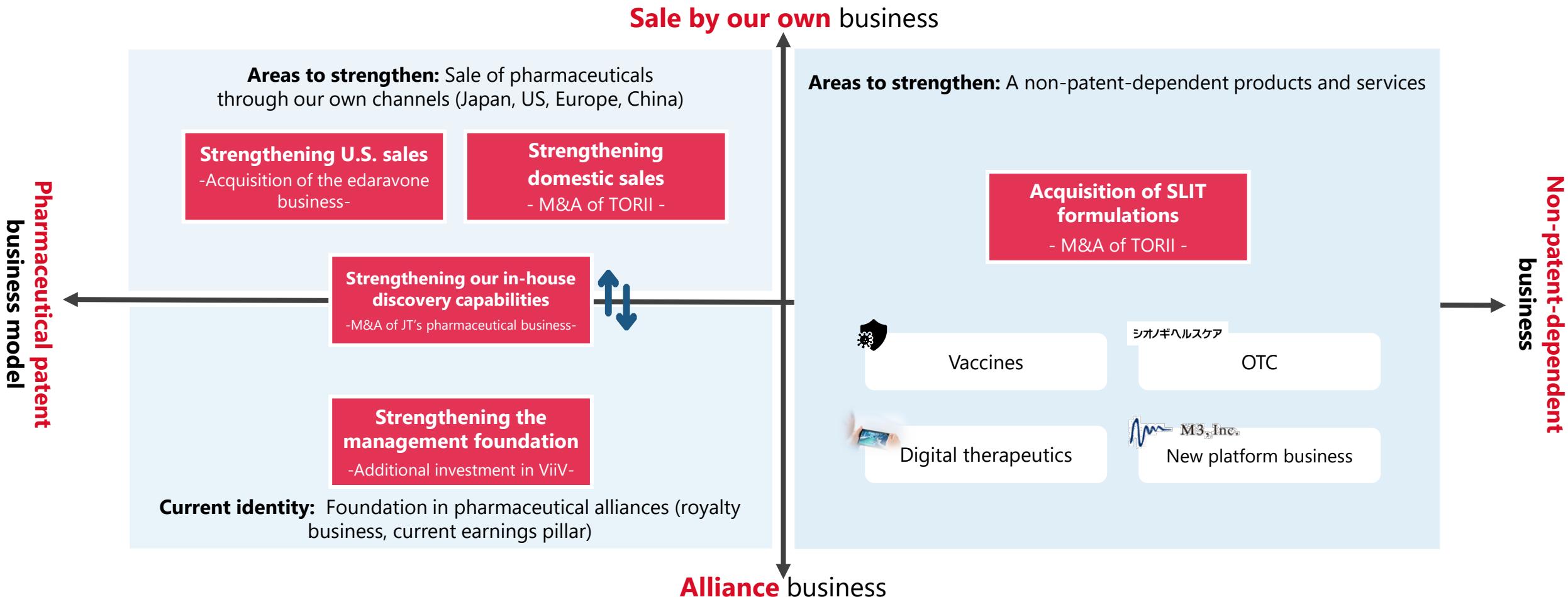
Zatolmilast
Fragile X Syndrome
Jordan syndrome

S-606001
Pompe disease

New Assets
- Research program of the former JT Pharmaceuticals Business
- Further acquisitions under assessment

Positioning of Business Investments within the Corporate Strategy^{*1}

We are making investments to strengthen SHIONOGI's foundation toward achieving the 2030 Vision



^{*1} June 2020 Presentation: 2030 Vision and Medium-Term Business Plan 'STS2030' (p.20)

Toward the Realization of the 2030 Vision

- Business Investment Progress
- Development Pipeline Progress



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Major Development Projects: Infectious Diseases

Project	Indication	Current stage*1	Update
Ensitrelvir	COVID-19 treatment	Submission	
	COVID-19 treatment (age 6-11)	Submission	
	COVID-19 PEP	Submission	
	COVID-19 treatment (age 0-5)	Phase 3	FPI*3 achieved
S-268024	COVID-19 (JN.1 vaccine)	Submission	Submitted in Japan
Cefiderocol	AMR*2 (Pediatric・Gram-negative bacterial infection)	Phase 3	
Olorofim	Invasive Aspergillosis	Phase 3	LPI*4 achieved
S-337395	RSV infections	Phase 2b	
S-892216	COVID-19 treatment (Oral pill・treatment)	Phase 2	
	COVID-19 (Long-acting injectable・pre-exposure prophylaxis)	Phase 1	
S-743229	AMR (Complicated urinary tract infection)	Phase 1	
S-649228	AMR (Gram-negative bacterial infection)	Phase 1	Obtained the topline result of Phase 1
S-567123	COVID-19 Prevention (Broadly protective coronavirus vaccine)	Phase 1	FPI*3 achieved

*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 AMR : Antimicrobial Resistance *3 FPI: First Patient In *4 LPI : Last Patient In

Major Development Projects: QOL Diseases with High Social Impact

Project	Indication	Current stage*1	Update
Zuranolone	Depression	Approved	Approved in Japan
Resiniferatoxin	Pain associated with knee osteoarthritis	Phase 3	
Zatolmilast	Fragile X syndrome	Phase 2/3	
	Jordan syndrome	Phase 2	LPI achieved
Redasemtide	Dystrophic epidermolysis bullosa	Phase 2	
	Acute ischemic stroke	Phase 2b	LPI achieved
SASS-001 (S-600918 + Combination medicine)	Sleep apnea syndrome (central component)	Phase 2	
SASS-002 (Sulthiame)	Sleep apnea syndrome (obstructive)	Phase 2	
S-606001	Pompe disease	Phase 2	
S-309309	Obesity	Phase 2	
S-531011	Solid tumors	Phase 1b/2	
S-151128	Chronic pain	Phase 1b	

Appendix

FY2025 Exchange Rate

Exchange rate (average during the period)

	FY2025	
	Forecast (10/27)	Apr.-Dec. Results
USD(\$) - JPY(¥)	146 yen	148.71 yen
GBP(£) - JPY(¥)	197 yen	198.98 yen
EUR(€) - JPY(¥)	171 yen	171.84 yen

Major Development Products

- Infectious 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)	Submission	- 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 (Broadly protective coronavirus vaccine)	Phase 1	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	Approved	FY2025
Resiniferatoxin	Pain associated with knee osteoarthritis	Phase 3	- FY2027
	Fragile X syndrome	Phase 2/3	- FY2027
Zatolmilast	Jordan syndrome	Phase 2	- FY2027
	Dystrophic epidermolysis bullosa	Phase 2	- FY2027
Redasemtide	Acute ischemic stroke	Phase 2b	FY2028-2030
	Sleep Apnea with a Central Component	Phase 2	FY2028-2030
SASS-001 (S-600918 + Combination medicine)	Solid tumor	Phase 1b/2	FY2028-2030
S-531011	Chronic pain	Phase 1b	FY2031-
S-606001	Pompe disease	Phase 2	FY2031-
S-309309	Obesity	Phase 2	Development Plan Under Consideration

R&D Milestones Planned for FY2025

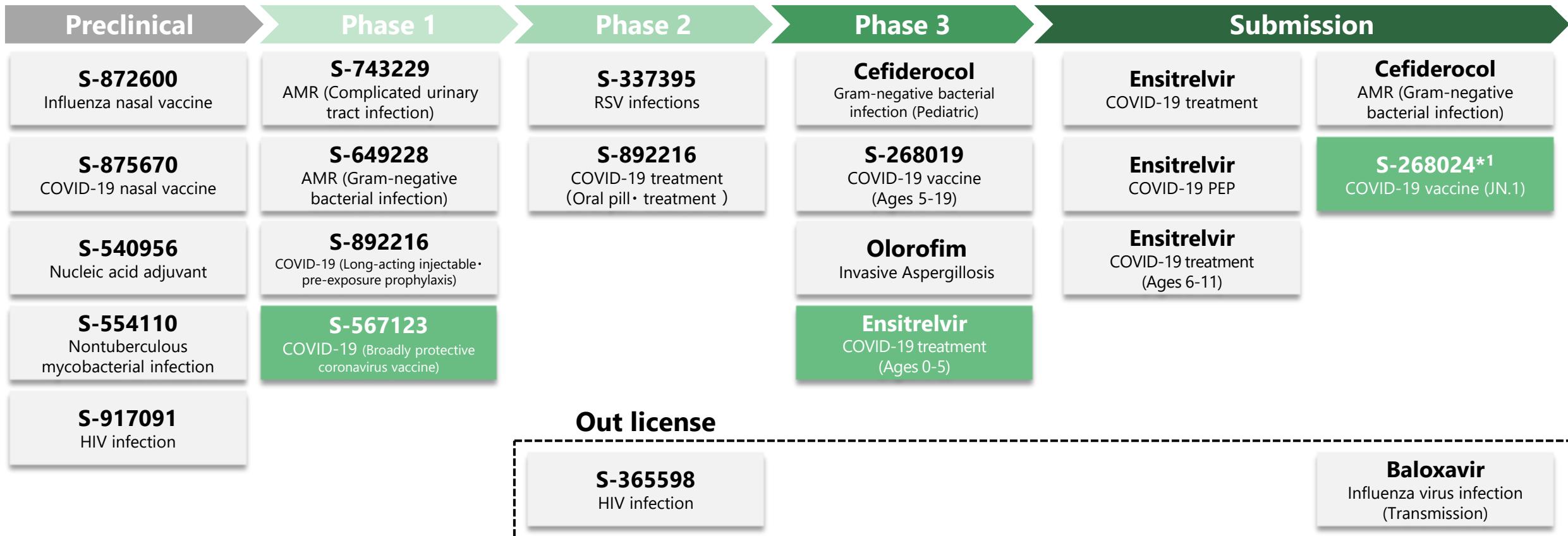
Red: Update from October 28, 2025, to January 30, 2026, ✓: Milestone-completed items

※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
Infectious 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)	Submission	Phase 3 Topline results	✓	Submission (Japan) ✓
	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	Approved			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 1 Topline results

Pipeline: Infectious Diseases

as of January 30, 2026



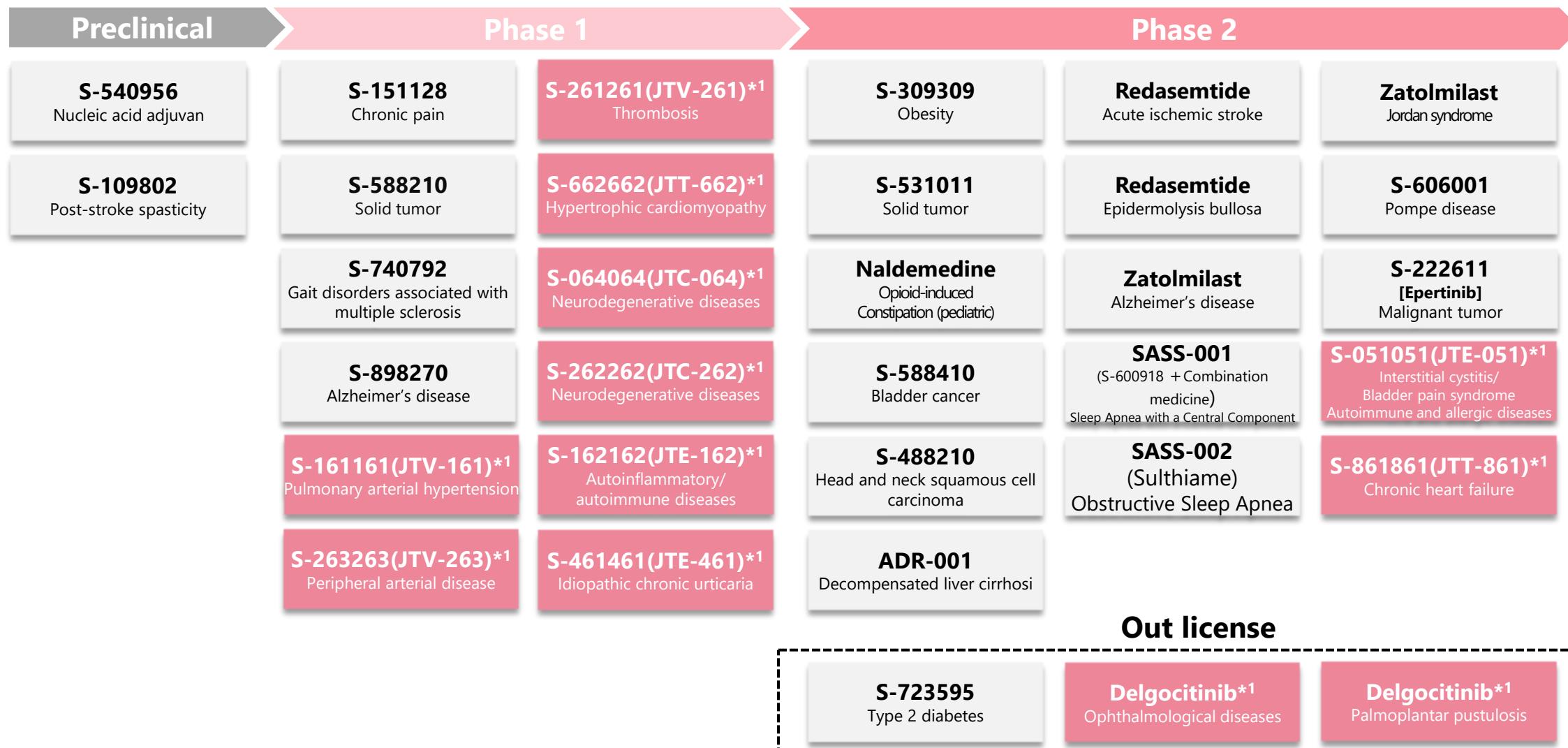
Change from October 28, 2025, to January 30, 2026

- Cefiderocol: Approved in China
- Ensitrelvir: Initiated a phase 3 trial
- S-567123: Initiated a phase 1 trial
- S-268024*1: Submitted in Japan
- S-268023: Deleted



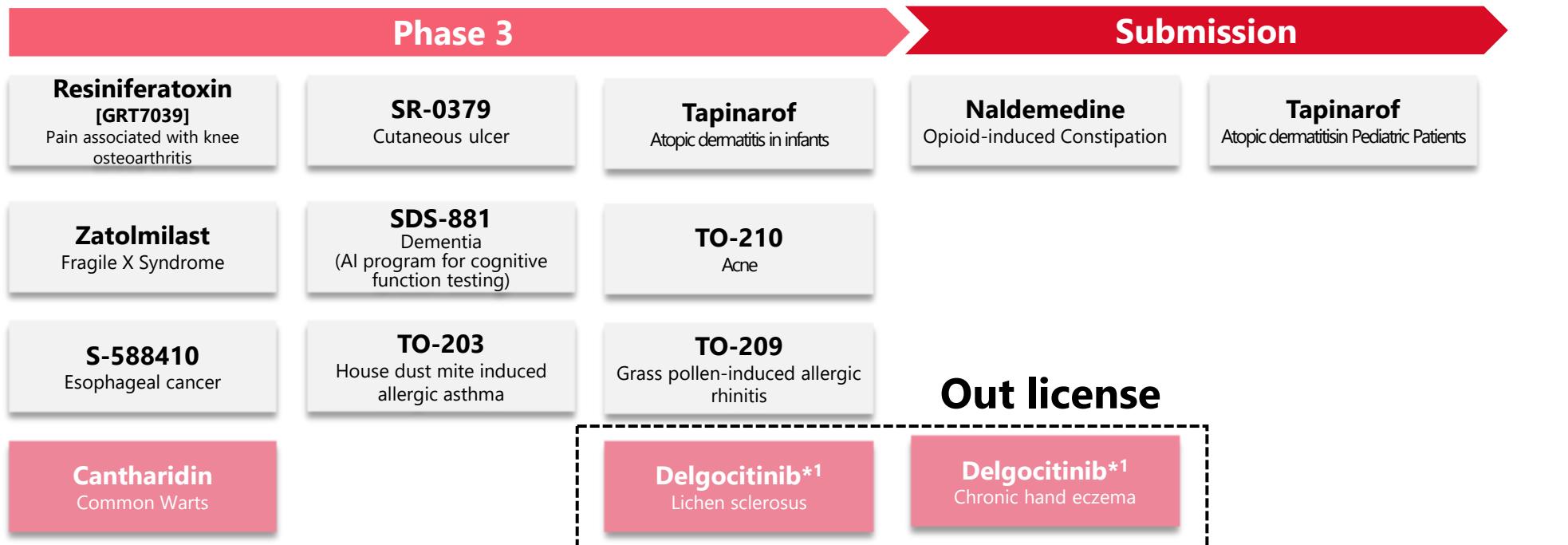
Pipeline: QOL Diseases with High Social Impact

as of January 30, 2026



Pipeline: QOL Diseases with High Social Impact

as of January 30, 2026



Change from October 28, 2025, to January 30, 2026

- Zuranolone: Approved in Japan
- Delgocitinib*¹ (chronic hand eczema): Submitted in China
- Cantharidin: Initiated a phase 3 trial
- Delgocitinib*¹ (Lichen sclerosus): Phase 3
- Delgocitinib*¹ (Ophthalmological diseases): Phase 2
- Delgocitinib*¹ (Palmoplantar pustulosis): Phase 2
- S-051051(JTE-051)*¹: Phase 2
- S-861861(JTT-861)*¹: Phase 2
- S-662662(JTT-662)*¹: Phase 1
- S-064064(JTC-064)*¹: Phase 1
- S-1611161(JTV-161)*¹: Phase 1
- S-162162(JTE-162)*¹: Phase 1
- S-261261(JTV-261)*¹: Phase 1
- S-262262(JTC-262)*¹: Phase 1
- S-263263(JTV-263)*¹: Phase 1
- S-461461(JTE-461)*¹: Phase 1

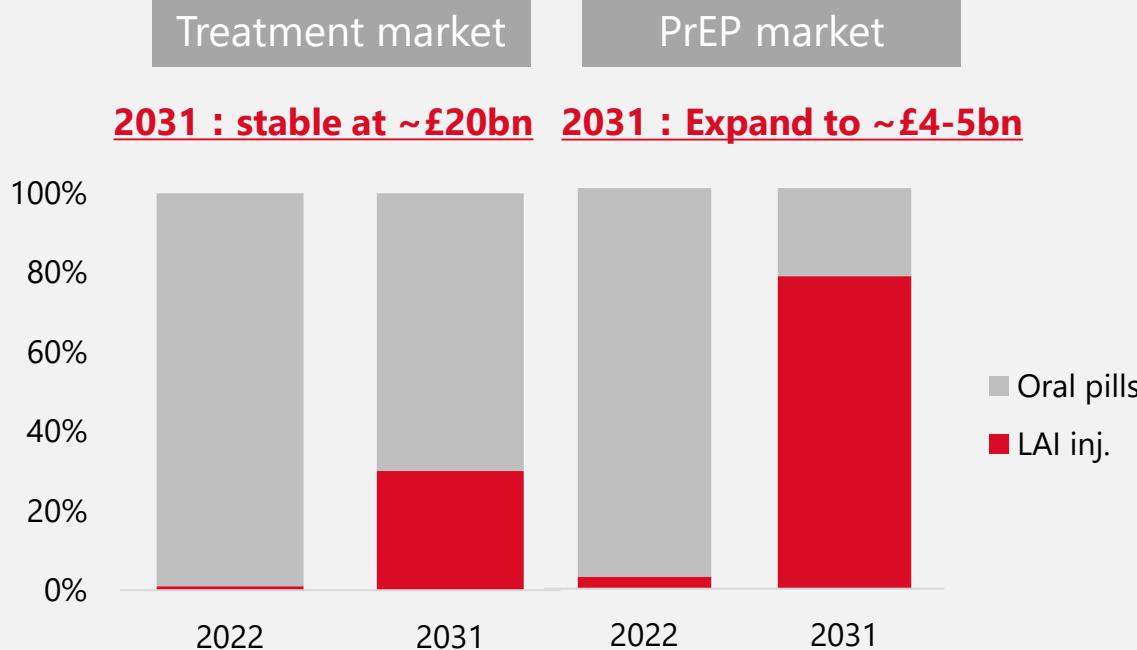
Anti-HIV Drug Released by ViiV

Product name	Formulations	Compounds* ¹	Administrations	Frequency	Indications	CY2024 Sales
Cabenuva	LAI formulations	CAB + RPV	IM injection	Q2M (LA)	Treatment	£ 1,013M
Apretude		CAB	IM injection	Q2M (LA)	PrEP* ²	£ 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 market, LA formulations will continue to drive growth

Outlook for the HIV Market*¹ (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*²
- 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*³
- 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 ViiV Healthcare Meet the Management *² <https://www.hiv.gov/hiv-basics/overview/data-and-trends/statistics>

*³ <https://www.cdc.gov/nchhstp/director-letters/expanding-prep-coverage>

Other Major progress^{*1}

- **November**

- Shionogi Pharma's Kanegasaki Plant Receives "BSI Kitemark™ for Minimized Risk of AMR" Certification for Antimicrobial Manufacturing
- New Clinical Data on the Efficacy of Antiviral Treatments for Post-COVID-19 Condition
- Launched XOFLUZA® Granules 2% – New Formulation for Influenza Treatment and Prophylaxis
- Shionogi & Co., Ltd. and Pixie Dust Technologies' joint invention receives the Invention Encouragement Award at the 2025 Kanto Region Invention Awards
<Modulated Sound Output Device Generates Gamma Wave Sound™ from Everyday Sounds>

- **December**

- Recognized with the Double A List for Leadership in Corporate Transparency and Performance on Climate Change and Water Security by CDP
- Received Approval in Japan to Manufacture and Market ZURZUVAE® Capsules 30 mg for the Treatment of Major Depressive Disorder
- Execution of a Joint Research and Development Agreement and an Investment Agreement with Salubritas to Demonstrate Hearing Function Improvement through Hair Cell Regeneration and to Create Innovative Pharmaceuticals

- **January**

- The antibacterial drug cefiderocol for gram-negative bacterial infections has been awarded the Minister of Health, Labour and Welfare Award at the 8th Japan Medical Research and Development Awards

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