SHIONOGI & CO., LTD.

1st Quarter of Fiscal 2023 Financial Results Conference Call

July 31, 2023

Presentation

Kyokawa: Thank you. I am Kyokawa, Corporate Communications, Shionogi & Co. Thank you all for joining us today despite your busy schedules.

We will now commence the Shionogi & Co financial results briefing for Q1 of the fiscal year ending March 31, 2024.

First, let me introduce today's speakers.

First is Dr. John Keller, Senior Executive Officer, R&D and Investment Strategy.

Keller: Thank you.

Kyokawa: Next, Dr. Toshinobu Iwasaki, Senior Executive Officer, Healthcare Business Supervisory Unit Pharmaceutical Commercial Division.

Iwasaki: Thank you.

Kyokawa: Next, Dr. Koji Hanasaki, Executive Officer, Supply Supervisory Unit and Global Business Division.

Hanasaki: Thank you.

Kyokawa: Next, Noriyuki Kishida, Senior Executive Officer, Corporate Supervisory Unit.

Kishida: Thank you.

Kyokawa: Dr. Ryuichi Kiyama, Senior Executive Officer, Corporate Strategy.

Kiyama: Thank you.

Kyokawa: Dr. Takeki Uehara, Corporate Officer, Drug Development and Regulatory Science.

Uehara: Thank you.

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

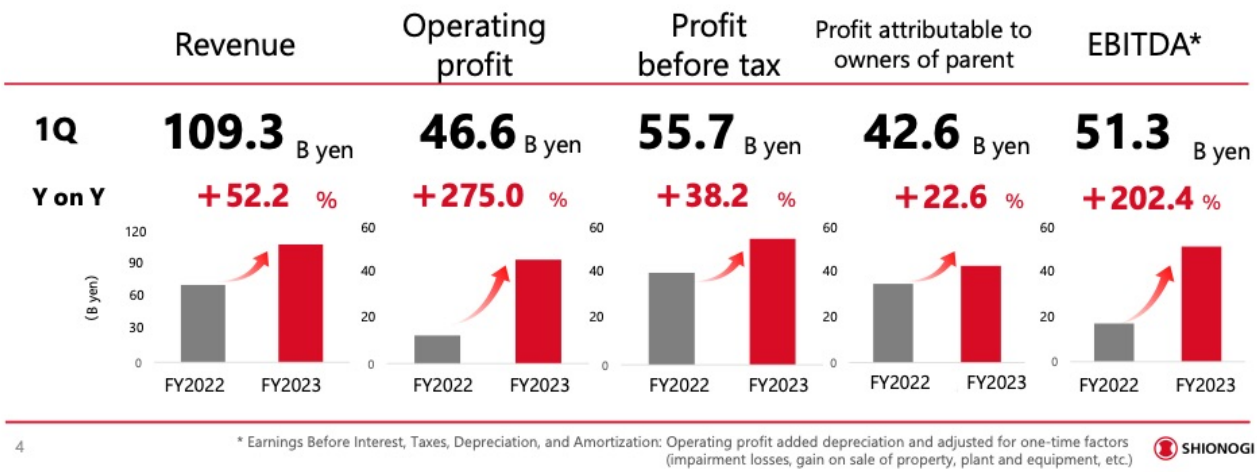
Kudou: Thank you.

Kyokawa: In today's session, first Ms. Kudou will provide an overview of the financial results. Then, Dr. Kiyama will present the main initiatives and results in Q1. Finally, we will take your questions.

Let's get started. Ms. Kudou, over to you.

Financial Highlights

- **Revenue and all profit categories increased YoY**
- **Despite continued aggressive investment, revenue and all profit reached record highs in 1Q**



Kudou: Thank you. Kudou here. I will now give an overview of the Q1 financial results.

First, on page four, are the highlights of the financial results.

For Q1 of the current fiscal year, revenue was JPY109.3 billion, operating profit was JPY46.6 billion, profit before tax was JPY55.7 billion, and quarterly income was JPY42.6 billion.

EBITDA, which was designated for the first time as a KPI in the STS2030 Revision medium-term management plan announced last month, was JPY51.3 billion.

For each, the percentage increase over the previous year is shown. As you can see, there was a significant increase in all figures, all of which were record highs for Q1.

Financial Results

(Unit : B yen)

	FY2023 Forecasts Full year	FY2023 Forecasts 1H	FY2023 Apr.-Jun. Results	FY2023 Achievement (%)	FY2022 Apr.-Jun. Results	Y on Y Change(%)	Y on Y Change
Revenue	450.0	217.0	**109.3**	**50.4**	71.8	**52.2**	**37.5**
Operating profit	150.0	80.5	**46.6**	**57.9**	12.4	**275.0**	**34.2**
Profit before tax	192.5	98.0	**55.7**	**56.8**	40.3	**38.2**	**15.4**
Profit attributable to owners of parent	155.0	78.0	**42.6**	**54.6**	34.7	**22.6**	**7.8**

Exchange Rate (Average)

	FY2023 Forecasts	FY2023 Apr.-Jun. Results
USD($) – JPY(¥)	130	137.50
GBP(£) – JPY(¥)	160	172.13
EUR(€) – JPY(¥)	140	149.59

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Continued on page five are the consolidated operating results.

Since we have not disclosed the forecast in Q1, this is the percentage of progress against the H1 forecast. We are making steady progress, as these figures are both above 50%.

Regarding foreign exchange rates, foreign exchange gains were posted in all areas due to the impact of a weaker-than-expected yen.

Statement of Profit or Loss

(Unit : B yen)

	FY2023 Forecast Full year	FY2023 Forecast 1H	FY2023 Apr.-Jun. Results	FY2023 Achievement (%)	FY2022 Apr.-Jun Results	Y on Y Change(%)	Y on Y Change
Revenue	450.0	217.0	**109.3***	**50.4**	71.8	**52.2**	**37.5**
Cost of Sales	69.0	31.5	**13.1**	**41.6**	12.9	**1.3**	**0.2**
	15.3	14.5	12.0		18.0		
Gross profit	381.0	185.5	**96.2**	**51.9**	58.9	**63.3**	**37.3**
Selling, general & administrative expenses, R&D expenses total	229.0	103.5	**49.0**	**47.4**	45.9	**6.8**	**3.1**
	50.9	47.7	44.9		63.9		
Selling, general & administrative expenses	130.0	54.0	**24.0**	**44.5**	23.4	**2.7**	**0.6**
	28.9	24.9	22.0		32.6		
R&D expenses	99.0	49.5	**25.0**	**50.5**	22.5	**10.9**	**2.5**
	22.0	22.8	22.9		31.4		
Other income & expenses	(2.0)	(1.5)	**(0.6)**	**37.8**	(0.5)	**5.8**	**(0.0)**
Operating profit	150.0	80.5	**46.6**	**57.9**	12.4	**275.0**	**34.2**
	33.3	37.1	42.6		17.3		
Finance income & costs	42.5	17.5	**9.1**	**52.1**	27.9	**(67.3)**	**(18.8)**
Profit before tax	192.5	98.0	**55.7**	**56.8**	40.3	**38.2**	**15.4**
	42.8	45.2	51.0		56.1		
Profit attributable to owners of parent	155.0	78.0	**42.6**	**54.6**	34.7	**22.6**	**7.8**

Main Variation Factors (Y on Y)

Revenue

- Increase : Domestic sales, Overseas subsidiaries /export, Royalty income

R&D expenses

- Increase : Investment in R&D activities including COVID-19 related projects

Finance income & costs

- Decrease in income: Received dividend from ViiV
  - FY2022 dividend increased temporarily for the following reasons
    - > Delayed receipt of dividends from ViiV which scheduled to be received in 4Q of FY2021
    - > Increased dividends due to ViiV receipt of lump sum payment from settlement with Gilead

⇒ Dividends are progressing as planned, excluding temporary factors

* Sales revenue includes Lump-sum income for transfer of ADHD drug

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Next comes page six, the consolidated statement of income.

As noted here, sales revenue increased significantly from the previous year due to the receipt of approximately JPY25 billion in upfront payments associated with the transfer of the license for the ADHD therapy. Even excluding that, all of our business areas, both domestic and overseas, are making steady progress.

R&D expenses increased by 10.9% YoY with solid investment in COVID-19-related and other major development projects. This is in line with the phase 2 mid-term management plan of our STS2030 vision.

Financial income and expenses were 9.1 billion yen, a significant decrease of 18.8 billion yen from the previous year. This is due to the impact of dividends last year from ViiV, which increased significantly due to the fact that we received one more dividend last year due to a delay in the payment period, and the receipt of a lump-sum payment associated with the settlement with Gilead.

Excluding these one-time effects, dividend payments are performing well as planned. For the full year, we expect regular receipts to be higher than last year.

The percentage increase from operating income to income before income taxes appears to be less than that of the previous year. This is also mainly due to a decrease in dividends from ViiV due to special factors.

Revenue by Segment

(Unit : B yen)

	FY2023				FY2022	Y on Y	
	Forecast		Apr.-Jun Results	Achievement (%)	Apr.-Jun Results	Change(%)	Change
	Full year	1H					
Prescription drugs	134.1	87.4	**45.9**	**52.5**	19.0	**141.6**	**26.9**
Overseas subsidiaries/export	96.6	28.0	**12.0**	**42.8**	8.8	**36.2**	**3.2**
Shionogi Inc. (US)	13.6	6.7	**4.0**	**60.3**	3.0	**34.5**	**1.0**
Fetroja	-	-	**3.2**	-	1.8	**82.1**	**1.4**
Shionogi B.V. (EU)	11.5	5.4	**3.0**	**54.9**	1.9	**61.3**	**1.1**
Fetcroja	-	-	**2.1**	-	1.4	**57.4**	**0.8**
Ping An Shionogi/C&O	58.0	13.2	**3.1**	**23.4**	2.5	**22.2**	**0.6**
Others	13.4	2.7	**1.9**	**69.9**	1.4	**31.7**	**0.5**
Contract manufacturing	13.8	7.3	**4.0**	**54.7**	3.4	**19.1**	**0.6**
OTC and quasi-drug	15.0	6.8	**2.3**	**33.3**	1.9	**16.6**	**0.3**
Royalty income	189.5	86.9	**44.8**	**51.6**	38.4	**16.7**	**6.4**
HIV franchise	185.0	86.0	**44.3**	**51.4**	37.3	**18.7**	**7.0**
Others	4.5	0.9	**0.6**	**65.5**	1.1	**(47.6)**	**(0.5)**
Others	1.0	0.5	**0.3**	**58.6**	0.3	**(7.3)**	**(0.0)**
Total	450.0	217.0	**109.3**	**50.4**	71.8	**52.2**	**37.5**

Main Variation Factors (Y on Y)

Prescription drugs

- Increase : Sales of Xocova
  : Receipt of Lump-sum income for transfer of ADHD drug
- Decrease: Sales of ADHD drug

Overseas subsidiaries/export

- Increase: Sales of cefiderocol (Fetroja、Fetcroja)
- Decrease: Change in Osphena sales scheme

Royalty income

- Increase: Strong sales of ViiV's HIV franchise

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Next on page seven is revenue by business segment.

Domestic sales of prescription drugs for the period from April to June totaled JPY45.9 billion, a significant increase over the previous year.

Sales of ADHD medications such as Intuniv decreased from the start of the fiscal year, but sales of COVID-19 therapy Xocova more than offset the decrease. In addition, the one-time payment for the transfer of the ADHD drug license, as explained earlier, resulted in an increase of 141.6% over the previous year.

Results for the overseas subsidiaries and exports segment also increased YoY due to the growth of cefiderocol in Europe and the US.

Progress in the Chinese business is at 23.4% of the H1 forecast. This is because we expect revenue to be weighted towards Q2, so performance is on schedule for Q1.

Royalty income grew significantly due to both actual sales and foreign exchange effects from the HIV franchise.

Prescription Drugs in Japan

(Unit : B yen)

	FY2023 Forecast Full year	FY2023 Forecast 1H	FY2023 Apr.-Jun. Results	FY2023 Achievement (%)	FY2022 Apr.-Jun. Results	Y on Y Change(%)	Y on Y Change
Infectious disease drugs	65.7	40.0	**9.3**	**23.1**	2.1	**348.9**	**7.2**
COVID-19 related products + Influenza franchise	57.3	35.8	**7.1**	**19.8**	0.1	-	**7.0**
Cymbalta	4.2	2.1	**1.1**	**52.6**	1.7	**(32.4)**	**(0.5)**
OxyContin franchise	4.1	2.1	**1.1**	**52.7**	1.2	**(6.8)**	**(0.1)**
Symproic	4.9	2.3	**1.0**	**45.2**	0.8	**29.7**	**0.2**
Actair	1.0	0.4	**0.1**	**35.0**	0.1	**13.9**	**0.0**
Mulpleta	0.1	0.1	**0.0**	**44.2**	0.0	**5.8**	**0.0**
Pirespa	1.9	1.1	**0.5**	**47.9**	0.7	**(25.7)**	**(0.2)**
Others	52.1	39.3	**32.7**	**83.2**	12.5	**162.5**	**20.3**
ADHD drug (Intuniv and Vyvanse)	25.0	25.0	**25.0**	**100.0**	4.9	**405.3**	**20.1**
Prescription drugs	134.1	87.4	**45.9**	**52.5**	19.0	**141.6**	**26.9**

COVID-19 related products
- Xocova
- COVID-19 vaccines

Influenza franchise
- Xofluza
- Rapiacta
- BrightpocFlu・Neo

Infectious disease drugs
- FINIBAX
- Shiomarin
- ISODINE
- Flumarin
- Baktar
- Flomox
- Flagyl

* Includes Lump-sum income from transfer of ADHD drug

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Page eight shows a breakdown of domestic prescription drug sales revenue.

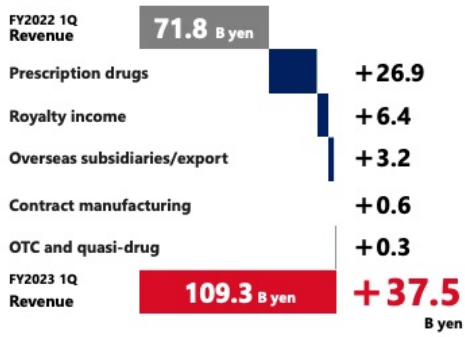
As I mentioned earlier, we have achieved solid results. Sales of COVID-19- and influenza-related products totaled JPY7.1 billion, an increase of JPY7 billion over the previous year. The bulk of the growth here came from Xocova sales.

The current situation for Xocova and its future prospects will be explained on page 11.

First Quarter Results and Progress

All businesses are strong, with top-line growing significantly year-on-year

- **Domestic**
  - Increased sales of Xocova outweighed decreased sales of ADHD drugs, resulting in overall growth
- **Overseas subsidiaries**
  - Strong growth of Cefiderocol（Fetroja, Fetcroja）
- **Royalty**
  - Strong growth of Dovato, Cabenuva, Apretude
- **Others**
  - Growth of Contract manufacturing and OTC and quasi-drug



At present, the forecast for the first half is expected to be achieved without revision

- Base business is expected to remain strong
- Steady penetration of Xocova and changes in current infection status

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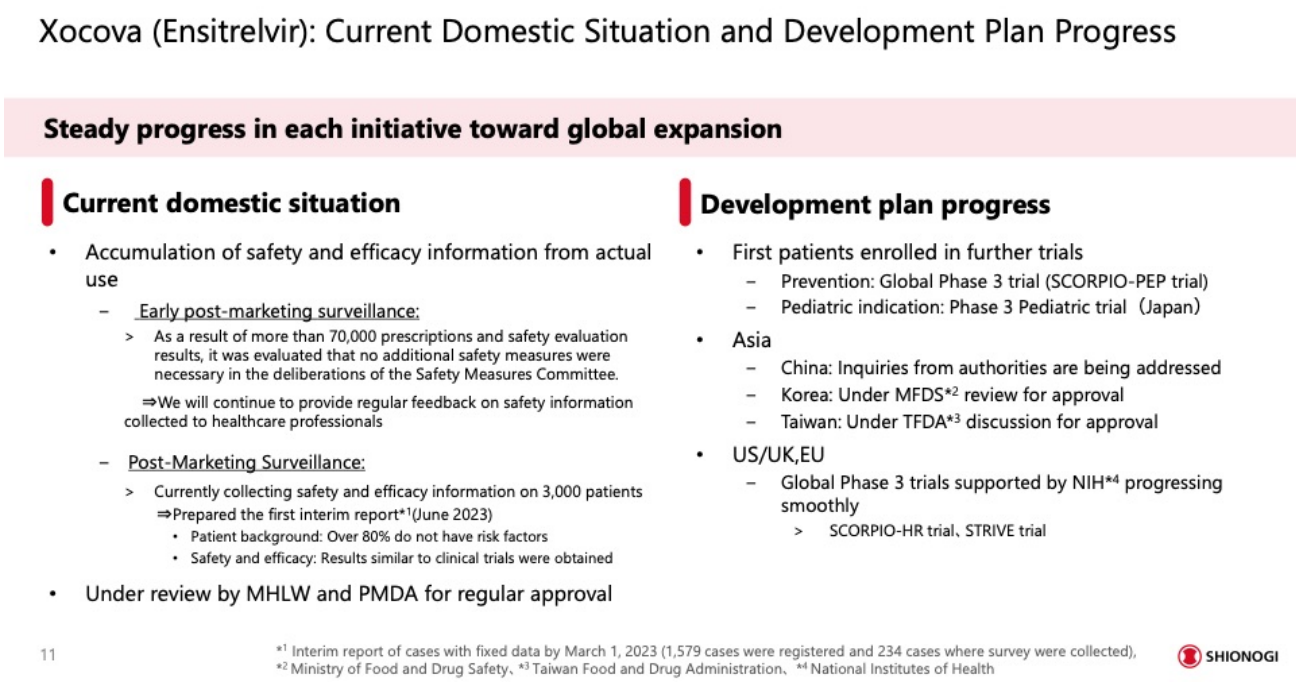
Page nine shows the Q1 summary.

Again, all business areas were strong, and the top line grew substantially YoY. Even excluding the JPY25 billion one-time payment related to ADHD, we believe that the Company's earning power is steadily increasing.

In addition to the expectation that these base businesses will remain strong, we currently believe that we will be able to achieve our H1 forecast due in part to the steady penetration of Xocova in Japan.

Thank you.



Kiyama: I will continue with a presentation of the main initiatives and results for Q1.

First, on page 11, I will discuss the current status of Xocova domestically and the progress of the development plan.

The product was launched for general distribution four months ago on March 31, and its use in Japan has made steady progress as the novel coronavirus was moved to category five status in May.

In the post-marketing surveillance conducted over a six-month period since the urgent approval, more than 70,000 patients have used the product. Safety information about the product has been accumulating. Following safety evaluation, the Safety Committee has concluded that no additional safety measures are necessary. Although the post-marketing surveillance has been completed, we will continue to report safety information collected on a regular basis.

In addition, a general use-results survey of 3,000 patients is underway to collect secondary information on safety and efficacy under actual conditions of use. The first interim report was recently submitted. As disclosed on our website for healthcare professionals, a variety of data has been collected in line with actual clinical conditions. Although this is an interim report, the results are similar to clinical trials in terms of efficacy as well as safety.

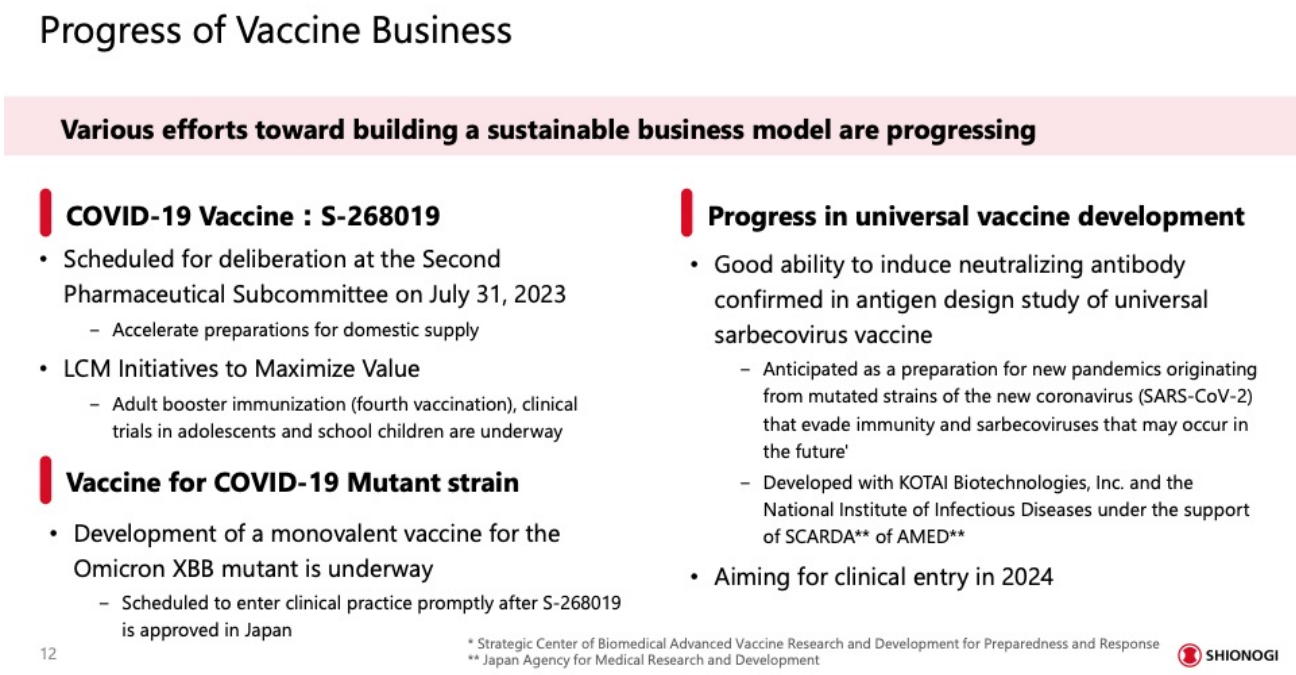
The fact that more than 80% of the registered patients have no risk factors reflects the current prescribing trend for Xocova. With current infection trends, prescribing opportunities are expanding, especially for patients without risk factors.

The right side of the slide shows the progress in our Xocova development plan.

Regarding the prevention of disease onset study and the domestic pediatric study, patient enrollment began in June, and the studies are currently in progress.

We also reported that we had filed an EUA application in Taiwan, but since the EUA application system has been terminated due to the fact that we are no longer in a pandemic, we have now started discussions with

the Taiwanese authorities for a regular approval application. We will continue to accelerate our global expansion in consultation with regulatory authorities in each country.

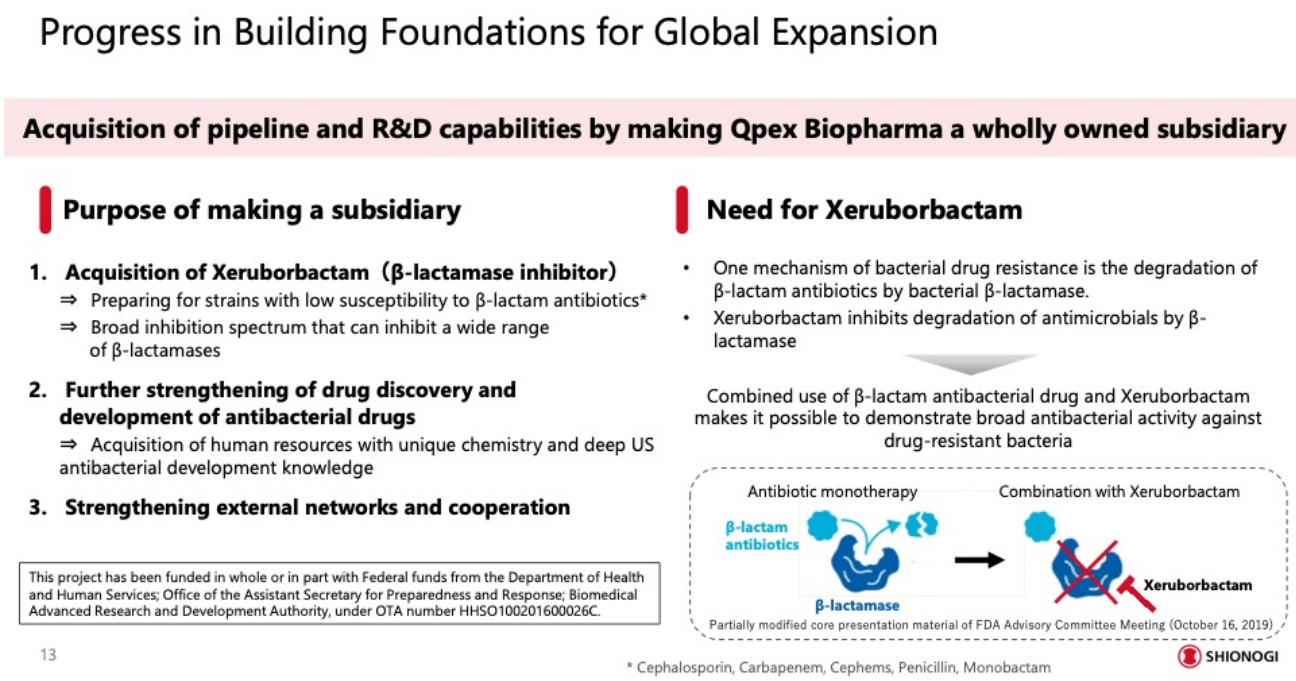


Next, on page 12, we discuss the progress of the vaccine project.

The recombinant protein vaccine S-268019 is currently being discussed at the Second Subcommittee on Drugs. We are accelerating preparations to supply the product as soon as we receive approval.

In addition, as part of our life cycle management initiatives, we are continuing to add additional indications for adolescents and school children. We are also preparing to start clinical trials for a unit vaccine for XBB mutant strains recommended by the WHO and the Ministry of Health, Labour and Welfare after the approval of S-268019 in Japan.

On the right side of the slide, you can see that we are also making very good progress with the universal vaccine and hope to start clinical trials in 2024.



Continuing on page 13, I would like to discuss progress in building a foundation for global expansion.

In June, we acquired Qpex Biopharma, a US bio-venture company, as a wholly owned subsidiary. Qpex is a venture company with strengths in research and development of antimicrobial agents, and has strong relationships with experts and solid experience working with US government organizations. We believe that the acquisition of Qpex as a subsidiary will generate a wide range of synergies in our infectious disease business, including strengthening research and development of antimicrobial agents and external collaboration.

The Company also acquired exclusive global development, manufacturing, and marketing rights for Xeruborbactam, a beta-lactamase inhibitor. When used in combination with Xeruborbactam, β-lactam antibacterial agents can exhibit broad-spectrum antibacterial activity against bacteria that are resistant to β-lactam antibacterial agents. We believe that providing a new treatment option for drug-resistant bacteria will help create an environment in which β-lactam antibacterial agents can be prescribed with confidence. We will continue to promote the development of Xeruborbactam.

Progress of Major Development Products

as of July 30, 2023

Disease area	Pipeline	Indication	Current stage	FY2023 / FY2024	Note
Infection	Olorofim	Invasive aspergillosis	Phase 3	Completion of Phase 3 case registration (4Q)	
	S-337395	RSV infections	Phase 1	Phase 1 topline results	FPI*1 (April 2023)
	S-892216	COVID-19	Phase 1	Phase 1 topline results	FPI*1 (May 2023)
QOL Diseases with High Social Impact	Zuranolone	Depression	Phase 3	Phase 3 topline results (3Q) Submission (4Q)	Add on trial LPI*2 (July 2023)
	Resiniferatoxin	Pain associated with knee osteoarthritis	Phase 3	Submission (4Q)	Breakthrough therapy designation*3
	SDT-001	ADHD	Phase 3	Submission	
	Zatolmilast	Fragile X Syndrome	Phase 2/3	Phase 2/3 topline results (2Q) Submission (3Q)	
	Redasemtide	Acute ischemic stroke	Phase 2b		
		Dystrophic epidermolysis bullosa	Phase 2	Submission (3Q)	Orphan drug designation*4
	S-309309	Obesity	Phase 2	Phase 2 topline results (4Q) Phase 3 start	FPI*1 (July 2023)
	S-531011	Solid tumor	Phase 1b/2	Phase 2 start (4Q)	
	S-151128	Chronic pain	Phase 1	Phase 1 topline results	FPI*1 (April 2023)

topline results: It is the timing of acquisition, and the timing of disclosure will be considered separately

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*1 First Patient In *2 Last Patient In *3 May 22, 2023 Grünenthal Press release *4 May 24, 2023 SHIONOGI Press release SHIONOGI

Next, on page 14, we show the progress and milestones of our major development projects.

Some of these projects are also undergoing investigator-initiated clinical trials other than those mentioned above, but only company-initiated clinical trials are shown on the slide.

The far right side of the table, in red, shows the most recent results for each project. We will explain about our focus on S-309309, an anti-obesity drug, and Resiniferatoxin, an analgesic drug, in the following pages.

Development Progress of Medium- to Long-term Growth Drivers

S-309309: Phase 2 trial overview*1 and future plans

MGAT2*2 inhibitor, novel mechanism of action

Country	U.S.
Subject	Adults with a BMI of 30 or higher
Design	Multicenter, randomized, double-blind, dose-ranging, placebo-controlled
Dosage Number of cases	• Oral once daily for 24 weeks • S-309309: 3 doses, placebo,80 in each group (320 in total)
Primary endpoint	Percent change in body weight from baseline (week 24)
Secondary endpoint	• Percentage of subjects achieving ≥5%/10%/15%/20% weight loss • Waist circumference, waist/hip ratio, BMI, abdominal fat

Plan to start global Phase 3 study immediately after obtaining POC*3 and determining optimal dose in this trial

Resiniferatoxin: favorable clinical trial results

TRPV1*4 agonist, non-opioid novel mechanism of action

Results from Phase 1 and 2

High efficacy	Long-lasting effect	High safety
Significant analgesic effect and functional improvements	An injection that can reduce pain and improve functionality by injecting once every six months on average	Favorable safety profile

Grünenthal received breakthrough therapy designation from FDA based on significant pain relief and favorable safety profile

15 *1 ClinicalTrials.gov: NCT05925114 *2 Monoacylglycerol transferase 2 (Appendix p.23) *3 Proof of Concept *4 Transient Receptor Potential Vanilloid 1 (Appendix p.24) SHIONOGI

Page 15. First, we have S-309309.

This is an anti-obesity drug with a novel mechanism that inhibits MGAT2, a monoacylglycerol transferase. It is different from the well-known GLP1 receptor agonists. This is one of our highest priority items and is being developed at top speed.

The table shows a summary of the Phase II study currently underway in the US. The efficacy and safety of S-309309 will be evaluated in a double-blind, randomized, placebo-controlled, once-daily, oral study in adults with a BMI of 30 or greater.

The primary endpoint will be the percent change in body weight from baseline at Week 24. Secondary endpoints will include the percentage of subjects who achieve a weight loss of 5%, 10%, 15%, and 20% or greater.

In addition, as a feature of this study, three doses were set in order to determine the dose that would show the maximum drug effect, both to obtain POC and to study the dose in the Phase III study. After obtaining the POC and determining the optimal dose for this study, we plan to initiate the global Phase III study as soon as possible.

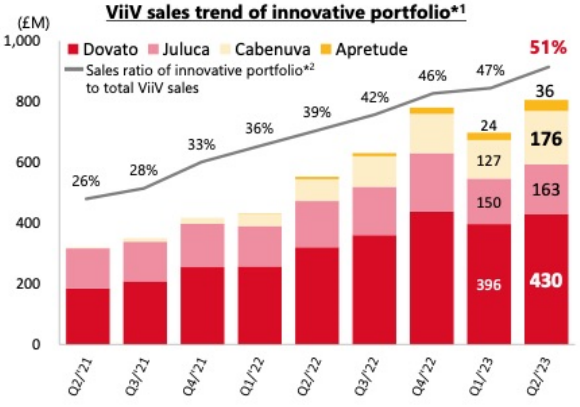
Next, on the right, we have Resiniferatoxin, introduced from Grünenthal. This is an analgesic affecting the nervous system that causes strong desensitization by acting on the enzyme TRPV1 on the sensory nerve that projects to the knee. This causes the sensory nerve to retract from the knee, thereby suppressing pain.

Currently, injections of hyaluronic acid or administration of NSAIDs, acetaminophen, and opioids are the main drug treatments for patients with knee osteoarthritis in Japan, but there is a need for a drug market with a balance between long-term efficacy and safety.

Clinical trials to date have confirmed that six-monthly administration to the knee joint significantly reduces pain and improves physical function. This dosing regimen is safe and well tolerated, and has been designated a breakthrough therapy by the FDA. These characteristics make it a drug that we are very excited about, as it has the potential to become a new treatment option to meet the unmet need of patients with osteoarthritis of the knee.

Progress of HIV Business by ViiV

Strong growth of oral two-drug regimens and LA formulations



- Sales ratio of innovative portfolio increased to 51%
- LA formulations
  - Cabenuva
    - > Compelling prescription growth driven by SOLAR study results*3
      ⇒>70% of sales from competitor regimens
  - Apretude
    - > Strong sales build in US
    - > Received positive CHMP opinion in Europe*4
- R&D pipeline includes multiple combination candidates for the creation of next-generation LA formulations
- Granted pediatric exclusivity by US FDA extending LOE by six months to April 2028

16 *1 Source: GSK financial statement *2 Oral two-drug regimens (Dovato, Julca) and LA formulations (Cabenuva, Apretude) *3 GSK press release (February 23, 2023) *4 GSK press release (July 24, 2023)

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Continuing on page 16, we look at the progress of ViiV's HIV business.

The bar graph on the left shows quarterly sales of new products, including Dovato and Juluca (oral regimens) and Cabenuva and Apretude (LA formulations). These are the main drivers of growth in the HIV business as a whole.

The line graph shows the percentage of sales of these four products to ViiV's overall anti-HIV drug sales. This proportion has recently risen to 51%.

Among the LA products that are particularly important for mid- to long-term growth, Cabenuva, which is indicated for treatment, showed significant sales growth, increasing by approximately GBP50 million in the previous quarter YoY. We believe this is the result of the SOLAR study comparing Cabenuva to Gilead's Biktarvy. This trial showed that approximately 90% of trial participants preferred treatment with Cabenuva over daily oral medications. In fact, we have heard that many clinics in the US are eagerly awaiting the start of Cabenuva administration.

We are also confident of future growth, as more than 70% of patients prescribed Cabenuva switched from a competitor's product.

Sales of Apretude, indicated for prophylaxis, also showed steady growth in the US.

We have also received a recommendation for approval from the European CHMP, and the European Commission will decide whether or not to approve the product. We consider this recommendation to be an important step toward approval.

In addition, ViiV plans to hold an HIV briefing in late September to provide an update on its mid- to long-term strategy, with a focus on its LA formulation.

Page 17. This section summarizes human capital management initiatives to achieve the 2030 Vision.

Since the time when STS2030 was formulated, the entire Shionogi Group has shared the eagerness to acquire new capabilities necessary for growth, and has been actively engaged in reskilling and training.

In July last year, we also established the Human Capital Strategy Office to study and implement various initiatives to maximize human capital. We have also been reforming and rerating our personnel system with the aim of accelerating Shionogi's growth with a diverse workforce, and introducing telecommuting and a four-day workweek to create an environment in which employees can work more comfortably. Furthermore, we have accelerated efforts to review our human resource portfolio, including the establishment of a JV with Accenture regarding indirect operations and the implementation of an early retirement program.

In the future, we will aim to achieve our 2030 vision by appointing external human resources with highly specialized skills, further strengthening the development of human resources who can respond to globalization, engaging in reforms to create an organizational culture that generates more challenges, and building a human resource portfolio that will enable growth.

Acquisition of Own Shares and Cancellation of Treasury Shares

- **Acquisition of own shares in consideration of the stock price level, which we believe is undervalued, and of our performance trend**
- **A record high of 75 billion yen (upper limit)**

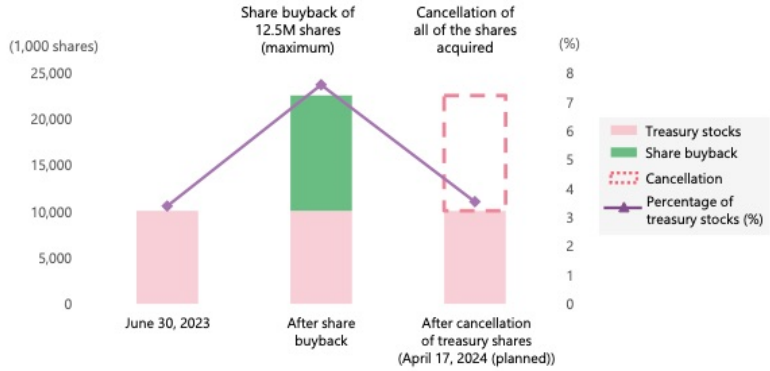
Share buyback

- Total number of shares to be acquired: 12,500,000 shares (maximum)
- Total amount of acquisition cost: 75 billion yen (maximum)
- Period of acquisition: August 1, 2023, to March 31, 2024

Depending on investment opportunities, market environment and other factors, it is possible that no share repurchase, or a share repurchase of only a portion of the above, will be carried out.

Cancellation of treasury shares

- Number of shares to be cancelled : All of the shares acquired
- Scheduled date of cancellation: April 17, 2024 (planned)



SHIONOGI

Lastly, we are committed to shareholder returns.

As part of the financial strategy for phase 2 of the "STS" medium-term management plan, the Company has decided to conduct a new buyback and cancellation of treasury stock.

The share repurchase program will be conducted from August 1 through March 31, 2024, for up to 12.5 million shares and JPY75 billion. This time, we plan to acquire the largest amount ever, taking into consideration the undervalued stock price level and performance trends. We will continue our efforts to strengthen shareholder returns and improve capital efficiency.

Thank you.

Kyokawa: Thank you.

Question & Answer

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

Mr. Yamaguchi of Citigroup Global Markets, please go ahead.

Yamaguchi : Yamaguchi here. I have two questions.

First of all, I don't have Xocova's stand-alone sales disclosure, but it seems to me that the flu, or the common cold, or various other things were going around, but looking only at IQVIA, I think Lagevrio is still selling quite well. It appears that it still needs to grow in terms of this prescription rate and market share. Could you please explain how you see the current situation?

Iwasaki : Iwasaki here I will answer your question.

Regarding Xocova, I have just read from an external data source that the overall treatment rate for the three drugs is roughly less than 20%. I don't know the exact information because it is from a fixed point of observation, but it is probably close to that. We believe that 60% of these patients were prescribed Xocova, which is mainly used in patients without risk factors.

Although it is said that the ninth wave has or has not arrived, we believe that the peak will be reached in August and September. We would like to improve the overall treatment rate first.

Yamaguchi : Thank you very much.

Just a quick follow-up, has the treatment rate gone up? I seem to recall that it was originally about 10%.

Iwasaki : It is gradually rising.

Yamaguchi : I see. Thank you very much.

Next, regarding the anti-obesity drug S-309309, according to clinical.gov, Phase II will take until April next year. I wonder if there is a possibility of interim analysis. I understand that your company will continue to work independently even after going to Phase III, but since the GLP1 player is very strong, I think it will be necessary to consider administration with GLP1, for example. Please tell us if there is any possibility of joint development in this area on a global basis.

Uehara : Thank you for your question. Uehara here.

As for S-309309, since the sample size itself is not that large, the evaluation will be conducted in a blinded fashion until the time of the primary endpoint evaluation at six months after the completion of the enrollment.

We are still in a state of flux, although we hope to have finished recruiting patients by the end of Q4.

As you pointed out, there is no doubt that the drug has great potential for combination administration, and we have received very strong deals and various offers from potential alliance partners outside the Company. Based on the results of the Phase II POC, we will continue to discuss what kind of alliance strategy we will adopt.

Yamaguchi : So there is a possibility of an alliance, and it's something you are considering.

Uehara : Of course. Relying on an alliance will delay the start of Phase III, so we will continue to shorten the timeline where we can, but we will also consider partnering.

Yamaguchi : Thank you. That is all.

Kyokawa : Thank you very much.

Next, Mr. Ueda from Goldman Sachs.

Ueda : Ueda, Goldman Sachs.

I would like to know about the situation with Xocova. I wonder if the progress rate in H1 is low in relation to the plan for infectious disease drugs this time. Could you give us your view of the progress against this plan and if there are any bottlenecks in the way of expanding prescriptions?

Iwasaki : Iwasaki here.

In terms of progress, the number of patients has not increased significantly, so I think sales themselves are not so good, but I think we have achieved a milestone in terms of prescription rate, which is 60% among the three drugs.

Since it has been classified as a 5th class, there is no restriction on expanding the number of facilities that prescribe Xocova, but medical institutions that provided outpatient fever treatment services are still mainly providing medical care that does not prescribe antiviral drugs. We are also working with academic societies and medical associations, as well as local governments, to promote the need for drug treatment. Based on the data coming out about Long COVID, we are aiming to increase the overall prescription rate of therapeutic drugs.

Ueda : Thank you very much.

Second, I would like to ask about the situation with cefiderocol. I think growth is very high compared to the same period last year and compared to the plan, and also progress is very strong.

Hanasaki : Hanasaki here.

As for the progress of cefiderocol, especially in the US, we are developing new facilities, but another factor is repeat orders at facilities following first use. In this sense, we believe that the current trend is steady, as the actual use of the medicine, the confirmation of its effectiveness, and the repeat use of the medicine have started to work well together.

In Europe, the product was launched in Spain in November last year. Negotiations regarding reimbursement in Italy and Germany have progressed well, and the market is currently growing at or above the planned level.

Thank you.

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

Kyokawa : Thank you very much.

Next, Mr. Hashiguchi of Daiwa Securities, please go ahead.

Hashiguchi : Hashiguchi here. Thank you.

Can you update us on the status of the approval for Xocova in China? I would like to know whether it is likely that you will be able to achieve your sales plan in China for this fiscal year, or if you will not be able to do so.

Hanasaki : Hanasaki here.

We have already submitted the data to the authorities, and we are in the process of discussing with them and responding to their inquiries in preparation for the application.

In China, the second wave of the outbreak gradually occurred in May and June. Considering the interval from the first wave, it takes about six months for antibody titers in the blood to drop, so there is a possibility that the third wave will occur this winter. In particular, from the viewpoint of preventing the spread of infection, we expect that this drug, which has a strong viral suppression effect, will be very promising.

Hashiguchi : Thank you very much.

Also, I think you explained that you can achieve your plan for H1, but I think the expenses for the special early retirement program, such as the special transfer payment, are scheduled to be recorded in Q2. Was this part of your original plan? Even if it is outside the plan, will other factors be sufficient to achieve an upward swing? Are you speaking in terms of excluding this impact? What is the best way to think about this?

Kudou : Kudou here.

Forecasts related to the special retirement program are not currently factored in, but the monetary impact of the program is currently under scrutiny based on the status of applications.

On the other hand, as I mentioned earlier, we believe that progress in H1 is very good, and we expect to achieve our goal with the inclusion of this factor.

Hashiguchi : Thank you very much. That is all.

Kyokawa : Thank you very much.

Next, Mr. Sakai from Credit Suisse Securities.

Sakai : Sakai, Credit Suisse.

Regarding Xocova, on the right side of page 11, you write about the situation in the US. I think there was a long COVID trial, is that included in SCORPIO? I would like to have a progress update on the status regarding long COVID. Can you tell me if there are any changes, or if any data is coming up, or if you see any trends?

Uehara : Thank you for your question. Uehara here.

As you can see from the slides, we presented data on long COVID at the CROI meeting. Specifically, we presented data on the three-month and six-month follow-up, which is the Phase III part of the current Phase II/III trial conducted mainly in Asia.

Now that the results of the 12-month follow-ups are available, we are preparing a late-breaking abstract for presentation at the European Society for the Study of Respiratory Infections (ESWI) conference scheduled for September. We are confident that our results will meet your expectations, and we hope that you will check our conference presentation materials or press releases for further information.

In the global SCORPIO-HR study, based on the evidence from 2/3 of the SR studies, we are now conducting a study to see if it is possible to reduce the risk of long COVID in countries around the world, with a pre-defined method of aggregating endpoints. We are currently conducting this study.

We are now in the process of accumulating cases. It will take some time, because this is a large-scale study. More than half of the cases have already been accumulated. We are now conducting the study so that we can disclose the results as soon as the study is completed.

Sakai : I understand. So it will be September, in any case.

One more thing that I think was a little bit interesting, on page 14, at the top of the progress of development projects, is Olorofim. I believe that F2G has filed in the US and have received a Complete Response Letter from the FDA. I think that was June.

However, the announcement said that your company will be collecting data in the future in consultation with the FDA, but this is a global item, so I was wondering if you could give us some update on your company's involvement, and then what the situation will be in Japan.

Uehara : Thank you for your question.

As you said, we have already received the results of the review in the US. However, we had been communicating with the FDA in response to F2G's strong desire to accelerate the application for approval based on the data obtained during the interim analysis. We have been trying to obtain an accelerated approval with limited data. The FDA has commented that additional data are still needed.

Incidentally, the final data set of all 200 cases, not the interim data, is now available. Based on this data, we are discussing with the FDA whether an early approval path is possible in the US. This is the current situation in the US.

We are only in a position to file for approval in the US. We are conducting Phase 3 studies in parallel in Japan, Asia, and Europe, where we have licensed the product.

Phase I trials are progressing smoothly, so we will be able to accumulate cases in Japan and China in order to complete the Phase III trials in 2023 or 2024.

Sakai : Thank you very much. Just to confirm, in terms of data, is the 200-case package complete in the US?

Uehara : The data are now available.

Sakai : Was that finalized after receipt of the Complete Response Letter?

Uehara : You are right.

Sakai : So it was after that?

Uehara : Yes.

Sakai : I understand. Thank you very much.

Kyokawa : Thank you very much.

Next, Mr. Wakao from JPMorgan Securities.

Wakao : Wakao, JP Morgan. Thank you.

I would like to ask you about Xocova. First, a question about the situation in Japan. The figure including Xocova in the April-June period was JPY7.1 billion. Can we assume that most of that figure is Xocova? I think it includes Xofluza and other factors, but I would like to know more about the breakdown of this JPY7.1 billion figure.

I believe that Xocova has been widely distributed in the market since coronavirus was categorized as class five. I think that sales to build up inventory are also included in this figure. What kind of image should we have in terms of inventory when considering this JPY7.1 billion figure? That's my first question.

Iwasaki : Iwasaki here.

I cannot give details of the breakdown, but as you have just commented, most of it is Xocova.

The number of cases is currently increasing, so it is not the case that there is an inventory buildup taking place.

Wakao : Understood. Thank you very much.

I would also like to ask about Xocova in China. Considering the current infection situation in China, and considering the status of oral drugs approved in China, even if they are approved, I believe it will be difficult to achieve the JPY40 billion to JPY50 billion that had been projected for H2. In particular, with regard to China, I believe that the accounting has been delayed by three months, so I was wondering if you could tell us a little more about the certainty of achieving the forecast of JPY40 billion to JPY50 billion in sales by December, after obtaining approval.

Hanasaki : Hanasaki here.

We have already submitted the data to the authorities and are discussing the matter with them.

As I commented earlier, based on the first and second wave of infections to date, we believe that infections will probably occur during the winter season. At that time, from the perspective of infection prevention, as I mentioned earlier, we are expecting an increasing need for this drug, thanks to its strong antiviral effects. In this sense, we expect approval and sales of this drug to progress, especially in H2.

Wakao : I think that oral therapeutics have already been approved, and my sense was that the ones that have already been approved would be used first. Is that being too pessimistic or conservative? Am I correct in assuming that if your Company obtains approval, it will be treated the same as existing drugs and sales will pick up?

Hanasaki : Imported drugs include Pfizer’s Paxlovid and Merck's molnupiravir, both of which are available in Japan and China. However, compared to these products, our encitrelvir has a stronger antiviral effect, so there is a need in that sense.

Wakao : I understand. That is all.

Kyokawa : Thank you very much.

Next, Mr. Barker from Jefferies.

Barker : Thank you. Stephen Barker, Jefferies.

First, with respect to Xocova, I would like to ask about the number of patients. I would like to know the number of COVID patients in Japan, the situation on the ground and the outlook. I think the co-payment for patients

is zero now, but how much will it be after September? Do you expect that to affect demand? I believe there will be an NHI price revision in April. What will happen to the NHI price for Xocova? Those are my questions about Xocova. Thank you.

Iwasaki : Iwasaki here.

Since the shift to category five, we do not know the exact number of patients. Based on various analogies, we estimate that 70,000 to 100,000 patients are now being infected each day. For the ninth wave, we can't be sure, but we think the peak will be in mid-August, or even October. We estimate that the number of patients will peak at 80% of the previous eight waves.

Next, regarding NHI drug prices and public funding, we have no control over this issue, so it is up to the government to make a decision. In May, the Japanese Association for Infectious Diseases made a request to the government that the use of public funds continue.

Some doctors are concerned that the current treatment rate is as low as 10% or 20%, as we have been saying regularly. When we see the next pandemic or wave this winter, if the subsidies are removed, the treatment rate will drop even further if the patients have to pay out-of-pocket.

For this reason, the academic societies have requested the extension of public subsidies. We are also making this request to the government, using our post-marketing and long COVID data to make the case for extended public subsidies. However, we cannot do this alone, so we would like to cooperate with the national government and academic societies.

As for the NHI price revision, we have not heard anything about that yet, so I cannot say today what will happen.

Barker : Thank you.

I would also like to ask about COVID-19 vaccine, S-268019. I understand that it is already being considered by the second subcommittee. If there is a positive result, when is the formal approval likely to be given? I think you are already in discussions with the government. Is there any word on the government purchasing it? Please tell us what you think about vaccine sales.

Iwasaki : Iwasaki here.

Normally, the items to be discussed would be posted a week or more in advance, but this time it was just before the meeting, and since we were notified that there would be no special review of coronavirus-related items, we are not sure when we will get approval through the subcommittee. I am not sure when it will pass through the subcommittee for approval, but I think it will not be too late.

We have not yet received a clear answer as to whether the government will or will not purchase the product, so we will be negotiating the purchase amount and price in earnest from now on, once we receive approval.

We are preparing to offer the product to the market as soon as we obtain approval, negotiate the price, receive the purchase, and decide on the distribution destination.

Barker : I understand. Thank you very much. That is all.

Kyokawa : Thank you very much.

Next, Mr. Tsuzuki from Mizuho Securities.

Tsuzuki : Tsuzuki, Mizuho Securities. I too would like to ask one question each on the coronavirus treatment and the vaccine.

First of all, regarding the treatment, if we consider the number of infections based on the fixed-point reports, from April to June and from July onward, the number of infections has tripled. The first and most important point is whether that understanding is correct.

The other is with regard to the situation on the ground, what has been the effect of immune imprinting? Regarding neutralizing antibodies, with a vaccine, even if a new one is given, the antibody level won't increase much. With that in mind, the demand for antiviral drugs may increase in H2. I would like to ask first about the treatment.

Uehara : Uehara here.

As you have already seen, the number of cases of infection is gradually increasing again. The number of cases in July has increased compared to the April-June period.

As Dr. Iwasaki mentioned at the beginning of this presentation, we have a 60% share of the market, and our market share is growing, especially among those who do not have any risk factors. Physicians and patients appreciate the benefits of reducing symptoms quickly and eliminating the virus. This is why our market share is growing.

The number of patients has increased, and the number of facilities using our products has also been gradually expanding. Therefore, we expect that sales will gradually increase.

As for the vaccine, it depends on the acquired immunity of the vaccine and neutralizing antibodies, as well as the prevalent virus strains that change. At present, infections are increasing among people who have previously been infected. In this situation, a vaccine for a different virus called XBB has been recommended, and we believe that the number of outbreaks will continue to increase.

This may be taken as bullish, but we believe that Xocova's sales will be solid in Q2 also.

Tsuzuki : Thank you very much.

My other question is about vaccines. I believe that there is a vaccine that is being developed for the XBB mutant strain, which you have just disclosed for the first time. Some may say that unlike an mRNA vaccine, the immune imprinting effect is limited for this vaccine type. How would you respond to this? I would also like to know about the progress of the expansion of manufacturing capacity. Thank you.

Uehara : Thank you for your question.

The modality of our vaccines is of course different, so the characteristics are different. We ourselves do not have the human XBB data at this time. However, the current prototype of the vaccine against the Wuhan strain has been shown to induce immunity relatively well and to sustain it for a long period of time, so I have high expectations that the XBB vaccine will be very useful by using the same manufacturing process to make recombinant protein vaccines and antigens.

We are now diligently acquiring such data, and we are in the process of acquiring clinical data and delivering new options as soon as they are ready.

Hanasaki : I will say a few words about manufacturing.

As for the production of S-268019, we are now moving forward with the initial production at the UMN Akita plant.

Unfortunately, we are still in the process of improving the cell culture and purification processes and other processes in order to scale up from the scale in Akita to the scale at UNIGEN in Gifu. We are currently considering the possibility of scaling up from the Akita scale to the UNIGEN scale.

We would also like to attempt manufacture at an intermediate scale, and we are moving forward with this, including the activities of our consignment partners. We would like to establish a production system that can flexibly produce products in various scales.

Tsuzuki : Understood. Thank you very much.

Kyokawa : Thank you very much.

Next, Ms. Sogi of Sanford C. Bernstein.

Sogi : Sogi, Bernstein. I have questions regarding the vaccine and the back office JV with Accenture. First, two questions regarding vaccines.

I understand that this vaccine cannot be used against Omicron or some other mutant strains. I would like to know how much you actually expect this vaccine to be used in the market after it is approved, including sales figures if possible.

Regarding the joint venture, I would like to know a little more about what exactly it entails. Please tell me the cost impact and in what time frame you expect to realize it.

Iwasaki : I will take the questions about the vaccine.

It is true this is not a mutant strain-specific vaccine, but we have seen neutralizing antibodies against mutant strains in non-clinical and other studies, and this information has been confirmed. We do not have clinical data showing a reduction in severity, or reduction on mortality. However, given the increase in neutralizing antibodies, we are confident that this vaccine will prove its worth.

Regarding messenger RNA in particular, a considerable number of people avoid vaccines because of pain or lethargy, especially when additional immunization is given. Our vaccine is compatible with the Wuhan strain, but we are also looking at additional immunity after the administration of mRNA vaccines. We are also considering vaccination for those who are avoiding the messenger RNA vaccine from the viewpoint of safety.

As for sales, as I mentioned earlier, this will be a matter of negotiation with the government, so at this point we have a blank slate.

Kishida : I will take your question about the JV.

Shionogi Business Partner, which was our subsidiary until the end of June, was originally a company that undertook all the practical operations of the group's administrative divisions, such as human resources, general affairs, and accounting. From a medium- to long-term perspective, it would be difficult to send personnel there in the future.

It is difficult for us to concentrate on our core and on investing in these human resources. We also knew that it would be difficult to train and mentor employees there, so we decided to partner with Accenture in order to achieve both overall cost control and growth and development of the employees who are currently transferred to Shionogi Business Partners, or who are employed by Shionogi Business Partner itself.

We are not disclosing specific efficiency figures, but we have decided to enter into a contract with Accenture with a slightly longer term view. We have agreed with them that we will improve efficiency to this extent over a slightly longer term of 10 years or more, and the contract will be divided equally over 10 years. We expect to be able to control labor costs and outsourcing costs to a certain extent.

Thank you.

Sogi : Thank you very much.

Kyokawa : Thank you very much.

This concludes the presentation of the first quarter financial results for the fiscal year ending March 31, 2024 for Shionogi & Co.

Thank you very much for joining us today.