1st Quarter of Fiscal 2024 Financial Results

July 29, 2024

Shionogi & Co., Ltd.

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Agenda

01 **Overview of Q1 FY2024 Financial Results** **（P.3-13）**

02 **Pipeline Progress** **（P.14-23）**

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Overview of Q1 FY2024 Financial Results

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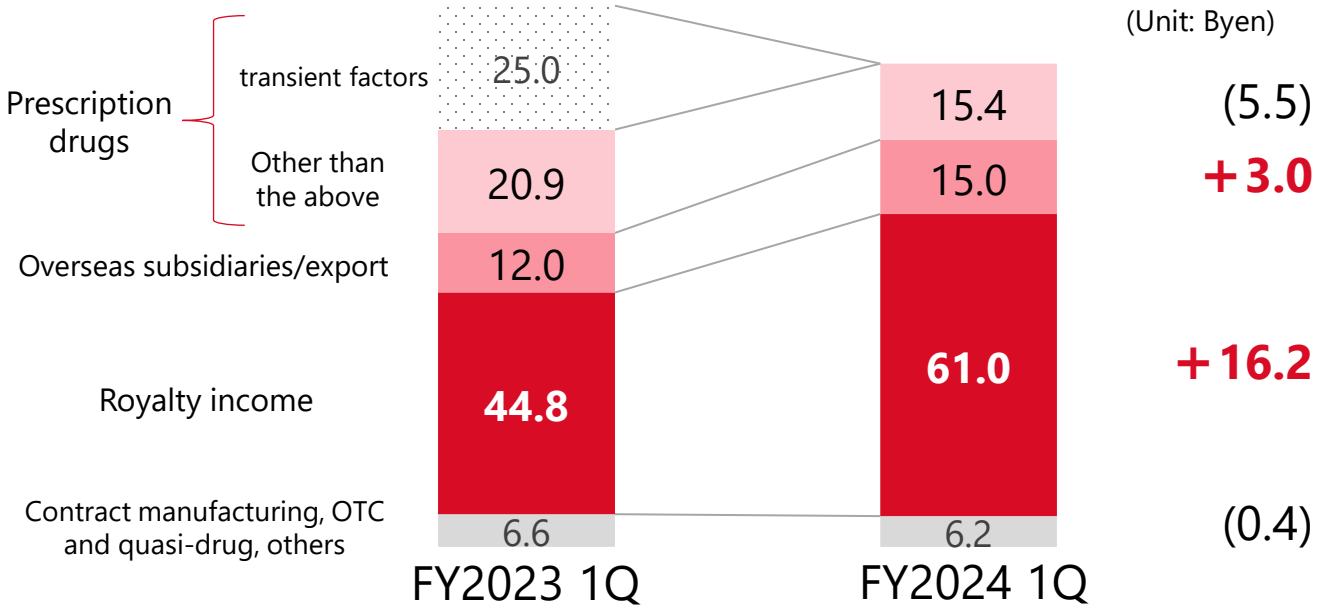
Highlight

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

Topline

(Excludes transient factors) **109.3 B yen (84.3 B yen)**

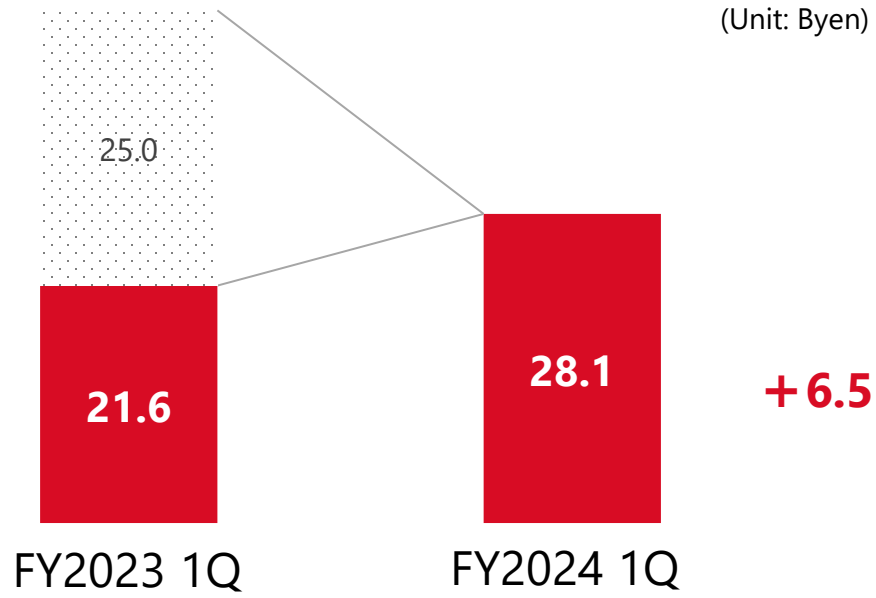
97.6 B yen



Operating profit

(Excludes transient factors) **46.6 B yen (21.6 B yen)**

28.1 B yen



* temporary income from transfer of ADHD drugs

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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 on Y	
	Forecasts		Apr.-Jun. results	Achievement (%)	Apr.-Jun. results	Change (%)	Change
	Full year	1H					
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 Apr.-Jun. Results
USD($) – JPY(¥)	145	155.86
GBP(£) – JPY(¥)	178	196.79
EUR(€) – JPY(¥)	155	167.85

* 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)

	FY2024 Forecast Full year	FY2024 Forecast 1H	FY2024 Apr.-Jun. Results	FY2024 Achievement (%)	FY2023 Apr.-Jun Results	Y on Y Change (%)	Y on Y Change
Revenue	455.0	210.0	**97.6**	**46.5**	109.3	**(10.7)**	**(11.7)**
Cost of Sales	14.5 66.0	13.6 28.5	14.8 **14.4**	**50.7**	12.0 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, R&D expenses total	49.8 226.5	52.9 111.0	55.9 **54.6**	**49.2**	44.9 49.0	**11.3**	**5.5**
Selling, general & administrative expenses	23.4 106.5	24.8 52.0	25.8 **25.1**	**48.3**	22.0 24.0	**4.6**	**1.1**
R&D expenses	26.4 120.0	28.1 59.0	30.2 **29.4**	**49.9**	22.9 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	35.2 160.0	32.9 69.0	28.8 **28.1**	**40.7**	42.6 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	44.0 200.0	39.3 82.5	37.4 **36.5**	**44.3**	51.0 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

Increase
- Royalty income
- Overseas subsidiaries /export

Decrease
- 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 Forecast Full year	FY2024 Forecast 1H	FY2024 Apr.-Jun Results	FY2024 Achievement (%)	FY2023 Apr.-Jun Results	Y on Y Change(%)	Y on Y 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)**	**(0.8)**
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

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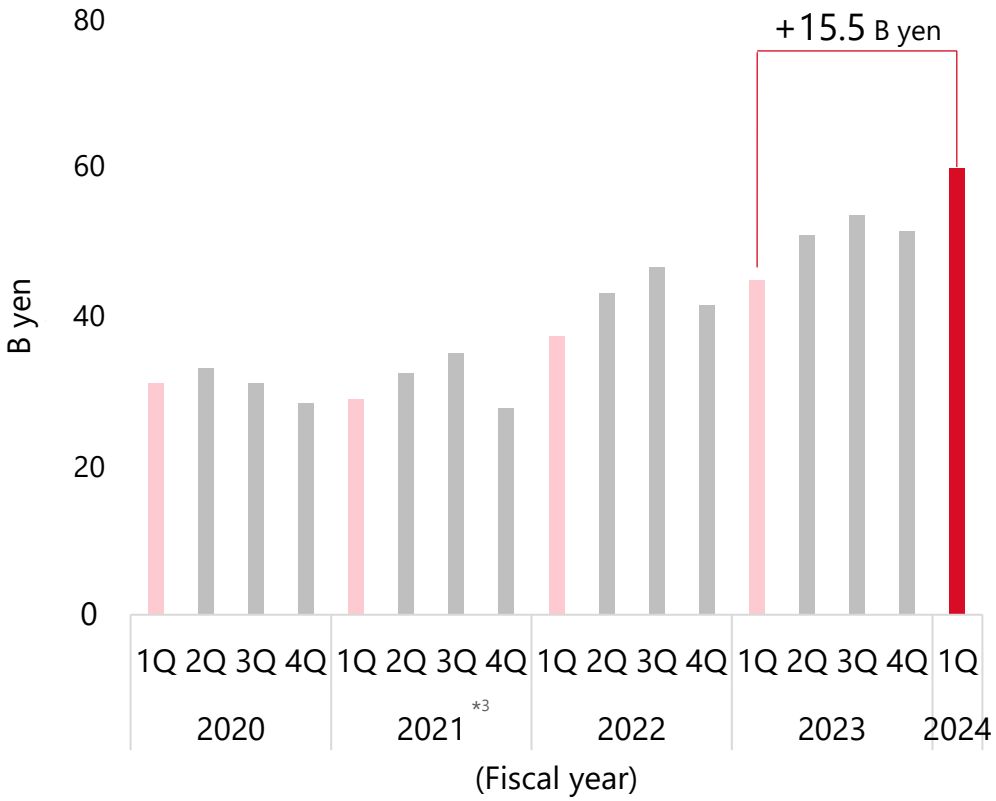
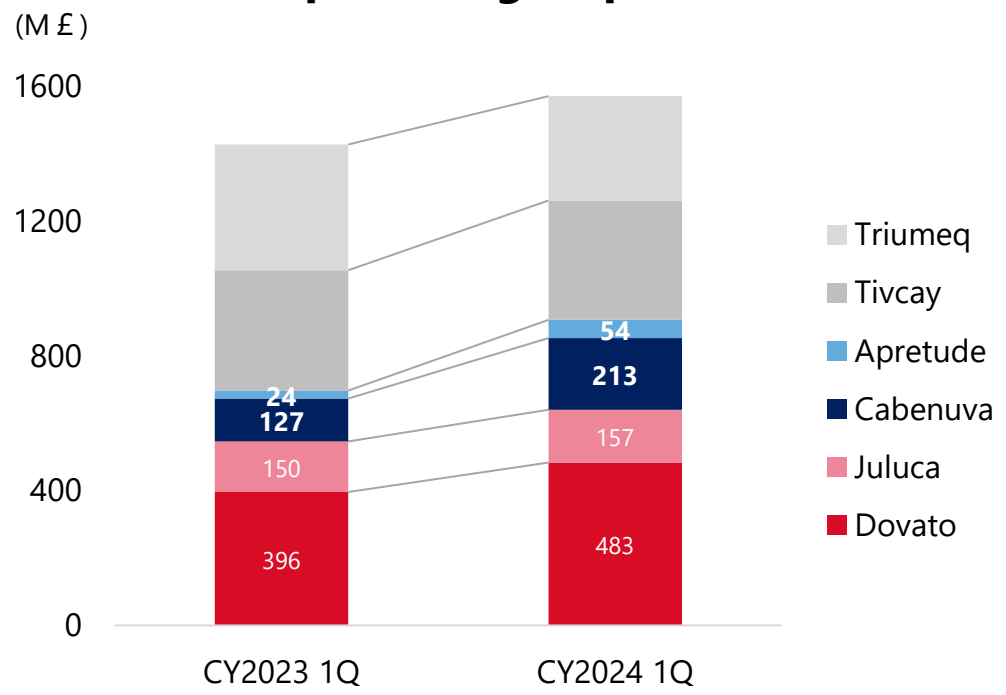
Expansion of the HIV Business

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

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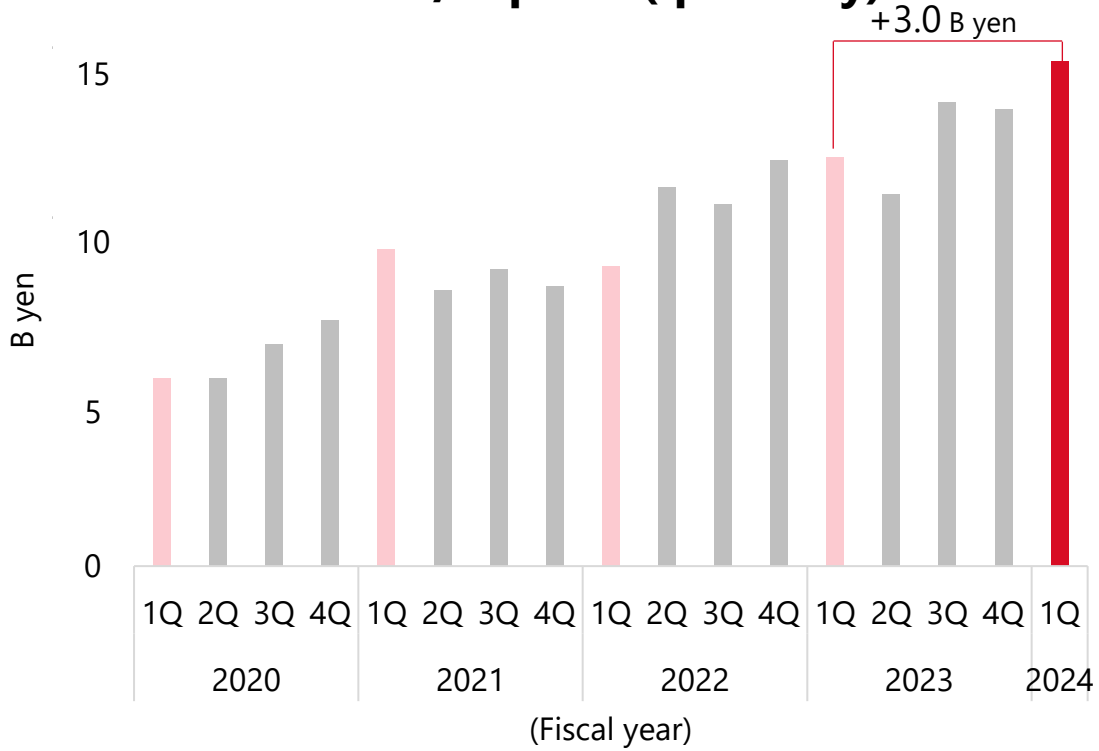
Expansion of Overseas Business

Steady growth in overseas business, centered on Cefiderocol

Sales revenue of overseas subsidiaries/exports (quarterly)



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

* Singapore: Commencement of provision under the Special Access Route (SAR) *2 Trial conducted in China targeting patients with complicated urinary tract infections

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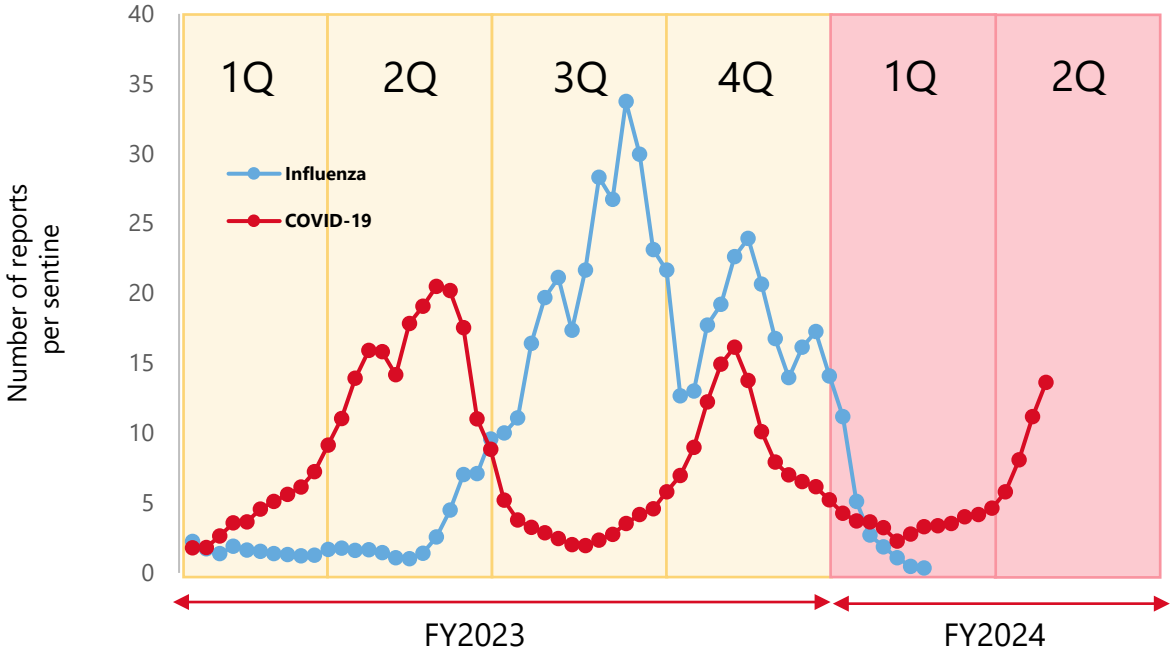
Acute Respiratory Infection portfolio - COVID-19 and influenza -

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

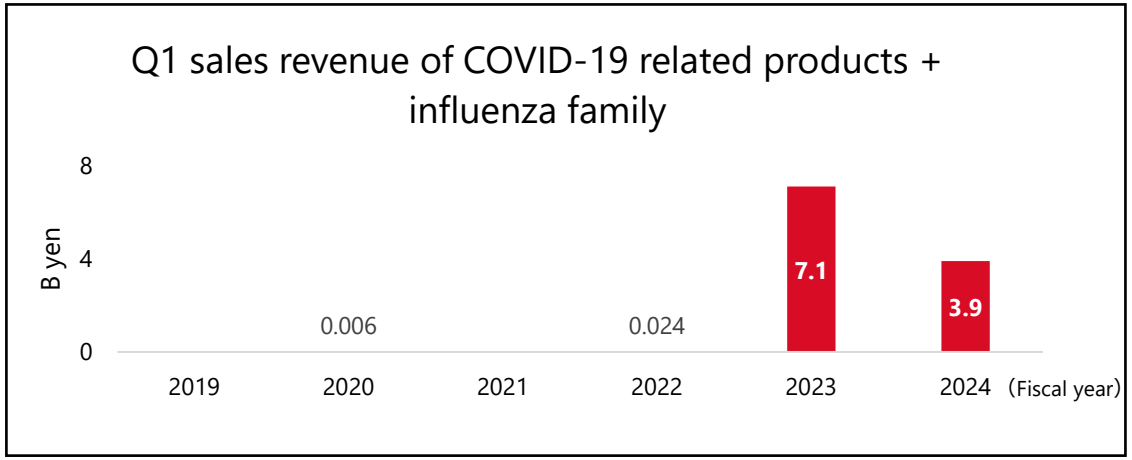
The infection status of COVID-19 and influenza*



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



* After changing the status of COVID-19 to Category 5 infectious disease Press materials about influenza |Ministry of Health, Labour and Welfare Press materials about new-style coronavirus infectious disease |Ministry of Health, Labour and Welfare

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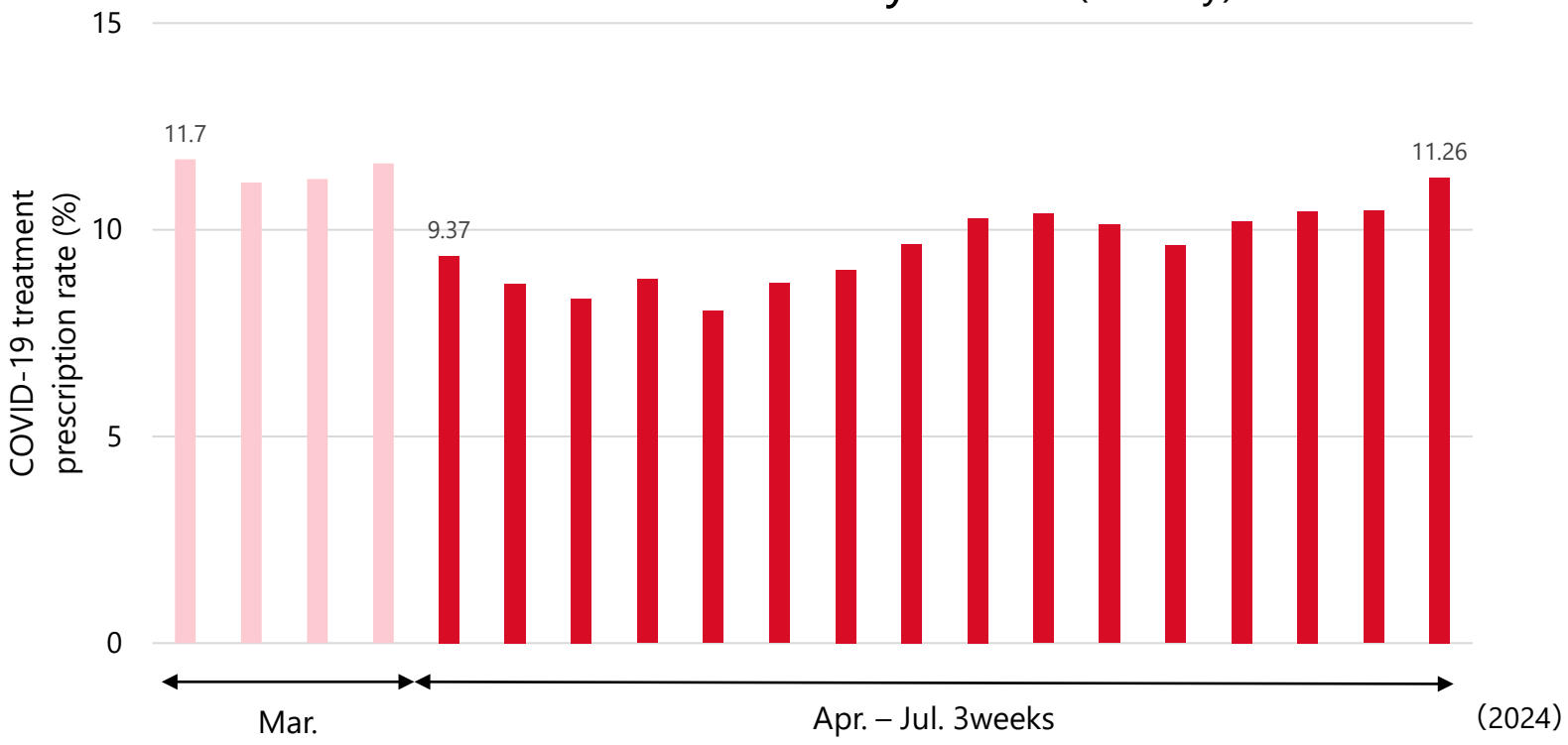
Oral COVID-19 treatment prescription rates change

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

* Quoted from JAMDAS: Usage rate of oral COVID-19 treatment drugs for patients who tested positive

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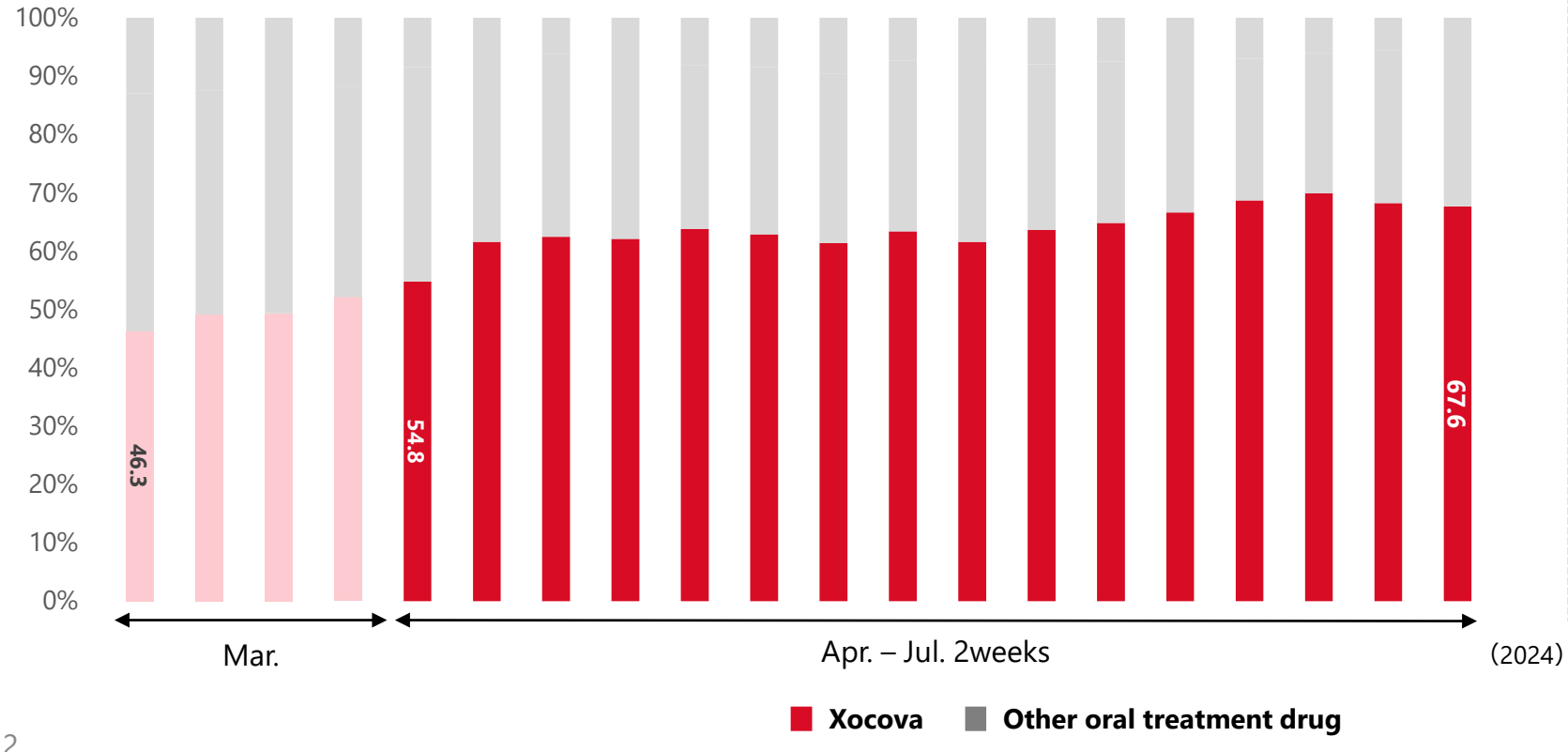
COVID-19 oral treatment drug share

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).

* Quoted from JAMDAS

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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

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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 ensitrelvir 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 ensitrelvir 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

* presented at the joint conference of the 98th Annual Meeting of the Japanese Association for Infectious Diseases and the 72nd Annual Meeting of the Japanese Society of Chemotherapy *2 JMDC Claims Database

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

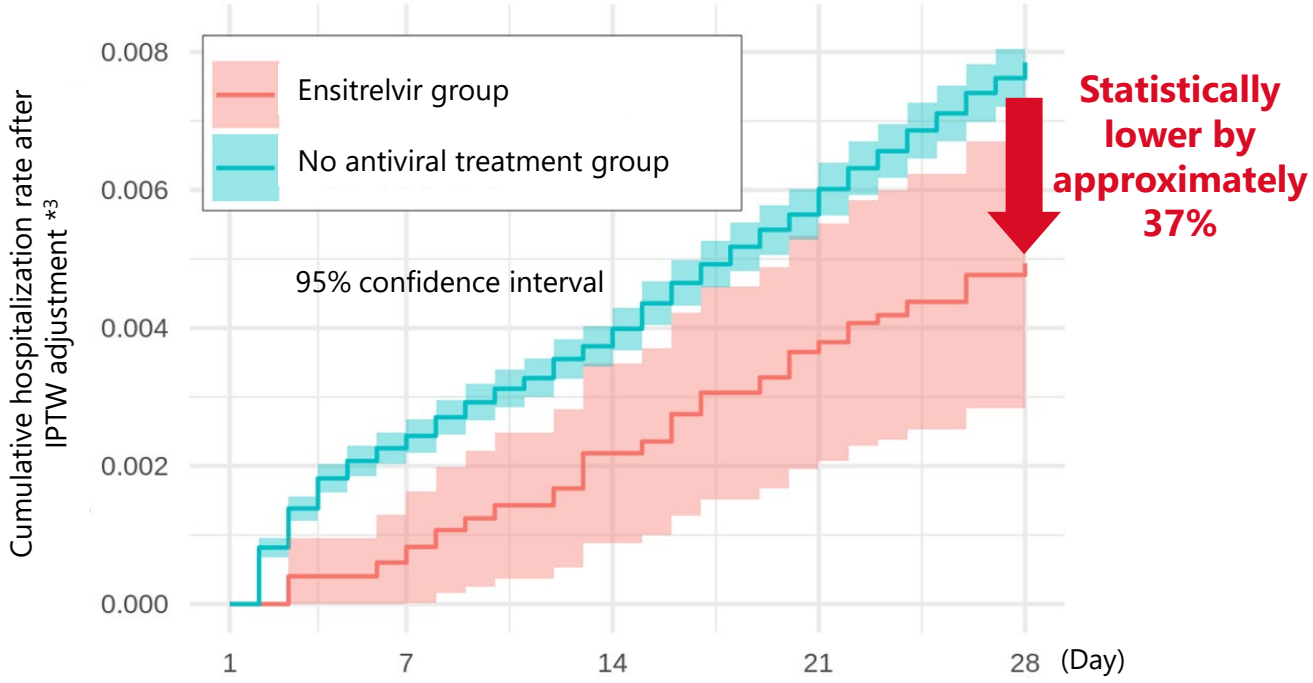
Trial Overview

Subject	Outpatients aged ≥18 years, who were at high-risk for severe disease*2
Subject	167,310 cases
Trial period	November 22, 2022 (emergency approval of Ensitrervir) - July 31, 2023
Primary endpoint	All-cause hospitalization during the 4-week period from the date of outpatient diagnosis and medication, comparing the ensitrelvir group and the no antiviral treatment group

Results

Cumulative hospitalization (after IPTW adjustment for patient background*3)

- Ensitrelvir group: 826.3/167,385.4
- No antiviral treatment group: 1,313.0/167,309.9



* 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 (Based on the Ministry of Health, Labor and Welfare's "Guidelines for the Treatment of Novel Coronavirus Infections, Version 10.1") Anyone who has been diagnosed with any of the following within 6 months prior to Day 1 *3 Adjusted for age, sex, and high-risk factors for severe desease (IPTW：Inverse probability of treatment weighting)

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Development Status of Ensitrelvir

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

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

* https://www.iasociety.org/conferences/aids2024

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-19 symptoms evaluated	Symptom resolution definition	Number of participants analyzed	Restricted mean symptom duration*9 (Days)				SCORPIO-SR trial - same analysis method* (P value)
					Ensitrelvir	Placebo	Difference (95% CI*6)	P value	
SCORPIO-HR (Global：Phase 3)	**Primary Endpoint**	15	≥2 consecutive days	1,888*5	12.5	13.1	-0.6 (-1.38, 0.19)	0.14*2	0.07
	Secondary endpoints*10	15	≥1 day	1,888*5	11.4	12.2	-0.8 (-1.54, 0.01)	0.05	0.02*3
		6*4	≥1 day		10.3	11.0	-0.7 (-1.48, 0.02)	0.06	0.02
SCORPIO-SR (Japan・Korea・Vietnam：Phase3)	**Secondary endpoints**	14	≥1 day	690*8	10.7	11.6	-0.8 (-1.94, 0.26)	---	0.03
	Primary Endpoint	5*7	≥1 day		10.1	10.9	-0.8 (-1.90, 0.28)	---	0.04*2

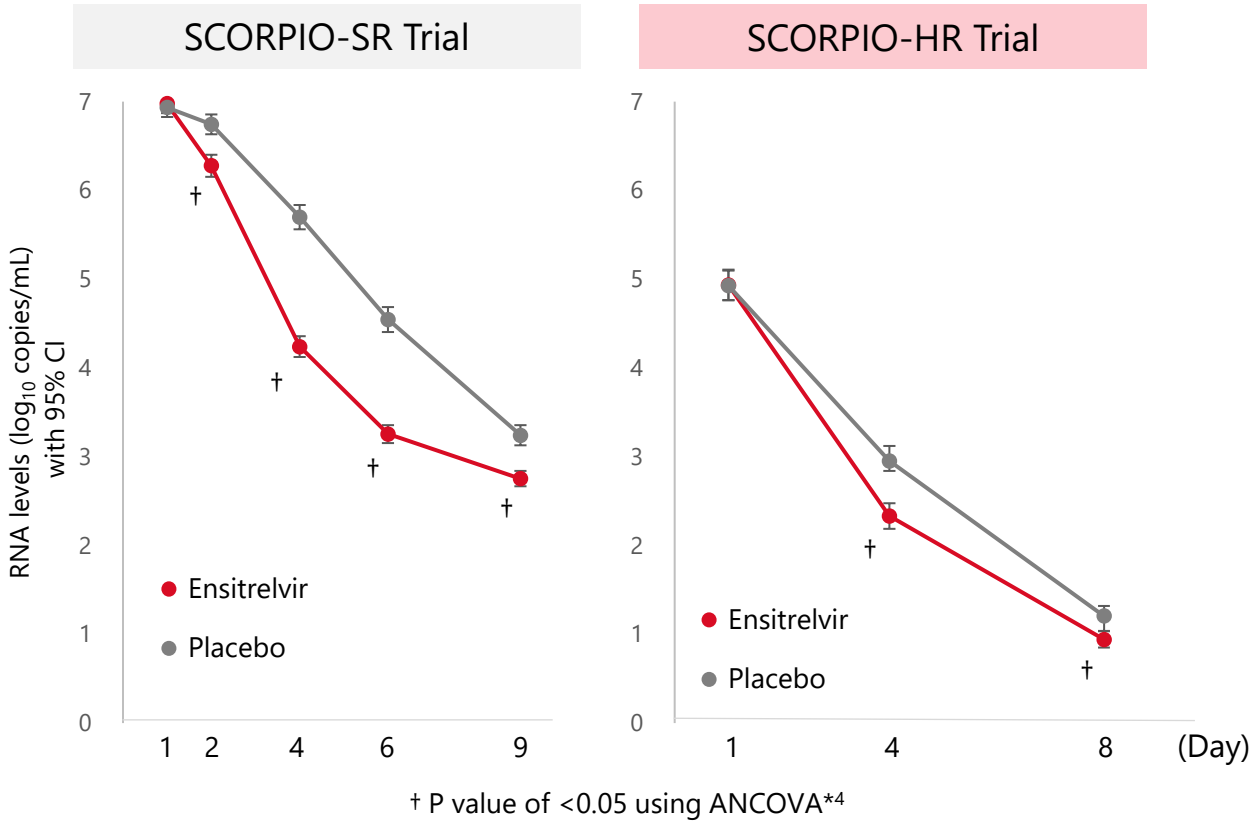
- No statistically significant differences were observed in the primary endpoints of SCORPIO-HR trial
- A pre-defined secondary analysis for time to resolution of six symptoms for one day using a statistical method similar to that used in the SCORPIO-SR Study yielded a significant difference ($p<0.05$)

*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* ―



† P value of <0.05 using ANCOVA*4

― Antiviral effects* ―

SCORPIO-HR trial		
	Ensitrelvir	**Placebo**
VC population*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

* These results are considered descriptive and should be interpreted in an exploratory manner *2 VC population: The virus titer positive population at baseline in the mITT population
*3 mITT population: participants who received the investigational drug within 3 days from symptom onset *4 ANCOVA : Analysis of covariance *5 Pre-MAA (Marketing Authorization Application)

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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*

Primary Endpoints	**Non-inferior Antiviral Efficacy Compared to Biktarvy**
Key Secondary 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% 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

Non-Clinical Trials	**Maintained antiviral activity against mutations resistant to existing integrase inhibitors**
Phase 1	**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

* ViiV Press Release *2 Ultra Long Acting, ViiV development numberVH4524184 *3 ViiV Press Release

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 Family	**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 3 topline results (FY24 4Q)	
	Ensitrelvir	COVID-19 (prevention)	Phase 3	→ Complete enrollment (FY24 2Q)	Phase 3 topline results（FY24 3Q）	
	S-268023	COVID-19 (XBB1.5,Vaccine)	Phase 3 † Data analysis in progress	→		
	S-892216	COVID-19	Phase 1	→ Phase 2 start (FY24 2Q)	Topline results (FY24 4Q)	
					⇢ Phase 3 start （FY25 1H）	
	S-567123	COVID-19 (Universal Vaccine)	Preclinical	→ Phase 1/2 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)	
	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）	**Phase 1 started (submitted INDA*): June 2024**

* Investigational New Drug Application

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	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 topline (FY25 1Q)	Submission (FY25 3Q)	**Fast Track Designation in US : March 2024**
	Redasemtide	Acute ischemic stroke	Phase 2b			
		Dystrophic epidermolysis bullosa	Phase 2			
	S-309309	Obesity	Phase 2	Considering future development 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		Phase 2 start (FY25 1Q)	

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Appendix

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Prescription Drugs in Japan

(Unit：B yen)

	FY2024 Forecast Full year	FY2024 Forecast 1H	FY2024 Apr.-Jun. Results	FY2024 Achievement (%)	FY2023 Apr.-Jun. Results	Y on Y Change(%)	Y on Y 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	**0.8**	**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)**

- Infectious disease drugs -

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

- COVID-19 related products-

- Xocova
- COVID-19 vaccines

-Influenza franchise-

- Xofluza
- Rapiacta
- BrightpocFlu・Neo

* Includes Lump-sum income from transfer of ADHD drug

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Pipeline: Infectious Disease

as of July 29, 2024

Preclinical	Phase 1	Phase 2	Phase 3		Submission
S-567123 COVID-19 Universal Vaccine	**S-337395** RSV infections	**S-337395** RSV infections	**Cefiderocol** AMR (Gram-negative bacteria infection)	**Ensitrelvir*** COVID-19 treatment	**Ensitrelvir*2** COVID-19 treatment
S-872600 Influenza nasal vaccine	**S-892216** COVID-19 treatment		**Cefiderocol** Aerobic Gram-negative bacterial infection (Pediatric)	**Ensitrelvir** COVID-19 prevention	**Baloxavir** Influenza virus infection (Granules, < 20kg)
S-875670 COVID-19 nasal vaccine	**S-743229** AMR (Complex urinary tract infection)		**S-268023** COVID-19 Prophylactic vaccine (XBB 1.5)	**Ensitrelvir** COVID-19 treatment (Ages 5-11)	
S-540956 Nucleic acid adjuvant	**S-649228** AMR (Gram-negative bacteria infection)		**S-268019** COVID-19 Vaccine (Ages 5-19)	**F901318** **[Olorofim]** Invasive Aspergillosis	
S-554110 Nontuberculous mycobacterial infection					

Out license

S-365598 HIV infection	**Baloxavir** Influenza virus infection (Transmission)	**Baloxavir** Influenza virus infection (Pediatric, < 1 year old)

Change from May 13 to 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

: Global development

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

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Pipeline: QOL Diseases with High Social Impact

as of July 29, 2024

Preclinical	Phase 1	Phase 2	Phase 3	Submission
S-540956 Nucleic acid adjuvant	**S-151128** Chronic pain	**S-309309** Obesity	**S-005151*3** **[Redasemtide]** Acute ischemic stroke	**S-812217** **[Zuranolone]** Depression	**SDT-001** ADHD (pediatric)
S-109802 Post-stroke spasticity	**S-588210** Solid tumor	**S-531011*** Solid tumor	**S-005151** **[Redasemtide]** Epidermolysis bullosa	**GRT7039** **[Resiniferatoxin]** Pain associated with knee osteoarthritis	
S-898270 Dementia		**Rizmoic*2** Opioid-induced Constipation (pediatric)	**BPN14770** **[Zatolmilast]** Alzheimer's disease	**BPN14770*5** **[Zatolmilast]** Fragile X Syndrome	
S-740792 Gait disorders associated with multiple sclerosis		**S-588410** Bladder cancer	**ADR-001*4** Decompensated liver cirrhosis	**S-588410** Esophageal cancer	
		S-488210 Head and neck squamous cell carcinoma	**S-222611** **[Epertinib]** Malignant tumor	**SR-0379** Cutaneous ulcer	
				Naldemedine Opioid-induced Constipation	

: Global development

Out license

S-723595
Type 2 diabetes

Change from May 13 to July 29, 2024

- Naldemedine (Opioid-induced constipation): Phase 3 in China
- S-898270 (Dementia): Preclinical
- S-740792 (Gait disorders associated with multiple sclerosis): Preclinical

: Progress from May 13 to July 29, 2024

* 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*

- **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"

* Progress from May 13, 2024 to July 28, 2024

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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