SHIONOGI & CO., LTD.

1st Quarter of Fiscal 2024 Financial Results Conference Call

July 29, 2024

Presentation

Kyokawa: I am Kyokawa, Vice President, Corporate Communications Department of SHIONOGI. Thank you very much for joining us today despite your busy schedule. We start SHIONOGI's financial results briefing for Q1 of fiscal 2024.

First of all, I would like to introduce today's speakers. John Keller, Senior Executive Officer and Senior Vice President, R&D Supervisory Unit.

Keller: Thank you very much. It's a pleasure to meet you all.

Kyokawa: Toshinobu Iwasaki, Senior Executive Officer, Senior Vice President, Healthcare Business Supervisory Unit.

Iwasaki: My name is Iwasaki. It's a pleasure to meet you all.

Kyokawa: Koji Hanasaki, Senior Executive Officer, Senior Vice President, Corporate Strategy Division.

Hanasaki: My name is Hanasaki. It's a pleasure to meet you all.

Kyokawa: Next, Kazuhiro Hatanaka, Senior Executive Officer, Senior Vice President, Corporate Supervisory Unit and Corporate Strategy Division.

Hatanaka: I am Hatanaka. It's a pleasure to meet you all.

Kyokawa: Next, Takeki Uehara, Corporate Officer, Senior Vice President, Drug Development and Regulatory Science Division.

Uehara: This is Uehara. It's a pleasure to meet you all.

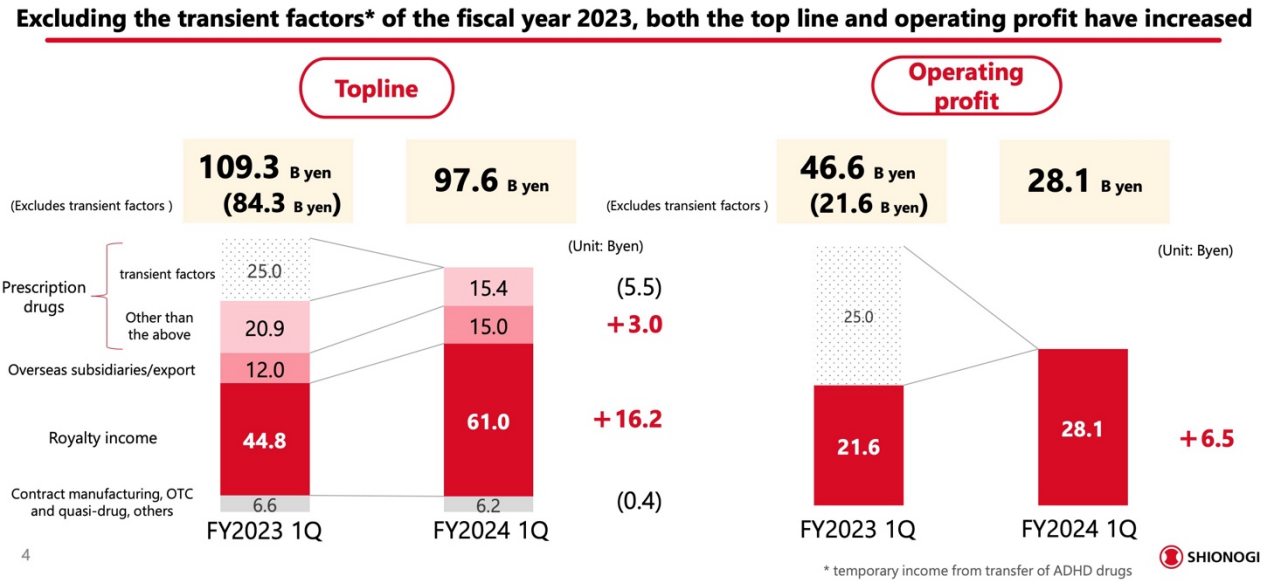
Kyokawa: Lastly, Masako Kudou, Vice President, Finance & Accounting Department, Corporate Strategy Division.

Kudou: I am Kudou. It's a pleasure to meet you all.

Kyokawa: Let me explain the flow of the briefing session today. First, I will give an overview of Q1 financial results and the progress of the pipeline, and then we will take time for a question-and-answer session.

Now let's get started. Ms. Kudou, please go ahead.

Highlight



Kudou: I will now explain the overview of the financial results for Q1. First, page four. We are pleased to present the highlights of the financial results.

On the left side, the top line was JPY97.6 billion this fiscal year, lower than last year's JPY109.3 billion, but this was mainly due to a one-time payment of JPY25 billion associated with the transfer of a license for an ADHD drug in Q1 of last fiscal year, and excluding this, royalty income and overseas business grew significantly, leading to a JPY13.3 billion increase in revenues.

For the same reason, excluding one-time factors, all of the various profit items also showed an increase in operating profit, shown on the right, increased by JPY6.5 billion, excluding one-time factors.

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.)

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Next are the consolidated financial results.

The results for Q1 of FY2024 were revenue of JPY97.6 billion, operating profit of JPY28.1 billion, profit before tax of JPY36.5 billion, and profit of JPY30.6 billion.

Overall, progress against H1 forecast may appear weak, but this is mainly due to the fact that Xocova's domestic sales forecast was more made for Q2. Q1 results were better than expected.

In the YonY comparison, both sales and profits declined due to the significant impact of the one-time ADHD payment in the previous fiscal year. However, excluding the one-time factors mentioned at the beginning of this report, the HIV business and the overseas business are growing strongly, resulting in increased sales and profit growth.

Regarding foreign exchange, the yen weakened more than expected, resulting in foreign exchange gains in each currency.

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	66.0	28.5	**14.4**	**50.7**	13.1	**10.1**	**1.3**
	14.5	13.6	14.8		12.0		
Gross profit	389.0	181.5	**83.1**	**45.8**	96.2	**(13.6)**	**(13.0)**
Selling, general & administrative expenses, R&D expenses total	226.5	111.0	**54.6**	**49.2**	49.0	**11.3**	**5.5**
	49.8	52.9	55.9		44.9		
Selling, general & administrative expenses	106.5	52.0	**25.1**	**48.3**	24.0	**4.6**	**1.1**
	23.4	24.8	25.8		22.0		
R&D expenses	120.0	59.0	**29.4**	**49.9**	25.0	**17.7**	**4.4**
	26.4	28.1	30.2		22.9		
Other income & expenses	(2.5)	(1.5)	**(0.5)**	**30.9**	(0.6)	**(18.3)**	**0.1**
Operating profit	160.0	69.0	**28.1**	**40.7**	46.6	**(39.7)**	**(18.5)**
	35.2	32.9	28.8		42.6		
Finance income & costs	40.0	13.5	**8.4**	**62.3**	9.1	**(7.7)**	**(0.7)**
Profit before tax	200.0	82.5	**36.5**	**44.3**	55.7	**(34.4)**	**(19.2)**
	44.0	39.3	37.4		51.0		
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

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Moving onto page six. This is the consolidated statement of profit or loss.

As I mentioned earlier, revenue started from minus JPY25 billion due to one-time factors in the previous fiscal year, but it landed better than expected. On the other hand, the cost of sales increased by 10.1% over the previous year. This is mainly due to changes in the product mix, mainly due to the growth of overseas businesses, and is almost in line with H1 forecast.

Selling, general, and administrative expenses increased by JPY1.1 billion over the previous year. As indicated in our medium-term management plan, we are currently focusing on global expansion and have used a larger amount of funds to strengthen our global sales structure than in the previous year.

R&D expenses increased by JPY4.4 billion from the previous year. The 17.7% YoY increase was due to the steady progress of the development pipeline and the fact that R&D expenses for Qpex which were not recorded in Q1 of the previous fiscal year were recorded this fiscal year.

At the same time, both SG&A and R&D expenses have been affected by foreign exchange rates more than ever this fiscal year due to the expansion of global initiatives.

In addition, from operating profit to quarterly profit, there appears to be a significant decrease from the previous year; however, if you take into account the fact that the JPY25 billion one-time factor of last fiscal year had a direct impact on both sales and profits, you can see that our business is performing very well.

Revenue by Segment

(Unit : B yen)

	Forecast Full year	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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Next, on page seven, we discuss revenue by business segment.

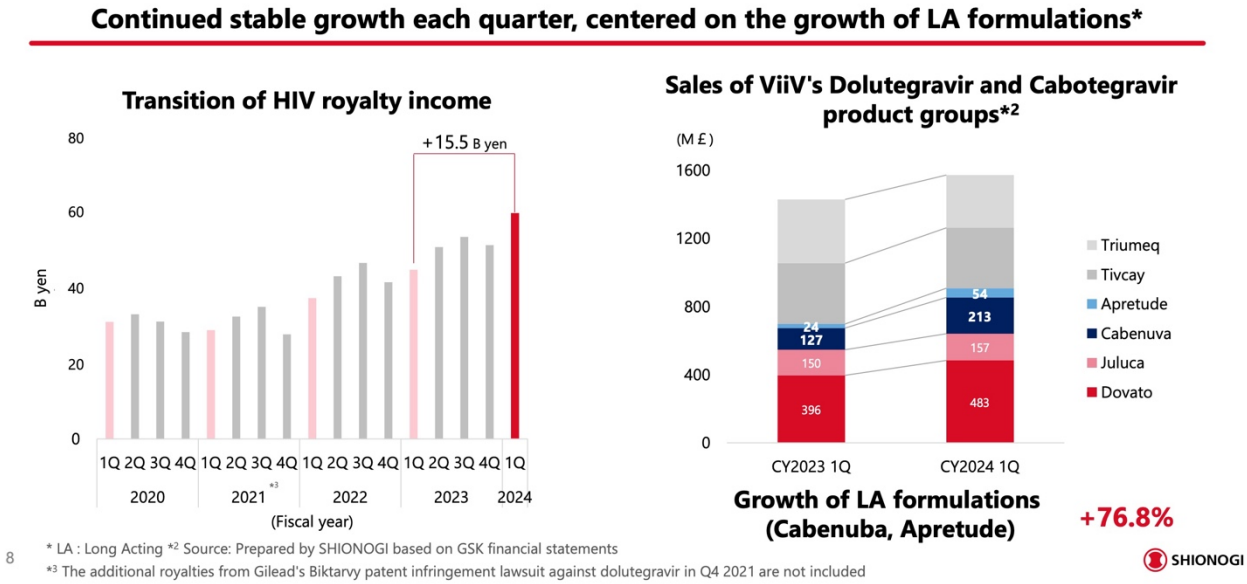
With respect to domestic prescription drugs, the impact of a one-time payment of JPY25 billion was significant, resulting in a 66.4% decrease compared to the previous year. As for infectious diseases, we will introduce them later, but sales are currently being increased in response to the epidemic situation.

Regarding exports to overseas subsidiaries, cefiderocol's sales revenue increased by 50.5% in the US and by 45.7% in Europe compared to the previous year. As a factor, although there was some impact from foreign exchange rates, sales were firm on a volume basis due to the expansion of countries where the product is sold and the expansion of sales in countries where the product has already been launched.

Royalty income increased by JPY15.5 billion YoY. The HIV franchise grew significantly due to the impact of actual sales and foreign exchange rates, respectively. Although we have already achieved more than 50% of our H1 forecast, we expect H1 of the fiscal year to end at the same level as our current forecast.

That is all from me.

Expansion of the HIV Business



Hatanaka: I, Hatanaka, would like to continue by presenting our Q1 results.

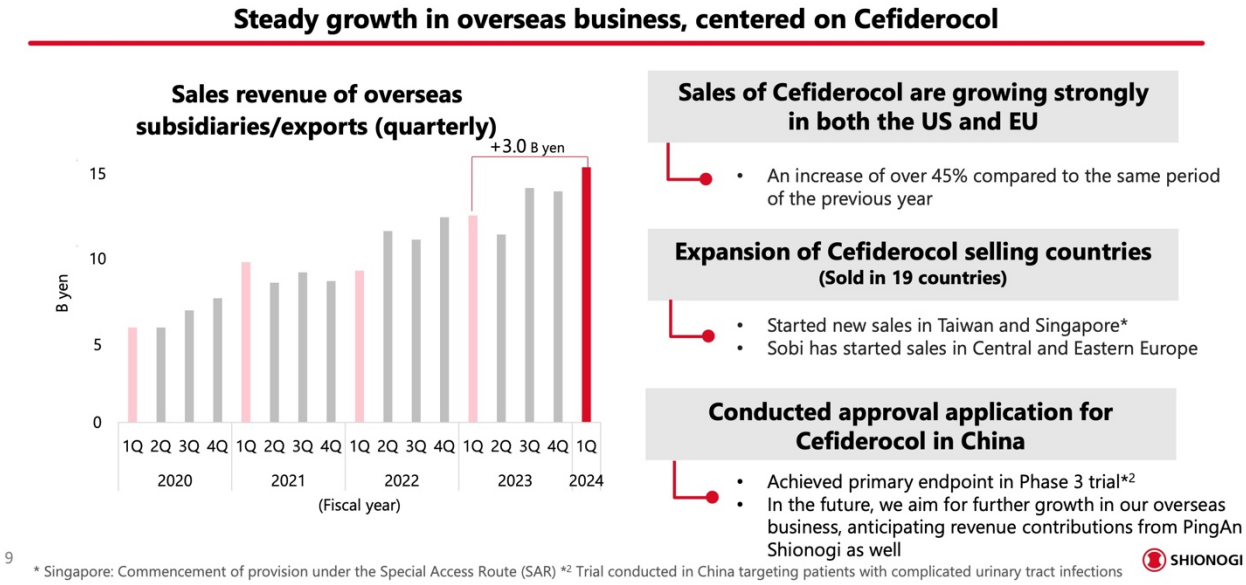
First, let's talk about the HIV franchise. The graph on the left side of the slide shows the transition of SHIONOGI's HIV royalty income by quarter.

As for the HIV franchise, quarterly revenues have been somewhat up and down for various reasons but have been increasing very steadily over the medium to long term. Compared to Q1 of the last fiscal year, there was a significant increase of JPY15.5 billion. The reason for the steady growth of the HIV franchise is the expansion of the market share of new product lines including LA formulations.

The graph on the right side of the slide compares sales of ViiV's six products, including dolutegravir and cabotegravir, to Q1 of last year.

The darker colors indicate sales of new product groups including LA formulations. Sales of new product groups have grown strongly, with LA formulations in particular showing a strong increase of 76.8% over the same period last year. We expect continued growth in the future, especially in new product lines.

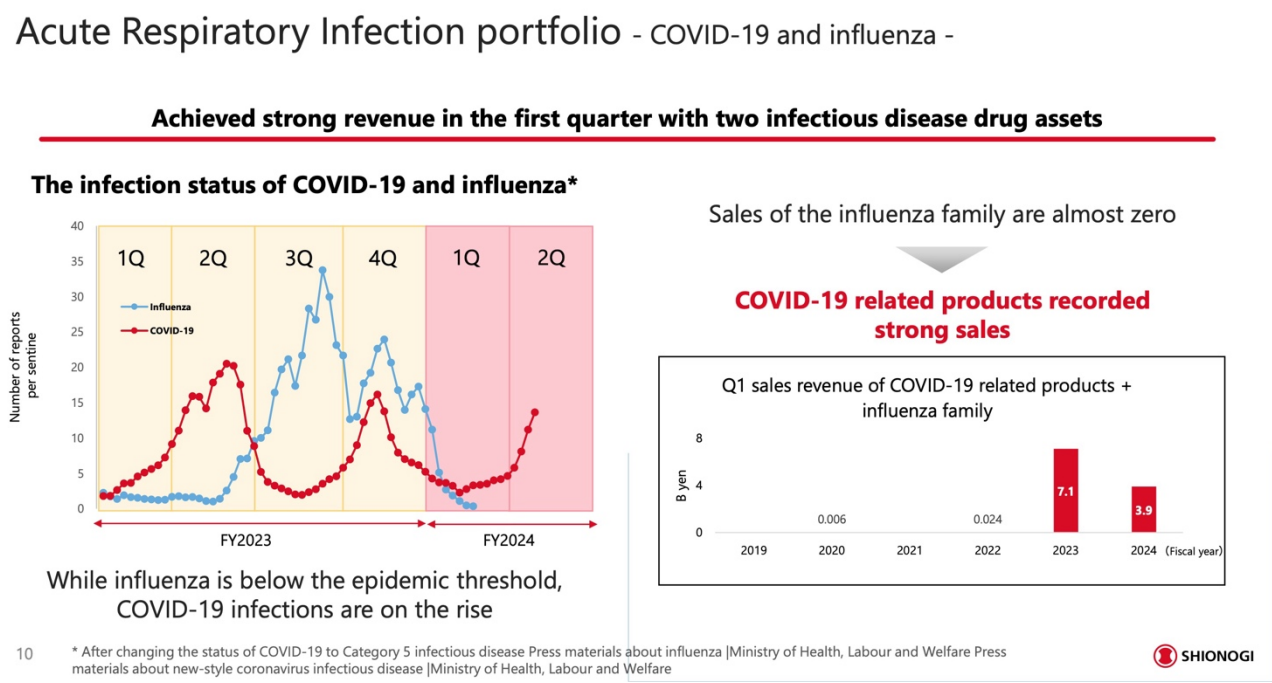
Expansion of Overseas Business



With regard to overseas operations, we have achieved steady growth, particularly with cefiderocol.

The graph on the left side of the slide shows the quarterly trend of overseas business sales, which increased significantly by JPY3 billion compared to Q1 of the previous year. With regard to cefiderocol, Sobi, with whom we concluded a marketing agreement last year, has begun marketing the product in Central and Eastern Europe, and we expect the penetration of the prescription in non-launching countries and the expansion of the number of countries where the product is sold to continue.

In China, the primary endpoint of the Phase III study has been achieved and we are preparing for submission for approval. We will continue to pursue further growth of our overseas business, including Ping An SHIONOGI.



I will now explain the status of acute respiratory infections, especially COVID-19, and other conditions.

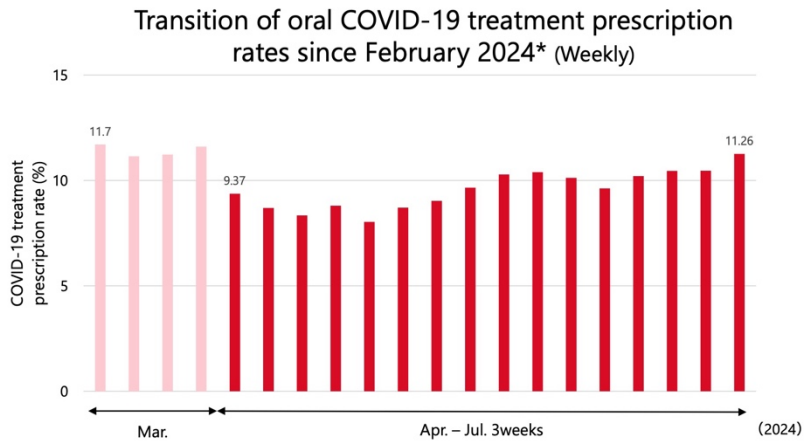
The graph on the left side of the slide shows the trend of the infection status of COVID-19 and influenza. Since Q1 of FY2024, while the influenza pandemic has rapidly subsided, COVID-19 transmission has gradually spread.

The next graph on the right side shows sales of acute respiratory infection drugs in Q1 of the past several fiscal years. As in the previous fiscal year, Q1 of this fiscal year saw almost zero sales of the influenza family, while Xocova recorded a certain number of sales.

In Q1 of each year, there have been almost no sales in the area of acute respiratory infections, but holding COVID-19 and influenza treatments, the Company is beginning to generate a certain level of revenue. We recognize that we are making steady progress in building a new business model for acute respiratory infections that aims to secure a certain level of revenue at all times by holding multiple infectious disease assets.

Oral COVID-19 treatment prescription rates change

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



- 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

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

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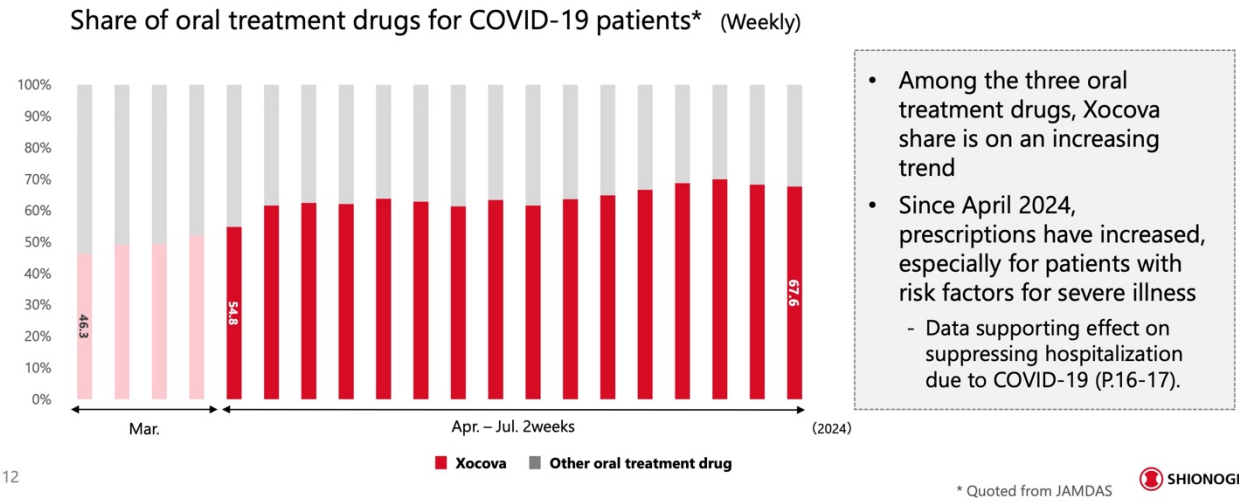
Now, I would like to introduce the status of Xocova's prescriptions.

The graph on the slide shows the trend in prescription rates for oral therapies for COVID-19 since March of this year. Although the special measure of full public payment ended in April and the amount of self-payment by patients became larger; however, the prescription rate has not dropped significantly, or on the contrary, has been gradually increasing, as the importance of early treatment with antiviral drugs has become more widely known.

In addition, the prescribing rate tends to increase as the number of infected patients increases, and we expect the prescribing rate to expand further in the future.

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



- 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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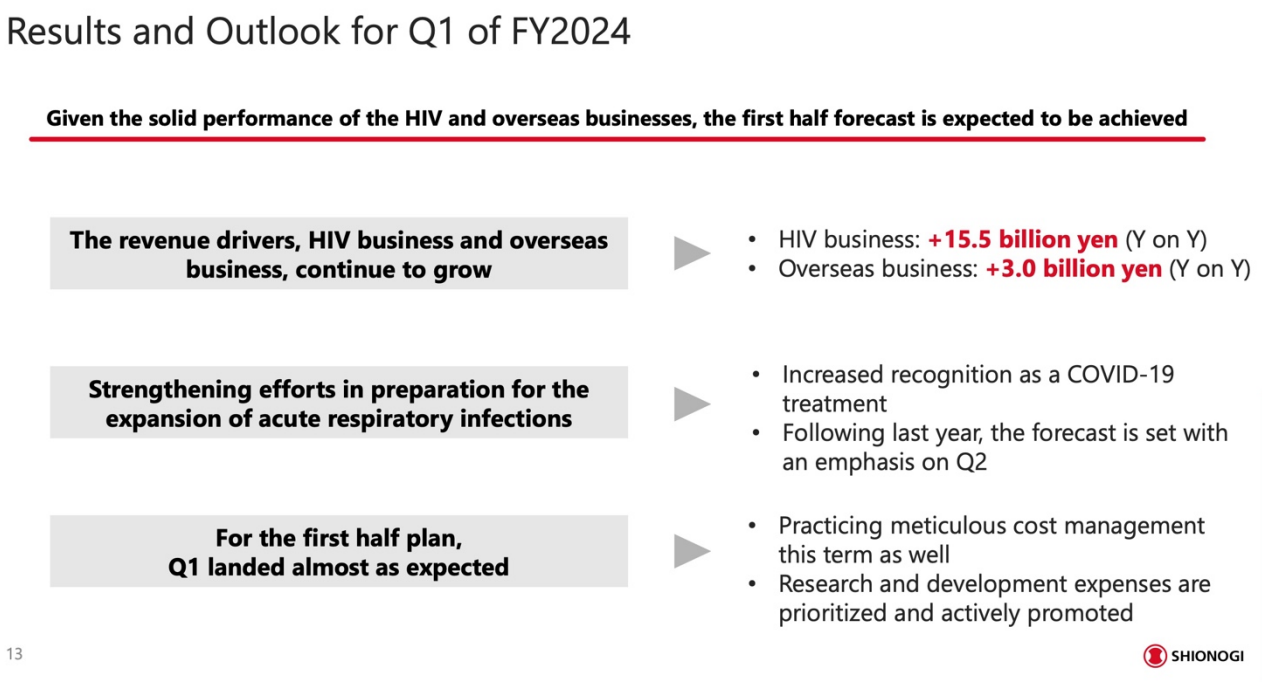
The graph on the slide shows the trend of the market share of three oral therapeutics, with Xocova's market share shown in red. Among these three drugs, Xocova's market share is on the rise, with prescriptions expanding significantly, especially among patients with risk factors for severe disease after April 2024.

As we will discuss in the latter part of today's presentation, various real-world evidence has been accumulated on Xocova, including its effectiveness in reducing hospitalization of patients with risk factors for severe disease. We will continue our efforts to deliver Xocova to patients who need it.



We are pleased to present a summary of Q1 and our outlook for H1 of 2024.

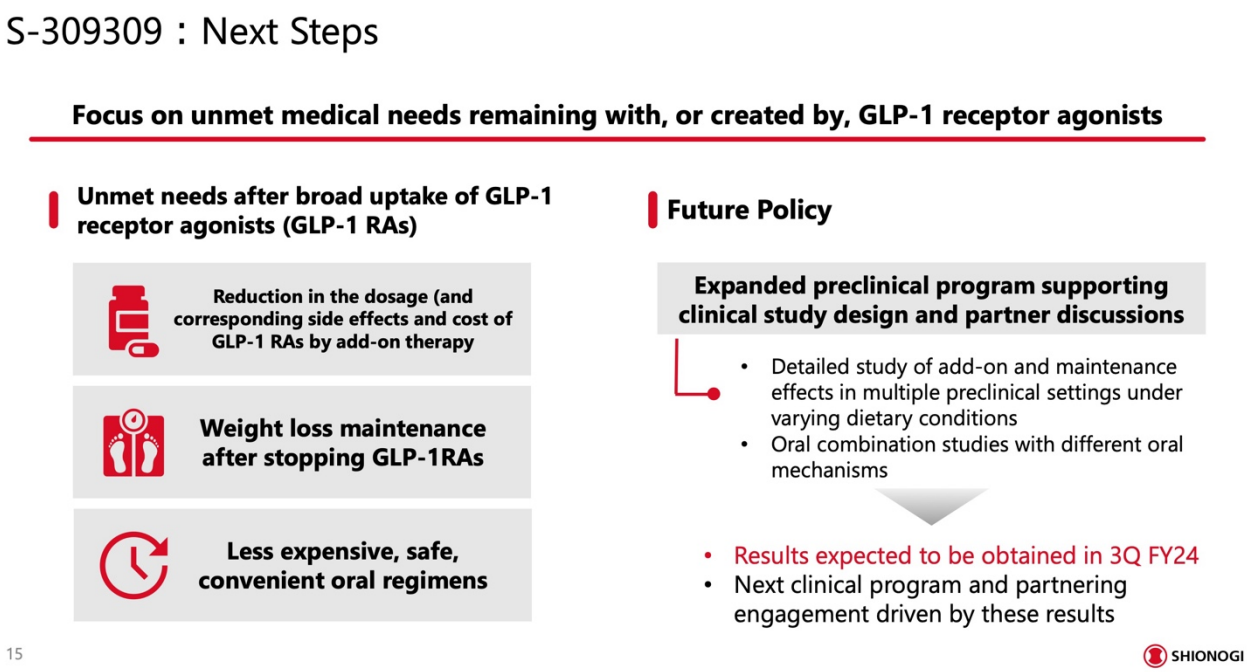
To reiterate, the top line, especially in the HIV business and overseas business, which are our profit drivers, has remained strong. Excluding transitory factors, we were able to achieve YoY revenue growth and believe that our earning power is steadily increasing.

For Xocova, we have set H1 forecast with an emphasis on Q2 in H1 of the year, assuming that the wave of the COVID-19 epidemic will hit in Q2. As a result of the steady increase in market share, we expect to achieve our H1 forecast for Xocova's sales revenue. We will continue to strengthen our efforts to prepare for the spread of acute respiratory infections.

In terms of costs, while continuing cost management, we will prioritize and aggressively promote research and development.

Taking into account the results of Q1 and future efforts in general, we currently believe that H1 forecast is achievable.

This concludes my explanation.



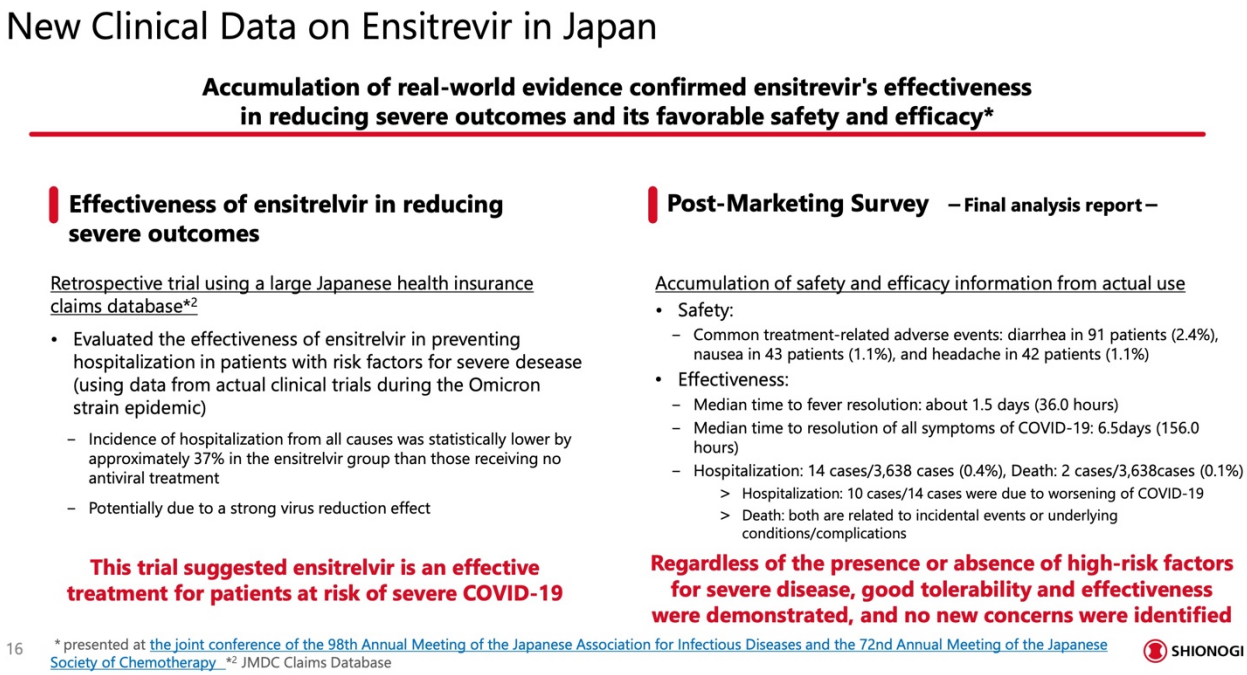
Uehara: Next, Uehara from the drug development division would like to talk about the progress of the development pipeline.

First, we have S-309309, an anti-obesity agent that is an MGAT2 inhibitor with a new mechanism of action that we have developed.

We mentioned at the recent R&D Day, we unfortunately did not achieve our original 5% weight loss standard in terms of single-agent treatment, but there is still an unmet need for anti-obesity agents with new mechanisms of action.

Specifically, is there any possibility of using the existing GLP-1 agonists in combination therapy to reduce the safety risk or cost of the existing GLP-1 agonists? We are currently conducting add-on or maintenance studies in a non-clinical environment with the goal of providing a safe and inexpensive oral drug that can be used as a maintenance therapy for weight loss after the use of a GLP-1 agonist.

In this context, we plan to obtain results by the timing of this H2, and based on these results, we plan to proceed with clinical development plans and partnering strategies.



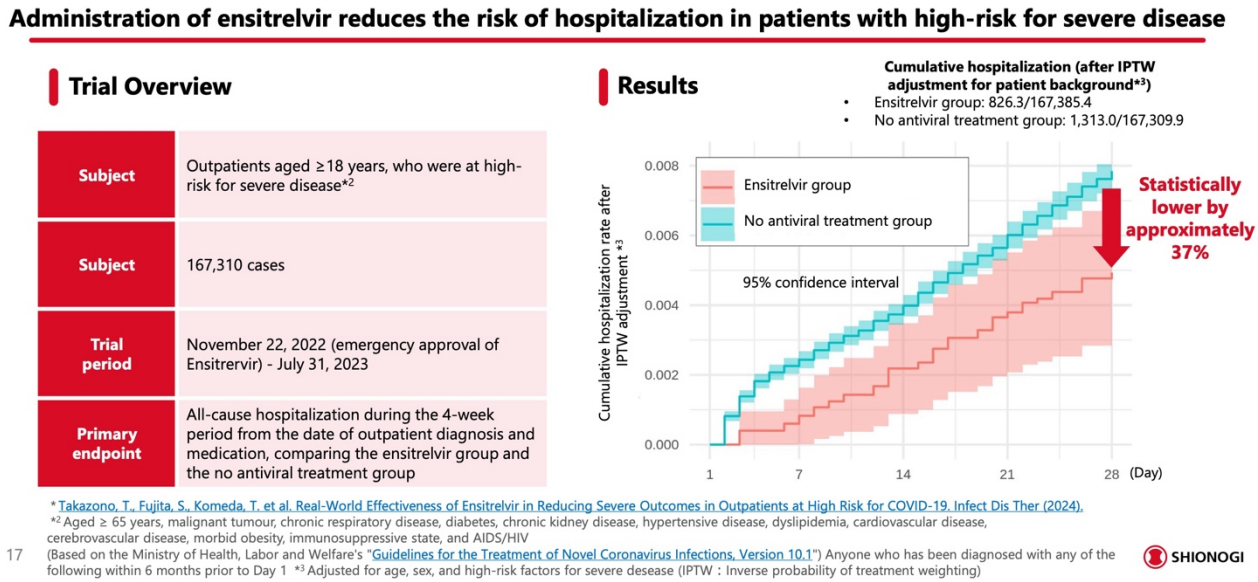
I will continue to discuss various new clinical data on Xocova, which is ensitrelvir.

First of all, in Japan, we have received approval for the drug and have accumulated a lot of data on it, both for patients with and without risk factors, as shown in the post-marketing survey on the right-hand side of the page.

We have presented safety data that were databased under clinical trials, as well as efficacy data, with no major changes to such trends, and data that confirm that the efficacy and safety obtained in a clinical trial environment have the same characteristics in actual clinical practice.

On the left side, we show the results of a retrospective cohort study using a large database of receipts to examine the effect of hospitalization reduction. I will show you more detailed data in the next slide. We have received many comments about the effectiveness of this treatment in patients with risk factors for severe disease, but we have found that the data showing clear suppression of the risk of severe disease have been obtained in the actual clinical environment in Japan.

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



* 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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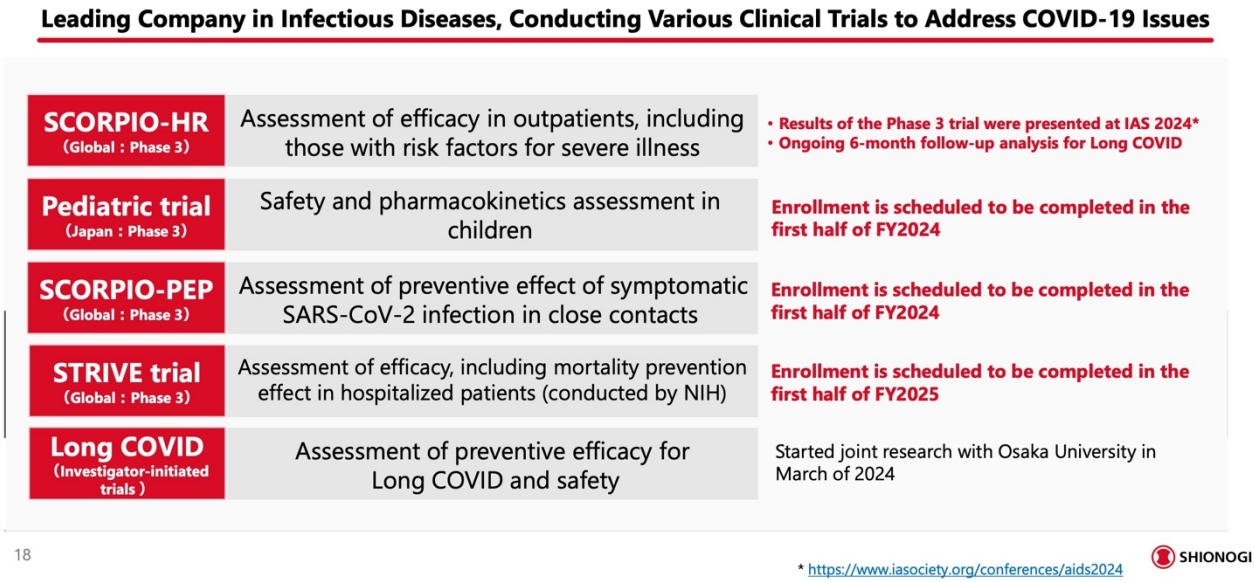
Here are the results of the verification of the effectiveness in reducing hospitalization using the receipt database mentioned earlier.

Specifically, we have compiled data on 167,310, a large number of patients who have taken the drug since its emergency approval in Japan until the end of July 2023. We have tabulated the rate of hospitalization during the first month after taking the medication, and the risk of hospitalization among those taking ensitrelvir compared to the standard symptomatic treatment.

The fact that the risk of hospitalization was reduced by 37%, with a statistically significant difference, strongly suggests that even in this Omicron epidemic, and even in the vaccination environment, the early use of drugs with such strong antiviral effects can prevent severe illnesses, we believe.

Development Status of Ensitrelvir



Now, I would like to talk about the progress of other global developments from various perspectives.

First is the Phase III SCORPIO-HR trial in the global treatment. Just last week, we presented the results of the Phase III study at an HIV conference in Munich, Germany. I would like to introduce some of those data in a later slide.

Long COVID was also followed up in this study. We have recently completed all six months of follow-up and have fixed the data and made the key break. We have obtained very interesting data. Therefore, we are in the process of discussing these results with NIH professors in order to present them at an international conference as soon as possible.

As for the study in children in Japan, we are still in the process of accumulating more cases. Since there is an epidemic situation in Japan just now, we would like to complete the registration and proceed with an additional application for approval during this summer season.

The same is true in the trial for prevention. This is a global study conducted in Japan, the US, and other countries in Asia and other regions. The purpose of the study is to prevent infection and disease transmission among persons in close contact with the patient by taking the medication. Currently, there are no oral drugs with such an indication. In order to make it available to the global community as soon as possible, we will complete the registration during H1, and we will announce the results when we get them at an appropriate opportunity.

The STRIVE trial, which aims to achieve an early return from hospitalization on a global scale, is currently under way to accumulate cases.

In Japan, we are also conducting a study to prospectively validate Long COVID by taking large-scale post-marketing data.

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

Now, here are the results of the SCORPIO-HR study with respect to the primary symptom endpoint.

First of all, the top section refers to the primary endpoints of the SCORPIO-HR study, which are the 15 symptoms. The primary endpoints were set based on the definition that these symptoms are considered to have disappeared only when it has been completely resolved for at least two days. The p-value for this study, which is shown here, was 0.14.

In the SCORPIO-HR study, the same statistical analysis method as in the SCORPIO-SR study, the generalized Wilcoxon test, was also used. The result is 0.07, which is very close to the standard for a significant difference but did not meet the standard of 0.05 that was set.

Although the primary endpoints were not met, the results of various pre-defined secondary endpoints and the results of the SCORPIO-SR trial, Phase III trial in Asia, are also shown in the lower part of this page.

The point I would like you to see at the bottom of the table, the bottom row shows the results of five symptoms, which are defined as the disappearance of symptoms for one day or more, and it shows a significant difference of 0.04.

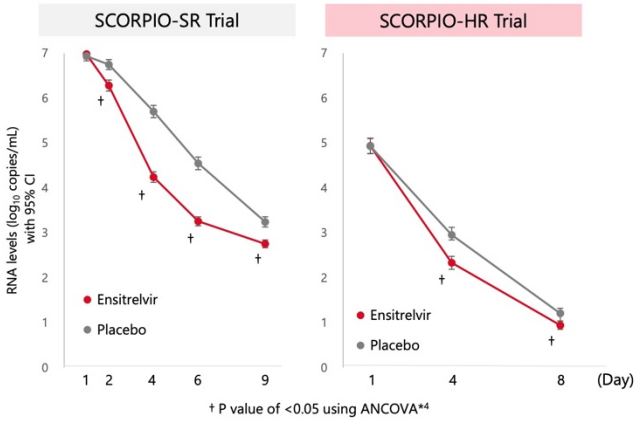
Therefore, the endpoints evaluated in Phase III in the Asian region in the SCORPIO-SR study were also evaluated in the global environment in terms of the disappearance of six symptoms, respiratory symptoms plus fatigue, plus fever, using the same statistical method, to clarify the significant difference. Therefore, the results of the Asian trials conducted to date were generally reproduced in the global environment. Regarding the direction of symptom recovery, we believe that the effect of the drug was always consistently confirmed in a positive direction.

Based on these results, we are discussing with various global authorities on how to proceed.

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 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

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* 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)

SHIONOGI

As for the antiviral effect, we are showing two studies side by side, the SCORPIO-SR study and the SCORPIO-HR study.

Naturally, the environment in which the tests were conducted was slightly different, so direct comparisons between the tests cannot be made, but PCR measurements were conducted at the same facility. As you can see on the left and right sides, under the global environment, the virus copy number is about two log lower than when the drug was administered, so we were able to confirm a statistically significant difference in the rapid reduction of the virus in those who received the drug, This means that we were able to confirm a clear antiviral effect in both the SCORPIO-SR study and the SCORPIO-HR study.

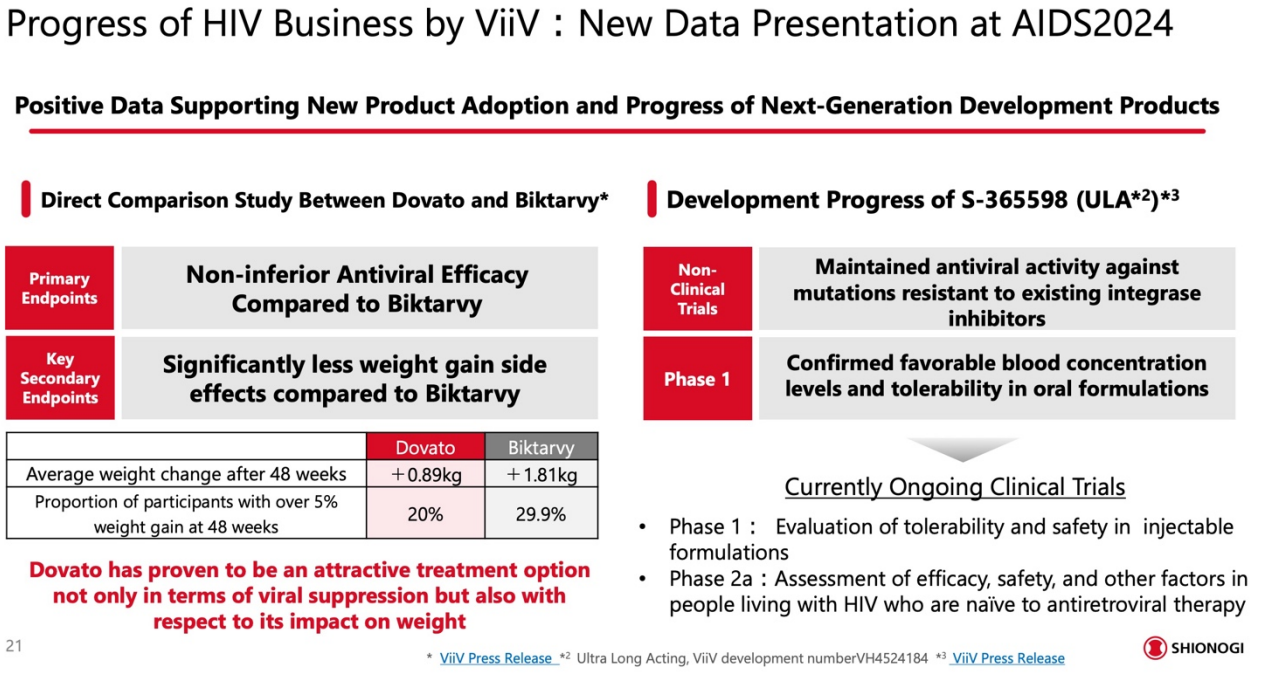
The virus titer is also shown on the right. The viral culture on the fourth day was negative in 95.5% of the patients who received the medication, which means that almost all of the patients were already negative for infectious viruses the day after they received the three-day medication. From this perspective, and because it has been confirmed that there are almost no rebounds and no recurrence of symptoms, it is considered that the rapid reduction of the virus, the viral titer, and the characteristics that make it difficult to cause recurrence of symptoms and rebounds have been confirmed in the third phase globally in various countries, which is a very wonderful result.

We are now in the process of pre-application consultations in various countries in the US, Europe, and Asia.

Kyokawa : Thank you very much. Please continue with Mr. Tsuzuki from Mizuho Securities.

Tsuzuki : I'm Tsuzuki, Mizuho Securities. Thank you.

First, I have a question about the SCORPIO-HR trial. I think you refer to the term Type C Meeting, so I was wondering if it is right to have an impression that you are positive about it with Type C instead of Type D. Also, if you have the next milestone scheduled in your company as a plan, could you tell us a little more about this area?



Keller: Thank you very much. I am Keller from R&D. I would like to share with you the progress of the HIV franchise and pipeline.

First of all, regarding the AIDS 2024 conference, as you can see on the left side, Dovato, oral two-drug regimen, is a very important product.

And as additional data to accelerate the use of Dovato, we were able to see non-inferior antiviral efficacy in a head-to-head comparison with Biktarvy.

And the side effects of weight gain were greatly lowered. So, we were able to prevent a weight gain of about 1 kg. The over 5% weight gain rate in Dovato group was lower by about 10% than that of the Biktarvy group. This means that not only its antiviral effect, but also statistically significant less weight gain side effects compared to Biktarvy was further observed.

On the right side is the ultra-long-acting formulation, S-365598. This was licensed out to ViiV and is a third-generation integrase inhibitor. The first thing we wanted to show non-clinically was that this S-365598 was able to maintain its antiviral activity. The results showed that the drug was effective even when the patient was resistant to other integrase inhibitors and the same to the tolerability.

Over the next nine months, data on three additional elements will be available for this compound. First of all, the oral data shows that the drug is well tolerated by HIV patients and reduces viral load. Then, injections are given at home once every two months with an injectable form of this compound. And with ultra-long duration, data for ultra-long-acting formulations will be obtained.

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)	
	S-567123	COVID-19 (Universal Vaccine)	Preclinical	Phase 3 start (FY25 1H) ⇢	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

Regarding the pipeline, as for infectious diseases, we have not yet been able to discuss some of the projects related to infectious diseases, but we were able to obtain domestic approval for the COVID-19 origin strain vaccine, Covgoze.

For S-337395, a human challenge study is ongoing. The top-line results will be available at the end of this year. With the acquisition of Qpex as a wholly owned subsidiary, we have also initiated the Phase I study of the combination of xeruborbactam and cefiderocol.

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) →	

As for QOL diseases, an application has been submitted for SDT-001, a digital treatment App for ADHD. As for zuranolone, we expect to be able to submit an application by the end of this summer. Zatolmilast is currently in pivotal clinical trials in the US for Fragile X.

S-606001, which is for Pompe disease from Maze, which is also a rare disease, is expected to start Phase II next year with a very high on-track rate.

And if you look at the slide again, the first combination for sleep apnea syndrome from JV with Apnimed, will enter Phase II around October. S-531011, CCR8 antibody for solid tumors, is also progressing well, and Phase II part in Phase Ib/II studies will be initiated.

Question & Answer

Kyokawa : Now, the first question, Mr. Yamaguchi from Citigroup Global Markets. Thank you.

Yamaguchi : This is Yamaguchi. Thank you. I would like to ask three simple questions.

First, you followed up about S-309309. I was a little confused about the part about add-ons and maintenance in a non-clinical environment, does this mean that this is not a clinical trial? Or do you mean on animals?

Uehara : It means on animals. We are considering clinical trials in the future after obtaining new data on monkeys, mice, and other animal species.

Yamaguchi : I understand. The results of that test will be available in your Q3, so October to December, so the timing for partnering would be next year, rather than this year, is this something in your image?

Uehara : Yes. You are quite right about that.

Keller : That's right. Future clinical planning and then partnering will be based on these results.

Yamaguchi : Secondly, thank you for explaining the sales of Xocova. I understand that sales will increase in Q2 due to various environmental factors, but I am not sure about the future, but I think that sales will be a little lower than last year. This is what I simply calculated.

Although your company has not disclosed the results of Q1, I guess that the total amount is probably around JPY60 billion, and based on this, I assume that you are making a forecast and doesn't this change your view that this is achievable.

Iwasaki : I, Iwasaki of the healthcare business, will answer. Compared to last year's epidemic, this year's was a little late, so I think that the start-up was slower than last year, including that. Reduction of patient burden by the Japanese government has been eliminated and the treatment rate has decreased, but recently the market share has increased from less than 50% last year to about 70% at this stage, due in part to the low drug prices.

Given this, we believe that if the number of patients continues at this pace and the epidemic accelerates, the goal will be achieved.

Yamaguchi : I understand. As a follow-up, the reason for the increase in market share is, of course, evidence, etc., but the biggest factor is the difference in self-payment due to the difference in drug prices. Is this right?

Iwasaki : That's right. Evidence such as long COVID and real-world data on serious illnesses has also emerged, which is very supportive, but I still think that the drug price and self-payments are significant.

However, the self-payment is 10% or 20% for the high-risk elderly patients, so I suppose that in this aspect, the drug price is not so important for the elderly population, but about evidence, evidence of serious illness, and real-world evidence, which is very effective in gaining market share.

Yamaguchi : I understand. Finally, I have a strange question. It would be a strange question to ask why something is not available even if there is nothing like that, but based on past patterns, you were very aggressive in Q1 last year with respect to share buybacks, and there seemed to be some expectation that it would do so again this year.

I understand that no announcement has been made at this time, but could you please reiterate your stance on share buybacks?

Kudou : Kudou will answer the question. We are continuing to consider business investment in the current fiscal year. In addition, we will consider share buybacks at the appropriate time, depending on the outlook for performance based on the epidemic of COVID-19 and other factors.

Yamaguchi : I understand. That is all from me. Thank you.

Kyokawa : Thank you very much. Now the second one, Mr. Ueda from Goldman Sachs, please.

Ueda : This is Ueda from Goldman Sachs. Thank you.

First of all, I would like to know about the HIV franchise. The rate of progress of royalty seems to be very high compared to the plan, but I wonder if there are any special factors here or if it is progressing very smoothly.

I think there was a presentation at the International AIDS Conference on the results of the expected expansion of the use of Apretude in addition to Dovato, as you introduced something this time. Could you also comment on the impact of these announced data on future sales forecasts? Thank you.

Keller : Thank you very much for your questions. First of all, royalties are in line with the plan. One thing is that ViiV's sales growth is very strong. That will continue this year. Therefore, there has been no particular change in such fundamental matters, and I think the exchange rate is also a tailwind.

As for Apretude, I think there are three things we can refer to. One is that Apretude is making very strong progress, and the plan is that the cabotegravir formulation is very capable with respect to the four-monthly follow-up, and we believe we will be able to launch it in 2026.

In the overall HIV market, we believe that the prevention market will continue to grow. Our own forecast is that the prevention market will grow threefold in the future. There are also projections of a further 10-fold increase.

And what I just mentioned is global, but in the US, the important factor, the one that can double, triple, or even multiply by 10 depends on how well the government supports the project. It is progressing well. It has not been finalized yet. And there is also the presidential election, so we cannot say anything for sure; however, we expect that government support will increase in the future.

Ueda : Thank you very much. The second point I would like to ask is about Xocova. I would like to know how you evaluate the current trends in the prescription rate and market share compared to the assumptions in the company's corporate plan.

You made a few comments earlier, but as you present this kind of data on antiviral activity and long COVID, etc., is the understanding in the clinical field changing? On the other hand, has the SCORPIO-HR trial failed to meet its primary endpoint, and has this had any negative impact? Could you comment mainly on domestic trends?

Iwasaki : Iwasaki would like to answer your question. We had predicted that when patients' co-payments were 30% from April onwards, the prescription rate for oral triple drugs in pateints with standard-risk would almost completely disappear, but at present it is around 6%, and Xocova has the market share of around 90% of that, so we believe that it is being used more than we expected.

From that point of view, we believe that we have missed our expectations in a good way. This is because, rather than the opinion that drug treatment is unnecessary, medical associations and academic societies are

also trying to control the severity of the disease, which can occur even in young people. In light of this, although money is an issue, we believe that the trend toward the need for treatment is stronger than expected, even if the cost is JPY15,000 or nearly JPY20,000 in the case of our company.

In July, the prescription was about only 10% lower than last year, so I think we are now moving in a positive direction in that aspect.

Ueda : I understand. That's all from me. Thank you.

Kyokawa : Thank you very much. Now, let's continue with Mr. Wakao from JPMorgan Securities. Thank you.

Wakao : I'm Wakao from JPMorgan. Thank you. The first point is a confirmation, but in terms of Mr. Ueda's question just now, is it correct to understand that HIV royalties are on an upward trend?

In your earlier explanation, you said that Q1 progressed well, but that H1 landed as expected, so I have the impression that momentum will slow down a bit in Q2. How should I understand this?

Kudou : Kudou will answer the question. HIV royalties, as I mentioned earlier, are over the budget due to the impact of the increase in sales volume.

In Q1, we saw a strong 35% increase year-over-year. However, we expect that the overall performance for the first half will land more or less in line with our initial projections. This expectation is based on the assumption that some of ViiV Healthcare's sales might have been brought forward into Q1. GSK's upcoming financial results may provide further insights, so please check their announcements as well.

WAKAO :

Kudou :

WAKAO : So, we shouldn't expect the strong first-quarter performance to necessarily continue into the second quarter. Understood.

Second, I wonder if you could tell us a little more about the status of your discussions with the FDA about Xocova. In terms of changes since the last time, is there anything you can tell us? Hasn't there been any change at all since the last time, or has there been any progress? Also, if you have any idea of when you can submit the application in the future, could you please let us know?

Uehara : Thank you for your question. We had a Type C meeting with the FDA once to discuss how to proceed in the future based on the current data.

The data we presented at that time included SCRPIO-SR trials, SCRPIO-HR trials, and the real-world evidence that we also presented today. We have presented such data and discussed various data.

In order to proceed to the application process with the FDA, we need to analyze and submit real-world data in accordance with the FDA guidelines, etc., and have various follow-up discussions. Therefore, we are in a situation where we are continuing to discuss about each SCRPIO-HR test in follow-up and also about the real world.

WAKAO : Since you are discussing something, are you saying that you are looking at something from the outside and you don't know if you have moved forward or not?

Uehara : Well, as a specific milestone, we are not in a situation that we have submitted the application, for example. Discussions are ongoing for the application.

WAKAO : You are seeing a good response. So, I wonder if you could tell us anything in terms of more certainty there or something like that.

Uehara : I will not answer whether or not the accuracy has increased since it might have my subjective viewpoint, but I do not think that the possibility has been eliminated.

Wakao : I understand. Finally, I would like to ask about S-309309. I would like to understand the current situation properly so please tell me some points. Should I think that at this time you are not yet engaged in partnering activities? Or have you shown potential partners the data you already have now?

In terms of partnering, can you tell us a little more about your current situation and how things are going?

Keller : We have been sharing data, and we believe that the non-clinical trial data we are currently verifying will become increasingly important. Given the mechanism of action of anti-obesity drugs, diet plays a significant role in their effectiveness. In both non-clinical and clinical settings, we are examining the effects under different dietary conditions. In non-clinical trials, we used a high-fat diet, while in clinical trials, we followed FDA requirements and reduced caloric intake by 500K calories.

Therefore, our partners are very interested in the results of the non-clinical trials that assess how different dietary conditions impact the treatment with S-309309.

Wakao : I understand. That's all from me. Thank you.

Kyokawa : Thank you very much. Please continue with Ms. Haruta from UBS Securities.

Haruta : This is Haruta from UBS Securities. As for the HIV franchise, I believe that the competitor Gilead has provided good data on prevention in a once-every-six-month trial. I understand that your company will be launching cabotegravir once every four months for prevention and treatment. What kind of marketing and differentiation strategies do you have in mind for this area?

I think you have already built a leading position in the long-acting, but how will you defend it? Please tell us about this point.

Keller : Thank you. Gilead's preventive medication is administered via subcutaneous injection, whereas our approach involves intramuscular injection. Gilead claims an advantage with their subcutaneous method, but there are also concerns reported regarding this approach. Additionally, for treatment, the indication is for multi-drug-resistant HIV-1 infections, so there are questions about how it will be labeled for prevention.

One of the concerns with subcutaneous injections is the formation of nodule at the injection site, which have been reported to occur with a frequency of around 25% to 30%.

The most important appeal of long-acting formulations is privacy, which likely accounts for about half of their attractiveness. While a dosing frequency of once every 5 to 6 months is beneficial, the formation of nodule or redness at the injection site that remain for 5 to 6 months can be noticeable both visually and by touch. Therefore, this might pose privacy concerns.

Haruta : I understand. So, privacy might be the point of differentiation, right? How about the period or timing, like four months and six months?

Keller : Certainly, dosing frequency is one of the differentiation points, and we are also developing our treatment with a six-month dosing interval. However, it is important to recognize that for patients, overall important factors include privacy concerns and ease of use, such as the potential for drug interactions, and not just the dosing frequency.

Haruta : I see. That is all.

Kyokawa : Thank you very much. Please continue with Mr. Tsuzuki from Mizuho Securities.

Tsuzuki : I'm Tsuzuki, Mizuho Securities. Thank you.

First, I have a question about the SCORPIO-HR trial. I think you refer to the term Type C Meeting, so I was wondering if it is right to have an impression that you are positive about it with Type C instead of Type D. Also, if you have the next milestone scheduled in your company as a plan, could you tell us a little more about this area?

Uehara : Thank you for your question. As you recognized, the fact that the FDA responded with Type C instead of Type D means that they want to discuss the entire package comprehensively, so we are positive about the FDA's decision to change from Type D to C.

As I mentioned in my response, however, follow-up discussions are still needed, and we will be holding another meeting with the FDA in the next few months to discuss each action, whether it is a Type D or C action.

Tsuzuki : I see. Thank you. And the other point is about HIV, I think there was an announcement at AIDS 2024.

Regarding S-365598, it was said that the resistance profile was good, so perhaps the effect of No. 148, 140, or 155 was good, I guess, and I was wondering if my understanding is correct.

Since this is about data from an oral drug this time, is it something that can be predicted internally, such as whether once every six months is enough or not based on this data? Please tell me how to look at this data as well.

Keller : Thank you. I think the oral data were very good. It was also consistent with the long-acting model. For the long-acting, we now have to compare clinical and animal data. This is because the properties of the long-acting are very different.

Based on the correlation with animals and the oral behavior and then the long-acting behavior with animals, we think that the long-acting would be good, but we still need clinical data for the long-acting.

Tsuzuki : I see. Is this still the point where we need to clarify additional data on injectable drugs, in terms of whether or not we can do it once every six months or so? How about these points?

Keller : This is also something that will come up in the next nine months. As I said, it will take a long time, so there will be three sets of data: the reduction of viral load in oral, then the two-month format at home, and then the six-month data. These three data are currently ongoing.

The six-month data take the longest time, so that comes out last.

Tsuzuki : I understand very well. That is all. Thank you very much.

Kyokawa : Thank you very much. Continuing, Ms. Sogi of AllienceBernstein, please.

Sogi : Thank you. First of all, I have a question regarding HIV royalties. I understand that loyalty is very growing. I understand that this of course reflects the growth of ViiV's HIV product portfolio, but my question is where the growth is coming from with regard to this HIV Dovato and then Apretude.

As you originally mentioned, the overall number of patients is increasing, and if we consider the market share among the increasing number of patients, in what portion do you think this is contributing to the growth of the market?

Keller : The increase in the number of patients is a single-digit growth rate. Therefore, the growth is primarily due to the market share.

The products that are driving this growth vary from region to region. First of all, Apretude is growing in all aspects. ViiV did not have such a PrEP product, so Apretude has been a market share growth factor for ViiV.

As for Dovato, Biktarvy is our competitor, and we face very stiff competition in the US market. And in Europe, in some countries and others, Dovato's growth rate is strong.

I think there is an overall cost difference there. Dovato is the most cost-effective as an integrase inhibitor. That is one factor, of course.

Sogi : Then I would like to know about cefiderocol. I understand that cefiderocol is a treatment used in hospitals. I think it is very good that this is growing so much, but I suppose the sales are growing because of the acceptance of this cefiderocol in each hospital account.

What is the growth potential if we think in terms of account acceptance at this point in time? What is the overall number of accounts you have received so far, and how many of your intended target accounts would you consider having already started using the drug?

Iwasaki : Iwasaki will answer the question. Do you mean about the overseas?

Sogi : Yes. That’s right.

Iwasaki : At the moment, I think we are at around 20% of the prescription share in large hospitals. Also, there is the introduction of diagnostic kits, etc. I thought that automated testing kits would be essential for large hospitals, and we are still in the process of rushing to develop such kits, so they have not been delivered to such places yet. In promoting the appropriate use of carbapenem resistance or emergency empirical use, I would say that this drug has about 25% of the market share.

In this context, we are currently at 20%, so we have another 5% to go. In Europe and the US, we think there is room for about that much more. In addition to GARDP and CHAI, which we are providing to LMICs, we would like to expand our business in ASEAN and other Asian regions to further increase the cefiderocol business.

Sogi : I understand. Thank you.

Kyokawa : Thank you very much. We have about three minutes left. Any other questions? Mr. Muraoka of Morgan Stanley, last but not least, please go ahead.

Muraoka : Hello, this is Muraoka from Morgan Stanley. Thank you. You have said that you are fine with Xocova's achievement of its H1 plan, but I think the answer is not favorable if it comes to a question on the current situation in Q2.

I remember that the budget for Xocova's annual domestic sales this year was about JPY60 billion, and I remember that you once said that the budget was about 50-50 split between H1 and H2. So, I feel there is quite a journey to the 3.9 billion in the first half, and I would be very happy if you could give me a little more explanation to understand that it’s okay.

Kudou : To add a little more detail, Xocova has been very popular since the beginning of July, and we expect to be able to achieve H1 sales goal, considering the pace of sales exceeding JPY10 billion for the single month of July.

Muraoka : I understand. Thank you very much. And one more thing, sorry.

You mentioned that you are focusing on business investment, but what scale of investment do you want to make this fiscal year? If you include the balance sheet and other financial assets, I think the total is about JPY560 billion, including cash. I don't think you will use all of it, but how much would you like to do this fiscal year?

Keller : We have not put a specific number for it, but I think you understand our current cash position, and at the same time we are looking at it conservatively as SHIONOGI.

However, we are actively seeking opportunities. Since we will be using shareholders' money, we want to ensure that we make a careful valuation when doing so. So, we are not setting a specific target, but we will just say that there are lots of activities going on.

Muraoka : I understand. Thank you. That's all from me.

Kyokawa : Thank you very much. We ran out of time, and this concludes the briefing for Q1 of fiscal year 2024 financial results of SHIONOGI.

Thank you very much for taking time out of your busy schedule to join us today.

[END]