1st Quarter of Fiscal 2024 Financial Results

July 29, 2024

Shionogi & Co., Ltd.



Agenda

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Pipeline Progress

(P.14-23)

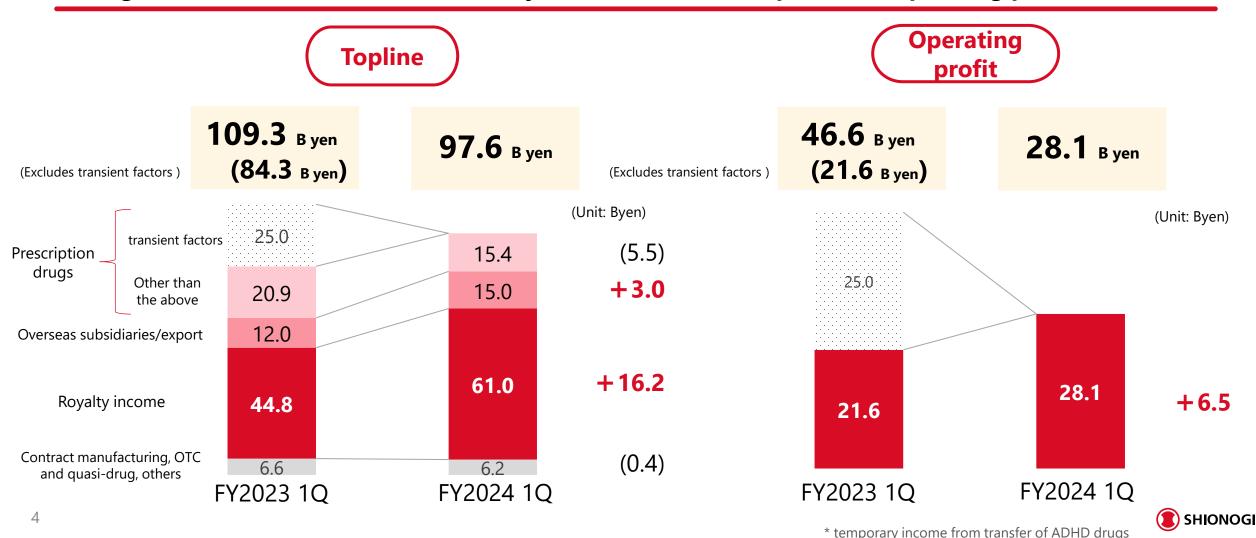


Overview of Q1 FY2024 Financial Results



Highlight

Excluding the transient factors* of the fiscal year 2023, both the top line and operating profit have increased



Financial Results

Summary

- Revenue and various profit items have landed above expectations compared to the first half plan
 - The overseas business and HIV business, which have grown as revenue bases, are also making steady progress this term
 - Since April, the domestic share of Xocova has expanded rapidly
- The one-time fee (25 billion yen) associated with the transfer of the license for the ADHD treatment drug recorded in the fiscal year 2023 has affected, resulting in a decrease in revenue and profit for this quarter
 - Excluding the one-time fee, sales revenue and various profit items have increased compared to the same period of the previous year

(Unit : B yen)

	FY2024			FY2023	Y or	ιY	
_	Foreca Full year	asts 1H	AprJun. results	Achievement (%)	AprJun. results	Change (%)	Change
Revenue	455.0	210.0	97.6	46.5%	109.3	(10.7)	(11.7)
Operating profit	160.0	69.0	28.1	40.7%	46.6	(39.7)	(18.5)
Profit before tax	200.0	82.5	36.5	44.3%	55.7	(34.4)	(19.2)
Profit attributable to owners of parent	163.0	66.5	30.6	46.1%	42.6	(28.0)	(11.9)
EBITDA*			33.1		51.3	(35.5)	(18.2)

Exchange Rate (Average)							
	FY2024 Forecast	FY2024 AprJun. Results					
USD(\$) – JPY(¥)	145	155.86					
GBP(£) – JPY(¥)	178	196.79					
EUR(€) – JPY(¥)	155	167.85					



Statement of Profit or Loss

(Unit: B yen)

			FY2024		FY2023	Y or	ı Y
	Foreca Full year	ast 1H	AprJun. A Results	chievement (%)	AprJun Results	Change (%)	Change
Revenue	455.0	210.0	97.6	46.5	109.3	(10.7)	(11.7)
Cost of Sales	14.5	13.6	14.8		12.0		
Cost of Sales	66.0	28.5	14.4	50.7	13.1	10.1	1.3
Gross profit	389.0	181.5	83.1	45.8	96.2	(13.6)	(13.0)
Selling, general & administrative expenses,	49.8	52.9	55.9		44.9		
R&D expenses total	226.5	111.0	54.6	49.2	49.0	11.3	5.5
Selling, general &	23.4	24.8	25.8		22.0		
administrative expenses	106.5	52.0	25.1	48.3	24.0	4.6	1.1
R&D expenses	26.4	28.1	30.2		22.9		
NOD expenses	120.0	59.0	29.4	49.9	25.0	17.7	4.4
Other income & expenses	(2.5)	(1.5)	(0.5)	30.9	(0.6)	(18.3)	0.1
Operating profit	35.2	32.9	28.8		42.6		
Operating profit	160.0	69.0	28.1	40.7	46.6	(39.7)	(18.5)
Finance income & costs	40.0	13.5	8.4	62.3	9.1	(7.7)	(0.7)
Profit before tax	44.0	39.3	37.4		51.0		
	200.0	82.5	36.5	44.3	55.7	(34.4)	(19.2)
Profit attributable to owners of parent	163.0	66.5	30.6	46.1	42.6	(28.0)	(11.9)

Main Variation Factors (Y on Y)

Revenue



- Royalty income
- Overseas subsidiaries /export



Domestic sales

Cost of Sales

Increase in expense

• Changes in product mix

SG&A expenses

Increase in expense

- Sales-related expenses for overseas business
- Impact of foreign exchange

R&D expenses

Increase in expense

- Pipeline assets are moving forward steadily
- Establishment of a U.S. base through the acquisition of Qpex
- Impact of foreign exchange



Revenue by Segment

(Unit: B yen)

			FY2024		FY2023	Y or	ı Y
	Foreca Full year	ast 1H	AprJun Results	Achievement (%)	AprJun Results	Change(%)	Change
Prescription drugs	134.9	58.0	15.4	26.6	45.9	(66.4)	(30.5)
Excluding temporary income	-	-	15.4		20.9	(26.2)	(5.5)
Overseas subsidiaries/export	53.7	24.7	15.0	60.6	12.0	24.9	3.0
Shionogi Inc. (US)	20.6	10.0	6.0	59.8	4.0	48.6	2.0
Fetroja	-	-	4.8	-	3.2	50.5	1.6
Shionogi B.V. (EU)	14.4	6.8	4.0	58.9	3.0	34.2	1.0
Fetcroja	-	-	3.1	-	2.1	45.7	1.0
Ping An Shionogi/C&O	11.2	4.7	2.3	48.8	3.1	(25.8)	(8.0)
Others	7.5	3.2	2.7	84.0	1.9	42.9	0.8
Contract manufacturing	15.5	6.5	3.6	55.2	4.0	(10.4)	(0.4)
OTC and quasi-drug	16.6	8.0	2.4	30.2	2.3	6.6	0.1
Royalty income	232.5	112.2	61.0	54.4	44.8	36.1	16.2
HIV franchise	224.6	111.2	59.8	53.8	44.3	35.1	15.5
Others	7.9	1.0	1.2	121.8	0.6	109.6	0.6
Others	1.8	0.6	0.2	27.6	0.3	(44.1)	(0.1)
Total	455.0	210.0	97.6	46.5	109.3	(10.7)	(11.7)

Main Variation Factors (Y on Y)

Prescription drugs

Decrease

 Last fiscal year, a one-time fee of 25 billion yen was received for the transfer of the ADHD treatment drug license

Overseas subsidiaries/export

Increase

 Sales of cefiderocol (US: Fetroja, EU: Fetcroja)

Royalty income

Increase

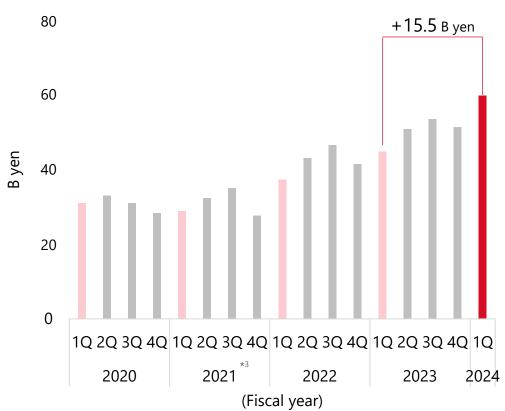
 Strong sales of ViiV's HIV franchise



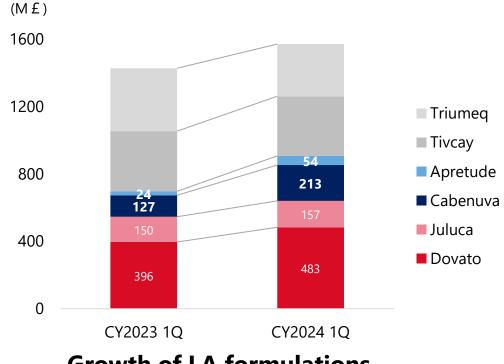
Expansion of the HIV Business

Continued stable growth each quarter, centered on the growth of LA formulations*

Transition of HIV royalty income



Sales of ViiV's Dolutegravir and Cabotegravir product groups*2



Growth of LA formulations (Cabenuba, Apretude)

+76.8%

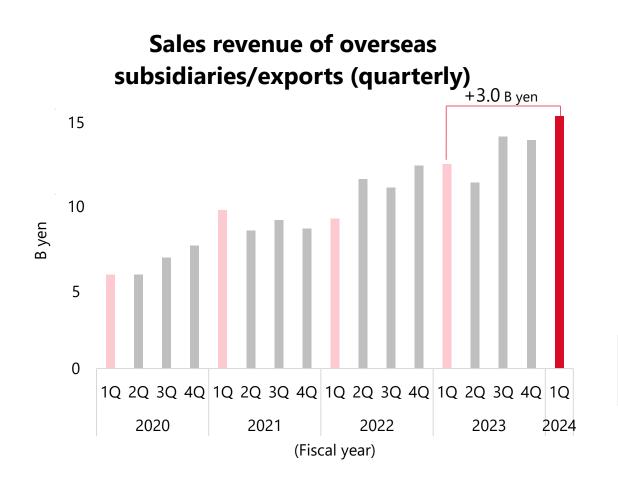


^{*} LA: Long Acting *2 Source: Prepared by SHIONOGI based on GSK financial statements

^{*3} The additional royalties from Gilead's Biktarvy patent infringement lawsuit against dolutegravir in Q4 2021 are not included

Expansion of Overseas Business

Steady growth in overseas business, centered on Cefiderocol



Sales of Cefiderocol are growing strongly in both the US and EU

 An increase of over 45% compared to the same period of the previous year

Expansion of Cefiderocol selling countries(Sold in 19 countries)

- Started new sales in Taiwan and Singapore*
 - Sobi has started sales in Central and Eastern Europe

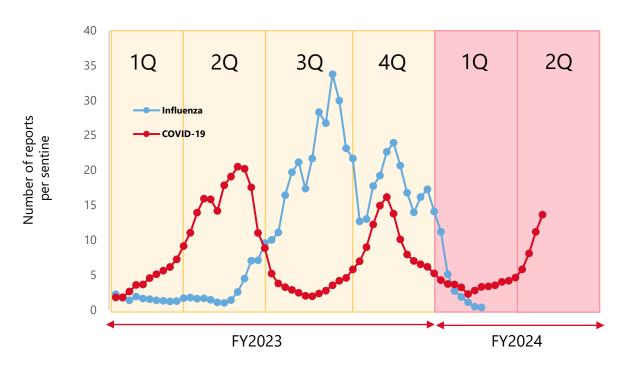
Conducted approval application for Cefiderocol in China

- Achieved primary endpoint in Phase 3 trial*²
- In the future, we aim for further growth in our overseas business, anticipating revenue contributions from PingAn Shionogi as well

Acute Respiratory Infection portfolio - COVID-19 and influenza -

Achieved strong revenue in the first quarter with two infectious disease drug assets

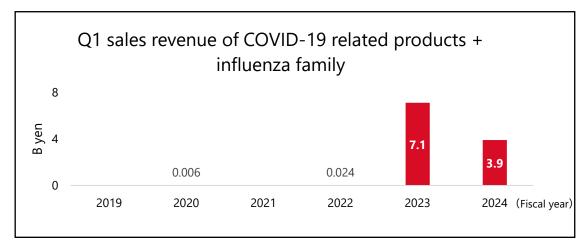
The infection status of COVID-19 and influenza*



While influenza is below the epidemic threshold, COVID-19 infections are on the rise

Sales of the influenza family are almost zero

COVID-19 related products recorded strong sales

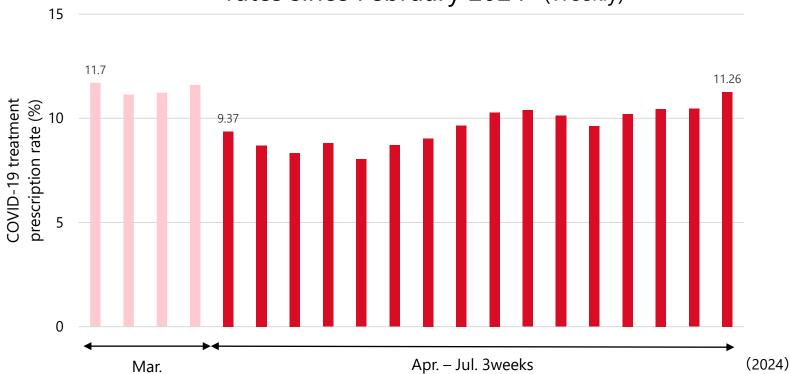




Oral COVID-19 treatment prescription rates change

No significant decrease in prescription rates even after public funding ended in April

Transition of oral COVID-19 treatment prescription rates since February 2024* (Weekly)



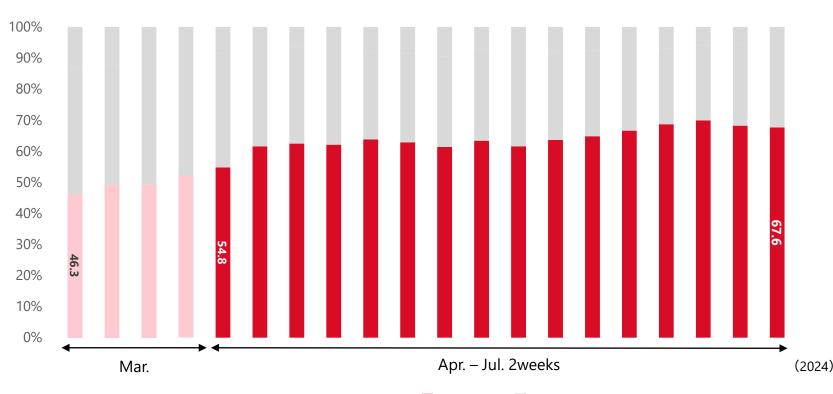
- Steady prescription rate is maintained even after the end of public funding
- Prescription rates are affected by the fluctuation in the number of infections
 - There is a tendency for prescription rates to increase with the rise in the number of infections
- The mainstream LB.1 strain and KP.3 strain may show high infectivity, and caution is needed



COVID-19 oral treatment drug share

The first quarter landed as expected, and the share of Xocova is expected to expand, making the first half forecast achievable

Share of oral treatment drugs for COVID-19 patients* (Weekly)



- Among the three oral treatment drugs, Xocova share is on an increasing trend
- Since April 2024, prescriptions have increased, especially for patients with risk factors for severe illness
 - Data supporting effect on suppressing hospitalization due to COVID-19 (P.16-17).



Results and Outlook for Q1 of FY2024

Given the solid performance of the HIV and overseas businesses, the first half forecast is expected to be achieved

The revenue drivers, HIV business and overseas business, continue to grow



- HIV business: +15.5 billion yen (Y on Y)
- Overseas business: +3.0 billion yen (Y on Y)

Strengthening efforts in preparation for the expansion of acute respiratory infections



- Increased recognition as a COVID-19 treatment
- Following last year, the forecast is set with an emphasis on Q2

For the first half plan, Q1 landed almost as expected



- Practicing meticulous cost management this term as well
- Research and development expenses are prioritized and actively promoted



Pipeline Progress



S-309309: Next Steps

Focus on unmet medical needs remaining with, or created by, GLP-1 receptor agonists

Unmet needs after broad uptake of GLP-1 receptor agonists (GLP-1 RAs)



Reduction in the dosage (and corresponding side effects and cost of GLP-1 RAs by add-on therapy



Weight loss maintenance after stopping GLP-1RAs



Less expensive, safe, convenient oral regimens

Future Policy

Expanded preclinical program supporting clinical study design and partner discussions



- Detailed study of add-on and maintenance effects in multiple preclinical settings under varying dietary conditions
- Oral combination studies with different oral mechanisms
- Results expected to be obtained in 3Q FY24
- Next clinical program and partnering engagement driven by these results



New Clinical Data on Ensitrevir in Japan

Accumulation of real-world evidence confirmed ensitrevir's effectiveness in reducing severe outcomes and its favorable safety and efficacy*

Effectiveness of ensitrelvir in reducing severe outcomes

Retrospective trial using a large Japanese health insurance claims database*2

- Evaluated the effectiveness of ensitrelyir in preventing hospitalization in patients with risk factors for severe desease (using data from actual clinical trials during the Omicron strain epidemic)
- Incidence of hospitalization from all causes was statistically lower by approximately 37% in the ensitrelyir group than those receiving no antiviral treatment
- Potentially due to a strong virus reduction effect

This trial suggested ensitrelvir is an effective treatment for patients at risk of severe COVID-19

Post-Marketing Survey — Final analysis report—

Accumulation of safety and efficacy information from actual use

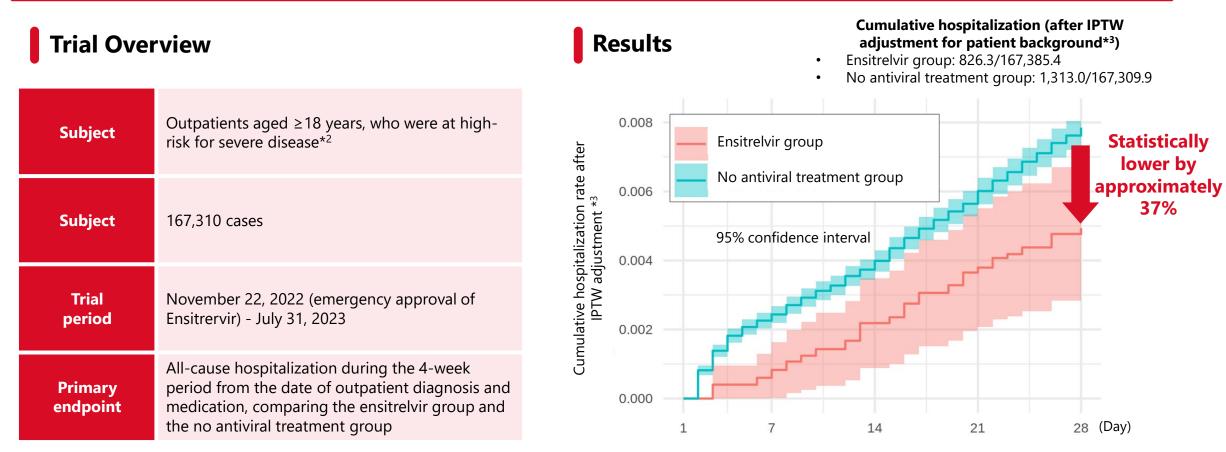
- Safety:
 - Common treatment-related adverse events: diarrhea in 91 patients (2.4%), nausea in 43 patients (1.1%), and headache in 42 patients (1.1%)
- Effectiveness:
- Median time to fever resolution: about 1.5 days (36.0 hours)
- Median time to resolution of all symptoms of COVID-19: 6.5days (156.0 hours)
- Hospitalization: 14 cases/3,638 cases (0.4%), Death: 2 cases/3,638cases (0.1%)
 - > Hospitalization: 10 cases/14 cases were due to worsening of COVID-19
 - > Death: both are related to incidental events or underlying conditions/complications

Regardless of the presence or absence of high-risk factors for severe disease, good tolerability and effectiveness were demonstrated, and no new concerns were identified



Real-World Effectiveness of Ensitrelvir in Reducing Severe Outcomes shown Using a large Japanese Health Insurance Claims Database*

Administration of ensitrelvir reduces the risk of hospitalization in patients with high-risk for severe disease



^{*} Takazono, T., Fujita, S., Komeda, T. et al. Real-World Effectiveness of Ensitrelvir in Reducing Severe Outcomes in Outpatients at High Risk for COVID-19. Infect Dis Ther (2024).



^{*2} Aged ≥ 65 years, malignant tumour, chronic respiratory disease, diabetes, chronic kidney disease, hypertensive disease, dyslipidemia, cardiovascular disease, cerebrovascular disease, morbid obesity, immunosuppressive state, and AIDS/HIV

Development Status of Ensitrelvir

Leading Company in Infectious Diseases, Conducting Various Clinical Trials to Address COVID-19 Issues

Assessment of efficacy in outpatients, including **SCORPIO-HR** Results of the Phase 3 trial were presented at IAS 2024* Ongoing 6-month follow-up analysis for Long COVID those with risk factors for severe illness (Global: Phase 3) Safety and pharmacokinetics assessment in **Pediatric trial Enrollment** is scheduled to be completed in the first half of FY2024 (Japan: Phase 3) children Assessment of preventive effect of symptomatic **SCORPIO-PEP Enrollment** is scheduled to be completed in the SARS-CoV-2 infection in close contacts first half of FY2024 (Global: Phase 3) Assessment of efficacy, including mortality prevention **STRIVE trial Enrollment** is scheduled to be completed in the effect in hospitalized patients (conducted by NIH) first half of FY2025 (Global: Phase 3) **Long COVID** Assessment of preventive efficacy for Started joint research with Osaka University in (Investigator-initiated March of 2024 Long COVID and safety trials)



SCORPIO-HR Trial: Efficacy regarding symptom resolution

Time to resolution of 15 COVID-19 symptoms was shortened, regardless of the presence or absence of risk factors for severe disease

		Number of COVID-	Symptom	Number of	Restri	(Days)	SCORPIO-SR trial		
		19 symptoms evaluated	resolution definition	participants analyzed	Ensitrelvir	Placebo	Difference (95% CI* ⁶)	P value	- same analysis method* (P value)
	Primary Endpoint	15	≥2 consecutive days	1,888* ⁵	12.5	13.1	-0.6 (-1.38, 0.19)	0.14* ²	0.07
SCORPIO- HR	HR Secondary endpoints*10	15	≥1 day	1.000*5	11.4	12.2	-0.8 (-1.54, 0.01)	0.05	0.02*3
(Global : Phase 3)		6* ⁴	≥1 day	1,888* ⁵	10.3	11.0	-0.7 (-1.48, 0.02)	0.06	0.02
SCORPIO- SR	Secondary endpoints	14	≥1 day	690* ⁸	10.7	11.6	-0.8 (-1.94, 0.26)		0.03
(Japan•Korea• Vietnam : Phase3)	Primary Endpoint	5* ⁷	≥1 day	090**	10.1	10.9	-0.8 (-1.90, 0.28)		0.04*2

- No statistically significant differences were observed in the primary endpoints of SCORPIO-HR trial
- A pre-defined secondary analysis for time to resolution of six symptoms for one day using a statistical method similar to that used in the SCORPIO-SR Study yielded a significant difference (p < 0.05)

^{*1} Peto-Prentice's generalized Wilcoxon test is a method that evaluates group differences by giving more weight to the early resolution of symptoms *2 Primary analysis *3 Additional analysis

^{*4} Symptoms similar to the primary endpoints in the SCORPIO-SR trial (runny nose, nasal congestion, sore throat, cough, feverishness or fever, malaise (fatigue)) *5 mITT population (participants who received the investigational drug within 3 days from symptom onset)

*6 CI : Confidence Interval *7 Runny nose or nasal congestion, sore throat, cough, feverishness or fever, malaise (fatigue) *8 Population with PCR positive at baseline randomized within 3 days from onset

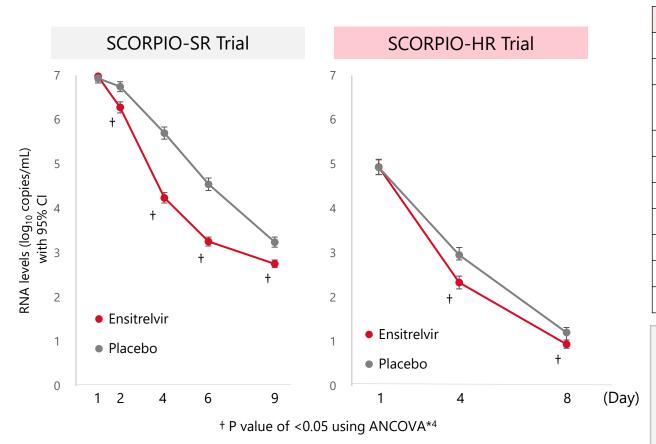
^{*9} In the SCORPIO-HR trial, the resstircted mean symptom duraion up to 28 days, and in the SCORPIO-SR trial, up to 21 days

^{*10} Secondary endpoints were not part of the statistical hierarchy, were not adjusted for multiplicity, and should be interpreted in an exploratory manner

SCORPIO-HR Trial: Antiviral Activity and Future Directions

Strong antiviral activity, with no observed rebound in viral titers associated with symptoms

Changes in viral RNA levels* —



Antiviral effects* —

SCORPIO-HR trial						
	Ensitrelvir	Placebo				
VC p	oopulation* ²					
Viral culture negative at day 4 - n (%)	274/287 (95.5)	210/280 (75.0)				
Risk difference (95% CI)	20.47 (14.	86, 26.08)				
P value	< 0.001					
mITT	population* ³					
Viral culture rebound - n (%)	6/945 (0.6)	13/943 (1.4)				
Risk difference (95% CI)	-0.74 (-1.	64, 0.16)				
P value	0.11					
Symptomatic Viral culture rebound	0	0				

Conducting discussions with regulatory authorities

- United States: Collaborating with NIH and continuing discussions with FDA
- Europe: Planning pre-MAA consultations*5 with EMA
- Asia: Conducting discussions with both China and Korea



Progress of HIV Business by ViiV: New Data Presentation at AIDS2024

Positive Data Supporting New Product Adoption and Progress of Next-Generation Development Products

Direct Comparison Study Between Dovato and Biktarvy*

Non-inferior Antiviral Efficacy

Compared to Biktarvy

Key Secondary Endpoints

Primary

Endpoints

Significantly less weight gain side effects compared to Biktarvy

	Dovato	Biktarvy
Average weight change after 48 weeks	+0.89kg	+1.81kg
Proportion of participants with over 5%	20%	29.9%
weight gain at 48 weeks	20%	29.9%

Dovato has proven to be an attractive treatment option not only in terms of viral suppression but also with respect to its impact on weight

Development Progress of S-365598 (ULA*2)*3

NonClinical
Trials

Maintained antiviral activity against
mutations resistant to existing integrase
inhibitors

Confirmed favorable blood concentration levels and tolerability in oral formulations

Currently Ongoing Clinical Trials

- Phase 1: Evaluation of tolerability and safety in injectable formulations
- Phase 2a: Assessment of efficacy, safety, and other factors in people living with HIV who are naïve to antiretroviral therapy



Phase 1

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
	COVGOZE (S-268019)	COVID-19 (Wuhan, Vaccine)	Approval			Approved in Japan: June 2024
	Ensitrelvir	COVID-19	Preparation for global submission			Phase 3 results to be presented at a conference: July 2024
	Ensitrelvir	COVID-19 (Pediatric)	Phase 3	Complete enrollment (FY24 2Q) Phase	e 3 topline results (FY24 4Q)	
COVID-19 Family	Ensitrelvir	COVID-19 (prevention)	Phase 3		e results(FY24 3Q)	
	S-268023	COVID-19 (XBB1.5,Vaccine)	Phase 3 † Data analysis in progress	(FY24 2Q)		
	S-892216	COVID-19	Phase 1	· · · · ·	esults (FY24 4Q)	
	S-567123	COVID-19 (Universal Vaccine)	Preclinical		Phase 3 start (FY25 1H) 4Q) Topline results (FY25 2Q)	
	Olorofim	Invasive aspergillosis	Phase 3			
Infection	S-337395	RSV infections	Phase 2	Topline results (FY2	4 3Q) Adult Verification trial start (FY25)	
diseases	S-743229	AMR (Complex urinary tract infection)	Phase 1	Phase1 (combined use) topline (F)	(24 30)	
	S-649228	AMR (Gram-negative bacteria infection)	Phase 1	Phase1 (combined use) start (FY24 2Q)		Phase 1 started (submitted INDA*): June 2024

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

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

Disease area	Pipeline	Indication	Current stage	FY2024	FY2025	Note
	SDT-001	ADHD	Submission	Approval (FY24 4Q)		
	Zuranolone	Depression	Preparation for application	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 toplin	e (FY25 1Q) Submission (FY25 3Q)	Fast Track Designation in US : March 2024
QOL Diseases		Acute ischemic stroke	Phase 2b			
with High Social Impact	Redasemtide	Dystrophic epidermolysis bullosa	Phase 2		→	
Impact	S-309309	Obesity	Phase 2	Considering future devel	opment strategies	
	S-600918 + Drug X	Sleep apnea syndrome	Phase 2	Phase 2 start (FY24 3Q)	Phase 2 topline (FY25 3Q)	
	S-531011	Solid tumor	Phase 1b/2	Phase 2 part start (FY24 2Q)		
	S-151128	Chronic pain	Phase 1b	Phase 1b topline (FY24 2Q)		Phase 1b LPO achieved: June 2024
	S-606001	Pompe	Phase 1	Phas	e 2 start (FY25 1Q)	

Appendix



Prescription Drugs in Japan

(Unit: B yen)

	FY2024				FY2023	Y on	Υ
	Foreca Full year	ast 1H	AprJun. Results	Achievement (%)	AprJun. Results	Change(%)	Change
Infectious disease drugs	91.2	37.6	6.1	16.2	9.3	(34.4)	(3.2)
COVID-19 related products + Influenza franchise	80.1	32.7	3.9	11.9	7.1	(44.9)	(3.2)
Symproic	6.5	2.9	1.1	37.5	1.0	6.0	0.1
OxyContin franchise	5.0	2.3	1.0	44.7	1.1	(6.7)	(0.1)
Actair	1.4	0.5	0.2	36.4	0.1	43.9	0.1
Cymbalta	3.3	1.8	8.0	44.7	1.1	(27.0)	(0.3)
Others	27.5	12.8	6.2	48.7	33.3*	(81.3)	(27.0)
Prescription drugs	134.9	58.0	15.4	26.6	45.9	(66.4)	(30.5)

- Xocova
- COVID-19 vaccines

- BrightpocFlu•Neo



⁻ Infectious disease drugs -

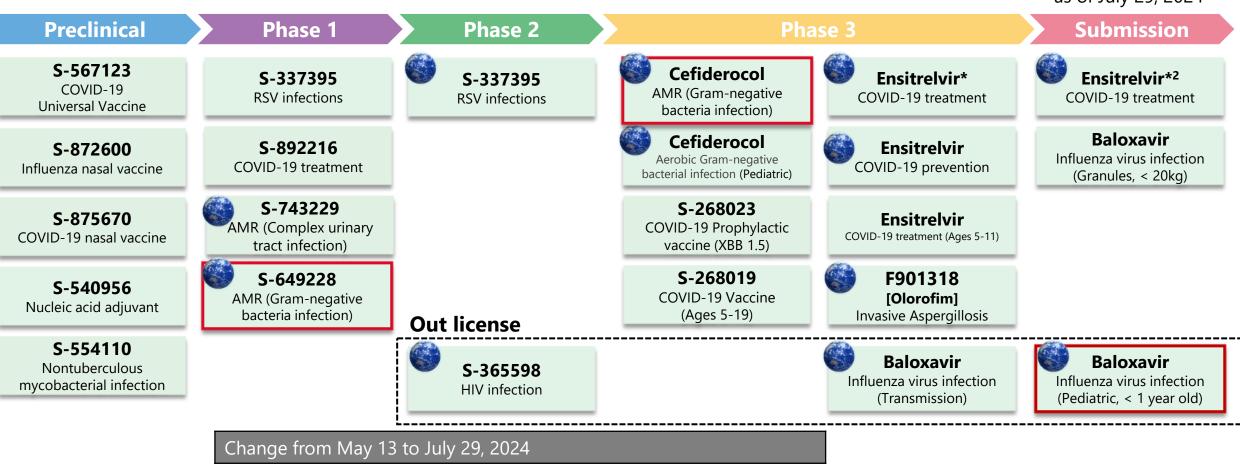
<sup>FINIBAX
Flumarin
Flomox
Shiomarin
Fetroja</sup>

⁻ COVID-19 related products-

⁻Influenza franchise-

Pipeline: Infectious Disease

as of July 29, 2024





- COVGOZE [S-268019] (COVID-19 Vaccine): Approved in Japan
- Cefiderocol (AMR): Phase 3 in China (Preparing for submission)
- Baloxavir (Influenza virus infection (Pediatric, < 1 year old)): Submitted in EU
- S-649228 (AMR): Phase 1 started



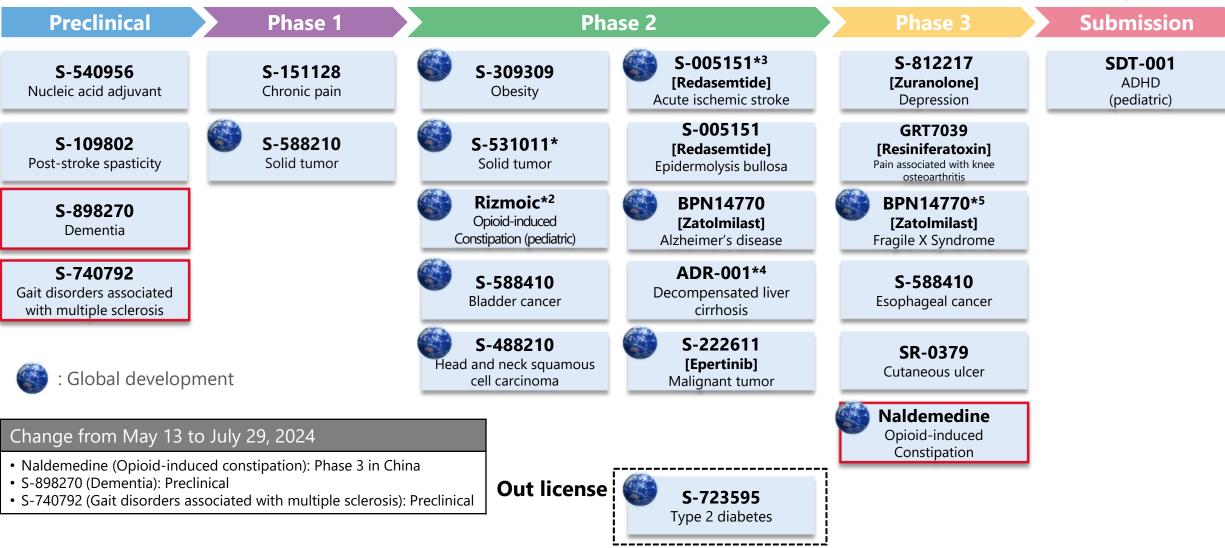
: Progress from January 31 to May 12, 2024

* Phase 2/3, Phase 3 ongoing *2 Korea, Singapore



Pipeline: QOL Diseases with High Social Impact

as of July 29, 2024





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	Long Acting	CAB	IM injection	Q2M (LA)	PrEP	149
Dovato	Two-drug	DTG + 3TC	Oral	Every day	Treatment	1,819
Juluca	regimens	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*

May

- Conclusion of the Basic Business Contract with Two Connect Co., Ltd. for Educational and Awareness Activities on the Actual Situation and Challenges of "Allergic Diseases"
- Selected as a "DX Notable Company 2024" for the Second Consecutive Year
- Receives an Additional \$10M Award by BARDA as Part of Qpex's Partnership to Advance its Portfolio of Antibiotics
 Addressing Drug-Resistant Infections

June

- Expands Global Infectious Disease and Antimicrobial Research Operations to U.S. to Address Current and Emerging Health Threats
- Awarded the Imperial Invention Prize for the invention of dolutegravir, the HIV integrase inhibitor
- Option Agreement with Cilcare for Development Compounds Addressing Hearing Loss

July

Domestic Launch of the In Vitro Diagnostic Pharmaceutical "Shionogi MIC Dry Plate Cefiderocol"



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.
- Materials and information provided during this presentation may contain so-called "forward-looking statements". These statements are based on current expectations, forecasts and assumptions that are subject to risks and uncertainties which could cause actual outcomes and results to differ materially from these statements.
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- For products that are approved, there are manufacturing and marketing risks and uncertainties, which include, but are not limited to, inability to build production capacity to meet demand, lack of availability of raw materials, and failure to gain market acceptance.
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