



SHIONOGI & CO., LTD.

3rd Quarter of Fiscal 2022 Financial Results Conference Call

January 30, 2023

Presentation

Kyokawa: Hello. My name is Kyokawa, Vice President, Corporate Communications at Shionogi & Co. Thank you for joining us. We will now commence the Shionogi & Co., Ltd. financial results briefing for Q3 of the fiscal year ending March 31, 2023.

First, let me introduce today's speakers. First of all, Dr. John Keller, Senior Vice President, R&D. Next, Dr. Toshinobu Iwasaki, Senior Vice President, Healthcare Business and Pharmaceutical Commercial Division. Dr. Ryuichi Kiyama, Senior Vice President, Corporate Strategy. Dr. Takeki Uehara, Senior Vice President, Drug Development and Regulatory Science. Finally, Masako Kudou, Vice President, Finance & Accounting. Thank you.

Ms. Kudou will give an overview of the financial results, followed by a presentation of the Q3 results and future growth initiatives from Dr. Kiyama. We will then take time for your question.

The session will end at 4:00 pm.

I would like to explain about simultaneous interpretation. Simultaneous interpretation is available for today's briefing. If you wish to use simultaneous interpretation, you can select either Japanese or English from the globe icon at the bottom of the screen.

Let us begin immediately. Ms. Kudou, please go ahead.

Financial Results

(Unit: B yen)

	FY2022			FY2021		Y on Y	
	Forecasts Full Year (Oct. 24)	Apr.-Dec. Results	Achievement (%)	Apr.-Dec. Results	Change (%)	Change	
Revenue	410.0	338.3	82.5	219.6	54.1	118.7	
Operating profit	120.0	146.5	122.1	60.4	142.4	86.1	
Core operating profit*	120.0	144.0	120.0	61.9	132.6	82.1	
Profit before tax	174.0	198.8	114.2	74.8	165.8	124.0	
Profit attributable to owners of parent	142.0	157.7	111.1	71.0	122.2	86.7	

- **Significant year-on-year increases in revenue and all profit categories**
- **All profit categories, including operating profit, exceeded full year record highs** as of 3Q**

Exchange Rate (average)	FY2022 Forecasts (Oct. 24)	FY2022 Apr.-Dec. results
USD (\$) – JPY (¥)	138	136.51
GBP (£) – JPY (¥)	162	163.96
EUR (€) – JPY (¥)	140	140.62

* Operating profit adjusted for one-time factors (impairment losses, gain on sale of property, plant and equipment, etc.)

** Record-highs Revenue : 420.2 B yen (FY2001,J-GAAP), Operating profit : 145.1 B yen (FY2018,IFRS), Profit before tax : 174.0 B yen (FY2018,IFRS), Profit attributable to owners of parent : 137.2 B yen (FY2018,IFRS)

4



Kudou: Kudou here. I will now give an overview of the Q3 financial results and the revised earnings forecast.

First of all, on page four, we have consolidated operating results.

The results for Q3 of this fiscal year were revenue of JPY338.3 billion, operating profit of JPY146.5 billion, profit before tax of JPY198.8 billion, and quarterly income of JPY157.7 billion. As you can see from the right-

hand side of the table, the change from the previous year, there was a significant increase in both revenue and profit in all profit categories. This was a result of the JPY100 billion in revenue recorded in Q3 from the Japanese government's purchase of Xocova and continued steady progress in the base business, excluding COVID-19 related business.

Since the year-to-year change is quite large and the percentage increase is difficult to determine, we have also added the increase as a multiple this time around. As of Q3, we have already exceeded the full-year forecast in all profit categories. We will discuss the forecast in detail later, but this is the second time we are raising the full-year forecast for this fiscal year.

In addition, operating profit, profit before tax, and quarterly income have already exceeded record highs for the full year at this time.

Statement of Profit or Loss

(Unit: B yen)

	FY2022		FY2021		Y on Y	
	Forecasts Full Year (Oct 24)	Apr.-Dec. Results	Achievement (%)	Apr.-Dec. Results	Change (%)	Change
Revenue	410.0	338.3	82.5	219.6	54.1	118.7
Cost of Sales	19.5	13.2	67.7	18.1	11.8	4.7
Gross profit	330.0	293.8	89.0	179.8	63.4	114.0
Selling, general & administrative expenses, R&D expenses total	50.7	43.9	86.6	53.4	26.6	31.1
Selling, general & administrative expenses	27.6	21.7	78.3	31.4	6.6	4.5
R&D expenses	23.2	22.1	95.3	22.0	55.1	26.6
Other income & expenses	(2.0)	1.1	-	(2.1)	-	3.2
Operating profit	29.3	43.3	147.8	27.5	142.4	86.1
Core operating profit	29.3	42.6	144.3	28.2	132.6	82.1
Finance income & costs	54.0	52.3	96.9	14.4	264.2	38.0
Profit before tax	42.4	58.8	138.2	34.1	165.8	124.0
Profit attributable to owners of parent	142.0	157.7	111.1	71.0	122.2	86.7

Main Variation Factors (Y on Y) ※Special Notes for 3Q

- **Revenue**
 - Increase: COVID-19 related products ※, Royalty income, Overseas subsidiaries/export
 - Decrease: Prescription drugs
- **R&D expenses**
 - Increase: Investment in R&D activities including COVID-19 related projects
- **Finance income & costs**
 - Increase in income
 - : Increased dividend reflecting ViiV's strong business
- **Profit attributable to owners of the parent**
 - Receipt of refund in 1Q FY2021 in respect of a favorable judgement regarding the complaint for the rescission of tax reassessment by the Osaka Regional Taxation Bureau



Moving on to page five. This shows the consolidated statements of income.

The purchase of Xocova by the Japanese government was a special factor in Q3, while other trends were the same as in Q2. In addition to the government purchase of Xocova, HIV royalties were very strong, both in terms of actual sales and due to the impact of foreign exchange rates. Sales of cefiderocol in Europe and the US were also strong.

As for cost of goods sold, we have made 55.7% progress toward the revised forecast. This is partly because we had originally made a conservative forecast due to the difficulty of accurately estimating the cost of COVID-19 related products. This is also incorporated in the revised earnings forecast.

In terms of selling, general and administrative expenses and research and development expenses, while we invested aggressively in R&D in particular, we were able to control expenses appropriately overall. This resulted in operating profit of JPY146.5 billion, well in excess of the full-year forecast of JPY120 billion.

Financial profit and expenses increased significantly from the previous year to JPY52.3 billion. This is due to the impact of the dividend from ViiV, the timing of which was delayed from March 2022 to April 1, in addition to the continued strong performance of ViiV.

This dividend from ViiV is conservatively projected for H2 due to fluctuations in the cash remaining from annual business activities at ViiV. However, as of Q3, 96.9% of the annual amount has been paid.

The slight decrease in the YoY percentage increase in quarterly pretax income is due to a refund from the Osaka Regional Taxation Bureau in the previous fiscal year.

Revenue by Segment

(Unit: B yen)

	FY2022			FY2021		Y on Y	
	Forecasts Full Year (Oct 24)	Apr.-Dec. Results	Achievement (%)	Apr.-Dec. Results	Change (%)	Change	
Prescription drugs	76.4	54.7	71.5	69.5	(21.4)	(14.9)	
Overseas subsidiaries/export	39.3	30.6	77.8	26.2	16.9	4.4	
Shionogi Inc.	14.4	11.5	79.4	11.1	3.1	0.3	
Fetroja®	-	7.3	-	4.7	53.3	2.5	
Ping An-Shionogi [*] /C&O	10.4	8.4	80.5	7.2	16.1	1.2	
Shionogi BV	8.6	6.6	77.4	3.8	72.9	2.8	
Contract manufacturing	14.8	10.3	69.6	11.8	(13.0)	(1.5)	
OTC and quasi-drug	13.2	10.1	76.0	8.4	19.8	1.7	
Royalty income	155.0	131.7	85.0	102.4	28.7	29.4	
HIV franchise	150.2	126.9	84.5	96.2	31.9	30.7	
Crestor®	-	1.3	-	1.2	15.4	0.2	
Others	4.8	3.5	72.8	5.0	(30.7)	(1.5)	
COVID-19 related products**	110.0	100.0	90.9	-	-	100.0	
Others	1.2	1.0	85.0	1.3	(23.6)	(0.3)	
Total	410.0	338.3	82.5	219.6	54.1	118.7	

Main Variation Factors (Y on Y) ※Special Notes for 3Q

- **Prescription drugs**
 - Increase: Sales of Intuniv® and Vyvanse®
 - Decrease: Sales of Cymbalta®
 - : Returns of Xofluz® and Rapiacta®
- **Overseas subsidiaries/export**
 - Shionogi Inc. (US)
 - > Increase: Sales of cefiderocol (Fetroja®)
 - > Decrease: Received in 1Q of FY2021 a one-time payment for the transfer of FORTAMET® sales rights (2.2 B yen)
 - Shionogi BV(Europe)
 - > Increase: Sales of cefiderocol (Fetroja®)
- **Royalty income**
 - HIV franchise
 - > Increase: Strong sales of ViiV's HIV franchise
- **COVID-19 related products**
 - Increase: Purchase of 2 million courses of Xocova® by the Japanese government ※

* OTC and quasi-drugs also include in revenue of joint venture ** Revenue from Xocova® and S-268019



Next on page six is an explanation of revenue by business segment.

Domestic sales of prescription pharmaceuticals for the period from April to December totaled JPY54.7 billion, a significant decrease from the previous year. While sales of Intuniv and Vyvanse increased steadily, this was offset by an increase in sales of generic Cymbalta and a decrease in sales due to a rebound effect on anti-influenza drugs from Q2.

Although progress to the full-year forecast is 71.5%, which appears to be slightly low, the weight of infectious disease-related sales tends to be large in Q4, so we consider it to be on-track in Q3.

Overseas subsidiaries/exports are steady. As for Shionogi Inc., although results appear to be unchanged YoY, the Company has just experienced a significant increase in sales due to a large growth in Fetroja. This takes into account a one-time payment of JPY2.2 billion associated with the transfer of Fortamet sales rights in the previous period.

Although contract manufacturing appears to be slightly behind schedule due to the postponement, we expect that there will be no difference from the forecast for the full year.

Sales of OTC drugs are doing well, partly due to the impact of the 8th wave of COVID-19 infection.

Royalty income continued to grow strongly in Q2, with the HIV franchise benefiting from both favorable actual sales and positive foreign exchange rates.

Regarding Crestor, we did not expect to receive royalties from AstraZeneca for sales during the current fiscal year, but received JPY1.3 billion as sales continued to be strong globally and exceeded the threshold amount to receive royalties.

For products related to COVID-19, the purchase of Xocova by the Japanese government amounted to JPY100 billion. Although we need another JPY10 billion to achieve the full-year forecast, we continue to make various efforts to achieve the full-year forecast in Korea and China.

Revenue Forecasts for Prescription Drugs in Japan

(Unit: B yen)

	FY2022			FY2021		Y on Y	
	Forecasts Full year (Oct 24)	Apr.-Dec. Results	Achievement (%)	Apr.-Dec. Results	Change (%)	Change	
Intuniv®	20.0	14.8	74.0	12.1	21.6	2.6	
Vyvanse®	1.3	1.1	84.4	0.6	90.1	0.5	
Infectious disease drugs	8.8	2.9	32.8	8.8	(67.2)	(5.9)	
Influenza franchise	0.1	(3.8)*	-	2.0	-	(5.8)	
Cymbalta®	6.1	4.4	73.0	14.1	(68.6)	(9.7)	
OxyContin® franchise	4.5	3.5	78.3	3.8	(7.1)	(0.3)	
Symproic®	3.4	2.6	76.4	2.0	29.9	0.6	
Actair®	0.6	0.4	70.2	0.4	10.4	0.0	
Mulpleta®	0.1	0.1	68.9	0.1	(13.6)	(0.0)	
Pirespa®	2.4	2.0	85.7	3.1	(33.7)	(1.0)	
Others	29.4	22.9	77.8	24.6	(7.1)	(1.7)	
Crestor®	3.9	3.2	81.9	4.7	(30.7)	(1.4)	
Prescription drugs	76.4	54.7	71.5	69.5	(21.4)	(14.9)	

<Products categorized as infectious disease drugs>

- Xofluza®
- Rapiacta®
- Brightpoc® Flu·Neo

Influenza franchise

- FINIBAX®
- Flumarin®
- Flomox®

- Shiomarin®
- Vancomycin
- Baktar®

- Flagyl®
- ISODINE®

7

* Approximately 5.3 B yen worth of products that expire this year were returned in the second quarter. Sales of 1.5 billion yen recorded for influenza family in April-December



Next on page seven is an explanation of domestic prescription drug sales revenue.

As I mentioned earlier, earnings from domestic prescription drugs have been mostly favorable.

As for the influenza family, sales were negative JPY3.8 billion due to the impact of JPY5.3 billion in returned goods in Q2, but as noted, sales were JPY1.5 billion from April to December.

Results and Progress in Q3 FY2022

Bringing COVID-19 treatment drug Xocova® to patients Outcome from our COVID-19 investment contributed to earnings

- **Providing new treatment options**
 - Antiviral drugs play an important role in normalizing society
 - Xocova® is an oral antiviral drug that can be used in a wide range of patients, regardless of immunizations status or risk level
 - Global registration of Xocova® is progressing
- **Progression of a purely domestic vaccine**
 - Filed for manufacturing and sales approval of S-268019
- **Contribution to earnings**
 - Exceeded each profit category in the full-year revised forecast
 - > There are many uncertainties regarding COVID-19-related products, so the initial guidance was set conservatively

Aiming to achieve the highest profit since our founding and expected to continue to contribute to business performance from the next fiscal year forward

Redeploy the learnings and profits obtained from COVID-19 related projects into creation of our next growth drivers

8



Next, on page eight, are the main results and progress for Q3.

What I would like to share with you in Q3 is that we are finally able to deliver Xocova to patients. We have made considerable upfront investment in COVID-19, and we believe that we have finally entered a phase in which this investment will contribute to our business performance in the form of earnings.

We also achieved a major milestone with the filing for manufacturing and marketing approval of the vaccine S-268019 in Japan. We are currently in the process of responding to the review by the authorities.

In terms of financial results, there were many uncertainties related to COVID-19 products in terms of costs, SG&A expenses, and other expenses.

Based on the above results, we have revised our full-year forecasts upward again, which will be explained on the next page and thereafter.

Regarding the Changes in Earnings Forecasts

Key Points of Earnings Forecast Revision

- In the initial forecast, the profit contribution of Xocova[®] was estimated conservatively, but following the emergency approval in Japan, various profit items including operating profit have been revised substantially upwards.
- The revised forecast may be further surpassed depending on global registration progress of Xocova[®]

Main points of earnings forecast revision

- **Upward revision of revenue and financial income**
 - Strong sales from ViiV
- **Reduction in selling, general & administrative expenses**
 - In order to prioritize COVID-19 related businesses, some of the originally planned growth investments will be shifted to the next fiscal year
- **Reduced cost of sales**
 - Reflected changes in the product mix
- **Increase in R&D expenses**
 - Aggressive investment in product development including COVID-19 related projects

10



Moving on to page 10. Changes in the forecast of financial results.

As for the changes to the forecast, first, we revised upward the royalty income from ViiV and the dividend to reflect the solid HIV business situation.

The reduction in cost of sales was mainly due to an improvement in the cost-to-sales ratio as Xocova's cost of sales was refined. The increase in production volume was another factor.

As for SG&A expenses, we expect an increase in R&D expenses due to aggressive investment in growth drivers, including non-COVID-19 products under development, while shifting some growth investments originally planned for the next fiscal year in order to prioritize COVID-19-related business.

Depending on Xocova's future global progress, the revised forecast may swing even higher, and we will naturally aim for that.

Revision of Earnings Forecast

(Unit: B yen)

	FY2022		Forecasts Full year		FY2021	Y on Y	
	Forecasts (May. 11)	Forecasts (Revised on Oct. 24)	Forecasts (Revised on Jan. 30)	Revised amount		Results	Change (%)
Revenue	400.0	410.0	421.0	11.0	335.1	25.6	85.9
Operating profit	120.0	120.0	147.0	27.0	110.3	33.3	36.7
Core operating profit*	120.0	120.0	144.5	24.5	110.6	30.7	33.9
Profit before tax	168.0	174.0	210.0	36.0	126.3	66.3	83.7
Profit attributable to owners of parent	136.0	142.0	170.0	28.0	114.2	48.9	55.8

- Reflecting the government purchase of Xocova® and the strong HIV business, implement the second upward forecast revision in this fiscal year to achieve the highest performance since our founding
- Further increase in sales may be expected from overseas progression of Xocova®

Exchange Rate (average)	FY2022 Forecasts (Oct 24)	FY2022 Forecasts (Jan. 30)	FY2022 Apr.-Dec. results
USD (\$) – JPY (¥)	138	135	136.51
GBP (£) – JPY (¥)	162	162	163.96
EUR (€) – JPY (¥)	140	140	140.62

* Operating profit adjusted for one-time factors (impairment losses, gain on sale of property, plant and equipment, etc.)

** Record-highs Revenue : 420.2 B yen (FY2001,J-GAAP), Operating profit : 145.1 B yen (FY2018,IFRS), Profit before tax : 174.0 B yen (FY2018,IFRS), Profit attributable to owners of parent : 137.2 B yen (FY2018,IFRS)

11



Moving on to page 11. From the beginning, we had announced that we would revise our forecasts whenever various uncertainties became clear. Now that the Xocova and HIV-related situations have become clearer, we have decided to revise upward for the second time in this fiscal year.

Although the operating profit forecast for the period from April to December and the revised full-year forecast do not appear to be very different, we have taken into account the uncertainties in Xocova's business development in Korea and China, as well as the investment required to transform the Company's structure in line with the STS2030 update, the medium-term management plan that is being considered for the coming spring.

As we continue to aim for the highest performance since the Company's inception, and there is ample potential for opportunities such as Xocova's global expansion, we expect to land in excess of this revised forecast.

Revision of Earnings Forecast: Statement of Profit and Loss

(Unit: B yen)

	FY2022 Forecasts Full year			Revised amount	FY2021	Y on Y	
	Forecasts (May. 11)	Forecasts (Revised on Oct. 24)	Forecasts (Revised on Jan. 30)		Results	Change (%)	Change
Revenue	400.0	410.0	421.0	11.0	335.1	25.6	85.9
Cost of Sales	22.0 88.0	19.5 80.0	15.7 66.0	(14.0)	16.5 55.4	19.1	10.6
Gross profit	312.0	330.0	355.0	25.0	279.7	26.9	75.3
Selling, general& administrative expenses, R&D expenses total	47.5 190.0	50.7 208.0	48.9 206.0	(2.0)	50.2 168.2	22.4	37.8
Selling, general& administrative expenses	30.0 120.0	27.6 113.0	24.5 103.0	(10.0)	28.4 95.2	8.1	7.8
R&D expenses	17.5 70.0	23.2 95.0	24.5 103.0	8.0	21.8 73.0	41.1	30.0
Other income & expenses	(2.0)	(2.0)	(2.0)	-	(1.2)	71.5	(0.8)
Operating profit	30.0 120.0	29.3 120.0	34.9 147.0	27.0	32.9 110.3	33.3	36.7
Core operating profit	30.0 120.0	29.3 120.0	34.3 144.5	24.5	33.0 110.6	30.7	33.9
Finance income & costs	48.0	54.0	63.0	9.0	16.0	294.8	47.0
Profit before tax	42.0 168.0	42.4 174.0	49.9 210.0	36.0	37.7 126.3	66.3	83.7
Profit attributable to owners of parent	136.0	142.0	170.0	28.0	114.2	48.9	55.8

12



Page 12 is a consolidated income statement that includes the information described earlier. I will not go into details here, but we will revise sales revenue and all profit items upward.

Revision of Earnings Forecast: Revenue by Segment

(Unit: B yen)

	FY2022 Forecasts Full year			Revised amount	FY2021	Y on Y	
	Forecasts (May. 11)	Forecasts (Revised on Oct. 24)	Forecasts (Revised on Jan. 30)		Results	Change (%)	Change
Prescription drugs	78.6	76.4	76.4	-	89.1	(14.3)	(12.7)
Overseas subsidiaries/export	41.6	39.3	39.3	-	34.4	14.4	5.0
Shionogi Inc.	13.0	14.4	14.4	-	13.8	4.8	0.7
Ping An-Shionogi [†] /C&O	14.8	10.4	10.4	-	10.2	2.1	0.2
Shionogi BV	8.4	8.6	8.6	-	5.0	71.7	3.6
Contract manufacturing	14.8	14.8	14.8	-	17.4	(15.3)	(2.7)
OTC and quasi-drug	13.4	13.2	13.2	-	11.2	18.7	2.1
Royalty income	140.4	155.0	166.0	11.0	181.3	(8.4)	(15.2)
HIV franchise	133.9	150.2	159.9	9.7	174.0	(8.1)	(14.0)
Crestor [®]	-	-	1.3	1.3	1.2	15.4	0.2
Others	6.5	4.8	4.8	-	6.1	(22.2)	(1.4)
COVID-19 related products ^{**}	110.0	110.0	110.0	-	-	-	110.0
Others	1.2	1.2	1.2	-	1.8	(32.6)	(0.6)
Total	400.0	410.0	421.0	11.0	335.1	25.6	85.9

13

* OTC and quasi-drugs also include in revenue of joint venture ** Revenue from Xocova[®] and S-268019



The next page, page 13, shows the revised revenue by business segment.

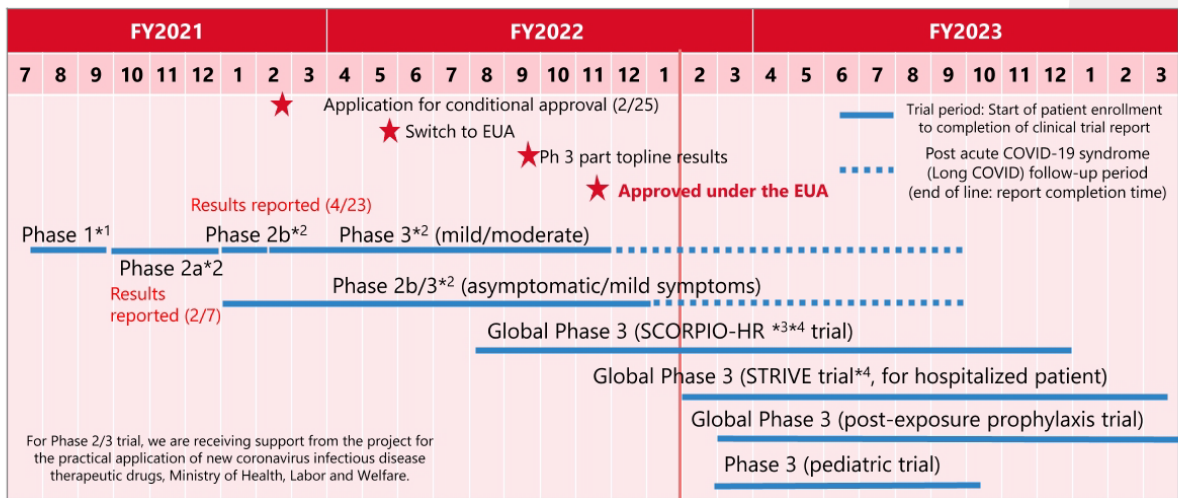
As explained earlier, we have also revised the HIV royalties from ViiV and royalty income from AstraZeneca for Crestor and other products.

While it is natural for us to achieve these strong business results for this fiscal year, we will continue to focus on increasing sales and profits in the next fiscal year as well. We believe that there will be further growth in HIV and cefiderocol, as well as an even bigger move on Xocova.

In the future, we believe that opportunities for use will increase as the treatment becomes available for general distribution in Japan. In addition, it is assumed that the shift to class 5 will increase the opportunities for use as well. We will continue to discuss how the national stockpiles should be in accordance with the demand for therapeutic drugs. There is a good possibility of a large upward swing in the future, depending on Xocova's global expansion, such as in Korea and China. We believe that there will be a move to approve the vaccine as well. We also plan to update our mid-term plan in the spring and are considering various measures and are actively engaged in BD activities. There are many things we cannot talk about at this time, but we are working on a number of initiatives for the next fiscal year.

This concludes my presentation.

Xocova®: Progress Summary



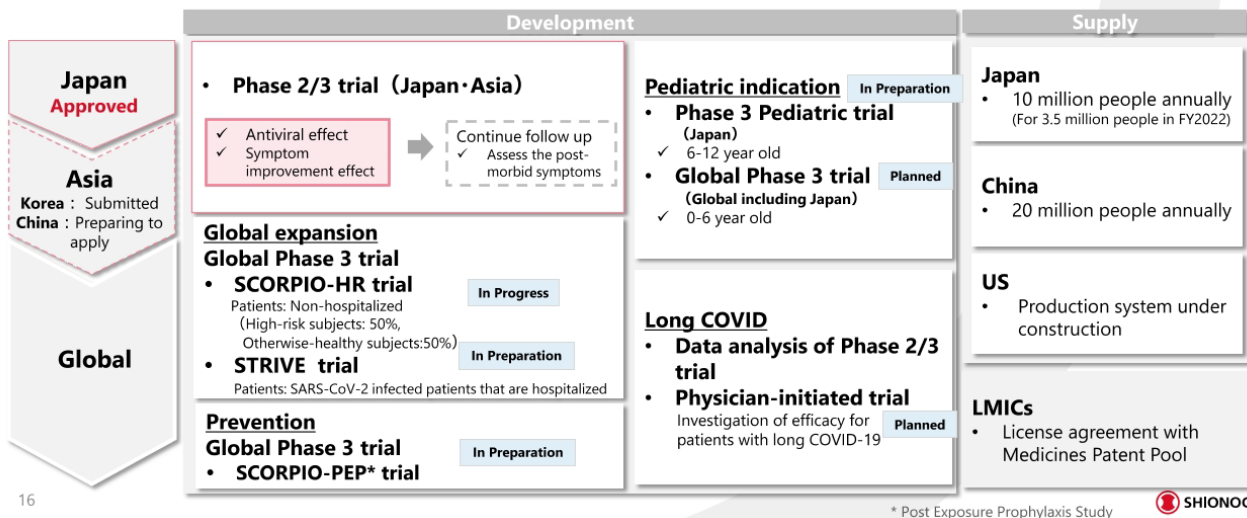
As of January 30, 2023

Kiyama: Next, I will present the Q3 results and future initiatives.

Page 15 covers the COVID-19 treatment Xocova. We have provided a progress summary here, and will explain the entire plan on the following pages.

Xocova®: Overall picture of the current situation and future plans

With the emergence of new mutant strains, the need for antiviral drugs remains
 Accumulating various evidence for the role of Xocova® in coexistence with COVID-19



Page 16. Although we received manufacturing and marketing approval based on the emergency approval system on November 22, 2022, the approval is not the goal but the starting line for SHIONOGI.

As viruses mutate at an alarmingly rapid rate and new mutant strains continue to emerge, the role and importance of antiviral drugs will continue to increase and the need for such drugs will remain.

SHIONOGI hopes to contribute to a return to normal life as coronavirus infections continue, by accumulating a variety of evidence not only for the global development of Xocova, but also for the highly needed pediatric field, prevention of the onset of disease to prevent the spread of infection, and management of long COVID, which is said to have a significant socioeconomic impact.

We remain committed to our efforts for COVID-19 as we move into an era of coexistence with COVID-19. I will introduce some of these initiatives in the next two slides.

Xocova® : Japan/Global Progress (1)

Japan

- Supply from government purchase, which is different from normal sales
- Collection and evaluation of safety information
 - Over 20,000 patients have taken Xocova®, and no major safety concerns have been identified
- Under discussion with MHLW and PMDA for general approval
- Additional data from Phase 3 Part of Phase 2/3 trial (Japan/Asia) will be announced at academic conferences, etc.
 - Antiviral reduction effect and long COVID follow-up Interim analysis results (around February 2023)

Korea

- Submitted an approval application (January 3, 2023)
 - Aiming to obtain approval by 4Q FY2022
- Continuing discussions with the Korean government and regulatory authorities

Global Studies

- **SCORPIO-HR**
 - Aiming for completion in 2023
 - Accelerating patient enrollment by expanding sites
- **STRIVE trial**
 - Start: Feb. 2023 (planned)
- **SCORPIO-PEP* trial**
 - Continuing protocol discussions with PMDA and FDA
 - Start: Feb. 2023 (planned)

Page 17. First, here is the situation in Japan after obtaining emergency approval. Currently, unlike normal sales, it is supplied under the purchase of the country. To date, more than 20,000 patients have taken the treatment, and no major safety concerns have been identified. Discussions with the MHLW and PMDA are ongoing for future regular approval.

We also plan to present at conferences our additional data from the Phase III part of the Phase II/III trial conducted in Japan and Asia. For example, at CROI, which will be held from February 19 to 22 next month, we plan to present the results of an interim analysis of antiviral efficacy and long COVID follow-up.

Next is South Korea. In South Korea, our partner Ildong Pharmaceutical submitted an application for manufacturing and marketing approval on the January 3. Although the application was initially submitted as a conditional application, as a result of subsequent discussions with the regulatory authorities, we have confirmed that the application will proceed to the regular approval process for expedited review. We will aim to obtain approval by the end of FY2022.

If you go to the right side, we will continue with the global situation, including the US and Europe. The slide shows the status of the global Phase III trial. The SCORPIO-HR trial is expanding to non-US sites to accelerate case enrollment and is expected to be completed by the end of 2023.

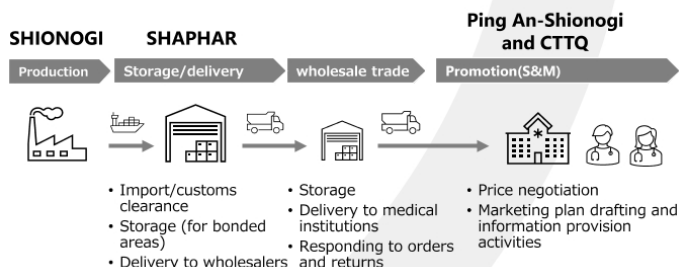
The STRIVE trial for inpatients is scheduled to start in February, and the SCORPIO-PEP trial for prevention of disease onset is also scheduled to start in February, following ongoing discussions with the PMDA and FDA regarding the protocol.

Xocova® : Japan/Global Progress (2)

China

- Ping An-Shionogi is preparing to apply for NDA
 - First of all, provide products manufactured in Japan
 - Switch to domestic production in China as soon as preparations are complete
- **Construction of production system**
 - Completed PV at drug substance and formulation plants
 - > Building a production system aiming to supply more than 20 million people a year
- **Construction of supply/sales system**
 - License agreement for import and distribution with Shanghai Pharmaceutical Co., Ltd (SHAPHAR)
 - License agreement for promotion with Chia Tai Tianqing Pharmaceutical Group, Co., Ltd. (CTTQ)

Roles in supply/sales of Xocova® imported from Japan



Page 18 covers China.

The switch to an economy-first policy in China has led to an increasing need for therapies, and Ping An Shionogi is currently preparing for a marketing authorization application based on Phase II/III trial.

In order to make Xocova available as soon as approval is obtained, we will first supply products from Japan, and then switch to the supply of products manufactured in China as soon as local preparations are ready.

As for local production, PV at the API and formulation plants were completed at the end of last year. At present, we have a production system to supply more than 20 million tablets per year. Also our Nanjing plant in China has the capacity to produce tablets for up to 100 million people per year, so it is possible to further increase production volume according to need.

As for distribution and sales, as announced in our press release at the end of last year, we have concluded partnering agreements with two of China's leading corporate groups. The roles of each company are shown in the diagram on the right side of the page, and this partnering agreement enables us to promptly deliver Xocova to patients throughout China after receiving approval.

Pipeline progress

Development updates from 3Q^{*1}

Pipeline	Indication	Progress
S-309309	Obesity	Confirmed favorable safety, tolerability and PK profile in Phase 1 interim report Phase 2 trial scheduled to start in 4Q FY2022
Olorofim (F901318)	Limited treatment options for invasive fungal infections	High efficacy and tolerability confirmed by date from the first 100 subjects in Phase 2b
	Invasive Aspergillosis	Phase 3 trial (ongoing)

Phase 2b Initial Results^{*2}

- Study 32: Open-Label Study in Patients with Limited Treatment Options (NCT03583164)
- 75% significantly immunosuppressed

- **Olorofim showed efficacy, including high survival rates, in infections due to a range of invasive rare molds**
- **Olorofim was well tolerated, even with dosing to ~2 years**

	Invasive Aspergillosis (n=53 of 1 st 100)	External Control (n=46)
Month 3 ACM ^{*3}	32%	87%
95% CI	20-46%	75-95%

New Drug Application (NDA) based on positive results is under review by FDA

Making steady pipeline progress

19

^{*1} R&D material P.112, 113 ^{*2} From F2G's announcement at ID Week 2022

^{*3} ACM = All-Cause Mortality; Month 3 is defined as Day 84-100 to encompass the ACM definitions used in the historical control datasets.



Continuing on page 19 is the progress of developed products.

Overall, development is progressing smoothly, but today I would like to introduce the progress of S-309309 and olorofim, milestones for which were presented at the R&D Day.

Regarding S-309309 (MGAT2 inhibition) this is indicated for obesity and is a unique treatment with a different mechanism than GLP-1: S-309309 can be provided at a low cost because of oral drug that can be chemically synthesized. It is expected to have reasonable efficacy based on favorable nonclinical data. For reasons such as the potential to be used in combination with GLP-1, we believe that we can offer a new treatment option and are developing this product on a global basis.

Preliminary results of the Phase I trial have confirmed a high level of safety and tolerability with no adverse events of concern throughout the study, and a favorable PK profile. Based on these favorable study results, we will promptly conduct a global Phase II trial.

Next is olorofim. This is an antifungal drug with a novel mechanism of pyrimidine synthesis pathway inhibition. We are developing this new option to meet the needs of patients who cannot be treated with existing antifungal drugs due to resistance, or patients who cannot use them due to safety concerns.

We are pleased to introduce the initial results of Study 32, a Phase IIb trial being conducted independently by F2G. Study 32 is a trial for patients with invasive cardiomyopathy who have no or limited treatment options. Of the target number of 200 cases, analysis of 100 cases has been completed, of which 53 cases of invasive aspergillosis have been analyzed. The lower left table shows the mortality results after three months.

Compared to the 87% mortality rate in the control group, olorofim significantly reduced the mortality rate to 32%. Thus, the high efficacy seen in clinical trials and the good tolerability at two years of administration were confirmed in clinical trials. Based on these results, F2G submitted a New Drug Application (NDA) in the US, which was accepted by the FDA.

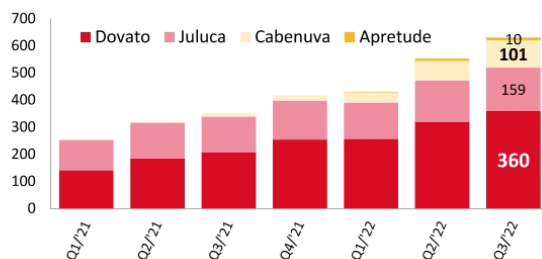
We will continue our efforts to advance the development of our pipeline, including the two products we have just reported on.

Progress of HIV Franchise by ViiV Healthcare

Strong uptake of innovative portfolio and continued pipeline progress

- Growth led by Dovato and long-acting regimens

Unit: million £ [Sales trends of innovative portfolio*1]



- Dovato (two-drug regimen)

- Sales of £360 million in Q3 2022 (increase 73% YoY)

- Cabenuva (LA injection: treatment)

- Sales of over £100 million in Q3 2022

- Apretude (LA injection: prevention)

- Submitted NDA to EMA (Oct. 2022)*2

- S-365598 (VH4524184*3, ultra LA injection)

- Initiated Phase 1 trial (Dec. 2022)*4
- > Oral administration

Steady growth of innovative portfolio and development progress of next-generation long-acting products to drive medium- to long-term growth

*1 Created by SHIONOGI from GSK financial results

*2 GSK press release: [European Medicines Agency validates ViiV Healthcare's marketing authorisation application for cabotegravir long-acting injectable for HIV Prevention | GSK](#)

20 *3 ViiV development number

*4 NCT05631704 : [A Study to Investigate Safety, Tolerability, and Pharmacokinetics \(PK\) of VH4524184 and the Potential for Changes in Cytochrome P450 3A \(CYP3A\) Activity - Full Text View - ClinicalTrials.gov](#)

SHIONOGI

Finally, we show the progress of the HIV franchise.

As the graph shows, ViiV's most recent financial data also confirms that sales growth of new product lines, such as Dovato and Cabenuva, are driving overall HIV franchise growth.

For Dovato, sales for the quarter exceeded GBP360 million, a strong 73% YoY increase. Quarterly sales since FY2021 have shown a steady increase, offsetting the decline in Tivicay and Triumeq.

Cabenuva also exceeded GBP100 million in June-September 2022, also exceeding expectations. We believe that long-acting injectables such as Cabenuva and Apretude are important growth drivers that could be central to the HIV market in the future and are on track to meet GSK's annual sales target of GBP2 billion by 2026.

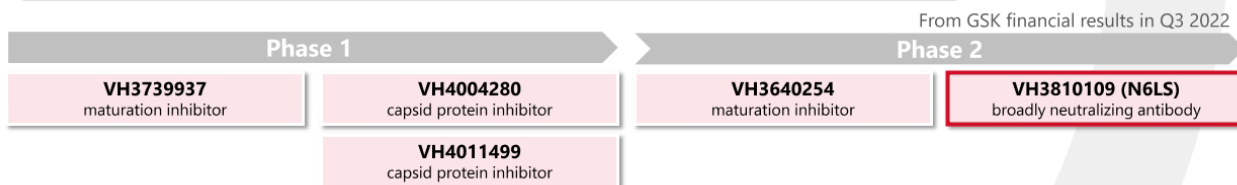
As for Apretude, it was launched in the US in early 2022 and is steadily penetrating the US market. A new drug application was filed for approval in Europe in October last year.

S-365598 is an ultra-long-acting injection drug that we licensed out to ViiV. It is expected to be administered once every three to six months, and has the potential to bring further innovation to HIV treatment. As planned, Phase I trials were initiated in December last year, and we will first confirm the safety of the drug when administered orally.

As described above, we are making steady progress in the development of next-generation long-acting injectable drugs for maximizing the value of new product groups and for medium- to long-term growth.

Progress of HIV Franchise by ViiV Healthcare

Development status of combination candidates for ultra LA injections*



Broadly neutralizing antibody N6LS**

- By blocking HIV's entry into human CD4+ cells, the HIV transmission process may be prevented
- **Positive results of Phase 2a**
 - A single infusion of N6LS demonstrated strong antiviral efficacy while also being well-tolerated by trial participants
 - Expect to begin a phase 2b trial of N6LS in combination with other anti-retrovirals in 2023

Accelerate development of combination candidates for the creation of ultra LA injections

21

* LA injections administered once every three to six months or more including Cabenuva and S-365598 (VH4524184)
** [ViiV Healthcare presents positive proof-of-concept findings for N6LS, an investigational, broadly neutralising antibody \(bNAb\) offering a potential new approach for the treatment of HIV | GSK](#)



Page 21. Here we present the development status of ViiV's ultra-long-acting injectable combination candidates.

The development products shown on the slide are not compounds discovered by Shionogi, but they are a very important group of compounds as candidates for adjuncts to therapies such as cabotegravir and S-365598.

In principle, when drug therapy is implemented for HIV treatment, drugs with different mechanisms of action should be used in combination in order to inhibit viral resistance. The creation of ultra-long-acting drugs similarly requires the development of combination drugs, and ViiV is currently developing five compounds in Phases I and II trial.

Today, as an update on them, we would like to share with you the progress of the broadly neutralizing antibody N6LS. This antibody has the potential to reduce viral replication by inhibiting HIV virus entry into CD4-positive cells. ViiV has already disclosed that Phase IIa studies have demonstrated strong viral reduction and tolerability when administered alone.

As for the future schedule, we plan to initiate a Phase IIb trial of N6LS in combination with other anti-HIV drugs by the end of 2023. Steady progress is being made toward the growth of the HIV franchise in the mid- to long-term.

That concludes my presentation.

Kyokawa: Thank you very much.

Question & Answer

Kyokawa : We will now move on to the question-and-answer session.

First of all, Mr. Kohtani from Nomura Securities, please go ahead.

Kohtani : Kohtani from Nomura Securities. Firstly, regarding Xocova, I expect that the category 5 infectious disease transition will lead to increased use. In countries that have used influenza medications such as Tamiflu, Inavir, and Xofluza for so long, it is hard to imagine not prescribing these medications.

After all, as you know, both Tamiflu and Xofluza have symptom improvement of less than 24 hours, which is not much different than Xocova. Also, if the reason for such widespread use in influenza is that it can cause severe illness in people who are not at risk, then there is a logical contradiction if we do not prescribe it for coronavirus, since it has sequelae even if the severity of the illness is the same.

The circumstances here are better than with influenza treatment. For example, influenza didn't have a commercially available antigen test kit, but now that antigen test kits are available OTC, anyone can get a diagnosis of coronavirus. And it is cheaper. If this is paid for with public funds for a certain period of time, it will be free for patients, so while it might sound optimistic, I think the situation is more conducive to the increased use of this therapy compared to influenza.

But still, preparations are for a scenario where it will not spread, and the current stock price reflects that. One possible roadblock could be drug-drug interactions. However, I do not think that will be such an issue.

With all that in mind, I would like to ask Mr. Uehara, to provide the devil's proof here. What exactly is a possible scenario in which a coronavirus switches to a class 5 infectious disease classification and Xocova use does not become widespread? Also, can you tell me if there are any flaws in what I have just said? This is the first question.

Uehara : We believe that Xocova is a treatment for patients who test positive for coronavirus, regardless of risk factors, and who go to their family doctor and test positive, and take the medication to stop the increase of the virus as quickly as possible and to relieve symptoms. This is similar to the situation with influenza. Xocova will quickly stop viral replication and relieve symptoms. We collected data based on the concept that we hope to prevent the spread of the virus not only among the patients themselves, but also among their families and communities through treatment.

As you have just mentioned, we believe that in the scenario where the product is switched from emergency approval to general distribution, we will be able to create an environment where it can be used more widely and easily.

I think your direct question was about what kind of implausible scenario exists where Xocova would not be widely used. At this point, with more than 20,000 cases, we have accumulated a lot of safety data in the post-marketing period and have not obtained any signals of particular safety concerns, so the drug can continue to be used. But if serious safety concerns arose in the future, there may be discussion about whether or not to allow people without risk factors to take the drug. We do not anticipate that happening at this time, but we want to make people aware of all possibilities.

Kohtani : Some people are saying that the potential drug interactions are too complicated and that is why use of Xocova is not spreading, but honestly, looking at your Company's attachment, the only drug that seems to be widely used by young people is Viagra, so I don't think it is that much of a problem, do you?

Uehara : I have heard that some hospitals and pharmacies are considering not to adopt because of the complexity of the process, such as obtaining written consent from the patient.

However, once these drugs are in general distribution, it will be relatively easy to consider prescribing them. As you mentioned, there are not so many drugs that younger people take on a daily basis. We have received feedback from doctors that once they become accustomed to prescribing these drugs, they will soon be able to distinguish whether or not there is a risk of being caught by DDI.

Kohtani : I understand. The second question is about your expectation for coronavirus treatments globally. I am a bit pessimistic here. Leaving Vietnam aside as it is a bit complicated, I would like to ask you about the situation in Korea and China.

South Korea's central disease control HQ did not request expedited approval for Xocova on December 28. From there, the stock price of your partner, Ildong Pharma, has been falling, and although it has since been announced that they have filed for regular approval, the stock price remains stagnant. So, what can we expect in Korea?

As for China, only old HIV drugs such as Azvudine and a Chinese herbal medicine called Qingfei Paidu are covered by the insurance, but Paxlovid is not. The results of a trial of VV116, a deuterated remdesivir, have been published in the NEJM, but if the Chinese-made drug is given priority, I'm a little skeptical, thinking that if Chinese medicine takes precedence, Xocova won't be used and deuterated ensitrelvir will widely use. I am a bit skeptical about whether the deuterated ensitrelvir will end up being widely used. Can you tell us about the prospects for Korea and China in this area?

Uehara : I will say a few words about the status in the Asian region.

First of all, in South Korea, we have heard from our partner company that, although the data obtained in the Phase III trial is not eligible for urgent approval, the results are sufficient for review by the regulatory authorities for approval. In fact, we have received a request from the Korean authorities to proceed to the regular approval application based on the expedited review process, even though we have already proceeded to the approval application once in the form of conditional approval. We are hoping that you will review the data from this point of view, but I think it is a point of discussion as to whether this Japan-centered data package is sufficient for the application for approval.

As for China, as you have already mentioned, there is news that China has gradually completed Phase III of its domestic drug production and some products have been approved on an emergency basis. We are currently reviewing the data on our drug from various angles, and through such data review, we believe that we will be able to establish whether or not our application for approval will be approved based on the data.

Kohtani : Last question. What is happening now with the SCORPIO-HR trial, the Phase III trial in the US and Europe? I was hoping that this would mean that they would change the protocol, but not much has changed. Again, this was a Japanese trial assessing the proportion of patients within 72 hours of onset who were free of 5 corona-related symptoms for 24 hours. However, SCORPIO-HR is the percentage of patients who have disappeared from 12 corona-related symptoms for 4 days or more among the patients recruited within 120 hours from the onset of symptoms. I think it's a little hard to consider the probability of success to be high now at this point because there will be more noise. Please let me confirm whether you can change the protocol for this Phase III trial in Europe and the US, or whether you are confident that it will be successful as it is now.

Uehara : We are currently in discussions with the FDA to change the protocol for the global Phase III trial.

As you know, the NIH is 100% committed to this trial. Discussions involving the NIH are taking some time, but we are currently in the process of changing the protocol.

Kohtani : I understand. We have high expectations. Thank you very much.

Kyokawa : Next, Mr. Ueda from Goldman Sachs.

Ueda : Ueda from Goldman Sachs. I would like to ask you first about the domestic situation for Xocova.

What is the expected timing of full approval in the future? Also, you mentioned earlier that the results of the follow-up on long COVID will be released, but could you please explain what evaluation items are being evaluated and whether or not the evaluation items have already been agreed upon with the authorities?

Uehara : First, the normal approval process. We are in the process of discussing the timeline with the MHLW and PMDA, so we will refrain from disclosing specific dates at this time.

As you are already aware, the current emergency approval is licensed based on approval being obtained within one year, so naturally, we would like to promptly submit all the data and proceed with the regular approval application.

Regarding your second question about long COVID, we asked all patients who participated in Phase II/III to answer the question whether or not they had long COVID symptoms at three months, six months, and one year, respectively. Naturally, we do not receive responses from all patients, but we do receive a very high frequency of feedback, mainly from Japanese patients. We are announcing that data at the February CROI meeting.

Specifically, we have asked the patients to fill out a questionnaire that includes 12 symptoms evaluated in the clinical trial, 14 COVID-19 symptoms including taste disorder and smell disorder, as well as psychiatric symptoms and various other symptoms that are said to be characteristic of post-coronavirus symptoms. They evaluated each of them as "with" or "without" and severity. We are planning to publish the results of the analysis to see how much the risk decreases when patients take the medication.

Ueda : Thank you very much. Can you also comment on whether this one is done with blinding in place and whether this evaluation item has been agreed upon with the authorities?

Uehara : All of this was done under unblinded conditions. The patients who participated in the clinical trial probably did not know whether or not they were on the actual drug, but a key was opened, so it was not a blinded evaluation.

At this point, there is no uniform method for defining long COVID and evaluating the suppressive effect of treatment. Therefore, we are considering analyzing the data we have obtained this time and discussing the results with experts, PMDA, the others and interpreting them together.

Ueda : By unblinded, do patients already know whether they were on the actual drug or the placebo?

Uehara : I think that the doctors at the facilities know, but we don't go out of our way to provide each person with an answer. Normally, patients would not be aware if it was actual medication or not.

Ueda : I understand. Thank you very much. The second question is the outlook for future R&D expenditures. What kind of level should we expect in the next fiscal year and thereafter?

I also wonder if this Xocova will have a significant impact on the level of your Company's R&D expenditures. Could you please explain the assumptions you make when formulating your R&D investment plans?

Kudou : Although some trials will be conducted in Q4 and next fiscal year to accumulate evidence and expand the indications for the COVID-19 treatment and vaccine, we do not think that the amount of money to be incurred as expenses there will be very large.

We will continue to invest aggressively in R&D to achieve STS 2030, but I hope you will consider that from the next fiscal year onward, we will return to a level somewhat similar to the R&D expenditures prior to COVID-19.

Keller : We think that there will be an impact on R&D expenses according to future strategies and activities, such as expansion of the strategic pipeline later. So we're going to calculate those spendings including Xocova sales, royalties and other factors in line with our medium- to long-term top-line outlook.

Ueda : Understood. That is all from me. Thank you very much.

Kyokawa : Mr. Yamaguchi from Citigroup Global Markets.

Yamaguchi : Thank you very much. Yamaguchi from Citi. The first question is to confirm once again the substance of the revision of the Company's forecast.

If I may ask about the part you explained, as far as Xocova is concerned, sales have not changed much, so I assume that profits increased because cost of goods and the others fell below the Company forecast. In other areas, we thought that there was a buffer of about JPY30 billion in the form of profit in the event that Xocova was not approved. Is there still remaining upside there?

Kudou : We had set some of the SG&A expenses as a buffer for investment in future growth, but there are still uncertainties regarding the global expansion of Xocova. As I mentioned earlier, we are planning to strengthen the management base, PT activities, and investment in growth drivers in line with the Medium-term Management Plan. We set the profit as the minimum number that can be achieved.

Yamaguchi : Could you tell me what date in April, if you know, is the date for the review of the medium-term plan?

Kudou : It is scheduled for the following spring, but a definite date has not yet been decided.

Yamaguchi : Finally, there were a lot of questions and answers about Xocova in Japan. Only Lagevrio is can be showed sales by IMS data, but I think it is doing quite well, of course. I think the figure is about JPY30 billion on a monthly basis.

On the other hand, I don't know the number of Xocova sales, because the IMS is not available under the national buyout, and I don't know about Paxlovid, but it is supposed to be 20,000 people, just to give you an idea. I understand that your Company is in a situation where marketing is not possible, but it seems to me that there is a bias that Lagevrio is currently used a lot and other drugs are not used much.

Please tell us the factors that contributed to this, and the possibility that this will be resolved in the future. Was there a confirmation of the drug's safety from a medical institution, feedback on the efficacy of this drug, and so on?

Iwasaki : Lagevrio, as you mentioned, is now in general distribution and the prescriptions are increasing. I think this is because it is publicly subsidized. As with Xocova, medical institutions wishing to use Paxlovid must be registered in advance, and I believe the number of registered medical institutions is currently around 13,000. If it shifts to general distribution, there is a possibility that this number will increase to nearly 40,000.

Another point is that, at present, there are procedures such as patient registration for use. If these procedures are changed from EUA to general approval, we believe that the number of patients will increase because these complications will be removed.

On the other hand, as was mentioned earlier, the new class 5 status will expand the number of potential institutions, but it is still unclear whether all general practitioners will accept coronavirus patients. It depends on the patients and the price of the drug, but assuming that public subsidies are available, we believe that a reasonable number of patients can be expected.

Yamaguchi : What feedback have you had on the drug, if any?

Iwasaki : Although it is sometimes underestimated that the improvement of clinical symptoms is only 1 day, all five symptoms are improved. On the clinical level, there are doctors who are very positive about individual symptoms such as fever reduction and improvement of sore throats. If you also consider the good antiviral effect, we have received many comments that once the drug is used, clinical and partial symptom improvement is very noticeable.

Yamaguchi : Thank you very much.

Kyokawa : Next, Mr. Sakai of Credit Suisse Securities.

Sakai : My name is Sakai from Credit Suisse. So I am sorry to be persistent, but I have two questions about Xocova.

One is the sales of JPY100 billion in Q3, how was this handled in the balance sheet? There does not seem to be much movement in balance sheet items in Q3.

Kudou : Regarding the government's purchase of JPY100 billion, the amount is divided into two installments. Currently, on the balance sheet, the first payment has already been received, and the second payment is currently recorded as trade receivables on the B/S.

We expect to see an increase in cash receipts in January as we move toward the end of the fiscal year.

Sakai : Then, since this is the government budget for March, is it my understanding that all the money will be deposited by the end of March and will be posted to cash?

Kudou : Yes. That's right.

Sakai : Thank you very much. And now, there was talk about the Category 5 and public subsidies. I think there is a bit of a risk if you think that it will automatically become a general distribution when it becomes Category 5. Could you please reiterate your Company's position on this? That is, the continuation of public subsidies, and the transition to category 5.

Iwasaki : Regarding public subsidies, other companies are still accepting them, so we are not sure if they will be fully covered until next fiscal year. There is talk of phased reductions, but we believe that public subsidies will continue through next fiscal year.

As for the transition to class 5, the Prime Minister officially announced it just last week. So it is not so much that it is related to Class 5, but rather that if it is put into general distribution and listed on the NHI drug price list, the distribution channels will be expanded and the amount used will increase accordingly. I think we still need to examine a little more closely how much of an impact there would be if it were to be class 5 on top of that.

Sakai : I'm sorry, just a confirmation. Am I correct in understanding that this will be on the agenda at the next NHI price listing?

Iwasaki : One point, which is also listed here, is the creation of special rules to expedite the so-called NHI price re-calculation due to the pandemic.

Regarding the other issue, whether the drug price should be similar to the price of coronavirus drugs or the same as the price of influenza drugs, there is a great deal of debate on this issue as well. However, since there are discussions on the establishment of such rules and new NHI pricing, it is difficult to say at this point where the issue will land.

Sakai : In other words, the government purchase price does not slide, is that correct?

Iwasaki : Yes. You can express it in that way.

Sakai : I understand. Thank you very much.

Kyokawa : Next, Ms. Kumagai of Mitsubishi UFJ Morgan Stanley Securities, please go ahead.

Kumagai : Thank you very much. I would like to ask about Xocova in Korea. Since this is where the government buyback is going to be, and since the JPY110 billion sales figure for COVID-19 related drugs has not changed this time around, can we subtract the 100 billion actual and see the remaining 10 billion as mostly South Korea? China has a December fiscal year, so I believe I have heard you say before that the sales that stand this year will be in the next fiscal year.

Keller : Regarding Korea, we are currently in negotiations.

Kudou : Regarding sales in China, as you mentioned, there is a three-month gap in the consolidated financial results, the figures up to December are reflected in the FY2022 financial results.

But if the sales are large or profitable, it is necessary to reflect them in the accounting.

Kumagai : I understand that you have a rolling submission process for China, but what is the timing of the application and the timing of approval?

Uehara : Thank you for your question. We are already in the process of rolling submissions, and as of now, we are providing all the data we can. We have received a variety of inquiries, and we are providing data as needed for additional analyses necessary for such considerations.

Kumagai : I understand. Lastly, in the HIV area, the penetration of Apretude seems to be a little slow. Is it an insurance reimbursement issue, or something like that?

Keller : There are two things to consider. Cabenuva was launched during the coronavirus pandemic, so it took a little time. Then, the purchase and billing process took a long time. There is about a 40% overlap between sites doing LA treatment and then LA prep. In the non-coronavirus window, many basic things must be done about Cabenuva. That must also apply to Apretude.

As for insurance reimbursement, it is currently on track. This is as we expected, however it would be very helpful to get more support from the government.

As for policy, there is a lot of discussion going on, but it is not yet at full support. It is on a state-by-state basis.

As you know, there is still much work to be done.

Kumagai : Thank you very much.

Kyokawa : We will conclude with the next question. Mr. Hashiguchi of Daiwa Securities, please go ahead.

Hashiguchi : Hashiguchi here. Thank you. I have two questions regarding Xocova's direction in Japan.

The first is that one of the key points for the prescription to expand significantly in the future may be that the guidelines will be rewritten. I think it says that currently the drug is to be administered to patients with no risk factors for severe disease, or that in mild cases with no risk factors for severe disease, the decision should be made with caution.

In order for the guideline to be more actively administered to a wider range of people, I believe that the guideline is still evidence-oriented, so I would like to ask what kind of data you expect to be published in the future to rewrite this guideline, including the expected timing when that data will be available.

Uehara : As indicated in the overview, under the current emergency approval, only the effect of shortening primary symptoms is included in the package insert.

First of all, as for the antiviral effect, we have already finished analyzing the results of Phase II and Phase III. We are planning to release to the public the data on the antiviral effect of the large-scale Phase III part against the Omicron strain that is currently prevalent, and how many hours and how much the virus shedding can be shortened by taking the medication.

Furthermore, there are two major aspects of not only these antiviral effects and symptom shortening, but also whether or not to take the drug, especially in those who do not have standard risk factors. The safety aspect I mentioned at the beginning. The other is that there are many people who do not have risk factors but suffer from post-infection symptoms.

We are collecting data in the Phase III part, and we are hoping that experts will review such data and, if there is evidence that the risk of post-illness symptoms can be reduced even slightly by taking the drug, we will recommend prescribing the drug in some form.

In the Phase III part, we are looking at post-illness symptoms, so it will take time to acquire data. So far we have 3-month and 6-month data, and we will present those results at the CROI conference in February. We are still collecting the one-year data.

Hashiguchi : Thank you. Will the data to be presented at the upcoming conference in February be enough to immediately rewrite the guidelines?

Uehara : It is difficult for me to give you an answer, but I hope that experts will take a look at it and consider its impact.

Hashiguchi : Thank you. The other question is about drug prices. I believe that the Chuikyo is discussing how to calculate the drug price for Xocova. As a member of the trade association, what kind of opinion would your Company like to see expressed by the trade association?

Iwasaki : The original intent for the pandemic was to predict when the seventh, eighth, or ninth wave would arrive, and based on that prediction, to cut the NHI price as quickly as possible, so then it is already possible to intentionally cut the NHI price at any time. The industry is now saying that we would like to make sure that this rule does not become universal and that it does not become a permanent system in which any drug is intentionally devalued at any time, and that the rule is only for this pandemic. We would like to make a clear request to the industry that this is a rule that applies only to this kind of pandemic.

Hashiguchi : Thank you very much. That is all.

Kyokawa : Thank you very much. This concludes the financial results briefing for Q3 of the fiscal year ending March 31, 2023 for Shionogi & Co.

[END]