SHIONOGI & CO., LTD.

1st Quarter of Fiscal 2025 Financial Results Conference Call

July 28, 2025

Presentation

Kyokawa: Thank you all very much for joining us today despite your busy schedules. My name is Yoshimasa Kyokawa, Vice President, Corporate Communications Department of Shionogi. We are starting Shionogi & Co., Ltd.'s financial results briefing for Q1 of FY2025.

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

Keller: I am Keller. Thank you.

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

Iwasaki: My name is Iwasaki. Thank you.

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

Uehara: This is Uehara. Thank you.

Kyokawa: Next, Masako Kudo, Corporate Officer, Senior Vice President, Corporate Strategy Division

Kudo: I am Kudo. Thank you.

Kyokawa: And finally, Takuji Fujiwara, Vice President, Finance and Accounting Department.

Fujiwara: I'm Fujiwara. Thank you.

Agenda

01 **Overview of Q1 FY2025 Financial Results** **(P.3-8)**

02 **Progress of HIV Business** **(P.9-11)**

03 **Toward the Realization of the 2030 Vision** **(P.12-23)**

- Integration with JT Pharmaceutical Division
- Advancement of the Pipeline

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Kyokawa: Now, let me explain the flow of the briefing session today. Page two, please.

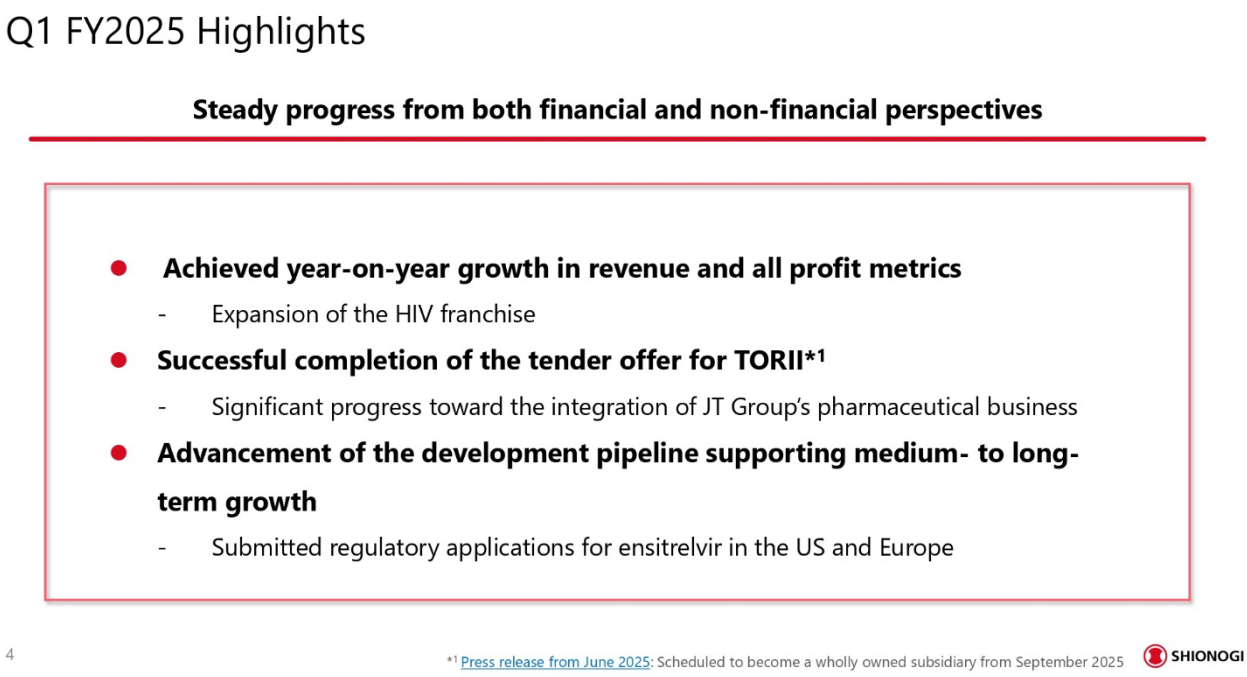
First, Fujiwara will give an overview of the Q1 financial results for FY2025.

Next, John Keller will explain the progress of the HIV business and the significance of M&A with the JT Group pharmaceutical business.

Uehara will then explain the progress of the development pipelines.

We will also take time for questions and answers at the end of the session.

Let’s begin. Mr. Fujiwara, please go ahead.



Fujiwara: So I will begin by presenting the highlights of Q1 on page four.

Q1 saw steady progress on important initiatives, both financial and non-financial. On the financial side, revenue and all profit metrics increased from the previous year. On the non-financial side, the tender offer for Torii Pharmaceutical was completed and progress was made toward merger and acquisition of the pharmaceutical business of JT Group.

In addition, we are making progress in our development pipelines, which will drive growth in the medium to long term, including the filing of ensitrelvir in Europe and the US.

Financial Results

Achieved year-on-year increases in revenue and across all profit categories

(Unit: B yen)

	FY2025				FY2024	Y on Y	
	Forecast Full year	Forecast 1H	Apr.-Jun. Results	Achievement (%)	Apr.-Jun. Results	Change (%)	Change
Revenue	530.0	233.0	**99.8**	**42.8**	97.6	**2.2**	**2.2**
Operating profit	175.0	82.0	**35.1**	**42.8**	28.1	**24.9**	**7.0**
Profit before tax	222.0	102.0	**46.3**	**45.4**	36.5	**26.8**	**9.8**
Profit attributable to owners of parent	180.0	86.0	**39.4**	**45.8**	30.6	**28.5**	**8.7**
EBITDA*1	196.0	93.0	**40.6**	**43.7**	33.1	**22.8**	**7.5**

*1 Earnings Before Interest, Taxes, Depreciation, and Amortization: Operating profit added depreciation and adjusted for one-time factors (impairment losses, gain on sale of property, plant and equipment, etc.)

I will continue on page five with an overview of the Q1 financial results.

On page five, we present the details of consolidated financial results.

For Q1 of FY2025, revenue is JPY99.8 billion, an increase of JPY2.2 billion from the same period last year. Operating profit was JPY35.1 billion, up JPY7 billion from the previous year. Profit before tax was JPY46.3 billion, an increase of JPY9.8 billion from the previous year. Profit attributable to owners of parent was JPY39.4 billion, an increase of JPY8.7 billion versus the previous year. EBITDA was JPY40.6 billion, an increase of JPY7 billion from the previous year.

We were able to achieve YoY increases in both revenue and all profit categories. I will explain this in detail from the next page onward.

Statement of Profit or Loss

(Unit: B yen)

	FY2025				FY2024	Y on Y	
	Forecast Full year	Forecast 1H	Apr.-Jun. Results	Achievement (%)	Apr.-Jun. Results	Change(%)	Change
Revenue	530.0	233.0	**99.8**	**42.8**	97.6	**2.2**	**2.2**
Cost of Sales	16.6 88.0	14.2 33.0	12.3 **12.3**	**37.3**	14.8 14.4	**(14.7)**	**(2.1)**
Gross profit	442.0	200.0	**87.5**	**43.7**	83.1	**5.2**	**4.3**
SG&A*1, R&D expenses total	49.6 263.0	49.8 116.0	51.3 **51.2**	**44.1**	55.9 54.6	**(6.2)**	**(3.4)**
SG&A*1	24.7 131.0	24.9 58.0	26.4 **26.3**	**45.4**	25.8 25.1	**4.6**	**1.2**
R&D expenses	24.9 132.0	24.9 58.0	24.9 **24.9**	**42.9**	30.2 29.4	**(15.4)**	**(4.5)**
Other income & Expenses	(4.0)	(2.0)	(1.2)	**58.6**	(0.5)	**152.8**	**(0.7)**
Operating profit	33.0 175.0	35.2 82.0	35.2 **35.1**	**42.8**	28.8 28.1	**24.9**	**7.0**
Finance income & costs	47.0	20.0	**11.2**	**56.2**	8.4	**33.5**	**2.8**
Profit before tax	41.9 222.0	43.8 102.0	46.4 **46.3**	**45.4**	37.4 36.5	**26.8**	**9.8**
Profit attributable to owners of parent	180.0	86.0	**39.4**	**45.8**	30.6	**28.5**	**8.7**

Main variation Factors (Y on Y)

Revenue
- Increase: Royalty income
- Decrease: Overseas subsidiaries /export, Prescription drugs

Cost of Sales
- Decrease: Changes in product mix

SG&A
- Increase: Selling-related expenses in US business

R&D expenses
- Decrease: Multiple large-scale clinical trials were conducted in FY2024
  - Ensitrelvir Phase 3 trials
  - S-309309 Phase 2 trial

Finance income & costs
- Increase: Dividends from ViiV
  - Strong sales performance in the HIV franchise

*1 Selling, general & administrative

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Page six, the Consolidated Statement of Profit or Loss.

As for revenue, while domestic and overseas business declined YoY, the HIV business grew strongly.

As for expenses, cost of sales was JPY12.3 billion, down JPY2.1 billion from the same period last year. The main factors were changes in the mix of segments and products, with an increase in royalty income offset by a decrease in sales of products with relatively high cost ratios.

SG&A expenses were JPY26.3 billion, an increase of JPY1.2 billion from the previous year, due to an increase in sales-related expenses in the U.S. business.

Research and development expenses totaled JPY24.9 billion, a decrease of JPY4.5 billion from the same period last year. As for R&D, this area was affected by the multiple large-scale clinical trials conducted in the previous fiscal year, and investments to nurture growth drivers are progressing as planned.

Financial income and costs landed at JPY11.2 billion due to higher dividend income from ViiV as a result of strong sales in the HIV franchise.

Each of the profit categories, all of them, increased significantly from the same period of the previous year.

Revenue by Segment

(Unit: B yen)

	FY2025				FY2024	Y on Y	
	Forecast Full year	Forecast 1H	Apr.-Jun. Results	Achievement (%)	Apr.-Jun. Results	Change(%)	Change
Prescription drugs	183.0	62.0	**14.1**	**22.8**	15.4	**(8.5)**	**(1.3)**
Overseas subsidiaries/export	54.9	25.7	**14.2**	**55.4**	15.0	**(4.9)**	**(0.7)**
Shionogi Inc. (US)	22.6	10.9	**6.2**	**56.8**	6.0	**3.7**	**0.2**
Fetroja	-	-	**5.9**	-	4.8	**23.2**	**1.1**
Shionogi B.V. (EU)	16.9	8.3	**4.7**	**56.7**	4.0	**17.4**	**0.7**
Fetcroja	-	-	**3.4**	-	3.1	**10.6**	**0.3**
Shionogi China	7.0	3.5	**1.5**	**42.8**	2.3	**(34.7)**	**(0.8)**
Others	8.4	3.0	**1.8**	**61.3**	2.7	**(31.6)**	**(0.9)**
Contract manufacturing	13.2	6.5	**4.5**	**68.5**	3.6	**24.1**	**0.9**
OTC and quasi-drug	18.5	8.9	**2.4**	**27.2**	2.4	**0.1**	**0.0**
Royalty income	257.9	128.7	**63.9**	**49.7**	61.0	**4.7**	**2.9**
HIV franchise	244.8	125.8	**61.2**	**48.6**	59.8	**2.3**	**1.4**
Others	13.1	2.9	**2.7**	**94.5**	1.2	**125.0**	**1.5**
Others	2.5	1.2	**0.6**	**52.7**	0.2	**282.1**	**0.5**
Total	530.0	233.0	**99.8**	**42.8**	97.6	**2.2**	**2.2**

Main variation Factors (Y on Y)

Prescription drugs
- Decrease: Sales of acute respiratory virus infection treatments

Overseas subsidiaries/export
- Increase: Sales of cefiderocol (US and Europe)
- Decrease: Sales of China business

Contract manufacturing
- Increase: Supply of APIs to ViiV and Roche

Royalty income
- Increase:
  - HIV franchise: Sales generated by ViiV
  - Others: Royalty income from Roche
    - > Influenza outbreaks in China and US

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

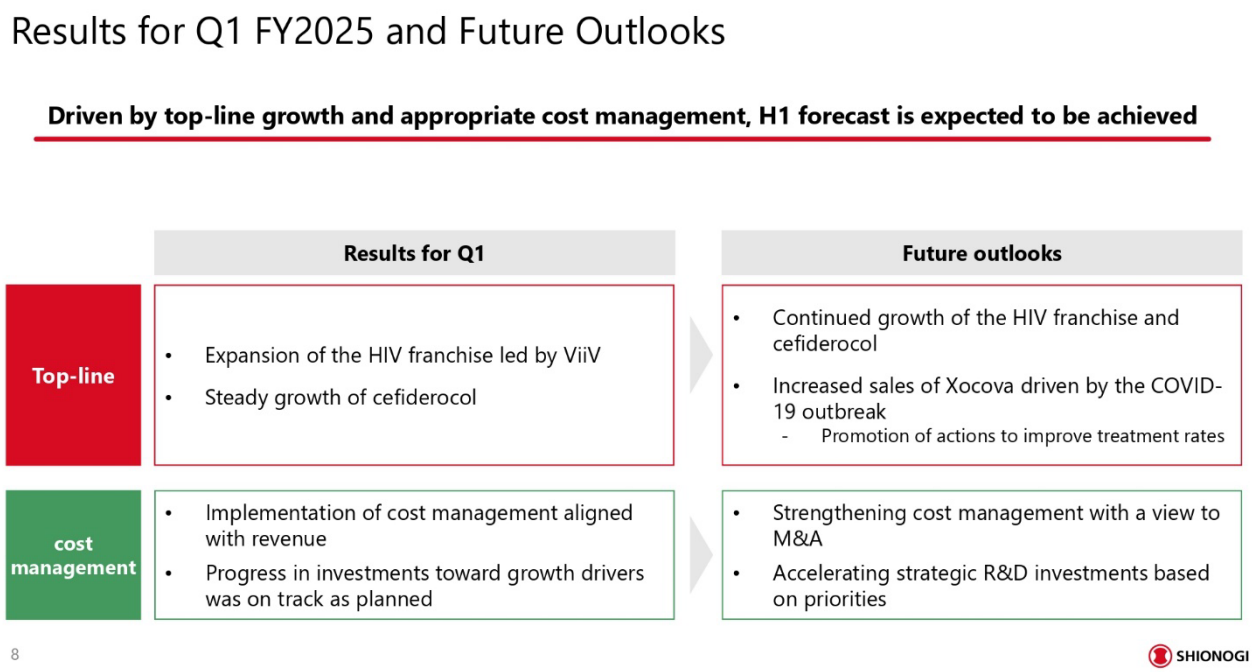
Domestic prescription drug sales totaled JPY14.1 billion, down JPY1.3 billion from the previous year. The decrease was mainly due to sales of drugs for acute respiratory virus infections.

As for the overseas subsidiaries/exports segment, it amounted to JPY14.2 billion, down JPY0.7 billion from the same period last year. While sales in the China business declined, sales of Fetroja and Fetcroja remained firm at JPY5.9 billion in the U.S. and JPY3.4 billion in Europe, thanks to expansion into new markets and increased sales in existing markets.

As for contract manufacturing, JPY4.5 billion, an increase of JPY0.9 billion from the previous year, due to an increase in supply of active pharmaceutical ingredients to ViiV and Roche.

Royalty income was JPY63.9 billion, an increase of JPY2.9 billion from the previous year, mainly due to two factors. The first factor is ViiV's strong sales of its HIV franchise, and the second is Roche's sales of its anti-influenza drug, Xofluza, which expanded as a result of the flu epidemic in China and the U.S., leading to higher royalty income.

As a result, total revenue amounted to JPY99.8 billion yen.



On page eight, we present a summary of results for Q1 and future outlooks.

We have organized them in terms of top-line and cost management.

First, on the left side, Q1 results included sales of the HIV franchise by ViiV, as well as expanded sales of Fetroja and Fetcroja in Europe and the United States. In addition, we were able to make the necessary investments to nurture growth drivers as planned, while practicing cost management in line with revenue.

On the right, as the future outlooks, we expect the growth of the HIV franchise, cefiderocol, Fetroja and Fetcroja, to continue in Q2. We also anticipate an increase in revenues of Xocova due to the COVID-19 epidemic and will promote efforts to improve treatment rates.

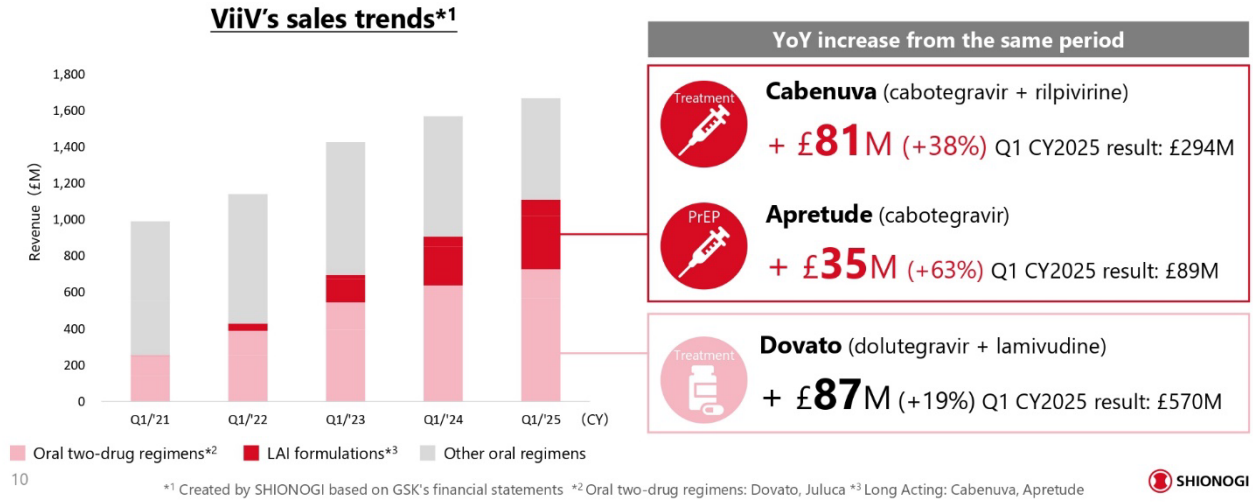
Furthermore, we intend to strengthen cost management in anticipation of M&A and accelerate aggressive R&D investment based on our priorities.

We expect to achieve the H1 forecast by achieving further growth in these top-lines and appropriate cost management.

This is the end of the explanation of the financial summary from me.

Progress of HIV Business by ViiV Healthcare

The expansion of Long-Acting Injectables and oral two-drug regimens is accelerating, driving overall growth in the HIV business



10

*1 Created by SHIONOGI based on GSK's financial statements *2 Oral two-drug regimens: Dovato, Juluca *3 Long Acting: Cabenuva, Apretude

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Keller: Thank you very much. I would like to begin my explanation on page 10.

Long Acting injectables (LAI) Cabenuva, Apretude, and Dovato, oral 2 drug regimens, are experiencing accelerated growth. And it is driving the growth of the HIV franchise as a whole. And strong growth patterns lead to overall HIV franchise growth.

Development of ULA*1 formulation: S-365598/VH184*2 (Third-generation Integrase Inhibitor)

Candidate for multiple LAI formats, including Q6M, with potential to cover strains resistant to current INSTIs

Key features of S-365598/VH184

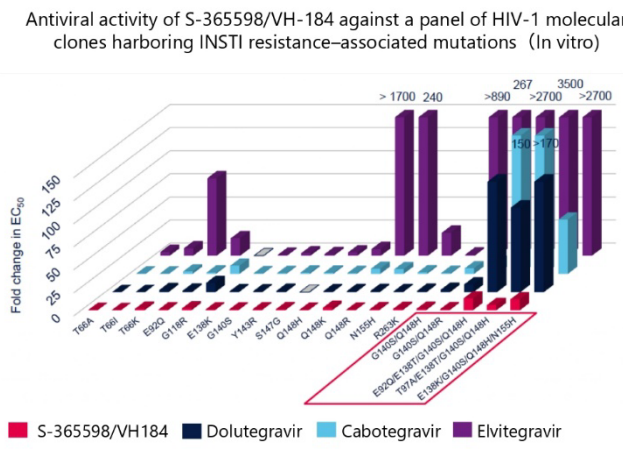
Distinct resistance profile compared with existing therapies

- Maintains antiviral activity against known resistance-associated mutations (highlighted in the red frame)

Development status

Q2M self-administration and Q6M formulation identified as a therapeutic candidates

- PoC*3 confirmed in an oral Phase 2 study
- Durability being evaluated in the Q6M formulation
  - Preliminary acquisition planned for CY2025



11

*1 ULA: Ultra Long Acting *2 The third-generation integrase inhibitor (development code: VH4524184) licensed out by Shionogi to ViiV *3 PoC: Proof of Concept

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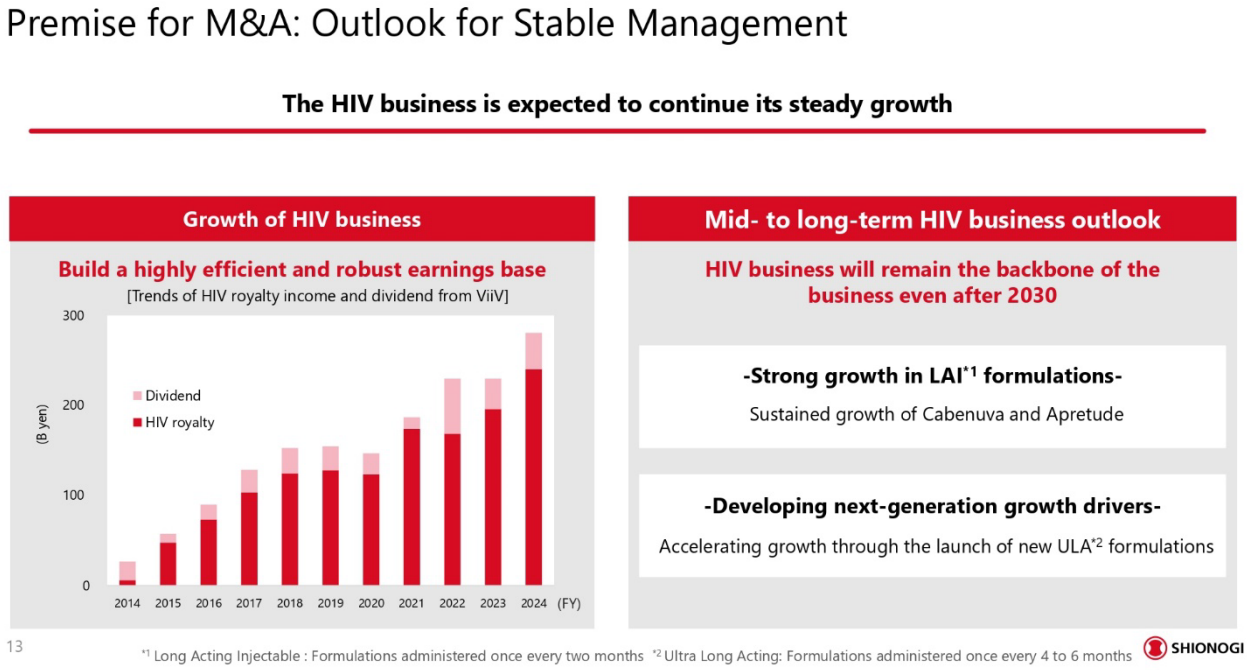
Page 11. And regarding S-365598, in ViiV, it is called VH184. It is a third-generation integrase inhibitor. It has already shown strong antiviral activity.

And this is being developed in various LAI formats. It is being developed as a once-every-two-months self-administered formulations method and as a once-every-six-months ULA. We expect to provide the results by the end of this year.

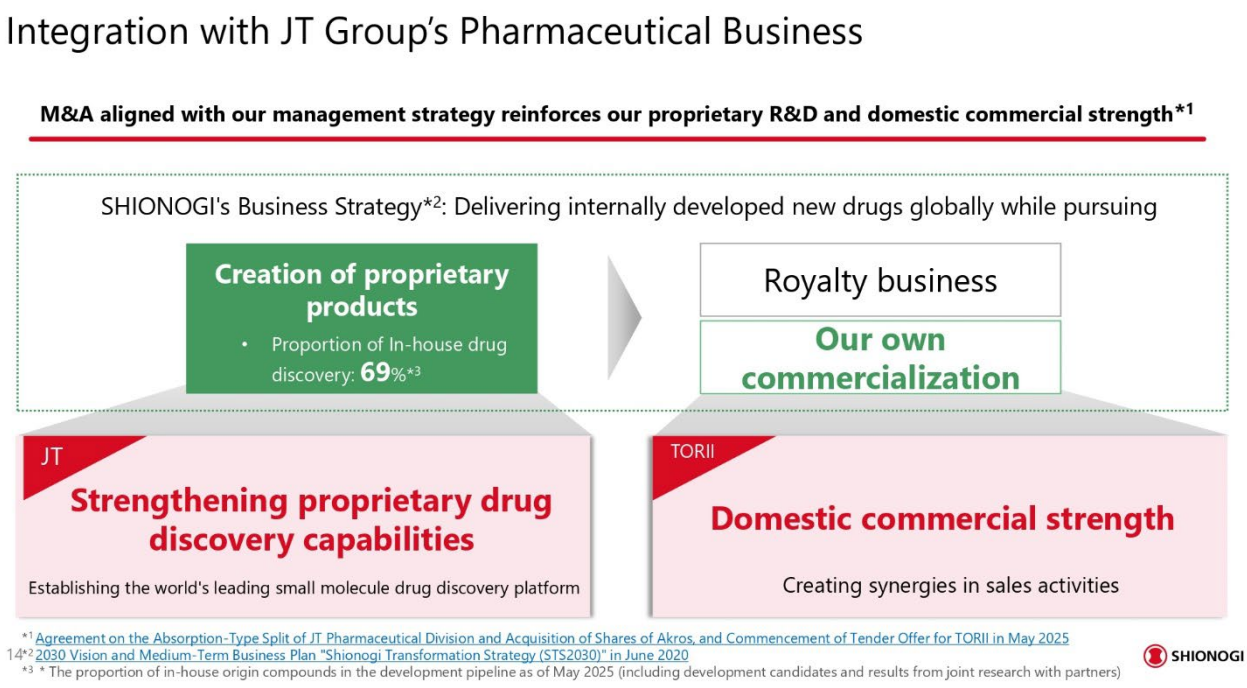
The results are superior to those of existing integrase inhibitors. And in various states of development, we are in the process of testing its durability in continuous injectable form. With various geopolitical changes, resistance may become a larger issue, and a threat, as a component of integrase inhibitors.

Therefore, we believe that S-365598 has excellent antiviral activity as a compound in the medium to long term, and that it has great potential as an LAI; in this sense, its merits in terms of supply are very important.



Page 13. And here is the outlook for the future which is the premise for M&A.

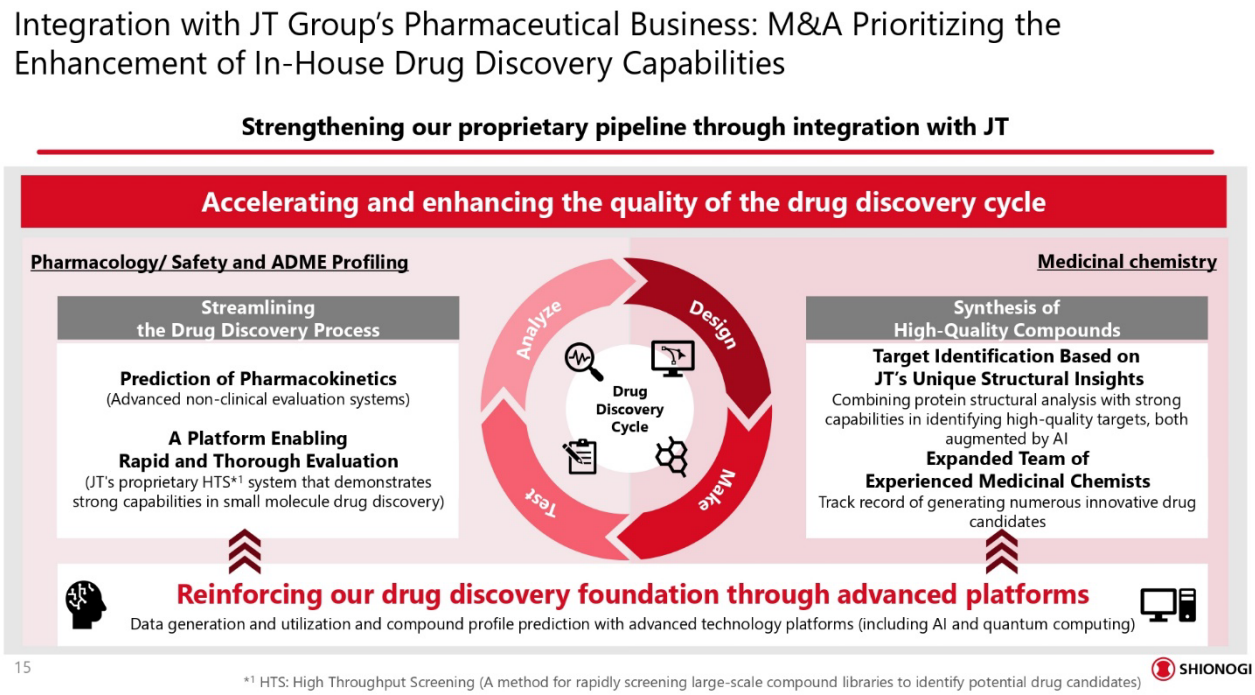
HIV's business is experiencing very impressive growth. We assume that this will continue to grow well beyond 2030. This will lead to further growth and development of LAI. We will continue to develop additional, newer format, more potent LA formulations.



Page 14. Therefore, together with the JT Group, we intend to strengthen our ability to create our own products. We are looking forward to pushing the pipelines forward and to more in-house drug discovery. It now accounts for 69% of the total. And we hope to continue this kind of strong drug discovery in the future.

We would also like to become the leading company in the world that can discover proprietary drugs with small molecule compound.

We will also strengthen domestic sales. We will create synergies between Torii and ourselves in our sales activities. With the capabilities of two companies, we plan to increase our sales performance in the country.

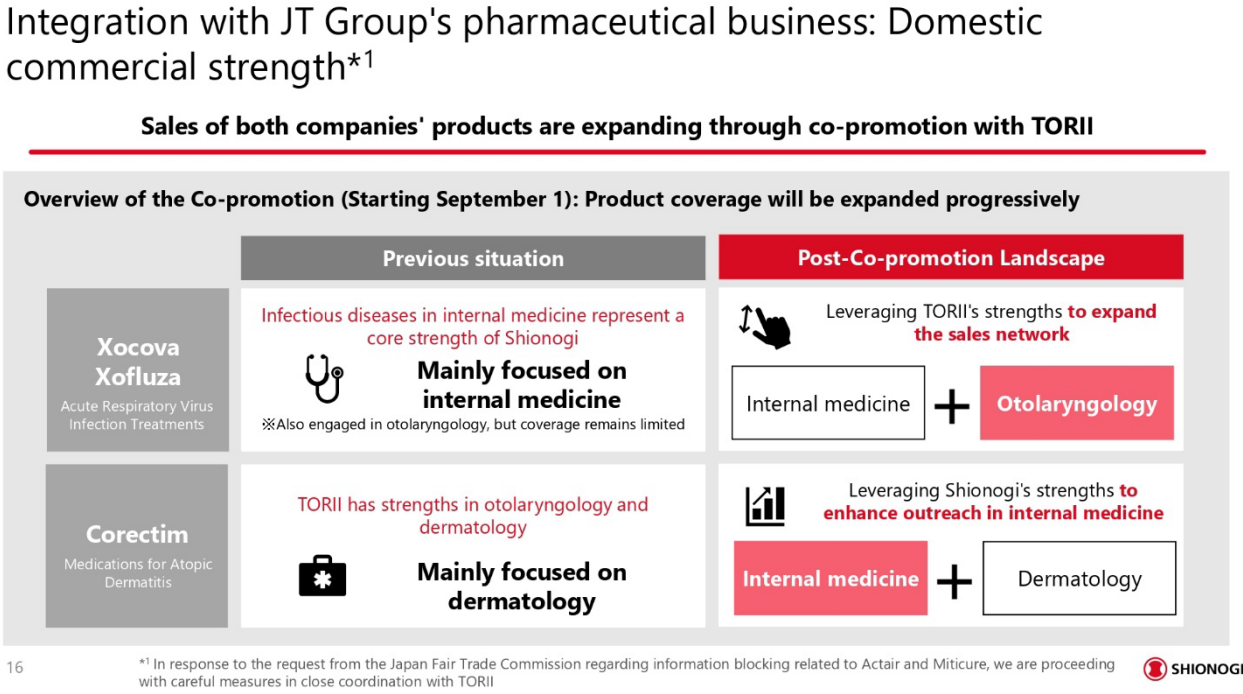


Page 15. Now, I would like to explain a little more.

As for drug discovery through the cooperation of these two companies, JT has the ability to identify targets, as shown on the right side. Then, using AI techniques, and again they can identify the structure. And by combining this with our efforts, we will strive to strengthen quality of life diseases in particular.

In addition, as I mentioned earlier, the role of the medicinal chemistry team. We believe that the combination of our team and JT's will strengthen our capabilities in this low-compound area with additional and very rare resources. Knowledgeable resources are not readily available elsewhere in the world.

And the left side, JT team has the ability to characterize. Then, when multiplied by our own capabilities, the candidates can be firmly identified, and then characterization and specialization of a wide range of aspects can be done. We would like to use our knowledge of pharmacokinetics, pharmacology, and toxicology to increase the probability of success in future development, using a multifaceted approach.



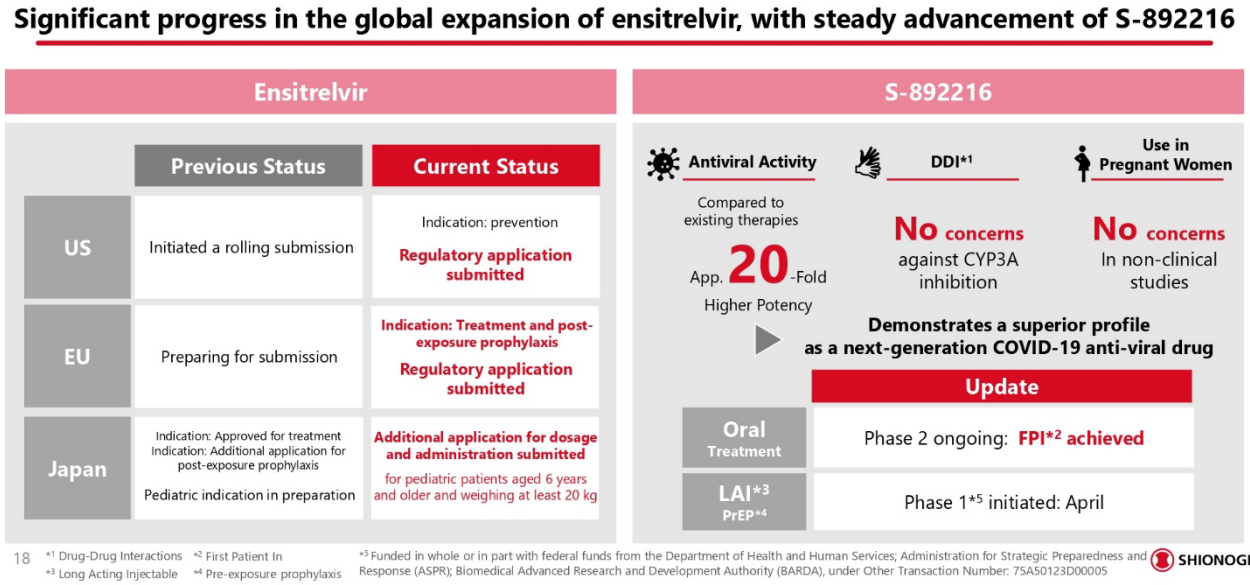
Now, on page 16, domestic business and sales.

Torii Pharmaceuticals is scheduled to become a wholly owned subsidiary of the Company on September 1. The co-promotion will then be initiated. This will cover Xocova, Xofluza, and Corectim. We plan to gradually expand the range of products subject to such co-promotion.

We are committed to bringing the products of both companies to even more patients. With this co-promotion, SHIONOGI will begin to promote Corectim, focusing on the field of internal medicine, where we have strengths. Torii Pharmaceuticals will also begin promoting Xofluza and Xocova. In particular, we will focus on otolaryngology and dermatology, where Torii Pharmaceuticals has strengths, as well as the treatment of COVID-19 and influenza in regions and during seasons when infectious diseases are prevalent.

We believe that expanding the number of information recipients regarding Xocova and Xofluza will be helpful to many patients. We believe that synergies in sales activities that leverage the strengths of both companies will further accelerate the growth of our domestic business.

COVID-19 Anti-Viral Drugs: Development Update



Uehara: I would like to talk about the progress of the pipelines. Please turn to page 18. First of all, as I mentioned at the beginning of this presentation, ensitrelvir have been submitted for approval in the US and Europe respectively. Specifically, in the US, we have completed the application for the prophylactic indication, and in Europe, for both treatment and prophylactic indications.

In Japan, the application for prophylaxis has already been completed, as I mentioned in the previous meeting, and as an update for this fiscal year, we have filed an application for additional dosage and administration for pediatric treatment.

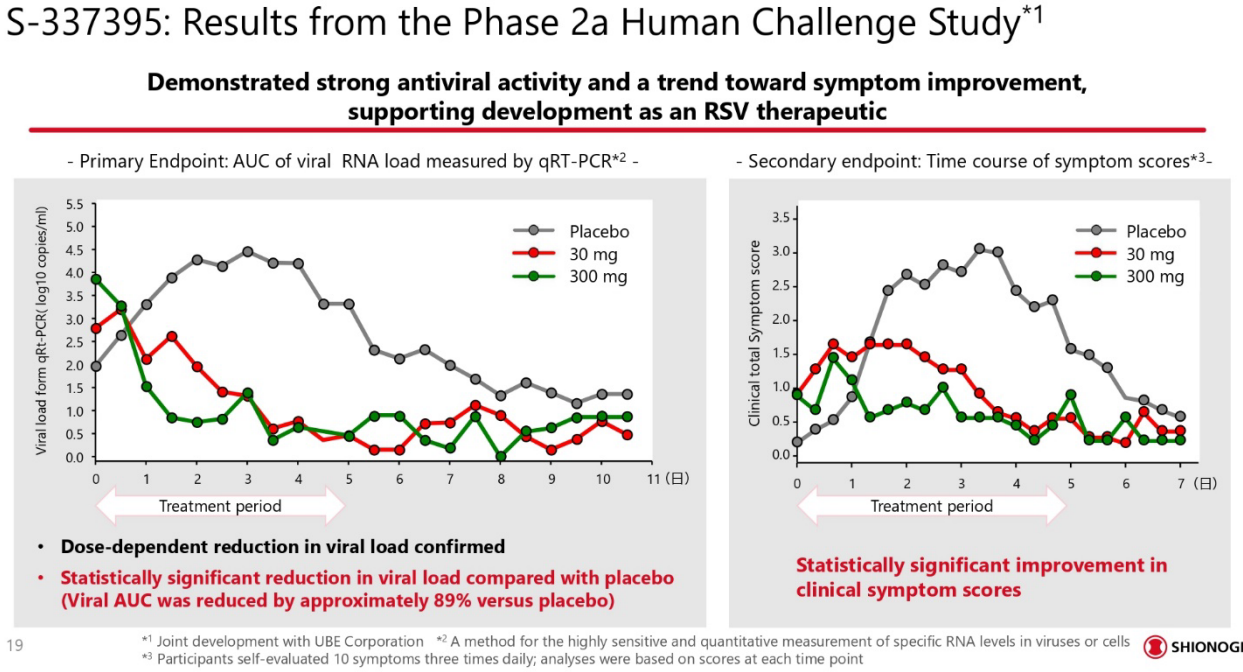
As you can see, the global development of ensitrelvir is progressing well, and the development of S-892216, a next-generation inhibitor of 3CL protease, is also progressing well.

As I have already mentioned, we have received a grant from BARDA in the US to develop this compound, and its antiviral activity is about 20 times higher than that of existing drugs, including Xocova.

Furthermore, Xocova cannot be administered in certain cases due to drug-drug interactions, or in pregnant women and those who may be pregnant. Therefore, we are currently developing a drug that does not have such profile concerns.

First, for the oral formulation, we are conducting Phase II trials in Japan and the US, and we are steadily accumulating the cases.

We have also initiated the Phase I study of a LA formulation of a persistent formulation for post-exposure prophylaxis and pre-exposure prophylaxis.



Page 19. This is an oral antiviral drug with a novel mechanism of action that is being developed for the treatment of RS virus infection. We have already talked about the completion of the challenge study in our press releases, and we have also finished the presentation at the international conference, and the data is shown on this slide.

The AUC of viral RNA quantified by PCR is shown on the left. As you have seen, in the placebo group, the virus proliferated and persisted in healthy adults after virus inoculation. In contrast, two doses of 30 mg and 300 mg of the drug demonstrated dose-dependent antiviral effects clearly.

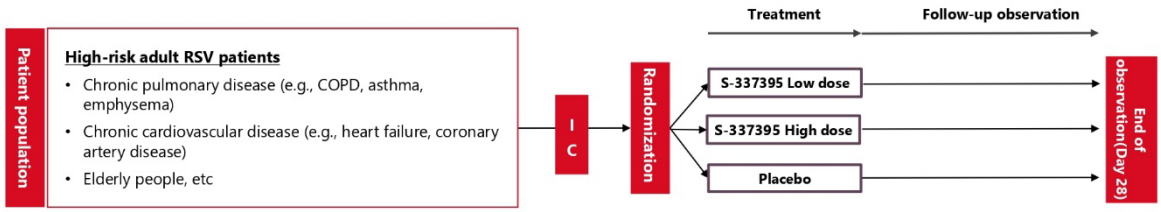
This represents a statistically significant reduction, with the viral AUC reduced by approximately 89% compared to the placebo. This is the largest reduction in viral RNA compared to other agents reported in the literature to date, and as shown on the right side of the graph, we have also confirmed results that suppress the onset of symptoms by suppressing viral increase, which leads to PoC.

Based on these results, we are now in the process of starting Phase IIb, a clinical trial in actual clinical practice.

S-337395*1: Upcoming Development Plan (Phase 2b trial overview and design)

Initiate a Phase 2b trial in high-risk patients before year-end, accelerating development toward the world's first oral RSV therapy

Primary Endpoint	Change from baseline in viral RNA load (qRT-PCR)
Secondary objectives	Efficacy assessment: time-course change from baseline in symptom severity score
Trial Design	Multicenter, randomized, double-blind, placebo-controlled, parallel-group design
Dosing Regimen Sample Size	• Randomization cohorts: placebo (n=64) • S-337395 low dose (n=64), high dose (n=64)



*1 Joint development with UBE Corporation

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Page 20. Here is the Phase IIb test design. We have selected two doses based on the challenge study mentioned earlier, and we will conduct a global double-blind placebo-controlled study.

Since the drug is intended for adult patients with risk factors, we are planning to enroll such patients and start a study to obtain data on antiviral efficacy, efficacy symptom scores, and safety after repeated dosing and have been in the process of starting trials to obtain that data.

COVID-19 Vaccine Portfolio

S-268024 achieved the primary endpoint, advancing the vaccine business to the next stage

Project	Antigen	Status	Remarks
COVGOZE	**Wuhan**	Approval (Q1 FY2024)	–
S-268023	**XBB1.5**	Phase 3 completed (Q2 FY2024)	・Primary endpoint*1 not achieved (Confirmation of neutralizing antibody induction against the XBB.1.5 variant) ・Favorable safety profile
S-268024	**JN.1**	Phase 3 in progress (Q1 FY2025)	**・Primary endpoint*1,2 achieved (Non-inferiority to intramuscular Nuvaxovid) ・Favorable safety profile**
S-567123	**Sarbecovirus (Universal vaccine)**	Phase 1 in preparation (As of Q1 FY2025)	Clinical trial designs are under consideration, and preclinical studies are ongoing

21

*1 Geometric mean titer of neutralizing activity and antibody response rate against JN.1 variant on Day 29 after vaccination *2 JRCT

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Page 21. Now, we have also made significant progress on our vaccine portfolio.

To date, COVID-19 vaccines, COVGOZE, targeting the original strain, have been approved for initial administration and initial immunization. To enable clinical use, it is necessary to obtain approval for additional immunization and booster administration, particularly targeting mutant strains.

We have completed a Phase III study of S-268024 for JN.1 strain. The results of this trial will be shown in detail on the next slide, but we were able to confirm a favorable safety profile and, as the primary endpoint, non-inferiority to Nuvaxovid, was also confirmed.

Based on these results, we plan to proceed with the application for approval of a new boosting indication for COVID-19. In addition, we are currently preparing for the implementation of the Phase I study for a universal vaccine, S-567123.

S-268024: Phase 3 Results

In the clinical trial, non-inferiority to vaccines of the same modality and favorable safety profile were confirmed

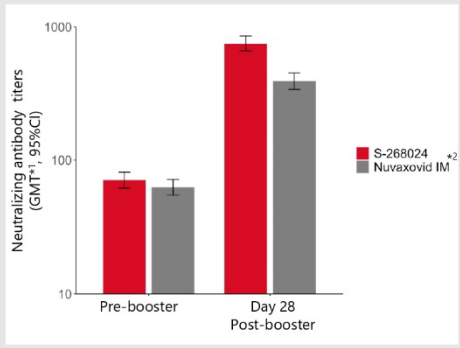
—Study objective and primary endpoint—

Purpose	Comparison of neutralizing antibody titers against the SARS-CoV-2 JN.1 variant following booster immunization with S-268024 versus intramuscular Nuvaxovid Participants: Individuals aged 18 years and older who have completed primary immunization
Primary endpoints	**Day 28 post-booster against SARS-COV-2 JN.1 variant:** • **Geometric mean neutralizing antibody titer (Non-Inferiority)** • **Seroconversion rate (Non-Inferiority)**

—Safety—

- S-268024 demonstrated **a favorable safety profile** comparable to COVGOZE and S-268023
- No new safety concerns were identified in this study

—Geometric mean neutralizing antibody titers (JN.1 variant)—



Non-inferiority to Nuvaxovid was demonstrated

22

*1 geometric mean titer *2 Intramuscular Injection

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Page 22. Here are the results of the comparative test with neutralizing antibody of the antigen vaccine against the JN.1 strain for the additional immunization in the Phase III trial that I mentioned earlier.

As shown in the slide on the right, S-268024, our vaccine, indicated by the red bar, showed clear non-inferiority and statistical superiority to Nuvaxovid 28 days after vaccination.

In terms of safety, we have newly obtained results that confirm a favorable safety profile similar to the data obtained to date.

Progress of Main Pipelines: QOL Diseases with High Social Impact

Steady progress toward establishing growth drivers in QOL indications

Pipeline	Indication	Update
Naldemedine	Opioid-induced constipation	**Completion of regulatory submission in China*1**
Redasemtide	Dystrophic epidermolysis bullosa	**Last Patient In (LPI) achieved for the additional Phase II clinical trial**
S-606001	Pompe disease	**Initiation of Phase 2**
S-898270	Alzheimer's Disease	**Initiation of Phase 1**
SASS-002 (Sulthiame)	Obstructive Sleep Apnea	**In-licensed to Joint Venture Shionogi-Apnimed Sleep Science*2 (Phase 2)**

*1 Press release (May 2025) *2 Press release (April 2025)

SHIONOGI

Page 23. While we have focused mainly on the pipelines update on COVID-19 infections, we are also making good progress on quality of life diseases that have a high societal impact.

For naldemedine, we have successfully completed a Phase III study for opioid-induced constipation and have submitted an application for approval in China. We have also completed patient enrollment for the additional biological study of redasemtide.

The Phase II study of S-606001 for Pompe disease, which is a global study, has started. S-898270 is also expected to improve cognitive function in Alzheimer's disease, and we have started Phase I trials.

Furthermore, we have introduced Sulthiame, a new candidate drug for sleep apnea syndrome, into Shionogi-Apnimed-Sleep Science, a joint venture established with Apnimed, and are currently preparing to initiate clinical trials.

This is all from myself.

Question & Answer

Kyokawa : Mr. Yamaguchi from Citi, please.

Yamaguchi : This is Hidemaru Yamaguchi from Citigroup. Thank you. First, I would like to ask you two questions about the HIV franchise.

One is whether or not there is any impact on the business environment, where your competitor, Gilead, has launched PrEP, a once-every-six-months product, and other is about the business environment in the US. Also, we don't know what will happen in the future, but there are going to be various reforms in drug price reductions and insurance coverage, and I wonder if there will be any impact on the HIV market, including PrEP.

First, I would like to ask about these two points.

Keller : Thank you for your question. First of all, regarding the once-every-six-months drug from Gilead, it is of course important to remember that there are two sides to the HIV market. Treatment, and then PrEP, i.e., prevention. PrEP constitutes 10% and treatment 90%.

We are also paying attention to the launch of Lenacapavir, which is administered once every six months, but it is intended solely for the PrEP market. As a treatment, it is being introduced for patients who have not responded well to existing regimens due to issues such as drug resistance or tolerability. Therefore, although it is a LA agent, it is not considered a main therapeutic option. Accordingly, we do not view it as a comparator to our S-365598/VH184.

Regarding competition in the prevention space, particularly with Apretude, these two drugs have slightly different characteristics. Due to differences in characteristics, we expect that selective use will occur among competing products. Furthermore, we would like to emphasize again that this competition is limited to the prevention segment, which accounts for only 10% of the overall market.

Next, regarding changes in pricing and policy in the U.S. market, we would like to begin by discussing funding issues.

Regarding funding for HIV treatment, such as Medicaid and OBBB, we do not expect a significant impact at this point.

However, what remains uncertain is Medicaid coverage and prevention. While there had been expectations for expansion in this area, the outlook has now become unclear.

The current prevention market is primarily composed of individuals covered by employer-sponsored health insurance, and Medicaid coverage remains limited. Given that the U.S. accounts for 90% of the global PrEP market, policy developments in the U.S. could significantly impact the pace of growth in the PrEP market.

However, due to the considerable uncertainty surrounding this area, it will be important to continue closely monitoring developments related to Medicaid.

As for tariffs and MFN policies, forecasting is extremely difficult. Of course, we are keeping a close eye on these issues, but ultimately, various factors—including individual trade deals and tariff-related matters—could influence the market. Therefore, at this point, we believe the best approach is to continue observing the situation.

Yamaguchi : Thank you very much. Just another question, in brief. As for Xocova, I understand that you have applied in the US. Has this application been accepted? Or if you are considering PDUFA, etc., could you please let us know?

Uehara : Currently, we have submitted all the data packages from SHIONOGI, and the FDA has just received them. We will receive another letter from the FDA after 60 days confirmation. We will make another announcement as soon as we know more about PDUFA, etc.

Yamaguchi : Thank you. That is all.

Kyokawa : Thank you very much. Mr. Ueda from Goldman Sachs, please go ahead.

Ueda : This is Akinori Ueda from Goldman Sachs. I would first like to ask you about your assessment of progress against the plan.

I think that the gross profit margin is higher than both the same period last year and the H1 plan; however, I am wondering if this can be explained solely by the product mix, and I also feel that R&D expenses are progressing slowly. Could you please explain how you are controlling this, taking into consideration Xocova's sales and other factors?

Fujiwara : I will answer this question. The first is gross profit, especially the cost portion. Specifically, this refers to areas of Chinese business where the cost ratio was relatively high, and last year, some of the sales that were exported were lusutrombopag, which generated significant revenue. These segments have a relatively high cost ratio.

So, at this point, we are analyzing the actual gross profit progress as a result of this mix of segments and products.

The second point is the progress of R&D. At this point, we are not exercising any particular control over this matter. As I mentioned briefly in my explanation, we were conducting Phase II trials of ensitrelvir and Phase II trials of S-309309 during the same period last year. We don’t have that trial anymore this year, so the current R&D expenses appear to be lower than those of the previous year.

Again, we are not in a situation where we are actively saving money in R&D. That is all.

Ueda : Thank you very much. I would like to ask a follow-up question about the cost. Compared to the current H1 plan, I assume that the cost ratio will increase from Q2 onwards. Is that correct? Could you tell us if there are any positive aspects to the plan?

Fujiwara : At this point, we believe that Q2 will proceed as originally planned, so there is a possibility of a slight increase. In addition, we have allocated the budget for this area in anticipation of the integration of Torii from September.

Ueda : Thank you very much. The second point, I would like to know about the Cabenuva trend. I would like to know what you think of the recent presentation at the IAS(International AIDS Society) 2025 conference and its impact on your future performance.

In your presentation the other day, you reported that the number of patients wishing to switch from Dovato to Cabenuva is very high, but looking at the current sales figures, I have the impression that Cabenuva has not yet penetrated the market to that extent.

What are the implications of these announcements for Cabenuva's future sales outlook? Could you also tell us what is needed to accelerate sales in the future?

Keller : Thank you very much for your questions. We believe that this data is extremely valuable as evidence showing that the majority of patients who have used LAI formulations prefer them and wish to continue using them.

Therefore, even for patients who have been cautious about using LAI formulations or have had concerns about injections, as well as for doctors and a broader range of patients, this serves as a strong indication that LAI formulations are an attractive treatment option.

Cabenuva continues to show steady growth, and approximately 70% of that growth comes from patients switching from other companies' regimens. According to existing forecasts, by 2031, one-third of the HIV treatment market is expected to be LAI.

We believe this is a fully achievable target—and possibly even one that could be exceeded.

Ueda : Thank you very much. That's all from me.

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

Wakao : I'm Seiji Wakao from JPMorgan. Thank you. There are a couple of questions, the first is regarding the question from Mr. Yamaguchi. I think you explained that the impact of Medicaid is limited. Let me understand that in more detail.

If anything, the Medicaid budget reduction seems rather large this time around, so I was wondering if there is a negative impact on this HIV market in the long term, if not in the short term, as the HIV treatment budget is reduced.

In your explanation, you also mentioned that Medicaid coverage will expand with regard to prevention and so on, and I was not quite sure what the factors are and what will happen in the end, so could you please tell me more clearly? That is my first question.

Keller : Thank you. With regard to Medicaid treatment, both the overall budget and the approach to the medical budget, HIV treatment is considered to be a protected area.

When budget pressures arise, each individual state's decision, and then the budget, must be budget allocations. Therefore, it is difficult to say that this is the case as a whole, but as a whole, I do not think that insurance policies for HIV treatment are moving negatively. I believe that the tone, at least in tone, will remain consistent and that the tone will continue to be to maintain treatment for HIV patients.

However, As for prevention, while other companies are forecasting that the prevention market will expand three to four times, we anticipate that it will roughly double over the next five years. However, this projection is based on strong support from the U.S. government—specifically, the expansion of Medicaid coverage for LAI formulations of PrEP.

The reason why the expansion of Medicaid coverage is so important is because 90% of the prevention market is in the U.S., and within the U.S., only one-third of patients who need prevention are actually receiving prescriptions. This one-third consists of individuals covered by private employer-sponsored insurance.

To further expand the prevention market, it is essential to reach those who still lack access to necessary prescriptions. This is where public health insurance programs like Medicaid play a critical role.

Under the Biden administration, recommendations were issued for Medicare to cover LAI formulations of PrEP, and there were expectations that this coverage would be extended to Medicaid as well. However, at this point, it remains uncertain whether that expansion will actually be realized.

Wakao : The second question is about drugs for the treatment of RS virus infections. I would like to know the time points that show a statistically significant reduction in virus load and a significant difference in the secondary endpoints items on the right when we look at the data.

I see the secondary endpoint, the symptom score, as being the primary endpoint when we eventually do Phase III, but I would like to know if that is correct, and if so, which date of data would be the key.

Also, how will you handle vaccines? I think the strategy was probably originally intended for the unvaccinated, but I would like to know how that is expected in the current plan, since RS virus vaccination will probably expand from here in the US as well.

Uehara : Thank you for your details. First of all, we have specified the analysis of the pre-specified statistics in terms of AUC. Therefore, we are conducting statistical analysis of the area between areas and the overall transition. However, if you look at the data, there is a clear division at every point, so although I have not marked each one as significant, I believe there will be a significant difference.

As for the actual primary endpoint, this will depend on the results of Phase II , so please do not let me get into that at this time. Specifically, we developed Xocova, as well as Xofluza, with the endpoint of symptom disappearance.

In this context, we believe that it is particularly important to focus on preventing severe cases of RS virus infections, and we are therefore registering individuals with risk factors.

In this context, we would like to proceed with Phase III trials using severe endpoints, such as hospitalization and mortality, if trials can be conducted on a scale that is realistic in terms of the severity of the endpoints.

In this sense, even when looking worldwide, there is significant debate, including among regulatory authorities, regarding what criteria should be used to determine Phase III primary endpoints for acute respiratory infections. Therefore, we plan to decide on the Phase III design based on data from evolving symptoms and the results of Phase IIb.

Our current thinking is that the inclusion or exclusion of vaccination depends on the results of the larger Phase III strategy.

Wakao : I understand very well. Finally, please tell us about Quviviq's progress. While we understand that sales are expected to grow in the second half of the fiscal year, the actual performance from April to June seems quite low compared to the 1.2 billion yen recorded in the first half. What are your thoughts on this?

Iwasaki : I will answer your question. We had originally planned to use the drug in both psychiatry and internal medicine, but the hurdle of a two-week prescription in the internal medicine field was higher than we had expected, so we have fallen short of our goal.

However, the drug has been highly evaluated by doctors who have introduced it, including its effectiveness in helping people fall asleep, and once a patient has used it once, prescriptions are being expanded, including switching from other drugs.

Therefore, based on the lifting of the prescription restriction in end of November, we are planning to achieve this goal through a two-pronged strategy of increasing the number of cases of adoption and increasing the number of prescriptions at medical institutions that have used the drug.

Wakao : I understand. Then I understand that the H1 forecast may not be achieved, but after the prescription restrictions are removed, you will do your best to make up the difference in H2 and thereafter. Is that correct?

Iwasaki : Yes, that's right.

Wakao : I understand. Thank you. That is all.

Kyokawa : Thank you very much. Next up will be Mr. Muraoka from Morgan Stanley MUFG Securities. Please go ahead.

Muraoka : Thank you. This is Shinichiro Muraoka from Morgan Stanley.

This is regarding sleep apnea. Recently, Apnimed announced successful results from their Phase III trial of AD109, a fixed-dose combination drug. It combines a muscarinic agent and an NRTI.

I have two questions. First, is that drug outside of your company's rights? And second, if I recall correctly, your SASS-001 program involves S-600918 in combination with another agent (referred to as "the combination agent X"). Is this combination agent X the same as Apnimed's AD109, which achieved success in this recent trial? Or is it a different compound?

The reason I'm asking is because I'm wondering whether your company could potentially benefit from Apnimed's positive results. I'd appreciate any insights you can share.

Keller : You're absolutely right. AD109 is not included within the scope of our joint venture agreement—it is outside of our rights. So while we'd like to congratulate Apnimed on their success, within the JV assets, the combination of S-600918 and the combination agent X is targeting a specific subset of the sleep apnea patient population.

To be more specific, AD109 covers a broader range of patients, whereas SASS-001 is designed for patients with a high loop gain phenotype—a distinct subtype of obstructive sleep apnea. While AD109 targets a wider population, patients with high loop gain have a particularly strong unmet need, as CPAP therapy tends to be less effective and current treatment options provide limited benefit. That's why we believe this focused approach has strong potential. Our combination specifically addresses patients who don't respond well to conventional treatments and require specialized care.

In addition, Sulthiame operates via a different mechanism than AD109. Although it is still at an early stage of development, it may potentially be effective in a broader patient population. Looking ahead, there may be opportunities for combination approaches, and while AD109 lies outside our rights, we maintain a close relationship with Apnimed. That said, our assets operate through different mechanisms of action.

Muraoka : Thank you. One more thing, regarding the question I asked earlier about the RSV S-337395, the graph on page 19, and the Phase IIb design, it is clear that the difference is greater than the placebo, though. When looking at 30 mg and 300 mg, it seems that 30 mg is more effective considering the AUC, and it also seems that the high dose and low dose in Phase IIb are not 30 mg and 300 mg. How should we organize this information and proceed?

Uehara : Thank you. The AUC itself is larger for 300 mg. So the visible result shows the dose dependency.

Since the challenge study was conducted with a limited number of cases, the baseline values inevitably differed slightly between groups, making comparisons between groups a little difficult.

As you saw, the downward slope of the green virus clearly shows that the higher dose reduces the viral load more rapidly. Based on this characteristic, we have set the dosage using 300 mg as the base and are now proceeding with the Phase IIb trial. While the exact dosage remains undisclosed, the base is 300 mg.

Muraoka : I understand. Thank you very much. Lastly, as someone asked earlier, I think the sales of Xocova, or acute respiratory infections, for the July to September period will be hard to reach JPY30 billion. In that case, can we assume that today's message is that the achievement of the plan for H1 is in view because the final adjustment can be made at the cost?

Fujiwara : I will answer your question. First, regarding Xocova, as of the end of July, we are hearing that infections are gradually spreading, and in line with this, our sales figures are also rising daily. We are currently monitoring the situation and believe that there is no significant difference that would warrant a change in our forecast at this point.

As you pointed out, in the unlikely event that sales are affected, we would like to proceed with cost control while keeping a close eye on the situation.

Muraoka : I understand. Thank you, that’s all.

Kyokawa : Thank you very much. Next, Mr. Sakai of UBS Securities. Thank you.

Sakai : This is Fumiyoshi Sakai from UBS Securities. Returning to Mr. Keller's comment, which was mentioned in the opening question. You mentioned about HIV, funding and geopolitical risk in the US, by issues. I understand that this is also important, but now the issue of resistant bacteria becomes very important.

I felt a huge jump or disconnect between these two issues but in what context did you talk about this, including confirming it one more time? This is the first and primary point.

Then, was it page 38? The chart that you have presented here shows that after 2023, the treatment market will be stable at GBP20 billion. As the patent expires, and thereby also the entry of generics. Including that, if you express the flat expectations as stability?

My personal impression is that the PrEP market will not be a growth driver, as President Teshirogi said, but given that the usage rate is around 90% in the US, I think ViiV is doing quite well in the US market, including DTC.

Even with that kind of thinking, do you still believe that it will still remain at this level? Let me confirm this point.

Keller : Thank you. Thank you for the opportunity to comment again regarding the resistance.

One point I would like to clarify in advance is that what I am describing reflects the current situation, particularly in low- and middle-income countries such as those in Africa. At present, resistance remains sporadic and rare, and it is not considered a threat in markets like the United States.

However, a large number of patients—approximately 25 million people—are receiving treatment with dolutegravir, and about 24 million of them live in low- and middle-income countries. If resistance emerges, it tends to be shared between dolutegravir and bictegravir, meaning that it would affect both drugs.

Geopolitical shifts have also led to major changes in the funding support for drug distribution from the U.S. government. This has had implications for how medicines are supplied to the Global South. While our collaboration with the Medicines Patent Pool (MPP) and the manufacturing of these drugs remain unchanged, the capacity to actually deliver these treatments to patients has been significantly affected. For example, in

many African countries, governments lack the infrastructure to fill these gaps on their own—there's a shortage of physicians and a lack of distribution networks.

While there is a possibility that funding support from USAID and PEPFAR will resume in the near future, it will be necessary to find and rehire medical staff and rebuild the healthcare network. In other words, patients in Africa may experience repeated interruptions and resumptions of treatment, which increases the risk of resistance development.

From the perspective of antiviral drug use, such on-and-off treatment patterns carry a very high risk of resistance emergence.

Therefore, I am not saying that resistance is an immediate concern. What I want to emphasize is that, from a medium- to long-term perspective, this kind of geopolitical situation could potentially lead to resistance becoming a significant risk. And unfortunately, due to the increasing interconnectedness brought about by globalization, we now live in a world where any virus can be transported from anywhere in the world almost instantly. This means that HIV resistance emerging in one region could potentially spread globally in the future.

Sakai : You are talking about USAID.

Keller : Yes, funding from USAID and PEPFAR has resumed, but these programs continue to play a critical role in the distribution of HIV medicines to the Global South.

As for your second question—apologies for all the percentages—I'd like to share how we see the market breakdown. We estimate that approximately 90% of the overall market is treatment, while the remaining 10% is for PrEP. Although the proportion of PrEP may increase depending on developments in the U.S. market, treatment will remain the dominant segment over the long term and continues to be the more important area of focus.

We expect the treatment market to remain stable and even grow moderately over time. Of that market, we anticipate that about one-third will shift to LAI. The current treatment market is valued at approximately $30 billion, so one-third of that would represent a market opportunity equivalent to today's total revenues.

Therefore, even just within the LAI segment, there is potential to sustain current levels of revenue and royalty income through and beyond 2030. While some fluctuations are possible, we anticipate that LAI usage could exceed 30% of the market, and we are confident in its continued growth.

Importantly, as of now, there is no sign that any other company will launch a LA integrase inhibitor before 2031. This means that ViiV will not only own a significant share of the overall market but effectively hold a monopoly on the LA integrase inhibitor segment during that period.

Sakai : I would like to ask one last point briefly. I don't know how to put it, but what was the final amount of cash outlay used for the Torii and JT acquisitions?

Fujiwara : We acquired shares through TOB for about JPY70 billion.

Sakai : So this means you were able to capture the cash that Torii has, right? If so, JPY70 billion would be cash out, which is net, is that correct?

Fujiwara : At this point, we have not yet completed the carve-out acquisition from JT. This will be completed by Torii's acquisition of its own shares from JT, and the funds have not yet been mobilized yet.

At this point, we have JPY70 billion in cash out in the form of shares purchased from the market.

Sakai : Okay, the payment to JT, I believe this was explained at the briefing, but has it not changed?

Fujiwara : It is scheduled for September 1.

Sakai : So the transaction will take place on September 1, is that correct?

Fujiwara : Torii will buy back its own shares from JT and eventually become a wholly owned subsidiary.

Sakai : I see. Thank you.

Kyokawa : Thank you very much. Since the scheduled time is approaching, we will conclude the session with the next question. Continuing on, Ms. Miki Sogi of AllienceBernstein, please.

Sogi : Thank you. I would like to ask about LA drugs. I understand that LAI is only your company's Cabenuva as far as treatments, so when you say that this is a third of the total treatments, I understand that this is a very good situation for your company.

On the other hand, as Gilead, they don't have their own LAI treatments, so I think the competition there is quite remarkable.

In such a case, your company's current assumption is that if the LA treatment is 1/3 of the total treatment, where would you assume that the LA treatment would come from? Does that mean that you will be using from your company's ViiV medicine or that you can win over the Gilead as well?

Keller : So far, 70% of Cabenuva's growth in the U.S. has come from patients switching from other companies' regimens. We expect this trend to continue, and Cabenuva's global market share—particularly in the U.S.—is steadily increasing.

Therefore, there is still significant room for conversion from oral therapies to LAI formulations. The results of the VOLITION study clearly demonstrated how much patients prefer LAI formulations, which is expected to further drive this growth.

This preference is increasingly understood not only by physicians but also across the broader patient community. In fact, surveys conducted among patient advocacy groups indicate that this awareness is steadily spreading.

Sogi : Thank you. One more thing regarding S-892216. I think that sales of Xocova may be difficult due to various factors such as the actual case number of infections, but I wonder if sales of Xocova will have an impact on whether or not to proceed with the development of S-892216 in the future.

Uehara : No, there is no impact. At least as for LA, we have received funding from BARDA, so the current sales of Xocova in Japan will not have any impact on it.

In this context, we do not plan to develop the product only for post-exposure prophylaxis or pre-exposure prophylaxis, so we will proceed with the development of S-892216 without relying on Xocova sales.

Sogi : Thank you.

Keller : If I may add one more point to the previous question—when considering the potential of LAI, we are not limiting ourselves to the current status quo. We are actively progressing toward treatment and prevention options with four-month dosing intervals, and beyond that, six-month dosing and self-administered formulations are also on the horizon.

In that sense, I'd like to emphasize that we are not just stopping at the current two-month injectable; we are committed to further advancing the LAI landscape and expanding the possibilities it offers.

Kyokawa : Thank you very much. This concludes the briefing for Q1 of FY2025 financial results of SHIONOGI.

Thank you very much for attending today.

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