3rd Quarter of Fiscal 2024 Financial Results

January 31, 2025

Shionogi & Co., Ltd.

SHIONOGI

Agenda

01 **Overview of Q3 FY2024 Financial Results** **（P.3-12）**

02 **Towards the Realization of the 2030 Vision** **（P.13-26）**

- Transformation of Chinese Business
- Pipeline Progress

Overview of Q3 FY2024 Financial Results

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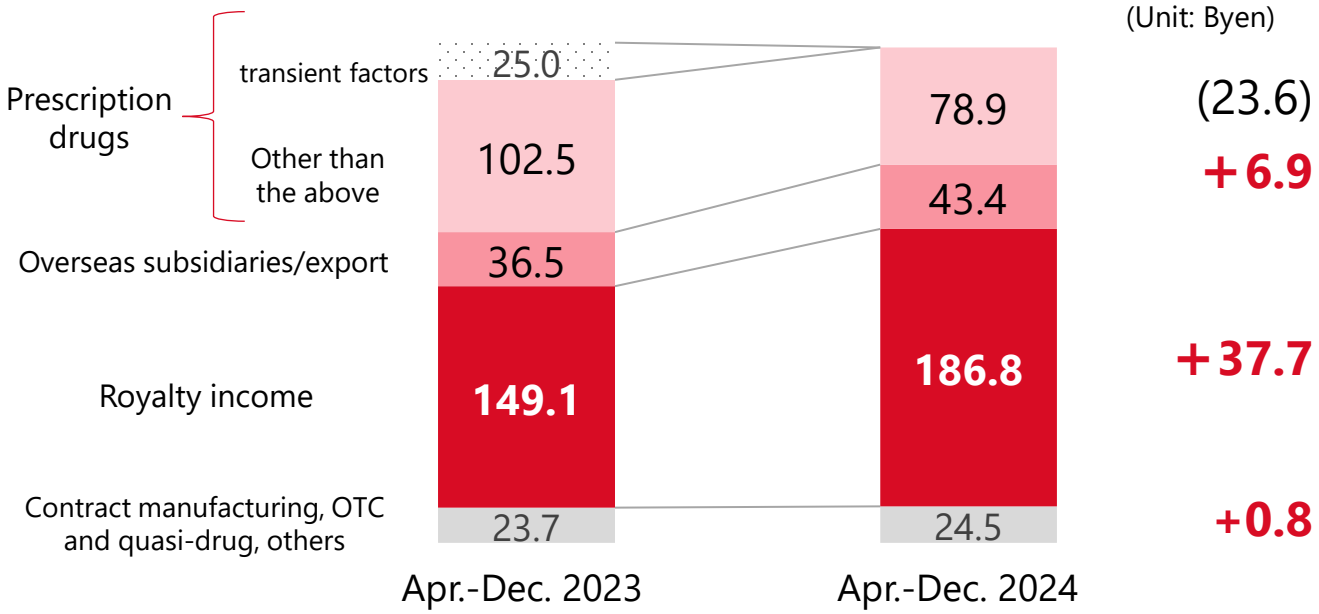
Highlight

Excluding the one-time payment* from last year, both the top line and operating profit have increased

Topline

(Excludes one-time payment) **336.8 B yen (311.8 B yen)**

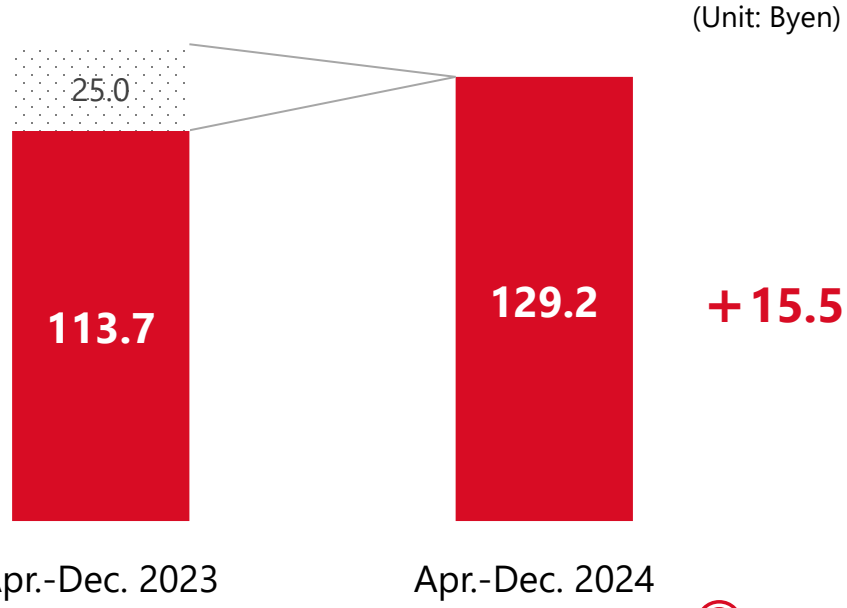
333.6 B yen



Operating profit

(Excludes one-time payment) **138.7 B yen (113.7 B yen)**

129.2 B yen



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

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Financial Results

Summary

- **Sales revenue and various profit items landed almost as expected against the full-year forecast**
  - The HIV business and overseas business continue to grow strongly
  - Domestic business is making steady progress due to the stabilization of the infectious disease business.
- **Compared to the same period last year, revenue and profit increased, excluding one-time payments**

(Unit : B yen)

	FY2024			FY2023	Y on Y	
	Forecasts Full year	Apr.-Dec. Results	Achievement (%)	Apr.-Dec. Results	Change (%)	Change
Revenue	460.0	**333.6**	**72.5**	336.8	**(1.0)**	**(3.2)**
Operating profit	165.0	**129.2**	**78.3**	138.7	**(6.9)**	**(9.5)**
Profit before tax	206.0	**155.9**	**75.7**	164.5	**(5.2)**	**(8.6)**
Profit attributable to owners of parent	171.0	**133.8**	**78.2**	127.2	**5.2**	**6.6**
EBITDA*	-	**146.4**	-	160.2	**(8.6)**	**(13.8)**

Exchange Rate (Average)

	FY2024 Forecast	FY2024 Apr.-Dec. Results
USD($) – JPY(¥)	148	152.64
GBP(£) – JPY(¥)	190	195.50
EUR(€) – JPY(¥)	161	164.89

* 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)

	FY2024			FY2023	Y on Y	
	Forecast Full year	Apr.-Dec. Results	Achievement (%)	Apr.-Dec. Results	Change (%)	Change
Revenue	460.0	**333.6**	**72.5**	336.8	**(1.0)**	**(3.2)**
Cost of Sales	14.6 67.0	13.8 **46.0**	**68.7**	12.6 42.4	**8.6**	**3.6**
Gross profit	393.0	**287.6**	**73.2**	294.4	**(2.3)**	**(6.9)**
Selling, general & administrative expenses, R&D expenses total	48.9 225.0	46.7 **155.9**	**69.3**	43.6 146.9	**6.1**	**9.0**
Selling, general & administrative expenses	23.7 109.0	22.9 **76.4**	**70.1**	22.1 74.3	**2.9**	**2.2**
R&D expenses	25.2 116.0	23.8 **79.4**	**68.5**	21.6 72.6	**9.4**	**6.8**
Other income & expenses	(3.0)	**(2.5)**	**81.7**	(8.8)	**(72.0)**	**6.3**
Operating profit	35.9 165.0	38.7 **129.2**	**78.3**	41.2 138.7	**(6.9)**	**(9.5)**
Finance income & costs	41.0	**26.7**	**65.0**	25.7	**3.5**	**0.9**
Profit before tax	44.8 206.0	46.7 **155.9**	**75.7**	48.8 164.5	**(5.2)**	**(8.6)**
Profit attributable to owners of parent	171.0	**133.8**	**78.2**	127.2	**5.2**	**6.6**

Main Variation Factors (Y on Y)

Revenue

Increase
- Overseas subsidiaries /export
- Royalty income

Decrease
- Prescription drugs

Cost of Sales

Increase in expense
- Changes in product mix

R&D expenses

Increase in expense
- Active investment in high-priority development products

Other income & expenses

Decrease in expense
- Costs related to implementation of early retirement program ※

※ Factors that occurred last fiscal year

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Revenue by Segment

(Unit：B yen)

	FY2024			FY2023	Y on Y	
	Forecast Full year	Apr.-Dec. Results	Achievement (%)	Apr.-Dec. Results	Change (%)	Change
Prescription drugs	124.7	**78.9**	**63.3**	127.5	**(38.1)**	**(48.6)**
Excluding temporary income	-	**78.9**	**-**	102.5	**(23.0)**	**(23.6)**
Overseas subsidiaries/export	57.6	**43.4**	**75.3**	36.5	**18.8**	**6.9**
Shionogi Inc. (US)	22.6	**17.5**	**77.4**	13.1	**33.6**	**4.4**
Fetroja	-	**14.7**	**-**	10.6	**39.6**	**4.2**
Shionogi B.V. (EU)	16.7	**12.9**	**77.5**	10.1	**28.5**	**2.9**
Fetcroja	-	**9.9**	**-**	7.9	**25.6**	**2.0**
Ping An Shionogi/C&O	9.1	**6.3**	**68.9**	8.3	**(24.4)**	**(2.0)**
Others	9.2	**6.7**	**72.5**	5.1	**32.1**	**1.6**
Contract manufacturing	16.5	**10.7**	**64.8**	11.7	**(8.9)**	**(1.0)**
OTC and quasi-drug	16.6	**12.7**	**76.5**	10.6	**20.0**	**2.1**
Royalty income	242.8	**186.8**	**76.9**	149.1	**25.3**	**37.7**
HIV franchise	234.9	**183.5**	**78.1**	146.1	**25.6**	**37.4**
Others	7.9	**3.3**	**41.2**	3.0	**7.7**	**0.2**
Others	1.8	**1.1**	**62.1**	1.4	**(18.2)**	**(0.2)**
Total	460.0	**333.6**	**72.5**	336.8	**(1.0)**	**(3.2)**

Main variation Factors (Y on Y)

Prescription drugs

Decrease

- Sales of Infectious disease drugs
- A one-time payment for the transfer of the ADHD treatment drug license※

Overseas subsidiaries/export

Increase

- Sales of cefiderocol (Fetroja, Fetcroja)

OTC and quasi-drug

Increase

- Strong sales of Rinderon and Mucodyne

Royalty income

Increase

- Strong sales of ViiV's HIV franchise

※ Factors that occurred last fiscal year

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Prescription Drugs in Japan

(Unit：B yen)

	FY2024			FY2023	Y on Y	
	Forecast Full year	Apr.-Dec. Results	Achievement (%)	Apr.-Dec. Results	Change (%)	Change
Infectious disease drugs	83.4	**50.0**	**60.0**	69.0	**(27.5)**	**(19.0)**
COVID-19 related products + Influenza franchise	72.3	**43.3**	**59.9**	62.0	**(30.2)**	**(18.7)**
Symproic	5.9	**3.8**	**65.0**	3.3	**15.5**	**0.5**
OxyContin franchise	5.0	**3.3**	**66.2**	3.3	**(0.4)**	**(0.0)**
Actair	1.3	**0.7**	**51.1**	0.5	**27.6**	**0.1**
Cymbalta	3.3	**1.9**	**56.4**	3.1	**(40.3)**	**(1.3)**
Others	25.8	**19.2**	**74.4**	48.2*	**(60.1)**	**(29.0)**
Quviviq	3.0	**0.5**	**16.5**	-	**-**	**0.5**
Prescription drugs	124.7	**78.9**	**63.3**	127.5	**(38.1)**	**(48.6)**

Infectious disease drugs

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

COVID-19 related products

- Xocova

Influenza franchise

- Xofluza
- BrightpocFlu・Neo*2
- Rapiacta

* Including temporary income from transfer of ADHD drugs *2 This product's sales are only recorded in the 2023 fiscal year results

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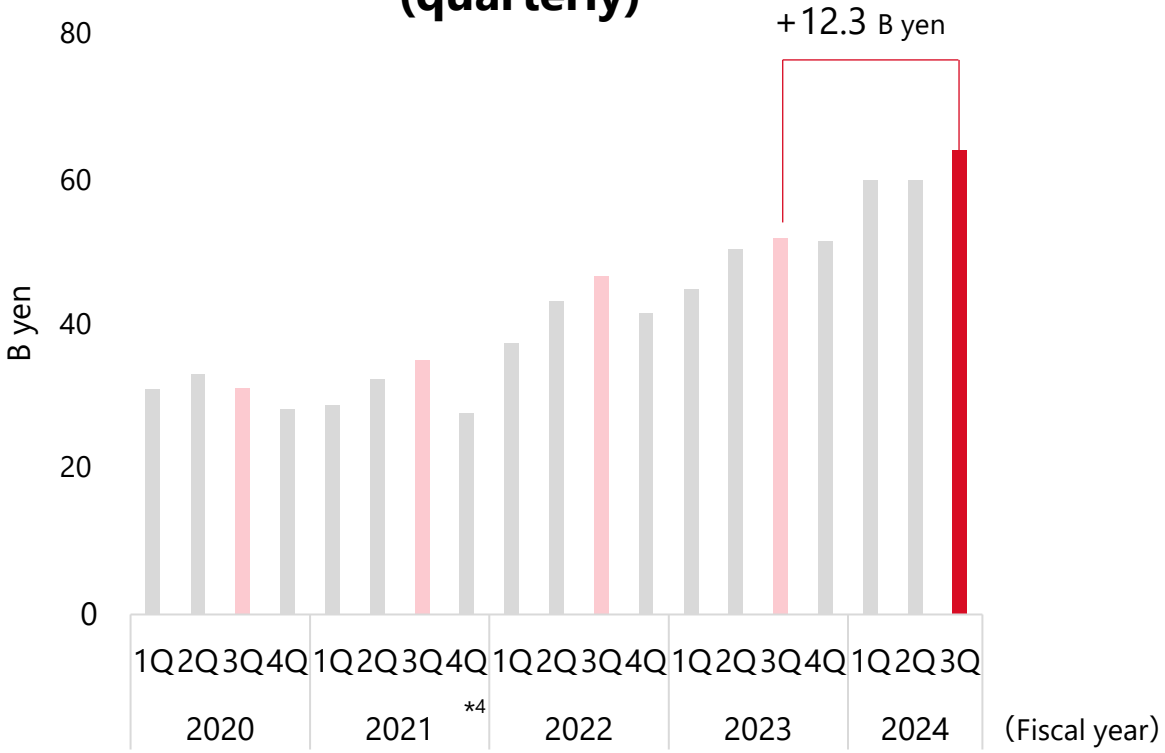
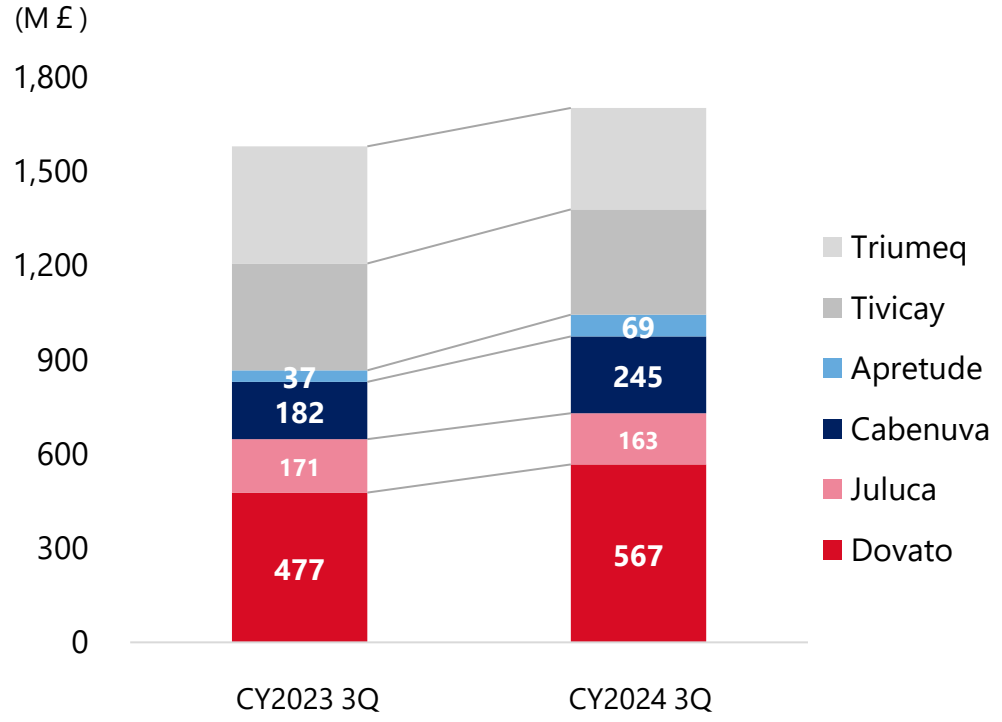
Expansion of the HIV Business

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

Transition of SHIONOGI's HIV royalty income (quarterly)



Sales of ViiV's dolutegravir and cabotegravir products*3



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

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

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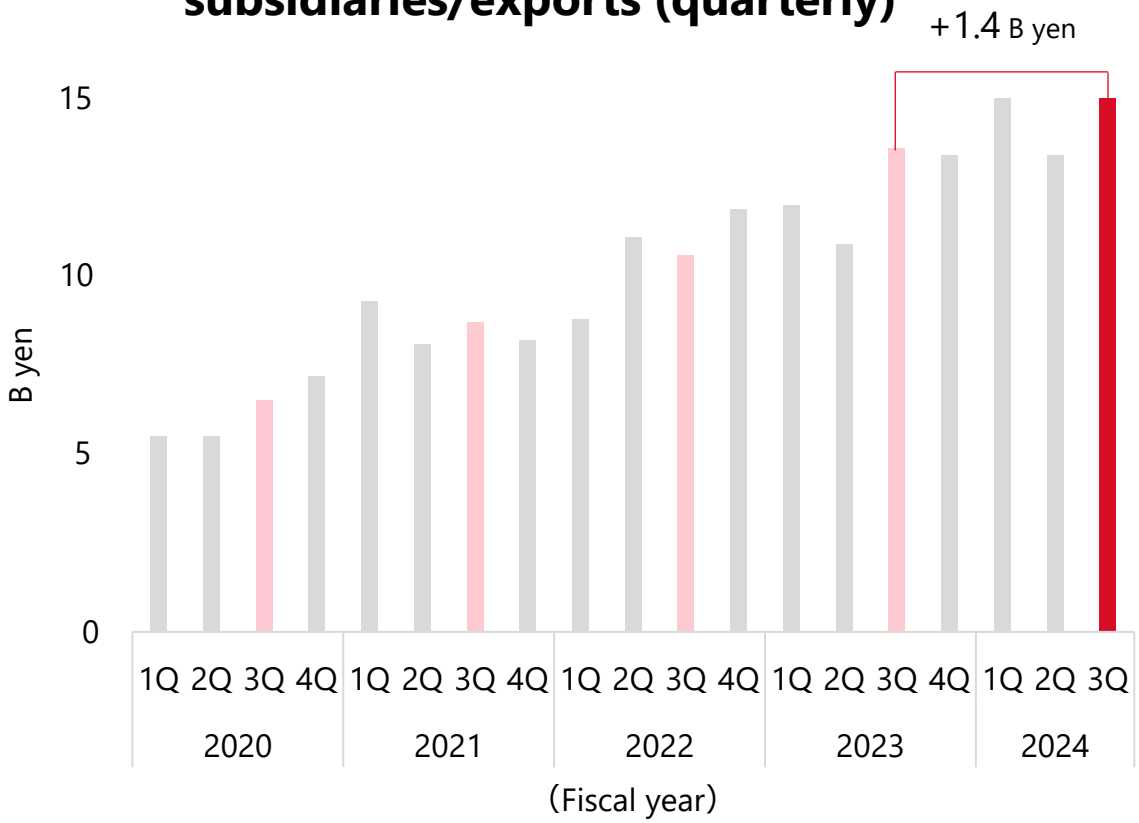
Expansion of Overseas Business

With the stable growth of Cefiderocol in Europe and the United States and the expansion of the countries where it is sold, the overseas business is poised for further growth

Sales revenue of overseas subsidiaries/exports (quarterly)



Strong YoY growth in cefiderocol sales

- US : +1.31 B yen, 32.1% growth
- EU : +0.25 B yen, 7.6% growth

Expansion of countries where Cefiderocol is sold
(Sold in 25 countries)

- Latest application updates
  - Australia: Approval application accepted, FY2024 3Q **new**
  - China: Approval application accepted, FY2024 2Q

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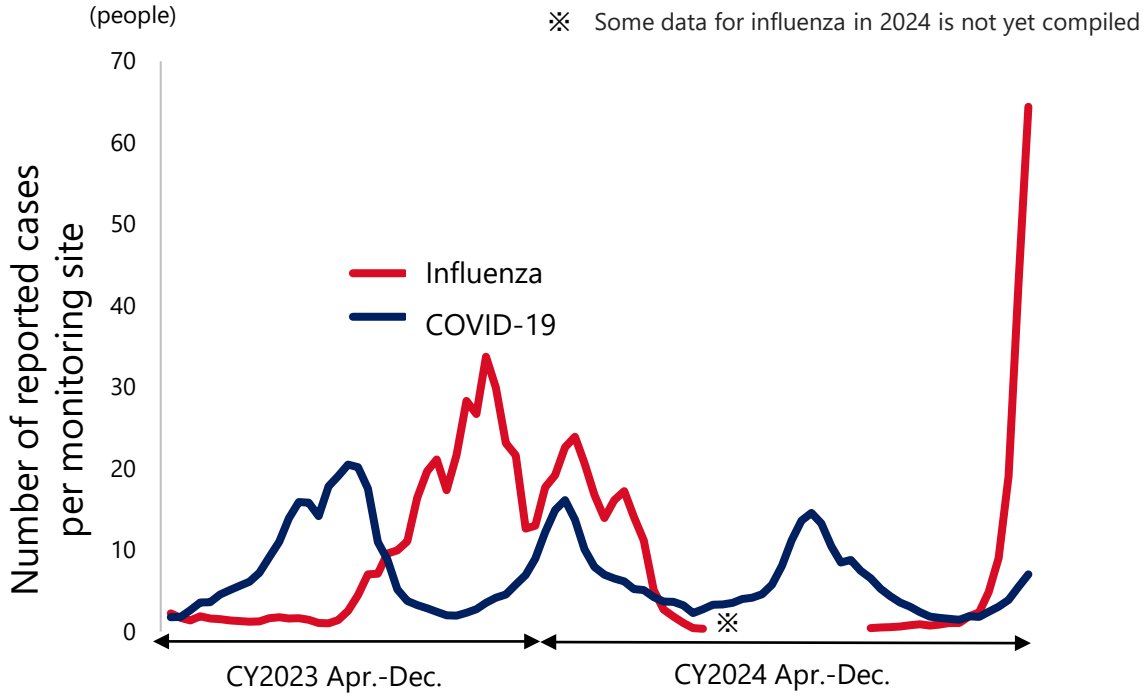
Status of Domestic Business (Influenza and COVID-19)

In the market for influenza and COVID-19 treatments,
we aim to expand our market share and contribute to stable performance in response to the epidemics

Patient trends* (From Apr. 4th week of 2023)

※ Some data for influenza in 2024 is not yet compiled



Over the past two years, at any given time, influenza or COVID-19 has been prevalent

Influenza Family*2 (Influenza treatment)

With the spread of infections,
the prescription of Xofluza has surged since December

Treatment rate*3	Consistently maintaining around **90%**
Market Share*4	It has **further expanded** since last year

Xocova （COVID-19 treatment）

Promoting awareness activities in preparation for the spread of infections in 4Q

Treatment rate*3	3Q has consistently been around **12-14%**
Market Share*4	It has been consistently around **65%**

*3 JAMDAS (COVID-19: Usage rate of oral antiviral drugs for COVID-19 patients, Influenza: Usage rate of antiviral drugs for influenza patients, Weekly data)

*4 Data referenced from JAMDAS

* Status updated following the reclassification of COVID-19 as a Category 5 infectious disease. Source: COVID-19 press releases by the Ministry of Health, Labour and Welfare *2 Xofluza and Rapiacta

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Results for Q3 of FY2024

**The growth of the HIV business and overseas business,
along with the stabilization of the domestic business, is expected to achieve the full-year forecast**

The HIV business and overseas business have grown significantly

- HIV business: **+37.4 billion yen** (Y on Y)
- Overseas business: **+6.9 billion yen** (Y on Y)

In the domestic business, we aim to stabilize the infectious disease business and build a new revenue base

- Both Xocova and the influenza family have secured a high market share and recorded stable sales during the spread of infections
  - Sales of influenza family expanded
- Launch of QUVIVIQ

All items landed as expected against the full-year plan

- Cost management is practiced in line with sales revenue
- Research and development are vigorously promoted with prioritized focus

Towards the Realization of the 2030 Vision

- Transformation of the China Business
- Pipeline Progress

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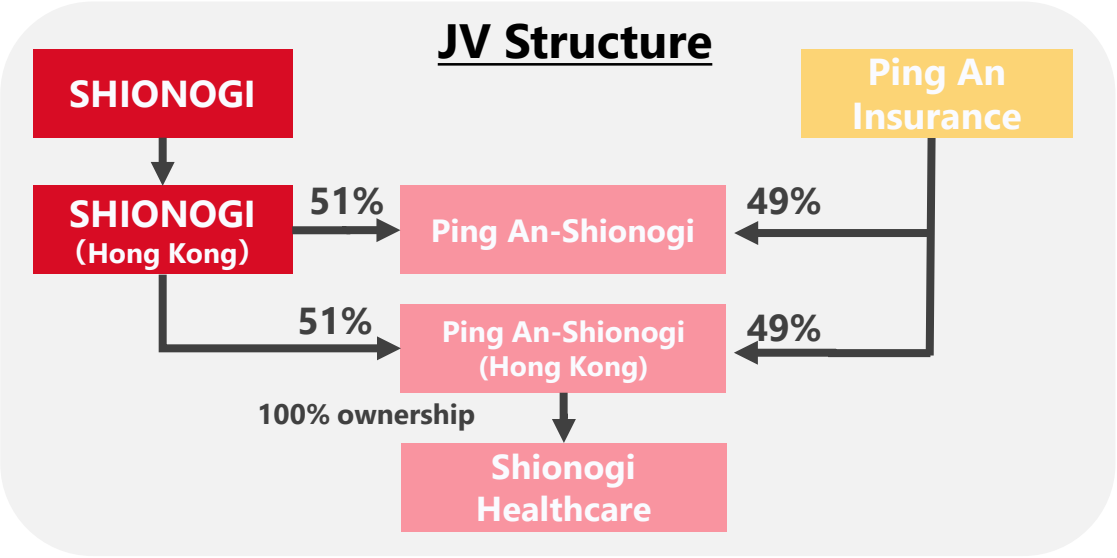
Dissolution of Joint Venture With Ping An Insurance

SHIONOGI will independently expand its business in China and the broader Asia region

Achievements of the joint venture and the structure

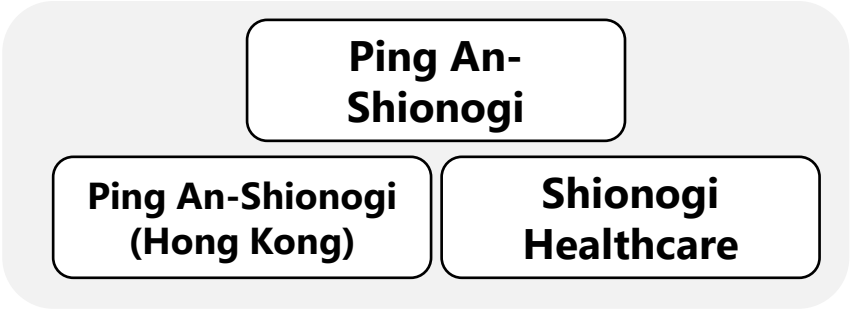
- Submission for approval of cefiderocol in China and its early use in designated medical zones
- Approval of Ensitrelvir and Cefiderocol in Singapore's SAR*
- Leveraging AI-driven drug discovery expertise and acquisition of candidate compounds



Evolutionary Dissolution

Future Framework

- SHIONOGI will fully acquire the following three subsidiaries
- Leveraging the expertise and know-how accumulated over the years, the company will expand its pharmaceutical development, manufacturing, and sales operations



Further details on the business plan will be disclosed in the full-year financial results for FY2024

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Future Outlook for the China Business

Achieving growth in China by focusing on the new drug business

- Accelerating the launch of SHIONOGI products and advancing new drug discovery in China
- Driving top-line growth through the continuous launch of new drugs starting in FY2025

Launch of SHIONOGI Products

Cefiderocol (AMR:Gram-negativebacteria infection)	**Naldemedine** (Opioid-inducedConstipation)
Already Submitted **Approval expected in 2025**	**Phase 3 Milestone Achieved** **Submission planned for 2025**
Ensitrelvir (COVID-19)	**Ololofim** (Invasive Aspergillosis)
Under Preparation for Submission	Global Phase 3 Trials Ongoing

New Drug Discovery in China

- Continued Drug Discovery Utilizing AI Technology
- Clinical validation is underway for new drug candidates independently developed by SHIONOGI

Candidate Compounds (IPF)
Ongoing Investigator-Initiated Clinical Trials

Towards the Realization of the 2030 Vision

- Transformation of the China Business
- Pipeline Progress

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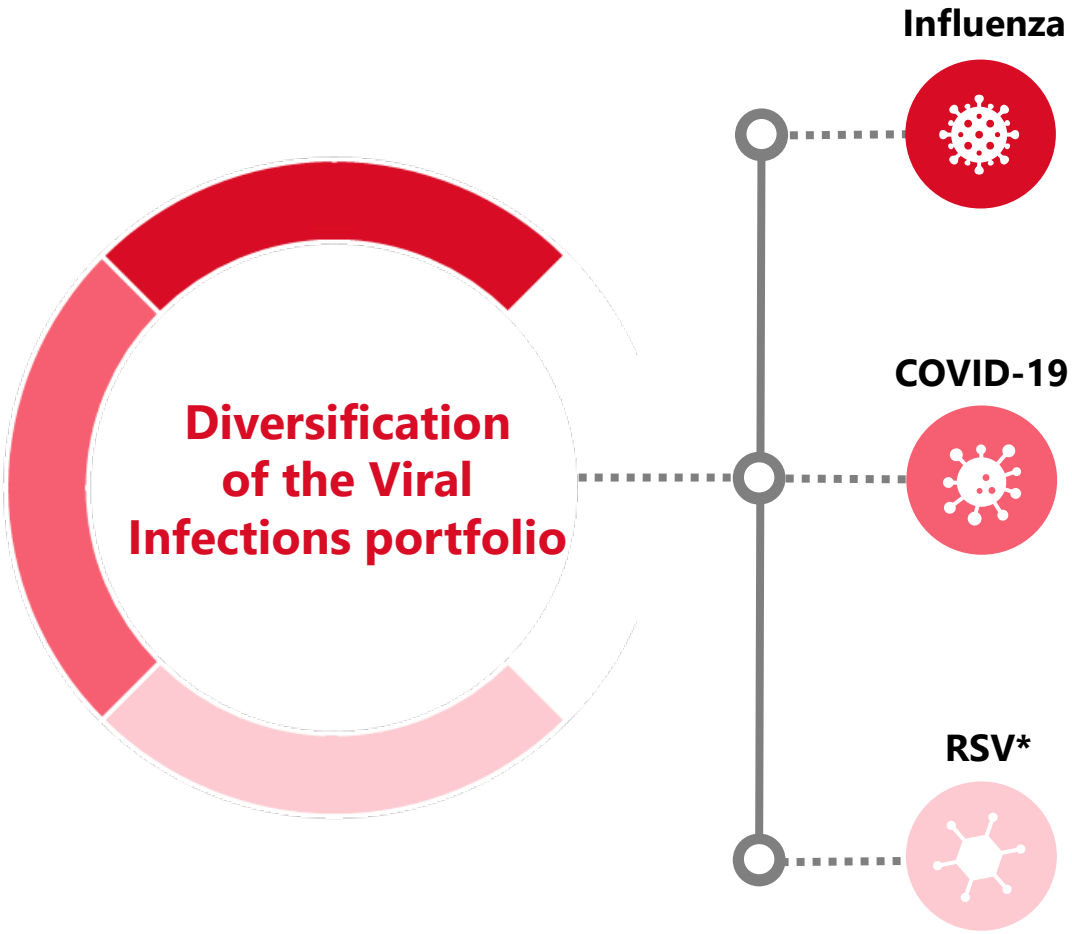
Acute Respiratory Infections Business：Diversification of Portfolio

Expansion of the disease portfolio and globalization of each drug, moving from "stabilization" to "growth"



Xofluza — **Completion of treatment and prevention with a single oral dose**

- Accumulation of new evidence to suppress virus transmission

Xocova — **Global expansion in treatment and Prevention**

- Under discussions with various regulatory authorities, including the FDA and EMA, with a view to global expansion

S-892216 — **Investigational Second Generation 3CL Protease Inhibitor**

- Developing treatments targeting oral formulations for therapy and long-acting injectable formulations for pre-exposure prophylaxis

S-337395 — **We are entering the third acute respiratory infection**

- Achievement of primary endpoints in Phase 2 trials, moving towards global development

* RSV: Respiratory syncytial virus

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COVID-19: Global Market Potential

COVID-19 continues to mutate and affects the health and lives of many people around the world

Estimated number of patients in US*

from September 29, 2024, to January 4, 2025

−COVID-19 Illnesses−
3.9 million - 7.0 million

−COVID-19 outpatient visits−
940,000 - 1.9 million

−COVID-19 hospitalizations−
110,000 -190,000

−COVID-19 deaths−
13,000-22,000

Total sales of two oral therapeutic products in US*2

from January to September 2024

Approximately **4.3** billion dollars

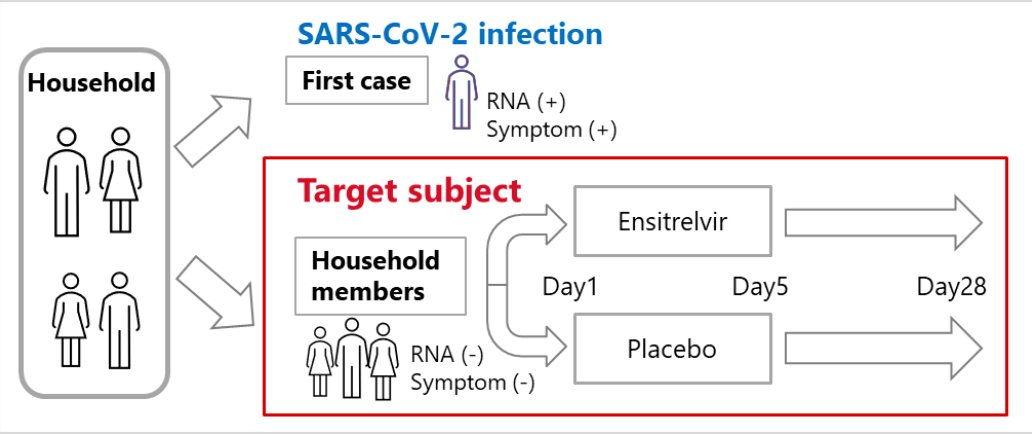
* Centers for Disease Control and Prevention website *2 Calculated by our company from Pfizer and Merck Q3 2024 financial reports

Ensitrelvir: Positive Results From the SCORPIO-PEP* Trial

Demonstrated the world's first preventive effect against the onset of COVID-19 with an oral antiviral drug*2

Trial design*3

Country	US, South America, Africa, Asia including Japan
Trial Design	Multicenter, randomized, placebo-controlled, double-blind trial
Subjects	Family members or cohabitants of COVID-19 patients (approximately 2,400 cases)
Dosing Regimen Sample Size	• Once daily for 5 days (Same as treatment indication) • Ensitrelvir: 1,200 cases, placebo: 1,200 cases
Main purpose	Verification of the effect of suppressing the onset of COVID-19 symptoms for10 days after starting ensitrelvir administration



Preliminary trial results

Results Summary	**—Achieved primary endpoints—** **<Primary endpoint>** • Significantly reduced the proportion of subjects who became infected with SARS-CoV-2 and developed COVID-19 symptoms within 10 days of administration **<Secondary endpoint>** • The proportion of subjects infected with SARS-CoV-2 also decreased • No new safety concerns • Pharmacokinetics similar to those in therapeutic trials
Detailed Report	Details will be announced at CROI*4 in March 2025 (Late-breaker)

* PEP: Post-Exposure prophylactic
*2 Press release dated October 29, 2024 *3 jRCT: 2031230124
*4 The Conference on Retroviruses and Opportunistic Infections

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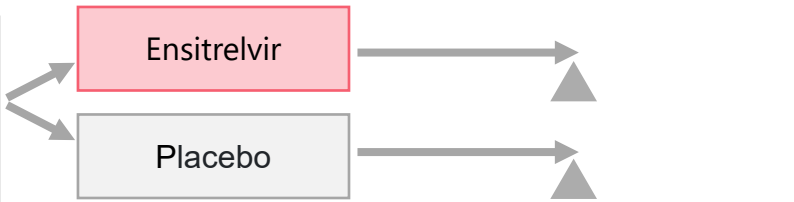
Ensitrelvir: Pediatric Trial Results in Japan

Promote development for expanded indications targeting pediatric patients aged 6 to under 12 years with limited treatment options

Trial design*

Country	Japan
Trial Design	Multicenter, randomized, double-blind, placebo-controlled trial
Subjects	Mild to moderate COVID-19 patients aged 6 to under 12 years (total of 120 cases)
Dosing Regimen Sample Size	• Once daily for 5 days • Ensitrelvir: 3 doses (total of 80 cases), placebo (40 cases)
Main purpose	Confirmation of safety, tolerability, and pharmacokinetics

Key inclusion criteria
- Participant who was diagnosed as SARS-CoV-2 positive within 72 hours
- Participant with body weight of >= 20 kg



Preliminary trial results

Results Summary	• Confirmed safety and tolerability • Good pharmacokinetics similar to adults
Detailed Report	The details of the trial results are scheduled to be reported at major conferences in Japan
Future Development Strategies	**Based on the trial results, we plan to submit an approval application in Japan**

* jRCT: 2031230140

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Ensitrelvir: Status of Global Development

Promoting various initiatives to maximize the value of ensitrelvir, including expanding indications and global deployment

Development status

Clinical trial	Status
SCORPIO-SR (Asia: Phase 3)	Achieved primary endpoints
SCORPIO-HR (Global: Phase 3)	Primary endpoint not achieved
Pediatric trial (Japan: Phase 3)	Confirmed preliminary trial results (safety and pharmacokinetics)
SCORPIO-PEP (Global: Phase 3)	Achieved primary endpoints
STRIVE trial (Global: Phase 3)	Ongoing
Long COVID (Investigator-initiated trials)	Collaborative research in progress with Osaka University

Status of applications to various countries/regions

Countries/region	Status
US	Pre-application consultation in progress
Europe	Pre-application consultation in progress
Japan	Normal approval obtained Application in preparation for expansion of indications pediatric and PEP
China	In discussion with regulators
Singapore	SAR approved Under review (Normal approval application completed)
Taiwan	Application for approval was submitted / Government stockpiling contract was signed
Korea	Plans to add data from the SCORPIO-PEP trial and resubmit application

S-892216: Investigational Second Generation 3CL Protease Inhibitor

Accelerating the development of new solutions to address significant public health challenges

S-892216 Profile

Mechanism of action

- SARS-CoV-2 3CL protease inhibition

Product Features

- Fewer drug interactions
- Strong antiviral effects
- No contraindications for pregnant women (no teratogenic effects observed in non-clinical studies)
- Different binding mode from other 3CL protease inhibitors, resulting in a distinct drug resistance profile

S-892216 Development plan

Oral pill*

- Indications: COVID-19 Treatment
- Development Plan: Phase 2 scheduled to start in 4Q FY2024 (Japan, US)

Long-acting injectable**

- Indications: COVID-19 pre-exposure prophylaxis
- Development Plan: Investigational new drug application and initiation of Phase 1 trial planned within 2025 (US)

$375 million provided by the Biomedical Advanced Research and Development Authority (BARDA) through the Rapid Response Partnership Vehicle (RRPV) Consortium to support development.

* This research and development is supported by AMED under Grant Number 21fk0108584 and 22fk0108522h0001

** 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.

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S-337395：Market Potential and Mechanism (RS virus infection)

A market with significant unmet medical needs due to the lack of effective treatments despite a large number of potential patients

Potential Patient Numbers in the US*1,2

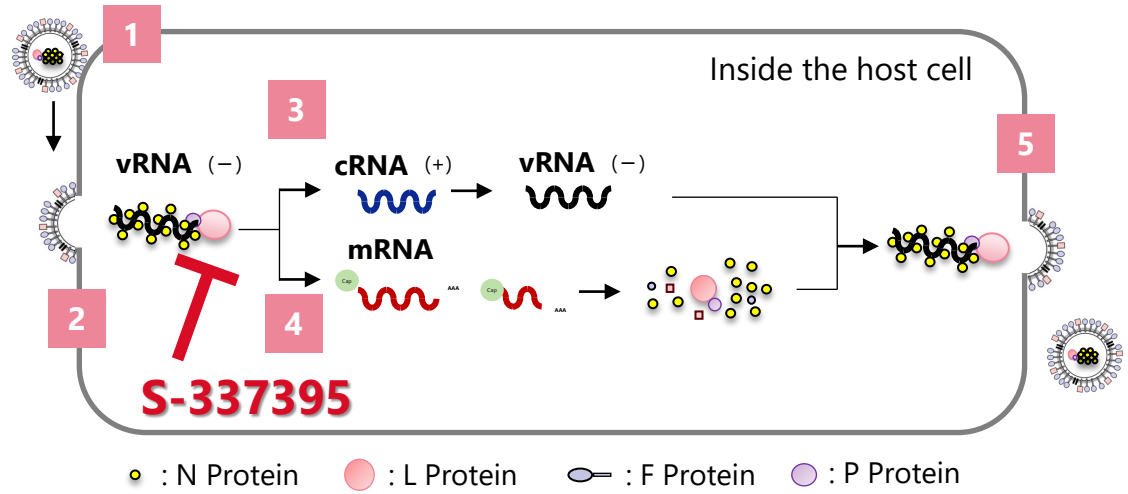
Infants and young children (0–5 years)	High-risk patients (65 years and older)
Approximately **2.1 M People**	Approximately **1.2 M People**
—Hospitalized patients— **58,000-80,000 People**	—Hospitalized patients— **-108,000 People**
—Number of deaths— **100-500 People**	—Number of deaths— **7,700 People**

A large market with over 3 million potential patients annually

Mechanism of S-337395*3

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

1.Adsorption → 2. Membrane fusion → 3. Replication → 4.Transcription → 5. Budding



*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"
*3 A compound discovered through joint research with UBE Corporation

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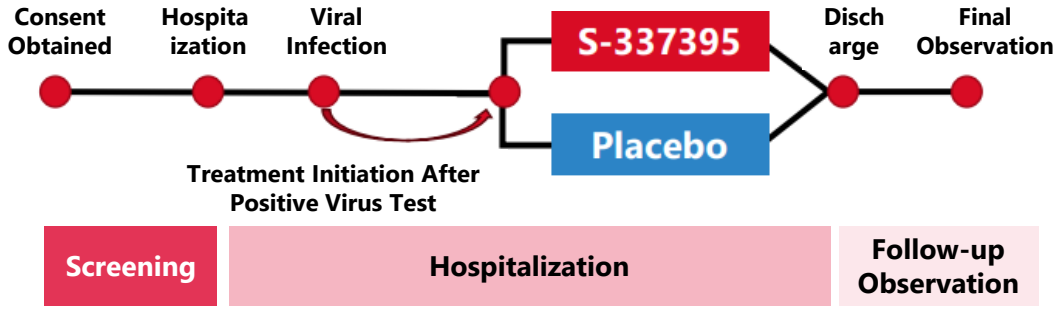
S-337395：Top-Line Result in Phase 2 Trial*

In the Phase 2 trial, a statistically significant reduction in viral load was confirmed

Trial Design

Country	United Kingdom
Trial Design	Randomized, placebo-controlled, double-blind comparative, Challenge Trial
Subjects	Healthy adults (Total: 114 participants)
Dosing Regimen Sample Size	• Once-daily oral administration for 5 days • S-337395： 4 dosage, Placebo: Minimum dose group 10 participants, Other groups: 26 participants
Primary Endpoint	AUC of RSV viral load measured by qRT-PCR



Preliminary Trial Results

Results Summary	**-Achieved primary endpoints-** • In the highest dose group, there was an 88.94% reduction in viral load (P<0.0001) • Dose-dependent reduction in viral load confirmed • Statistically significant improvement in clinical symptom scores • No concerns regarding tolerability and safety
Detailed Report	Detailed results of the trial will be reported at major international conferences
Future Development Strategies	Based on these trial results, we are considering development strategies to conduct late-stage global trials

*3 Joint devlopment with UBE Corporation

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Progress of Major Development Products - Infection diseases -

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

Disease area	Pipeline	Indication	Current stage	FY2024	FY2025	Note
COVID-19 treatments	**Ensitrelvir**	COVID-19	Preparation for global submission	→		
	Ensitrelvir	COVID-19 (Pediatric)	Phase 3	→ Complete enrollment (FY24 2Q)		**Confirmed preliminary trial results: January 2025**
	Ensitrelvir	COVID-19 PEP	Phase 3	→ Complete enrollment (FY24 2Q)		**Primary endpoint achieved : October 2024**
	S-892216	COVID-19	Phase 1	→ Phase 2 start (FY24 4Q)	→ Topline results (FY25 3Q)	
		COVID-19 PrEP	Preclinical	→	→	
COVID-19 vaccines	**COVGOZE (S-268019)**	COVID-19 (Wuhan, Vaccine)	Approval	→		
	S-268024	COVID-19 (JN.1, Vaccine)	Preclinical	→ Phase 2 start (FY24 4Q)	→ Topline results (FY25 2Q)	**Preparing for Phase 3 trial**
	S-567123	COVID-19 (Universal Vaccine)	Preclinical	→ Phase 1 start (FY24 4Q)	→ Topline results （FY25 2Q）	
Infection diseases	**Olorofim**	Invasive aspergillosis	Phase 3	→	→	
	S-337395	RSV infections	Phase 2	→ Topline results (FY24 3Q)	⇢ Adult Verification trial start (FY25)	**Primary endpoint achieved : January 2025**
	S-743229	AMR (Complex urinary tract infection)	Phase 1	→ Phase1 (combined use) topline （FY24 3Q）		
	S-649228	AMR (Gram-negative bacteria infection)	Phase 1	→ Phase1 (combined use) start （FY24 2Q）	→ Topline results （FY24 3Q）	

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

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

Disease area	Pipeline	Indication	Current stage	FY2024	FY2025	Note
QOL Diseases with High Social Impact	**SDT-001**	ADHD	Submission	Approval (FY24 4Q)		
	Zuranolone	Depression	Submission	Submission (FY24 2Q)	Approval (FY25 2Q)	
	Resiniferatoxin	Pain associated with knee osteoarthritis	Phase 3		Submission (FY25 3Q)	
	Zatolmilast	Fragile X Syndrome	Phase 2/3		Phase 2/3 topline (FY25 1Q) Submission (FY25 3Q)	
		Jordan syndrome	Phase 2	Phase 2 start (FY24 3Q)		**Phase 2 started (IND application*): November 2024**
	Redasemtide	Acute ischemic stroke	Phase 2b			
		Dystrophic epidermolysis bullosa	Phase 2			
	S-309309	Obesity	Phase 2	Additional non-clinical trials underway		
	SASS-001 (S-600918 + Drug X)	Sleep apnea syndrome	Phase 2	Phase 2 start (FY24 3Q)	Phase 2 topline (FY25 4Q)	
	S-531011	Solid tumor	Phase 1b/2	Phase 2 part start (FY24 2Q)		
	S-151128	Chronic pain	Phase 1b	Phase 1b topline (FY24 2Q)		
	S-606001	Pompe	Phase 1		Phase 2 start (FY25 1Q)	**Rare pediatric disease Designation granted by the FDA**

* Investigational New Drug Application

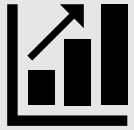
Appendix

Zatolmilast: Development Targeting Jordan Syndrome

Initiating clinical trials targeting Jordan syndrome, aiming to develop the world's first treatment

What is Jordan Syndrome?

A rare genetic disorder characterized by developmental delays



Estimated 250,000–300,000 potential patients globally

No approved treatments currently available

Significant unmet medical needs related to cognitive impairments

Features and Development Plan of Zatolmilast

The world's first treatment to address existing unmet medical needs

- Mechanism of Action: Selective allosteric inhibition of PDE4D
  - Enhances cognitive function by regulating intracellular signaling pathways in neurons
- Designated as a rare pediatric disease in the US

Initiated Phase 2 trials, aiming for approval in 2026

- Conducting development in parallel with fragile X syndrome studies

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Pipeline: Infectious Disease

as of January 31, 2025

Preclinical	Phase 1	Phase 2	Phase 3		Submission
S-567123 COVID-19 Universal vaccine	**S-337395** RSV infections	**S-337395** RSV infections	**Cefiderocol** Aerobic Gram-negative bacterial infection (Pediatric)	**Ensitrelvir*** COVID-19 treatment	**Ensitrelvir*2** COVID-19 treatment
S-872600 Influenza nasal vaccine	**S-892216** COVID-19 treatment		**S-268023** COVID-19 vaccine (XBB 1.5)	**Ensitrelvir** COVID-19 prevention	**Baloxavir** Influenza virus infection (Granules, < 20kg)
S-875670 COVID-19 nasal vaccine	**S-743229** AMR (Complex urinary tract infection)		**S-268019** COVID-19 vaccine (Ages 5-19)	**Ensitrelvir** COVID-19 treatment (Ages 6-11)	**Cefiderocol*3** AMR (Gram-negative bacteria infection)
S-540956 Nucleic acid adjuvant	**S-649228** AMR (Gram-negative bacteria infection)		**Olorofim** Invasive Aspergillosis	**Cefiderocol** AMR (Gram-negative bacteria infection)	
S-554110 Nontuberculous mycobacterial infection		**Out license**			**Baloxavir** Influenza virus infection (Pediatric, < 1 year old)
S-268024 COVID-19 vaccine (JN.1)		**S-365598** HIV infection			**Baloxavir** Influenza virus infection (Transmission)
S-917091 HIV infection					
S-892216 COVID-19 Prevention					

Change from October 29, 2024, to January 31, 2025

- Ensitrelvir (COVID-19 treatment): Submitted in Taiwan
- Ensitrelvir (COVID-19 treatment): NDA withdrawal in Korea
- Cefiderocol (AMR): Submitted in Australia
- Baloxavir (Influenza virus infection (Transmission)): Submitted in US
- S-892216 (COVID-19 Prevention): Preclinical

: Global development

: Progress from to October 29, 2024, to January 31, 2025

* Phase 3 ongoing *2 Singapore, Taiwan *3 China, Australia

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Pipeline: QOL Diseases with High Social Impact

as of January 31, 2025

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

: Global development

Change from October 29, 2024, to January 31, 2025
• Zatolmilast (Jordan syndrome): Phase 2 started in US

: Progress from to October 29, 2024, to January 31, 2025

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

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Anti-HIV drug released by ViiV

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

Other Major Progress*

- **October**
  - Disclosure of Materials on Measures to Achieve Management that Considers Capital Costs and Stock Prices
- **December**
  - Integrated Report 2024 Wins Bronze Award (Honorable Mention) at the WICI Japan Integrated Report Awards 2024
- **January**
  - AdvanSentinel Inc. has launched a joint research project with Tottori University and Kagoshima University to establish and utilize a highly sensitive detection method for highly pathogenic avian influenza viruses in the environment
  - The "Resource Circulation Project", which aims for horizontal recycling of label backing paper, has won the World Star Awards 2025
  - Shionogi & Co., Ltd. has entered into a business partnership with Hitachi, Ltd. to develop innovative services for the pharmaceutical and healthcare industries by leveraging data and generative AI
  - Sponsorship for the New COVID-19 Treatment Insurance: "COVID-19 Treatment Benefit Insurance"

* Progress from October 28, 2024 to January 30, 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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