SHIONOGI & CO., LTD.

2nd Quarter of Fiscal 2023 Financial Results

November 1, 2023

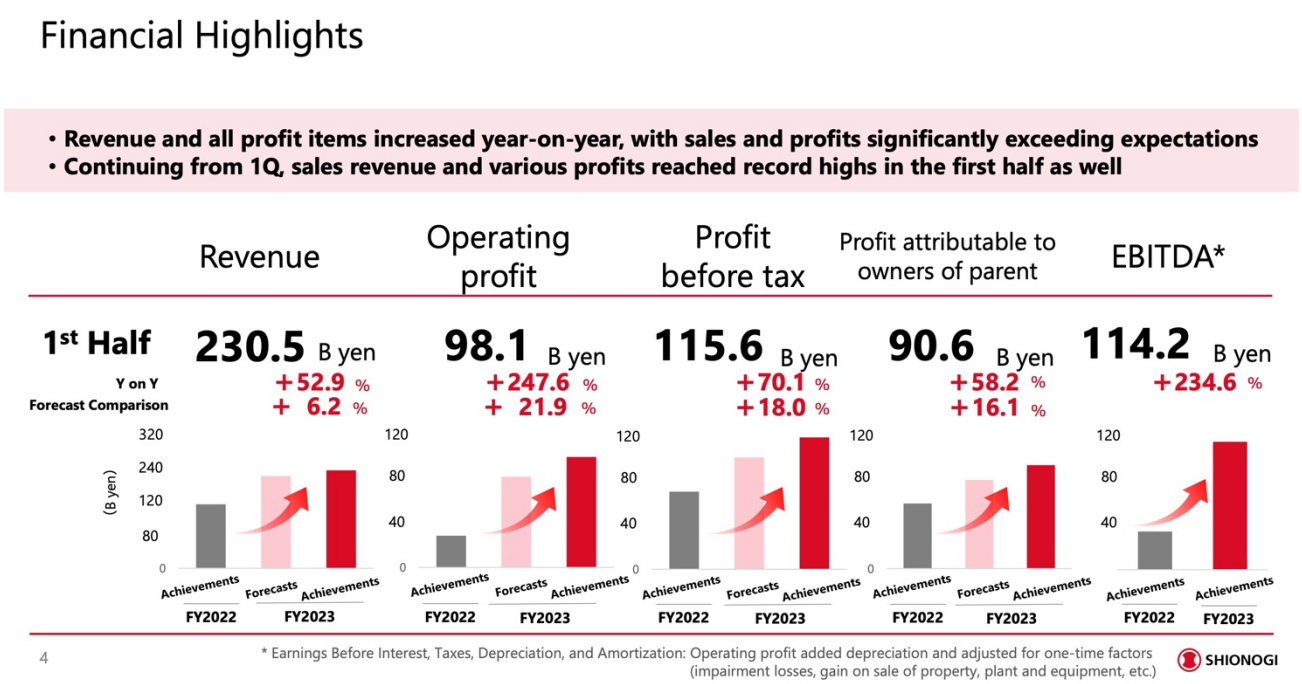
Presentation

Kyokawa: I am Kyokawa, Vice President, Corporate Communications Department of SHIONOGI & CO., LTD. Thank you very much for joining us today despite your busy schedule. We start SHIONOGI's financial results briefing for Q2 of FY2023.

Now, let me explain the schedule of today's briefing session. First, Teshirogi will start with an overview of Q2 financial results and explain about shareholder return according to the agenda. John Keller of R&D Supervisory Unit will then explain the pipeline agenda following the update of COVID-19 treatment, followed by a Q&A session.

Let's begin. President Teshirogi, please go ahead.

Teshirogi: Thank you. As Kyokawa just mentioned, Uehara, who is actually involved in R&D for products from COVID-19 to S-309309, will talk about R&D. After that, John will explain about OSA with Apnimed which was announced this morning and HIV business. I appreciate your understanding.



I will start with page four. I am sure that most of you understand the figures, so let me just make a few points.

Revenue was JPY230.5 billion, an increase of 52.9%, and operating profit was JPY98.1 billion, approximately 3.5 times from the previous year. Although the previous term was particularly bad, this term is very strong. Profit before tax was JPY115.6 billion, up 70.1%, and profit attributable to owners of parent was JPY90.6 billion, up 58.2%.

In the STS2030 revision announced in June this year, we also include EBITDA, which we consider as an important KPI. It was JPY114.2 billion, approximately 3.5 times from the previous term which results were not good.

Financial Results

(Unit：B yen)

	FY2023				FY2022	Y on Y	
	Forecasts		1H Results	Achievement (%)	1H Results	Change(%)	Change
	Full year	1H					
Revenue	450.0	217.0	**230.5**	**106.2**	150.8	**52.9**	**79.8**
Operating profit	150.0	80.5	**98.1**	**121.9**	28.2	**247.6**	**69.9**
Profit before tax	192.5	98.0	**115.6**	**118.0**	68.0	**70.1**	**47.6**
Profit attributable to owners of parent	155.0	78.0	**90.6**	**116.1**	57.3	**58.2**	**33.3**

Exchange Rate（Average）

	FY2023 Forecasts	FY2023 1H Results
USD($) – JPY(¥)	**130**	**141.06**
GBP(£) – JPY(¥)	**160**	**177.63**
EUR(€) – JPY(¥)	**140**	**153.46**

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Page five, please. This slide is for H1 achievement. The leftmost column shows the full-year forecasts and H1 forecasts, and the fourth column from the left shows H1 achievement rates. From 106% to 122%, we believe that we have almost achieved what we wanted to do in H1.

The yen has been weakening, and of course there are areas where costs will increase, such as R&D expenses, but royalties and overseas sales of Cefiderocol and others are benefiting from the weaker yen, which is a positive factor for us at this point.

Statement of Profit or Loss

(Unit : B yen)

	FY2023				FY2022	Y on Y	
	Forecast		1H Results	Achievement (%)	1H Results	Change (%)	Change
	Full year	1H					
Revenue	450.0	217.0	**230.5**	**106.2**	150.8	**52.9**	**79.8**
Cost of Sales	15.3 69.0	14.5 31.5	12.1 **27.9**	**88.5**	18.2 27.4	**1.9**	**0.5**
Gross profit	381.0	185.5	**202.7**	**109.2**	123.4	**64.2**	**79.2**
Selling, general & administrative expenses, R&D expenses total	50.9 229.0	47.7 103.5	41.8 **96.5**	**93.2**	64.5 97.2	**(0.8)**	**(0.7)**
Selling, general & administrative expenses	28.9 130.0	24.9 54.0	21.4 **49.2**	**91.2**	32.1 48.5	**1.6**	**0.8**
R&D expenses	22.0 99.0	22.8 49.5	20.5 **47.2**	**95.4**	32.3 48.7	**(3.1)**	**(1.5)**
Other income & expenses	(2.0)	(1.5)	**(8.1)**	**-**	2.0	**-**	**(10.1)**
Operating profit	33.3 150.0	37.1 80.5	42.6 **98.1**	**121.9**	18.7 28.2	**247.6**	**69.9**
Finance income & costs	42.5	17.5	**17.5**	**100.0**	39.8	**(56.0)**	**(22.3)**
Profit before tax	42.8 192.5	45.2 98.0	50.1 **115.6**	**118.0**	45.1 68.0	**70.1**	**47.6**
Profit attributable to owners of parent	155.0	78.0	**90.6**	**116.1**	57.3	**58.2**	**33.3**

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On page six, I would like to talk a little bit about just a few key points. The fourth column from the left, H1 achievement shows that revenue was 106% while cost of sales was 88.5%, and on the right side, in terms of YoY, revenue change was 50% while cost of sales change was only 2%. This was the most significant factor in the very strong operating profit.

The increase in revenue was, of course, thanks to JPY25 billion from Takeda Pharmaceutical for the transfer of ADHD drug, and also to very strong royalty income, which are revenues without costs. However, sales of Xocova, Xofluza, and Rapiacta, which we research, develop, and manufacture in-house, and are very favorable in terms of cost contributed to the cost of sales.

Our ideal business model is to manage successful royalties and licensing-out, and to increase the percentage of our own developed products, if possible. So, in this H1, I think we are seeing a good pattern emerging in terms of the kind of business we want to do.

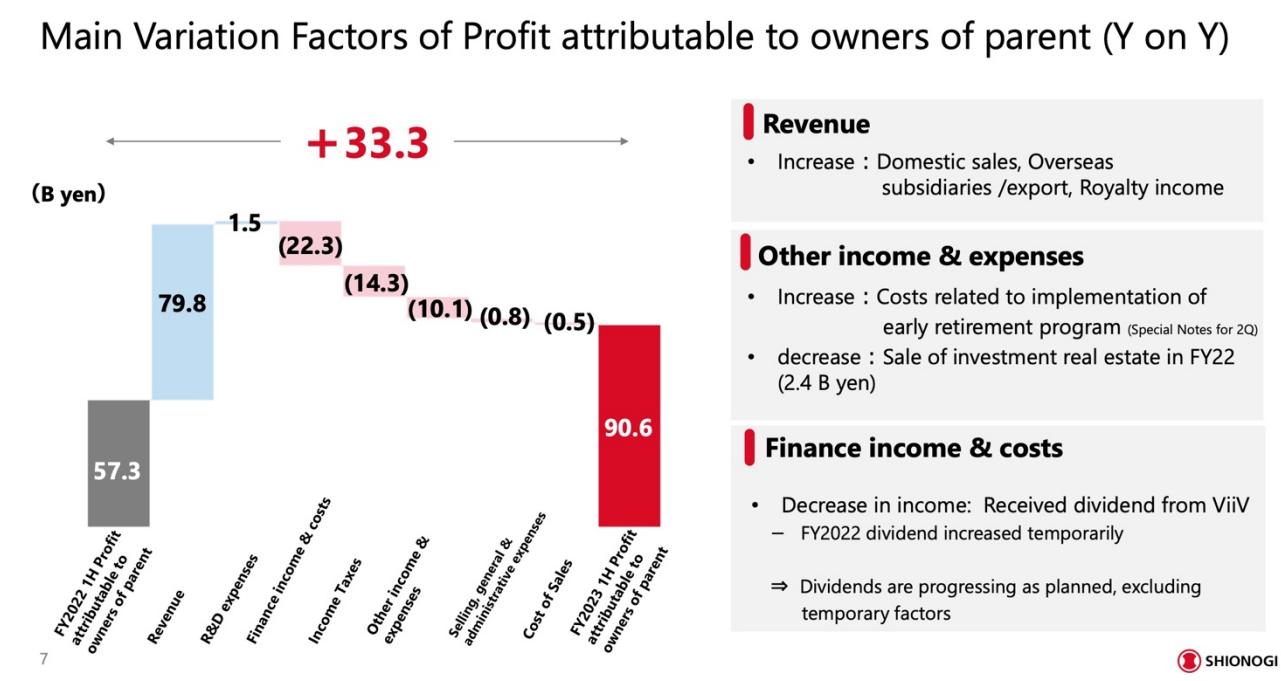
Selling, general and administrative expenses are JPY 49.2 billion and JPY 47.2 billion this time, with achievement rates of 91% and 95%, respectively, and on the far left is the full year figure of JPY229 billion. As I will explain later, we would like to increase this figure slightly to JPY 231 billion for full year, and we would like to reduce SG&A expenses and increase R&D expenses as a percentage, so that we can conduct more aggressive R&D activities in H2.

There is a negative figure of JPY 8.1 billion in other income and expenses, of which JPY6.6 billion is for the special early retirement program for 301 employees that was announced yesterday. If we interpret this as it is, it will have a negative effect of about JPY3 billion on a personnel cost basis from the next fiscal year onward, but on the other hand, we would like to expand our new business, so we would like to hire people mainly from overseas as well.

On a management committee basis, we are enthusiastically discussing strategic recruitment, and by doing so, we are oriented to hire probably about one-third of recruitment as experienced workers. Therefore, I do not think it will have an overall effect, but if we look only at the next fiscal year, I think the result will have a slightly negative impact on personnel expenses.

Then the third line from the bottom shows finance income and cost. From the far left, the full-year forecast is JPY 42.5 billion, the H1 forecast is JPY 17.5 billion, and the first-half result is JPY 17.5 billion. Dividend from ViiV has been very strong and has really outperformed our expectations. We expect it to strengthen a bit more in H2, but at this point we think it will probably not fall below JPY 42.5 billion level.

Concerning the negative figure of JPY 22.3 billion on the right side, as I have repeatedly mentioned, it is from the total amount of JPY 22 billion which includes five dividends received the last year and a portion of the large lump-sum payment we received as a dividend from the settlement between Gilead and ViiV. The fact that the amount is entirely negative does not change the fact that we are receiving a solid dividend.



Page seven is where we have explained it. One thing I didn't mention earlier is that in the revenue decline, the third item from the top, the sale of real estate is gone this year.

By the way, we also talked quite intensively at yesterday's board meeting about how to reduce cross-held shares. As for our own shareholding this year, it will be around 30% or so, but we will reduce it, we are discussing with the Board of Directors to reduce it consistently.

Of course, this will not be reflected in the P&L, but we hope you will understand that we are making progress in this area of governance, albeit slowly and surely.

Revenue by Segment

(Unit：B yen)

	FY2023				FY2022	Y on Y	
	Forecast		1H Results	Achievement (%)	1H Results	Change (%)	Change
	Full year	1H					
Prescription drugs	134.1	87.4	**96.4**	**110.2**	33.4	**188.8**	**63.0**
Overseas subsidiaries/export	96.6	28.0	**22.9**	**81.9**	19.9	**15.1**	**3.0**
Shionogi Inc.（US）	13.6	6.7	**8.1**	**121.8**	7.4	**10.3**	**0.8**
Fetroja	-	-	**6.5**	**-**	4.7	**37.6**	**1.8**
Shionogi B.V.（EU）	11.5	5.4	**6.1**	**112.5**	4.3	**43.0**	**1.8**
Fetcroja	-	-	**4.6**	**-**	3.2	**41.2**	**1.3**
Ping An Shionogi/C&O	58.0	13.2	**5.2**	**39.7**	5.6	**(6.4)**	**(0.4)**
Others	13.4	2.7	**3.4**	**127.6**	2.7	**28.3**	**0.8**
Contract manufacturing	13.8	7.3	**7.9**	**108.3**	7.4	**7.8**	**0.6**
OTC and quasi-drug	15.0	6.8	**7.1**	**104.1**	6.3	**13.1**	**0.8**
Royalty income	189.5	86.9	**95.6**	**110.0**	83.3	**14.8**	**12.3**
HIV franchise	185.0	86.0	**94.5**	**109.8**	80.4	**17.6**	**14.1**
Others	4.5	0.9	**1.1**	**125.7**	2.9	**(61.5)**	**(1.8)**
Others	1.0	0.5	**0.6**	**127.8**	0.6	**5.6**	**0.0**
Total	450.0	217.0	**230.5**	**106.2**	150.8	**52.9**	**79.8**

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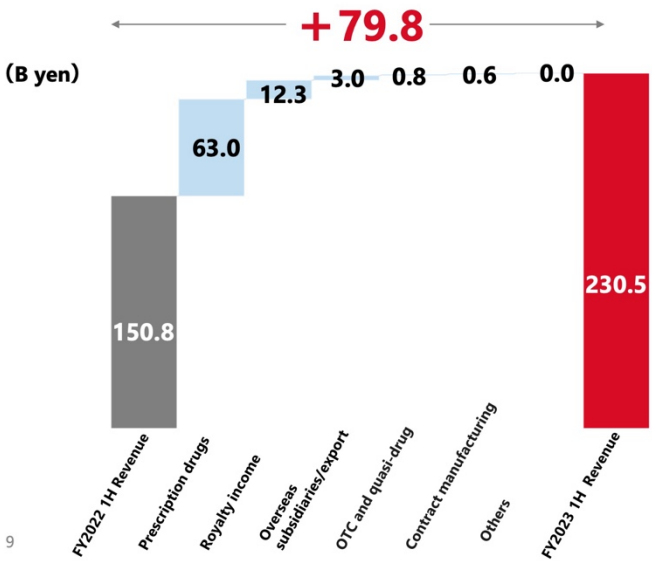
On page eight, you will see that in terms of YoY changes, Ping An Shionogi outstand. YoY decrease was 6.4%, or JPY 400 million. The existing business was not so much damaged, but we originally thought a fairly strong performance with COVID-19 products from H1, and that is the part that did not come through.

Other than that, I think the results of H1 were strong with both the achievement rates and YoY changes are positive.

Royalty income was YoY increase 17.6%, roughly two-thirds of which was thanks to the growth of our business, and one-third was from foreign exchange. Anyway, with an increase of JPY14.1 billion, the performance of royalty income was very strong.

Main Variation Factors of Revenue (Y on Y)



Prescription drugs

- Increase : Sales of Xocova and Xofluza
  : Receipt of Lump-sum income for transfer of ADHD drug
  : Returns of Xofluza and Rapiacta in FY2022 (5.3 B yen)
- Decrease: Sales of ADHD drug

Royalty income

- Increase: Strong sales of ViiV's HIV franchise

Overseas subsidiaries/export

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

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Page nine explains what I just mentioned.

Cefiderocol is doing very well in the US and Europe, with sales of JPY6.5 billion in the US and JPY4.6 billion in Europe, exceeding JPY10 billion for the first time in a half year. We expect H2 of the fiscal year to be reasonably strong as well and have set a target of about JPY30 billion for the fiscal year.

Nevertheless, I do not think it is right to sell JPY50 billion or JPY100 billion worth of drugs for multidrug-resistant bacteria, and I believe that each country should strictly control proper use of these drugs.

The reason for the growth is that we are gradually increasing the number of countries in which we launch our products, especially in Europe. In Italy, for example, there are existing markets that are still growing, and we are trying to expand into new areas and aim for nearly JPY30 billion.

Prescription Drugs in Japan

(Unit : B yen)

	FY2023				FY2022	Y on Y	
	Forecast		1H Results	Achievement (%)	1H Results	Change (%)	Change
	Full year	1H					
Infectious disease drugs	65.7	40.0	**49.0**	**122.5**	(0.6)	-	**49.6**
COVID-19 related products + Influenza franchise	57.3	35.8	**44.4**	**124.1**	(5.0)*	-	**49.4**
Cymbalta	4.2	2.1	**2.1**	**98.1**	3.0	**(31.2)**	**(1.0)**
OxyContin franchise	4.1	2.1	**2.2**	**103.2**	2.3	**(5.3)**	**(0.1)**
Symproic	4.9	2.3	**2.1**	**92.4**	1.6	**28.8**	**0.5**
Actair	1.0	0.4	**0.3**	**78.0**	0.3	**20.2**	**0.1**
Mulpleta	0.1	0.1	**0.0**	**78.4**	0.1	**(7.1)**	**(0.0)**
Pirespa	1.9	1.1	**1.0**	**95.6**	1.4	**(25.5)**	**(0.3)**
Others	52.1	39.3	**39.6**	**100.6**	25.3	**56.5**	**14.3**
ADHD drug (Intuniv and Vyvanse)**	25.0	25.0	**25.0**	-	10.1	**147.8**	**14.9**
Prescription drugs	134.1	87.4	**96.4**	**110.2**	33.4	**188.8**	**63.0**

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

Influenza franchise
- Xofluza
- Rapiacta
- BrightpocFlu・Neo

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

* Returns of Xofluza and Rapiacta ** Includes Lump-sum income from transfer of ADHD drug

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Page 10 is regarding the domestic market. FY2022 H1 results, the third line from the right says minus JPY5 billion. We took back Xofluza and Rapiacta market inventory, and we would like to aim for business operations that minimize disposal in the future.

From the perspective of the SDGs, it would never be right to send a lot of products in the winter, have it returned, and then dispose of it. We are aware that the doctors or wholesalers are not 100% happy with us, but we are trying to control this steadily.

In fact, the actual amount of Xofluza used and the amount of our supply have been in line with each other, and from this fiscal year, we are making good efforts in terms of communication with the society regarding influenza.

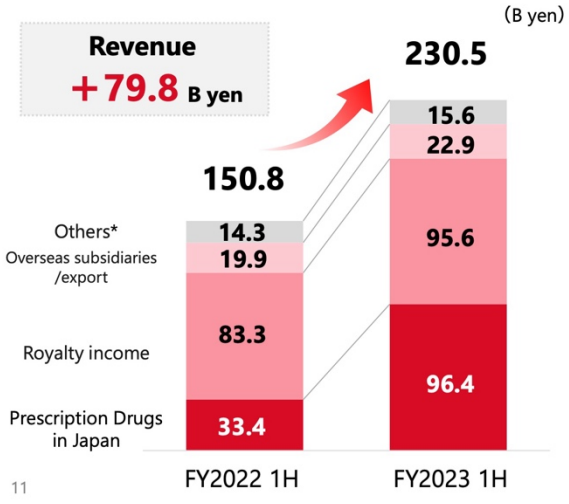
In addition, COVID-19 related and influenza franchise contributed to about JPY50 billion in revenue growth, with the H1 revenue of JPY44.4 billion and negative JPY5 billion in the previous year.

Then, for the ADHD drug, FY2022 revenue was JPY10.1 billion, or about JPY10 billion. FY2023 H1 result was JPY25 billion, which is a factor of about JPY15 billion increase.

Revenue increase of about JPY50 billion from influenza and COVID-19, and ADHD, could explain almost all the increase of JPY63 billion.

Top-line grew significantly due to expansion of in-house sales

Continuing from 1Q, sales continued to increase in all businesses



Key drivers of top-line growth

- Domestic : Xocova sales strongly drive top-line growth
  : Strong growth of Influenza franchise
- Overseas subsidiaries : Strong growth of Cefiderocol (Fetroja, Fetcroja)
- Royalty income : Growth of Dovato and expansion of share of cabotegravir
- Others : Growth of Contract manufacturing and OTC and quasi-drug

* Total of Contract manufacturing and OTC and quasi-drug, others

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Page 11 is explaining what I have just mentioned. In general, all sales are moving in a positive direction, and I believe that we have made a good start for H1.

1st Half Results and Future Outlook

Steady progress in transforming the company into a company that can expand globally

Top-line growth

Achieved record highs in sales revenue and all profit items

- Significant growth in all businesses (Y on Y)
- Revenue and various profit items exceeded budget

Establishment of growth drivers

Progress in development pipeline

- Safety and tolerability data from Phase 1 study of S-309309 presented at Obesity week
- Started development of a combination of cefiderocol + Xeruborbactam

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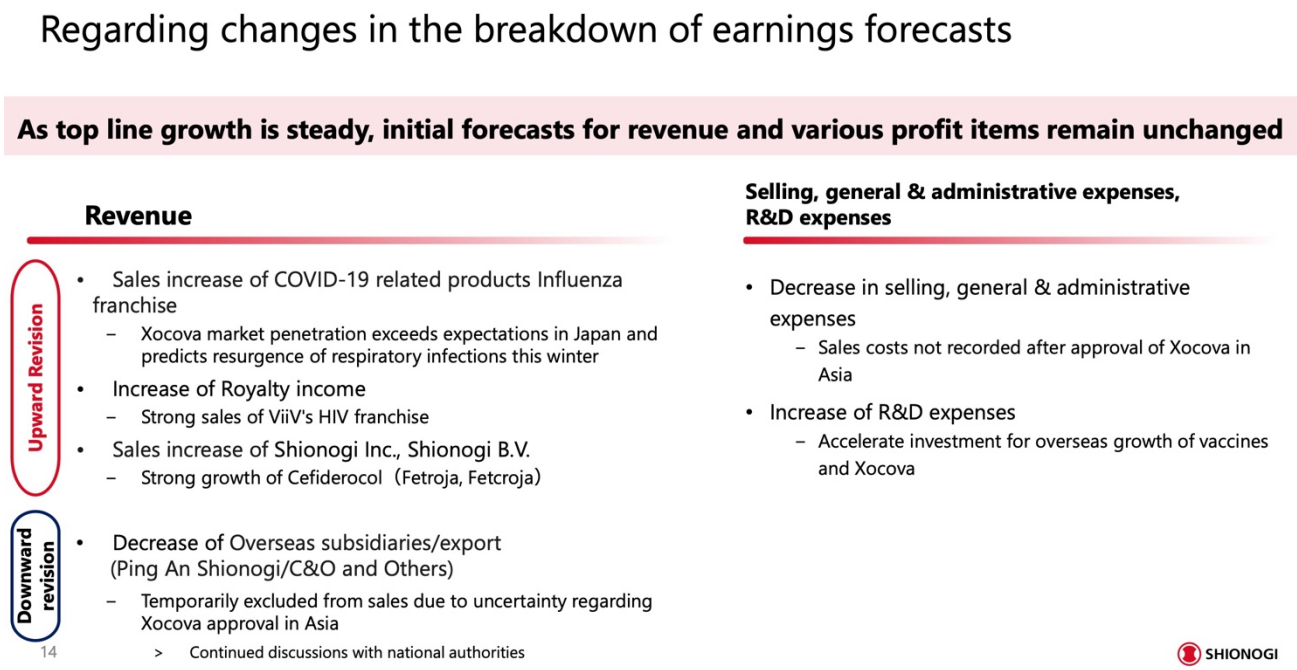
Please see page 12. In addition to the marketing activities, we bought Qpex, which allows SHIONOGI to have a β-lactamase inhibitor. Actually it is the first time for SHIONOGI to have a full-fledged β-lactamase inhibitor, and this has allowed us to enhance our development pipeline.

Also, after very good Phase I of S-309309, Phase II which Uehara will talk about it later, the enrollment is over, so now we have six months of observation period, plus one month of follow-up period, and we hope to get the results soon.



See page 14. The earnings forecast based on these has also been discussed extensively at the Management Committee and Board of Directors meetings and is presented here.

From the bottom, we are still in ongoing discussion with the authorities regarding Xocova and Ensitrelvir in Asia. Frankly speaking, now that emergency period is over, each country is in a mood where they are not in such a hurry and the normal approval process is fine. Their reviewing process is slower than we expected.

In response, we still believe that there is a possibility of Chinese and Korean sales in H2. However, rather than making a large projection by expecting this, we will reset our forecast for this fiscal year, and I believe that drug sales for respiratory viral infections including influenza in Japan, sales of Cefiderocol in the US and Europe, and strong royalty income will be enough to compensate for the current situation.

In conclusion, I would like to start here with the original revenue forecast of JPY450 billion, which remains unchanged.

Naturally, the Board of Directors also discussed the possibility that the market would be more receptive to an upward swing. However, since this is the first year of the STS2030 Revision, the Board of Directors has given its approval for us to start by ensuring that we exceed the announced figures.

In addition, we had originally included in our plan that Xocova in China would incur considerable SG&A expenses because of our partnership with Chia Tai Tianqing and Shanghai Pharmaceuticals. By eliminating that, or rather, not reducing it to zero, but a certain amount is included, but by reducing it by about half, there will be a decrease in SG&A expenses. The basic idea is to add that to R&D.

Financial Results

(Unit : B yen)

	FY2023 Forecast		FY2022 Results	Y on Y	
	Full year	2H	Full year	Change (%)	Change
Revenue	450.0	219.5	426.7	**5.5**	**23.3**
Operating profit	150.0	51.9	149.0	**0.7**	**1.0**
Profit before tax	192.5	76.9	220.3	**(12.6)**	**(27.8)**
Profit attributable to owners of parent	155.0	64.4	185.0	**(16.2)**	**(30.0)**

		FY2023 Forecasts (May. 10)	FY2023 1H Results	FY2023 Forecasts (Oct. 31)
Exchange Rate (Average)	**USD($) – JPY(¥)**	**130**	**141.06**	**141**
	GBP(£) – JPY(¥)	**160**	**177.63**	**173**
	EUR(€) – JPY(¥)	**140**	**153.46**	**151**

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H2 forecast on page 15 is the full-year forecast minus H1. We are aiming for a 5.5% increase in revenue and a 1% increase in operating profit, which would be the highest revenue and operating profit in our history.

Statement of Profit and Loss

(Unit : B yen)

	FY2023 Forecasts Full year			FY2023 Forecasts 2H			FY2022	Y on Y	
	Forecasts (May. 10)	Revised (Oct. 31)	Revised amount	Forecasts (May. 10)	Revised (Oct. 31)	Revised amount	Results	Change(%)	Change
Revenue	450.0	**450.0**	**-**	233.0	**219.5**	**(13.5)**	426.7	5.5	23.3
Cost of Sales	15.3 69.0	13.2 **59.5**	**(9.5)**	16.1 37.5	14.4 **31.6**	**(5.9)**	14.6 62.2	(4.4)	(2.7)
Gross profit	381.0	**390.5**	**9.5**	195.5	**187.8**	**(7.7)**	364.4	7.2	26.1
Selling, general & administrative expenses, R&D expenses total	50.9 229.0	51.3 **231.0**	**2.0**	53.9 125.5	61.3 **134.5**	**9.0**	47.8 203.9	13.3	27.1
Selling, general & administrative expenses	28.9 130.0	26.4 **119.0**	**(11.0)**	32.6 76.0	31.8 **69.8**	**(6.2)**	23.8 101.5	17.2	17.5
R&D expenses	22.0 99.0	24.9 **112.0**	**13.0**	21.2 49.5	29.5 **64.8**	**15.3**	24.0 102.4	9.4	9.6
Other income & expenses	(2.0)	**(9.5)**	**(7.5)**	(0.5)	**(1.4)**	**(0.9)**	(11.5)	-	2.0
Operating profit	33.3 150.0	33.3 **150.0**	**-**	29.8 69.5	23.6 **51.9**	**(17.6)**	34.9 149.0	0.7	1.0
Finance income & costs	42.5	**42.5**	**-**	25.0	**25.0**	**-**	71.3	(40.4)	(28.8)
Profit before tax	42.8 192.5	42.8 **192.5**	**-**	40.6 94.5	35.0 **76.9**	**(17.6)**	51.6 220.3	(12.6)	(27.8)
Profit attributable to owners of parent	155.0	**155.0**	**-**	77.0	**64.4**	**(12.6)**	185.0	(16.2)	(30.0)

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Page 16 explains the details. I think SG&A and R&D expenses are distinctive. For the full year, SG&A expenses decrease by JPY11 billion, R&D expenses increase by JPY13 billion, and cost of sales decreases by JPY9.5 billion which we may increase if the product is launched in China and Korea.

If the product is launched in China and Korea cost of sales and SG&G may increase .By eliminating that, the cost of sales will be a little lower, SG&A expenses will be lower, and of course, we will prepare, so there is a

significant reserve for sales of Xocova and Ensitrelvir in the United States, Europe and China, and that is included in the negative JPY11 billion. Including that, we are willing to defend our forecast for the full year.

Revenue by Segment

(Unit : B yen)

	FY2023 Forecasts Full year			FY2023 Forecasts 2H			FY2022	Y on Y	
	Forecasts (May. 10)	Revised (Oct. 31)	Revised amount	Forecasts (May. 10)	Revised (Oct. 31)	Revised amount	Results	Change(%)	Change
Prescription drugs	134.1	**167.0**	**32.9**	46.7	**70.6**	**24.0**	179.7	(7.1)	(12.7)
Overseas subsidiaries/export	96.6	**49.2**	**(47.4)**	68.6	**26.2**	**(42.4)**	42.5	15.7	6.7
Shionogi Inc. (US)	13.6	**17.0**	**3.3**	7.0	**8.8**	**1.9**	15.4	9.7	1.5
Fetroja	-	**-**	**-**	-	**-**	**-**	10.0	-	-
Shionogi B.V. (EU)	11.5	**13.0**	**1.5**	6.1	**6.9**	**0.8**	9.1	43.7	4.0
Fetcroja	-	**-**	**-**	-	**-**	**-**	6.6	-	-
Ping An Shionogi/C&O	58.0	**12.1**	**(46.0)**	44.8	**6.8**	**(38.0)**	12.0	0.7	0.1
Others	13.4	**7.1**	**(6.3)**	10.7	**3.7**	**(7.0)**	6.0	18.4	1.1
Contract manufacturing	13.8	**16.4**	**2.6**	6.5	**8.4**	**2.0**	15.3	6.7	1.0
OTC and quasi-drug	15.0	**14.8**	**(0.2)**	8.2	**7.7**	**(0.5)**	13.1	12.4	1.6
Royalty income	189.5	**201.2**	**11.7**	102.6	**105.7**	**3.1**	174.7	15.2	26.5
HIV franchise	185.0	**196.5**	**11.5**	99.0	**102.0**	**3.1**	168.5	16.7	28.1
Others	4.5	**4.7**	**0.2**	3.6	**3.6**	**-**	6.2	(24.1)	(1.5)
Others	1.0	**1.5**	**0.5**	0.5	**0.8**	**0.3**	1.3	14.2	0.2
Total	450.0	**450.0**	**-**	230.0	**219.5**	**(13.5)**	426.7	5.5	23.3

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Page 17 shows the breakdown. As for Japan, due to the fact that it was difficult to know if public spending will continue after October, we initially had a fairly large Xocova in China and South Korea, and Japan was in a considerably small.

But, it does not seem that the use of antivirus drugs will be reduced to zero so suddenly, given the trend in October. Of course, we believe that the decrease due to the decline in the number of infections is very significant, but if the 10th COVID-19 wave, as it is commonly referred to in the public opinion, is expected to hit Japan during December and January, we expect the revenue of domestic prescription drugs to be about this level with a positive of JPY24 billion.

On top of that, this is mostly for COVID-19, an infectious disease drug, plus influenza, but we decrease Xocova in overseas including Ping An, Korea and Southeast Asia.

Royalties and Cefiderocol of Shionogi Inc. and Shionogi B.V. are increased. The decrease of JPY13.5 billion is equal to increased revenue in H1. We would like to use this as a starting point and hope that we can manage to exceed this figure.

Prescription Drugs in Japan

(Unit : B yen)

	FY2023 Forecasts Full year			FY2023 Forecasts 2H			FY2022	Y on Y	
	Forecasts (May. 10)	Revised (Oct. 31)	Revised amount	Forecasts (May. 10)	Revised (Oct. 31)	Revised amount	Results	Change(%)	Change
Infectious disease drugs	65.7	**97.5**	**31.8**	25.7	**48.5**	**22.8**	112.1	(13.0)	(14.6)
COVID-19 related products + Influenza franchise	57.3	**88.6**	**31.3**	21.5	**44.2**	**22.7**	103.6	(14.5)	(15.0)
Cymbalta	4.2	**4.2**	**-**	2.0	**2.1**	**0.0**	5.4	(23.5)	(1.3)
OxyContin franchise	4.1	**4.3**	**0.1**	2.0	**2.1**	**0.1**	4.4	(3.5)	(0.2)
Symproic	4.9	**4.9**	**-**	2.7	**2.8**	**0.2**	3.4	44.6	1.5
Actair	1.0	**1.0**	**-**	0.6	**0.7**	**0.1**	0.5	91.0	0.5
Mulpleta	0.1	**0.1**	**-**	0.1	**0.1**	**0.0**	0.1	25.9	0.0
Pirespa	1.9	**1.9**	**-**	0.9	**0.9**	**0.0**	2.5	(24.4)	(0.6)
Others	52.1	**53.1**	**1.0**	12.8	**13.5**	**0.8**	30.6	73.6	22.5
ADHD drug (Intuniv and Vyvanse)**	25.0	**25.0**	**-**	-	**-**	**-**	20.6	21.4	4.4
Prescription drugs	134.1	**167.0**	**32.9**	46.7	**70.6**	**24.0**	179.7	(7.1)	(12.7)

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

Influenza franchise
- Xofluza
- Rapiacta
- BrightpocFlu・Neo

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

18

* Returns of Xofluza and Rapiacta ** Includes Lump-sum income from transfer of ADHD drug

SHIONOGI

Page 18 explains the Japanese market as I mentioned earlier. With COVID-19 plus influenza drugs, the full year forecast is JPY88.6 billion. We aim to sell about the same amount as in H1.

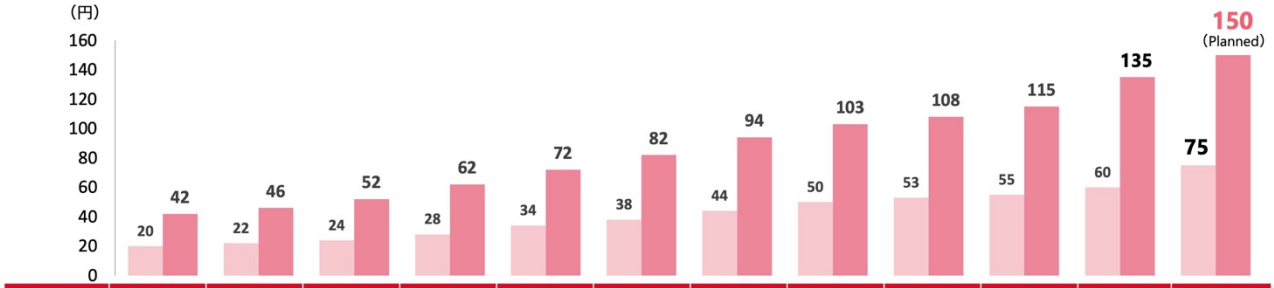
In fact, I don't think we are alone in October, but although the spread of COVID-19 is slower a bit, the spread of influenza is quite strong, and I think we can manage to achieve this figure of JPY44 billion.

We have now discussed revenue, etc.

I would like to answer any questions you may have, including detailed ones, since Iwasaki and Hanasaki, who is responsible for global sales, are also present today.

Flexible and Prompt Capital Strategy

- **Shareholder return policy through which shareholders can feel our growth**
  - Enhance capital efficiency through share buybacks, cancellation of treasury shares, and unwinding of cross-shareholdings
  - Increased dividend by 15 yen from the previous interim period
  - Plan to increase dividend again for the 12th consecutive year in FY2023



FY		12	13	14	15	16	17	18	19	20	21	22	23
Treasury stocks	Buyback	-	-	30 B yen	-	35 B yen	29.4 B yen	50 B yen	50 B yen	50 B yen	-	49.4 B yen	75 B yen**
	Cancelation	-	-	-	-	22 M shares	5 M shares	7.35 M shares	5.2 M shares*	-	-	4.2 M shares	-
DOE (%)		3.7	3.5	3.7	4.1	4.5	4.6	4.6	4.0	4.1	3.8	3.9	4.0 (expected)
ROE (%)		17.5	9.2	9.4	13.6	16.3	19.4	20.9	15.5	13.9	12.5	17.8	13.5 (expected)

Values calculated based on IFRS after 2019

* Resolution passed on March 30, 2020, and treasure shares cancelled on April 6, 2020 ** Total amount of acquisition cost: 75 billion yen (maximum)

SHIONOGI

The last page 20 is about dividends. Currently, we are implementing a share buyback program amounting to JPY75 billion. Apart from that, we would like to consistently increase dividends, and once we have paid a six-month dividend, for example, JPY75 at the end of last fiscal year, we would like to set that as the minimum level. We have been doing so for the past 12 years.

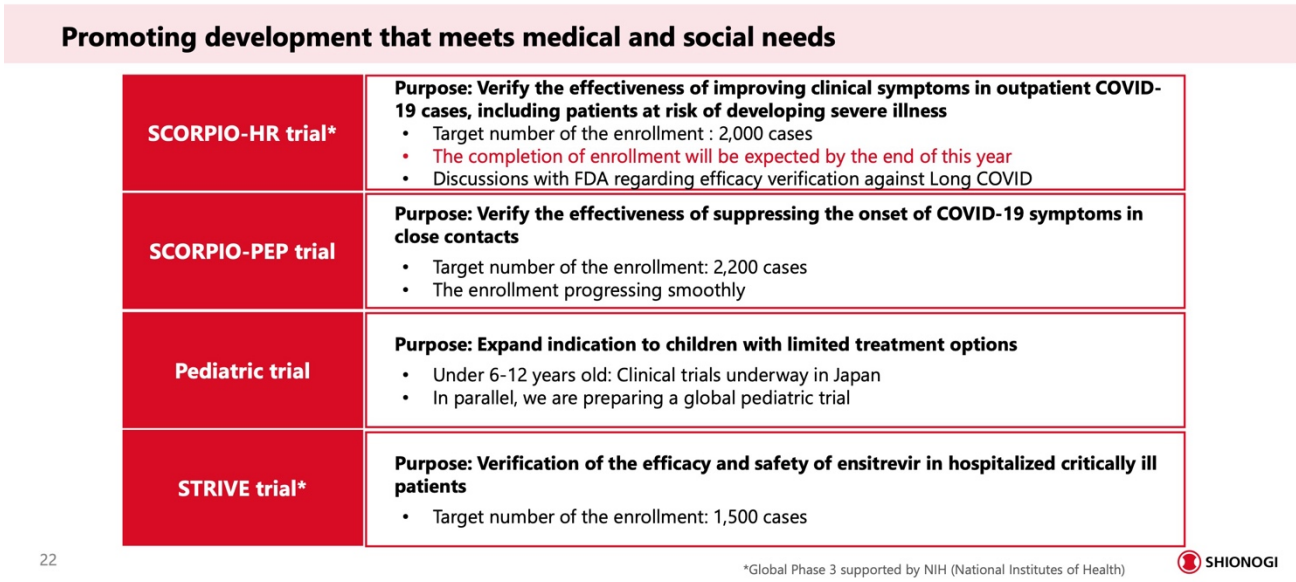
So again, I would like to start the interim dividend at JPY75, an increase of JPY15 compared to the previous interim period, and JPY150 for the full year.

However, as you are all aware, we always discuss the possibility of raising the year-end dividend when results are good, and we will aim to raise it again this year as much as possible.

My presentation was rather long, but I would like to share with you the results and our thoughts for the full year.

Now, Uehara will give you an update on COVID-19 treatment, main pipeline and S-309309.

Xocova: Development Plan



Uehara: I will continue the presentation. Thank you. First is COVID-19 treatment, Xocova. The material you have before you describes the progress of the trials.

At the top is the global Phase III trial. This is a trial that will enroll more than 2,000 cases in the United States, Europe, Africa, India, and other countries. We have been conducting Phase III trials in Japan and other Asian countries, and one of the Phase III trials, which were urgently approved in Japan, has already been completed. This is also a global study that includes high-risk patients regardless of risk factors.

This trial has already started to show signs of completion of case enrollment. We expect to complete the enrollment by the end of December and are working on the final phase.

One major update is about Long COVID, which I have been talking about for a while. The primary endpoint here is the time to symptom disappearance and how quickly symptoms heal. But Long COVID is also a point where unmet needs remain now. Therefore, we are currently discussing the final protocol with FDA for a trial design that will test whether taking the drug will reduce the risk of Long COVID in actual clinical practice in various countries around the world.

With these results, we would like to conduct Long COVID, specifically follow-up up to three months under blind, once enrollment is complete, so we will have an opportunity to explain the data obtained afterwards.

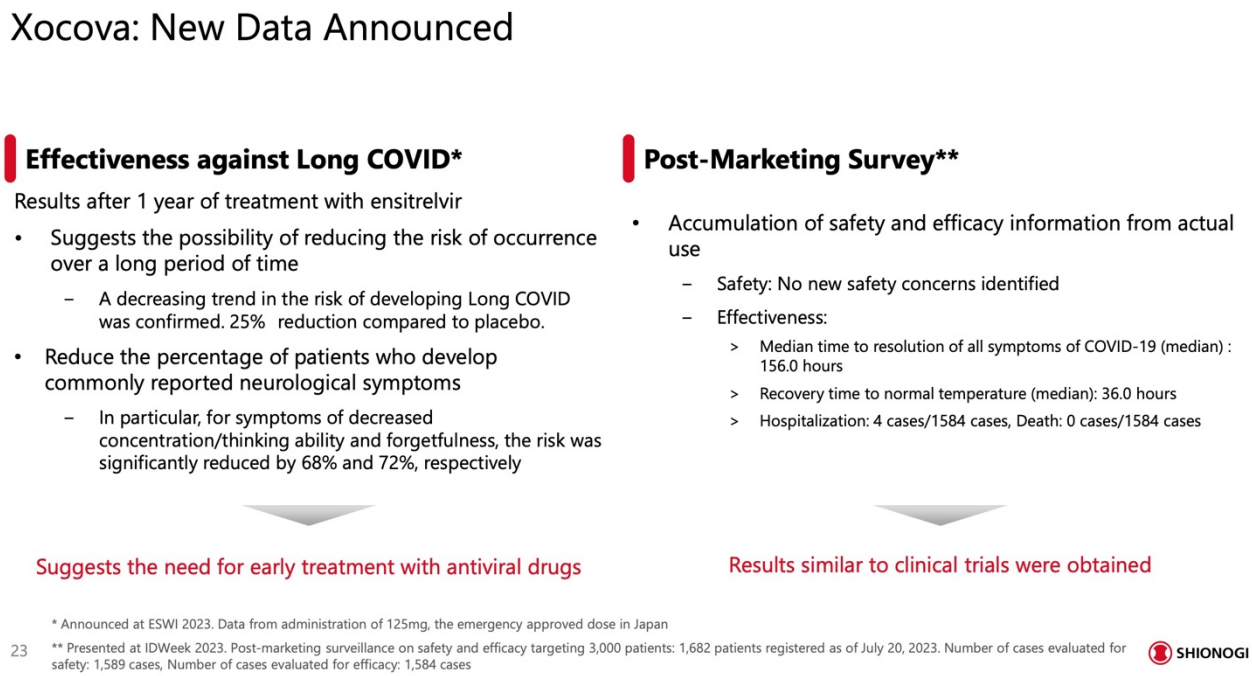
The next trial is testing prevention. This trial is to verify the effectiveness of suppressing the onset of COVID-19 symptoms after taking the drug in various countries. This trial is also to enroll more than 2,000 cases. Specifically, we are hoping that Xocova's antiviral effect will lead to a prophylactic indication that has not been achieved by any existing oral drugs, and we are continuing to work on this as one of our top priorities in order to create an environment in which the drug can be used worldwide.

The enrollment of cases is also progressing well, and like the above mentioned global Phase III trial, we are now at the stage where we are hoping to complete the enrollment this winter.

The third trial, pediatric trial, is to first prepare a slightly smaller tablet, mainly in Japan, that can be taken by school children; specifically, as the infection spreads from elementary schoolers to adults, there is currently

no oral drug that can be taken by children. We are currently conducting clinical trials so that we can deliver this product as soon as possible.

Finally, concerning the bottom trial, there are doctors all over the world who have high expectations for the antiviral effect of Xocova, so global trials are now being conducted around the world to see if the use of this drug as an add-on for patients hospitalized with serious illnesses can be expected to be effective in terms of mortality rates or early discharge from the hospital.



New data to be announced and one is for Long COVID. I mentioned earlier that we will be verifying this in global Phase III. The reason for this is that in the Phase III trial conducted in the Asian region, the risk of Long COVID was lower for patients who took the medication at either three or six months, and now we have one-year follow-up data.

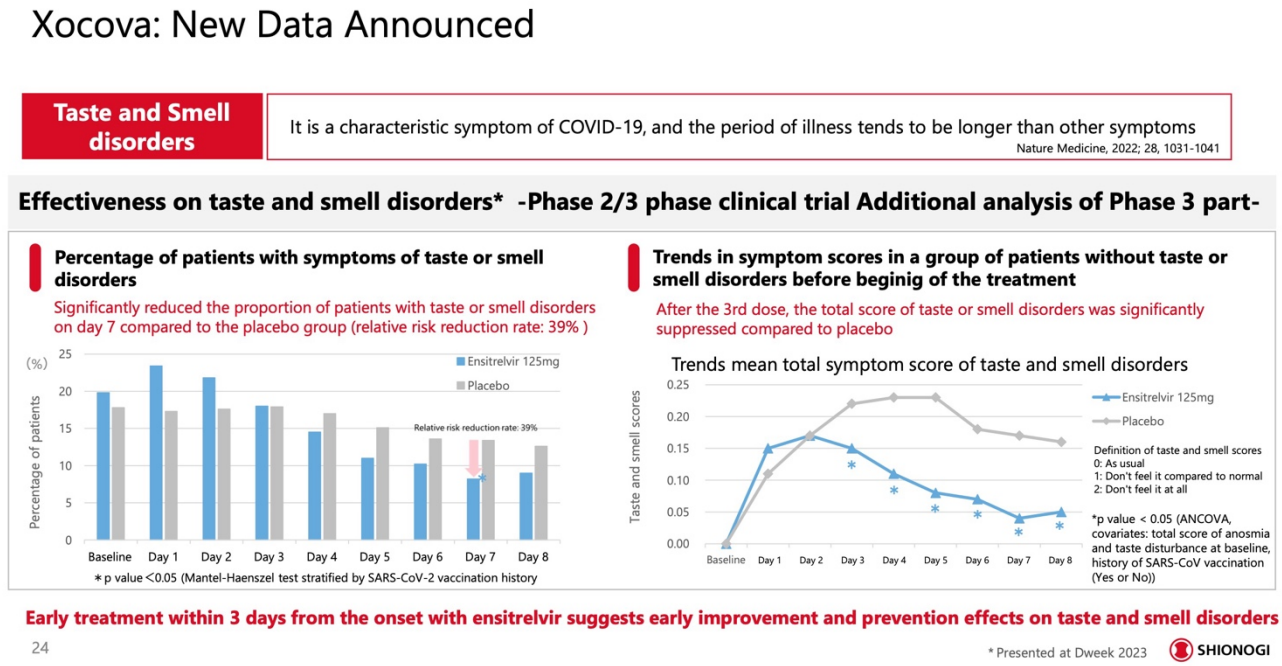
The same trend as three and six months, specifically a clean reduction in the risk of occurrence, with a 25% relative risk reduction compared to placebo, was observed.

In particular, there are a few patients who continue to report difficulty concentrating, fogginess, memory loss, and even fatigue. We have also observed a statistically significant risk reduction trend of 68% and 72%, respectively, and based on these data, we are now in the process of verifying the results in a global Phase III trial.

Furthermore, by continuing to collect safety data from many users in Japan under the emergency approval, we are summarizing the interim report on the post-marketing survey on the right side. The safety of the product has been confirmed in clinical trials to date, and there have been no new events in actual clinical practice that would require additional safety care.

In addition, this is not data compared to placebo, but data on efficacy that is roughly equivalent to that obtained in clinical trials to date, specifically time to resolution of fever, time to resolution of symptoms, and effects on hospitalization and death. As you can see, four out of 1,584 patients were hospitalized after receiving the medication, but there were no deaths.

Naturally, this is a test to read safety data, but we believe that we have been able to provide data on efficacy that is fairly solid and understandable.

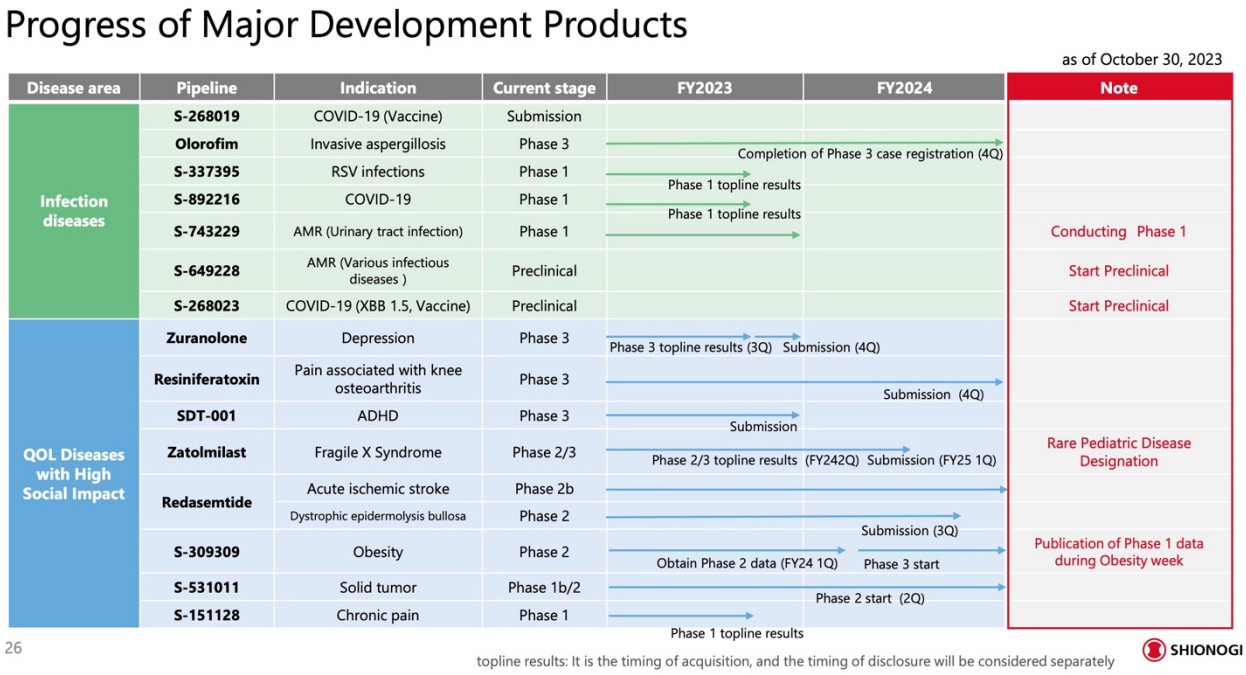


Furthermore, in terms of new data, it is for taste and smell disorders. As you are well aware, COVID-19 infection causes taste and smell disorders. It is commonly believed that the virus does not actually infect the cells of taste and smell, but if the number of the virus increases and the inflammation spreads to the surrounding sensory tissues, these sensory cells are damaged and lose their function.

Therefore, the data suggest that it is very important to stop the virus from multiplying as soon as possible after infection and to prevent the spread of inflammation throughout the body. Specifically, the bottom row, patients who took the drug are less likely to complain that their taste and smell symptoms are abnormal.

In particular, the graph on the right, confirmed by those who had no symptoms to begin with, shows that the first and second days are happening acutely, even if there are no symptoms at baseline. Therefore, although a certain degree of symptoms do occur, including with the actual drug, as you can see, at the latter point in time, those who took the COVID-19 drug were dramatically less likely to develop such symptoms.

Therefore, although the disease is said to be basically curable without medication, we believe that these data may indicate the effectiveness of eliminating the virus as early as possible before it increases.



I would like to continue to talk about the rest of the pipeline items, the important ones. Please see slide 26. Here is a list of our projects. Due to the schedule for today, I will not be able to explain all of the projects, but I would like to pick out some of the major ones to discuss.

Regarding infectious diseases, in addition to the therapeutic drugs for COVID-19, we are preparing COVID-19 vaccines, the top item S-268019, which I will talk about later, is a vaccine for the Wuhan strain, the strain of origin, and the bottom item, a mutant strain vaccine against XBB 1.5.

In addition to these vaccines, we are steadily developing a treatment for RS virus, a new treatment for AMR following the acquisition of Qpex, a treatment for Aspergillus in collaboration with F2G, and a treatment for various infectious diseases with high unmet needs.

In addition, we have also picked up other items of importance. Particularly, S-309309, which I am going to talk about today, is an anti-obesity drug. Phase 1 has been completed and Phase 2 is currently being implemented. I will discuss this later with the data.

Progress of Vaccine Development

Efforts toward building a sustainable business model are progressing

COVID-19 Vaccine

- Establish a recombinant protein vaccine platform and aim for full-scale supply of vaccines against mutant strains in the fall/winter season of 2024
- Actions towards establishing a platform
  - Obtaining approval for S-268019
    - > Continuing discussion: Additional evaluation based on onset prevention trial* data
  - Application for changes based on clinical trial data for XBB1.5 strain vaccine
    - > Developing a monovalent vaccine for the XBB1.5 strain
    - > Scheduled to start case registration in 3Q of 2023

※ Platform
For vaccines that have been established as a platform, if there is a commitment to obtain data on quality, efficacy, safety, and immunogenicity after marketing, it is possible to apply for a complete change to the current recommended strain with the latest quality and preclinical test results

Development of new technology

- Universal vaccine
  - Creation of antigen for development of universal sarbecovirus vaccine completed
  - Steady progress toward clinical entry in 2024
- Nasal vaccine
  - "Research and development of influenza/new coronavirus nasal vaccines" was selected as a vaccine/new modality research and development project solicited by AMED's*2 SCARDA*3

*1 Global Phase 3 NCT05212948
*2 Strategic Center of Biomedical Advanced Vaccine Research and Development for Preparedness and Response
*3 Japan Agency for Medical Research and Development

SHIONOGI

Next is the vaccine situation. As you are aware, one of our priorities has been to develop a vaccine for COVD-19 with a recombinant protein vaccine.

Regarding S-268019, the vaccine corresponding to the strain of origin, we have obtained data showing superiority of neutralizing antibody titer over other agents and have proceeded to submit an application for approval, but the committee recommended submission of additional data.

Specifically, the Phase 3 trial has been completed in Vietnam that evaluated the efficacy of the vaccine in preventing the onset of infection, the so-called true hard endpoint, and it is the MHLW's intention to submit that trial as well and then evaluate the data inclusively to review the application for approval. Therefore, we are now preparing to provide such data.

On the other hand, since many people have already been vaccinated with messenger RNA and other vaccines against the origin strain, we are now preparing to develop a mutant strain vaccine that corresponds to the strain that is actually prevalent, specifically the XBB 1.5 strain.

If we can actually get approval for the origin strain and then XBB 1.5 after conducting clinical trials for the XBB 1.5-compatible vaccine this winter, we will endorse the continued development of the vaccine as a platform. We are continuing to work diligently on the development of both vaccines.

We are also developing a universal vaccine that will make it as unnecessary as possible to constantly change vaccines. Spike protein changes its face and the shape rapidly, so we have succeeded in acquiring an antigen that is immune to the unchanged parts.

Although this vaccine is tried only with animals, it has been shown to induce very high neutralizing antibody titers and has neutralizing activity against a variety of the Omicron variant. We are working hard on trials to introduce it to the clinical situations as soon as possible.

Furthermore, progress is being made on COVID-19 vaccines, which are being developed as a vaccine that can be used intranasally as well as by injection, and on new routes of administration.

Strengthen Pipeline by Making Qpex Biopharma a Wholly Owned Subsidiary

As a leading company in infectious diseases, further accelerating efforts to overcome AMR*1

Driving the development of a combination of the β-lactamase inhibitor xeruborbactam with β-lactam antibiotics

S-649228: xeruborbactam + cefiderocol

- Injection in combination with cefiderocol
- Phase 1 trial scheduled to start in Q1 2024

Future studies to assess the utility of cefiderocol with xeruborbactam in the treatment of infections due to AMR

S-743229: xeruborbactam + ceftibuten

- Oral formulation in combination with the cephem antibiotic ceftibuten
- Phase 1 trial ongoing

Combined effect of xeruborbactam against Enterobacteriaceae, which is a problem in AMR*2

	MIC_{90}*3	
	ESBL*4 (N=515)	CRE*5 (N=292)
Meropenem (IV)	0.06	>64
+Xeruborbactam	**≤0.03**	**0.06**
Cefepime (IV)	>64	>64
+Xeruborbactam	**≤0.03**	**0.25**
Ceftibuten (oral)	>64	>64
+Xeruborbactam	**≤0.03**	**0.06**

*1 Antimicrobial resistance *2 Olga Lomovskaya, IDWeek 2023, Oct 11-15, Boston, MA *3 Minimum Inhibitory Concentration (μg/mL) *4 Extended Spectrum β-Lactamase *5 Carbapenem-Resistant Enterobacterales

Funded in whole or in part with federal funds from the U.S. Department of Health and Human Services, Administration for Strategic Preparedness and Response, Biomedical Advanced Research and Development Authority (BARDA) under OTA number HHSO100201600026C.

SHIONOGI

As Teshirogi mentioned at the beginning of this presentation, we acquired Qpex, a company that specializes in xeruborbactam, a β-lactamase inhibitor for co-administration for AMR.

Specifically, these two programs are at the stage of being ready to share with you at this time.

The upper row is S-649228, specifically, the co-administration of Cefiderocol and Xeruborbactam, which we expect will be a very promising product for AMR, allowing for longer use of Cefiderocol products in the mid- to long-term. We are now starting clinical trials.

In addition, there is another co-administration drug, called ceftibuten, which is an oral drug. Xeruborbactam in prodrug form, and ceftibuten, another old product of ours, can be combined to make an oral formulation that maintains very high efficacy.

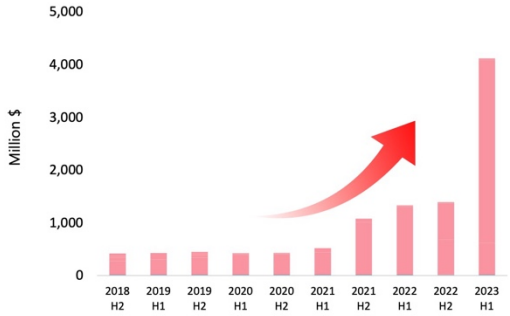
In fact, severe infections are treated by intravenous infusions during hospitalization, etc. If such an oral drug against AMR could be developed, the economic effect on medical care would be greatly enhanced. So, we develop easy to take AMR antibiotics.

Since Qpex has already started Phase 1, we will continue the global Phase 1 study in the form of a co-administration drug.

S-309309： Anti-Obesity Drug Market and Strengths of S-309309

An oral agent with a revolutionary mechanism provides an innovative option for the ever-expanding obesity market

Anti-obesity drug market in US



The obesity market is expanding explosively with the entry of GLP-1 injection into the market

Differentiating points of S-309309 (MGAT2* inhibitor)

- **Strong inhibition of triglyceride resynthesis in small intestinal epithelial cells**
  - Suppression of food intake through increased secretion of appetite regulators
  - Suppresses absorption of triglycerides
  - Increase of energy expenditure for enhance β-oxidation of accumulated fatty acids

  ⇒ **Demonstrated greater weight reduction in preclinical studies**
- **Offering non-injectable, small molecule option**
  - Reducing the financial burden on patients
  - Additive effect of combination with GLP-1 analogs (including orals)
- **Good PK and safety, tolerability**
  - Publication of Phase 1 data（Next page）

* Monoacylglycerol transferase 2 (App : P.34)

SHIONOGI

Next is S-309309, an anti-obesity drug. As you know, the obesity drug market has become very active with the rise of GLP-1.

However, this drug of ours is different from GLP-1. The drug inactivates MGAT2, an enzyme in small intestinal epithelial cells, specifically the enzyme necessary for the process of absorbing triglycerides, breaking them down, and absorbing them one more time in the cell.

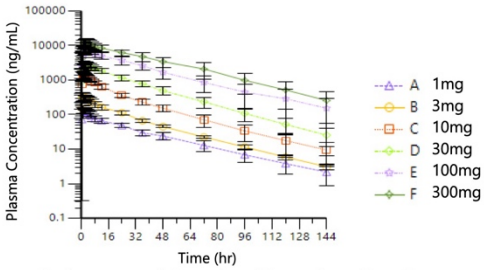
This is not a drug that specifically stops fat absorption, although stopping fat absorption is one of its mechanisms. In fact, such a process in the cell can cause negative feedback to the food center and increase energy metabolism, which is a mechanism of action that modulates the body's metabolism and diet in some way and has been shown to have the effect of clean weight loss in animals.

Furthermore, data have been obtained showing further additive efficacy against GLP-1. Now, GLP-1 has many challenges. Specifically, we are developing anti-obesity drugs that can be used with a slightly higher drug price, or in oral dosage forms that are safer and easier to use.

S-309309： Phase 1* Data Published during Obesity Week

There were no safety concerns, and the drug showed an excellent PK profile after single and multiple administrations

PK profile and Selection of target concentration



Phase 2 dose was determined based on the above results and target plasma concentration

Phase 2 trial progressing as planned after achieving FPI in July

30

Summary

Good PK profile

- Can be administered once a day (half-life: 20-24hr), linearity confirmed, small individual differences (variation in Cmax/AUC)
- No difference in PK between healthy and obese subjects
- No food effect on PK exposure, no drug-drug interaction with midazolam (CYP3A)

Well tolerability

- All AEs were mild, no dose-dependent increase in AE incidence rate
  - No serious side effects including gastrointestinal disorders
- No risk of QTc prolongation

* Phase 1 study (conducted in the US): : NCT05247970

SHIONOGI

Very well tolerated data were identified during the Phase 1 trial. The profile of PK is shown on slide 30.

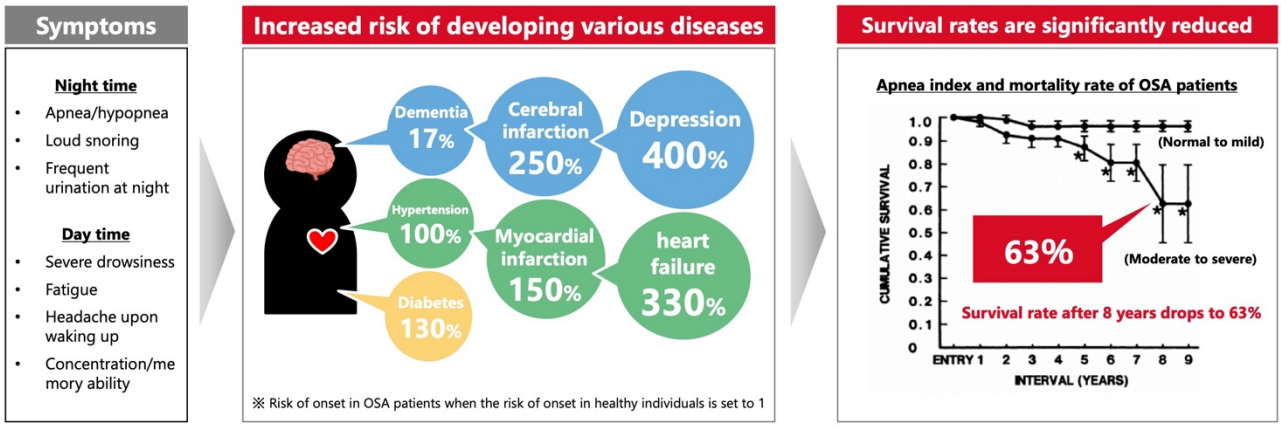
The situation is dose-dependent, escalating from 1 mg to 300 mg with no particularly significant adverse event onset and a clean proportional rise in exposure.

Based on these data, a Phase 2 PoC trial has already started in the US. We are conducting a middle sized trial of over 300 cases, all of which have been enrolled, and we will be able to discuss such efficacy results as soon as we have follow-up data, which we expect to be early this spring.

That is all.

New Focus Research Area ：Obstructive Sleep Apnea (OSA)

- **OSA is a QOL disease with high social impact and is at risk of progressing to various diseases**
- **OSA is a disease with high unmet needs as there are no effective pharmacologic treatment options**



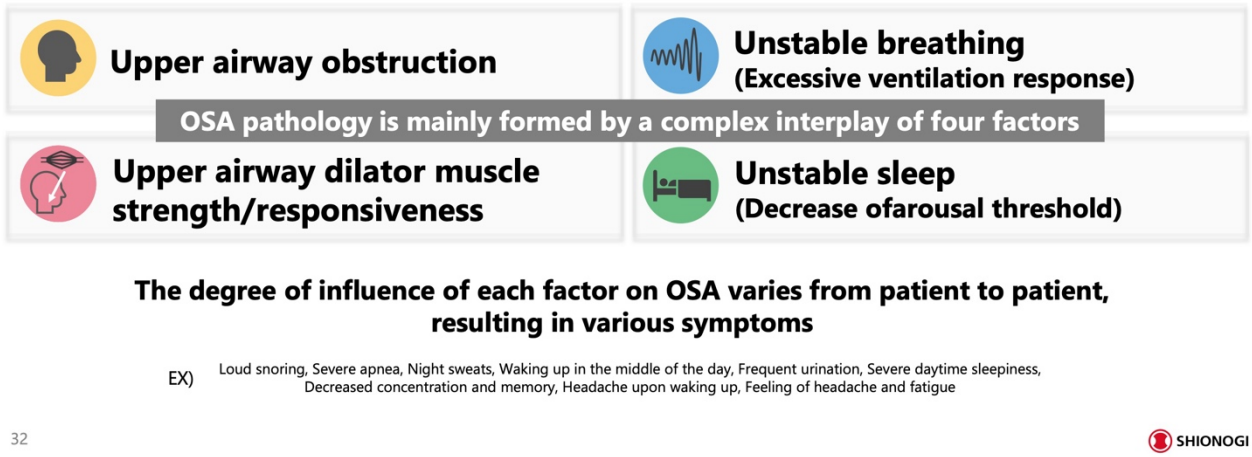
DataSource： *Am Rev Respir Dis* (1988) 138(2):337-40, *PharmacoEconomics* (2021) 39:653–665, *J Abnorm Child Psychol* (2019)47(8):1327-1338. *Eur Respir J* (2016) 47(4):1162-1169, *Chest* (1988) 94(1):9-14

SHIONOGI

Keller: Now I would like to talk about our new research area. This is about OSA., it interferes with sleep. It also affects things like sleep at night and memory the next day. Just such a cascade of impacts, moderate and then severe, further it can cause depression and heart failure. It has a significant impact on overall life and quality of life. After 8 years survival rate is 60%. The reason why this disease has not been solved with drugs or successfully tested until now is because it is a very complex disease. And it has a very significant impact on sleep, etc.

New Focus Research Area：Vision for Drug Discovery for OSA Treatment

We take a multifaceted approach to provide the right treatment options for each patient



The degree of influence of each factor on OSA varies from patient to patient, resulting in various symptoms

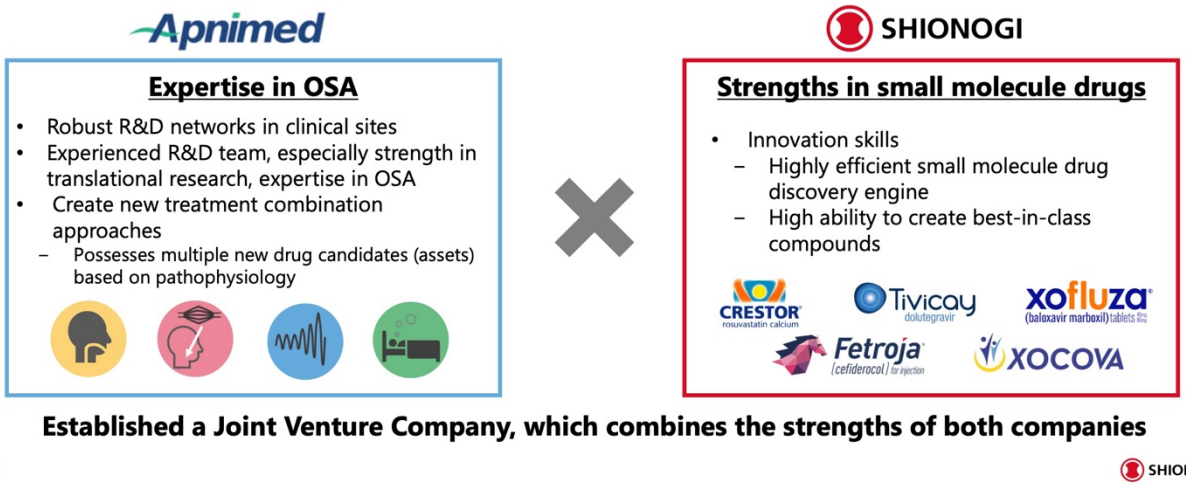
EX) Loud snoring, Severe apnea, Night sweats, Waking up in the middle of the day, Frequent urination, Severe daytime sleepiness, Decreased concentration and memory, Headache upon waking up, Feeling of headache and fatigue

SHIONOGI

All of these have four subcomponents. For example, obesity is considered a major risk factor, which, however, only affects the airways. For other components, it is different. So, we have to combine treatments, and what combination is best depends on the patient and is different for each patient.

New Focus Research Area : Established *Shionogi-Apnimed Sleep Science, LLC*

Build a system that enables the creation of solutions according to the four main factors of OSA and address to solve social issues



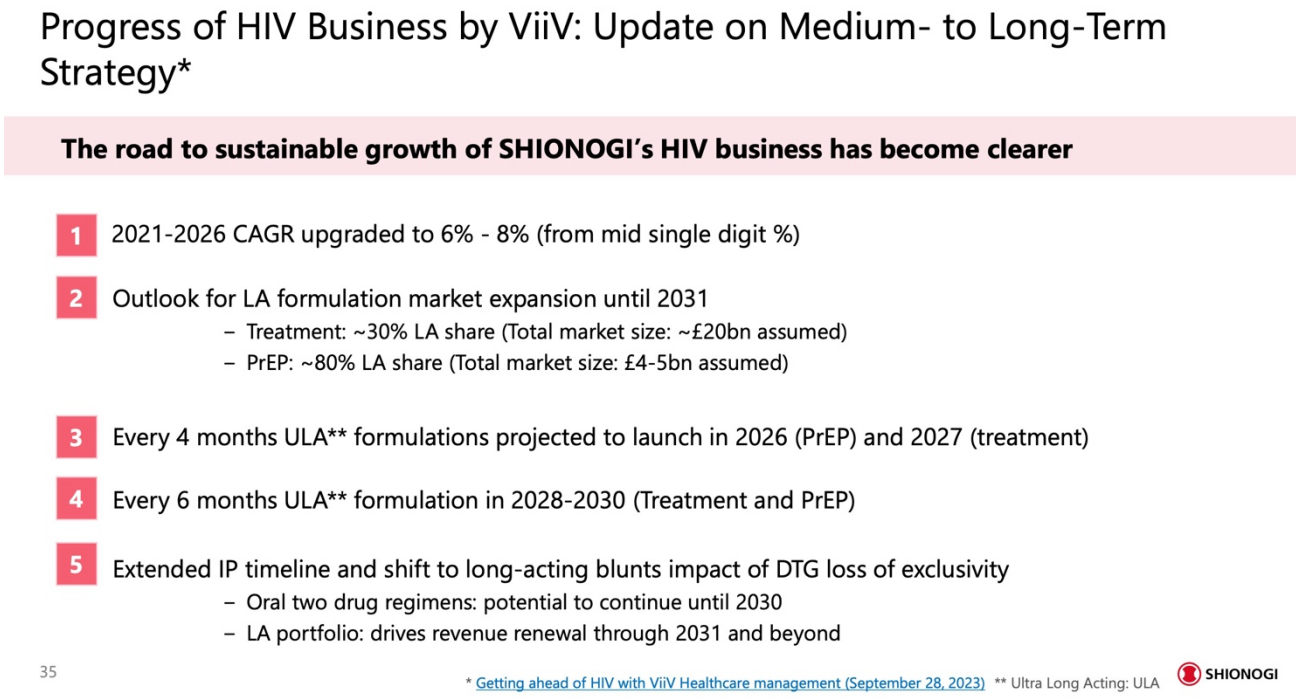
Established a Joint Venture Company, which combines the strengths of both companies

SHIONOGI

So I spoke with Apnimed, although there are not many expert companies. This company is knowledgeable about translational medicine and has clinical experience. Here, we can immediately test it in a clinical setting.

The company can identify what the key components are in the disease for the patient and then immediately conduct a clinical trial. The mechanism of these combinations is then something that can be examined to see if it really works.

Of course, we will contribute to this collaboration as a pharmaceutical company with strengths in small molecules. So, when we identify these mechanisms, we can immediately consider not only existing combinations, but also better NCEs. By doing so, we can provide even better medicine.



Next, I will discuss the HIV business.

As has been mentioned several times, the HIV business has been discussed with ViiV and we are updating our mid- to long-term strategy. The period from 2021 to 2026 is upgraded from 6% to 8%.

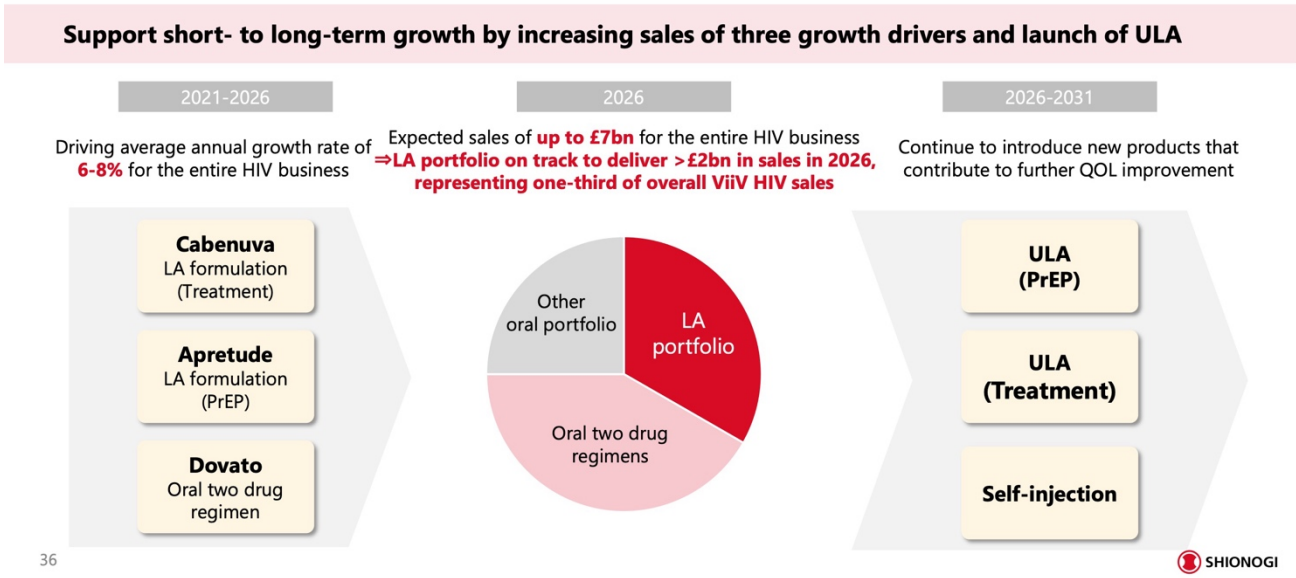
We also see prospects for expansion in the long-duration formulation market. In particular, the rate is 30% for long-acting injectables and 80% for prophylaxis by 2031. These are clear indications of the benefits of long acting.

Currently it is administered once every four months, which is up from once every two months to once every four months, and then we will look into the possibility of once every six months. These are all in both prevention and treatment.

Another thing I would like to mention is that the IP timeline, the existing Dovato and JULUCA, which are related to the dolutegravir, will also be extended to 2030 and 2029.

Then, as for the long-acting portfolio, this will also expand beyond just 2031. This will be through formulation as well as other long acting portfolio technologies.

Progress of HIV Business by ViiV: Sustainable Growth Strategy Centered on LA and ULA



So we will focus on growing the existing portfolio from now until 2026. Cabenuva long acting, Apretude long acting prevention, and then Dovato best-in-class oral.

With this portfolio, ViiV sales are expected to grow to GBP7 billion by 2026. GBP2 billion of these will be from long acting. As for ViiV's portfolio, a third of it is already long acting.

After that, we are considering further growth. After 2026, we will consider ultra-long acting, which means every four to six months, and also self-administered drugs. This is highly beneficial to the patients.

Progress of HIV Business by ViiV: Development of Once Every Four Months Administration Formulation (CAB 400)

Contribute to further QOL improvement by reducing the number of doses per year

- >2x half-life when dosed intramuscularly or subcutaneously, enabling every-four-month (Q4M) dosing with the potential for up to every six-months (Q6M)
- Launched before the dolutegravir patent cliff, further accelerating market penetration of LA portfolio
  - PrEP: 2026
  - Treatment: 2027
- Two options (one to be selected in 2024), aiming for launch in 2027
  - Cabotegravir (CAB 400) + rilpivirine
  - Cabotegravir (CAB 400) + novel bNAb N6LS (VH3810109)
    ⇒Phase IIb clinical trial ongoing
- CAB 400 data to be presented at CROI 2024 (March 3 to 6, 2024)

SHIONOGI

So, how do we accomplish this? We call it CAB400, which is a once-every-four-months formulation. This has worked out very well. The half-life is doubled for both intramuscular and subcutaneous injections. This allows for four or even six months to be considered.

In addition to this, there is also a combination and single agent prevention, which means that this will be sold with respect to dolutegravir. 2026 for prevention and 2027 for treatment.

Second, with regard to treatment, two medications are required. Currently, there are two leading options. One is to use a modified version, and the second is ViiV's new neutralizing antibody, N6LS, which is currently in Phase 2/b trials. A final decision will be made next year.

Which of these two will be chosen for the 2027 launch will be decided next year. Further data will be disclosed in CROI 2024.

Progress of HIV Business by ViiV: Main Milestones for Medium- to Long-Term Growth Drivers

Accelerate medium- to long-term growth with integrase inhibitor-based ULA

<table>
<tr><th></th><th>CY2023</th><th>CY2024</th><th>CY2025</th><th>CY2026</th><th>CY2027</th><th>CY2028-2030</th></tr>
<tr><td>ULA
(PrEP)</td><td rowspan="2">Cabotegravir
400mg/ml
dose selection</td><td>Q4M
Registrational
study
start (H1)</td><td></td><td>Q4M
file and launch</td><td>Q6M
Registrational
study
start</td><td>Q6M
file and launch</td></tr>
<tr><td>ULA
(Treatment)</td><td rowspan="2">Q4M
regimen
selection (H2)</td><td rowspan="2">Q4M
Registrational
study start (H2)</td><td></td><td>Q4M
file and launch</td><td rowspan="2">Q6M
file and launch</td></tr>
<tr><td>Self-injection
(Treatment)</td><td></td><td colspan="2">Q6M
regimen selection・Registrational
study start</td><td></td></tr>
<tr><td>Self-injection
(Treatment)</td><td></td><td>regimen
selection (H2)</td><td>Device set-up
(H2)</td><td>Registrational
study start</td><td></td><td>file and launch</td></tr>
</table>

SHIONOGI

Next is the overall schedule. The key here is to launch once every four months in 2026, then launch in 2027 with respect to four-month treatments, and if possible, every 6-month treatments between 2028 and 2030.

We will gradually look at Q4M and Q6M, and these will be based on commercial or patient needs.

Then there is another interesting one**:** self-injection. As for self-administration, it is a little later than before, but only because of the complexity of the device, so it will be after 2028.

So, the very important thing is to format every four months. This is both treatment and prevention. I am looking forward to seeing better results.

Question & Answer

Kyokawa : Now, let's move on to the question-and-answer session. Mr. Ueda.

Ueda : This is Ueda from Goldman Sachs. I would like to start by asking about the status of Xocova in Japan. Could you please explain the prescribing rate and market share trends? In particular, what has the prescription rate been since October? Also, regarding market share, I know that your company has published various data in IDWeek, ESWI, etc., so I would appreciate it if you could let us know if there are any changes in the evaluation of your products in the clinical field.

Iwasaki : I am Iwasaki in charge of the domestic business and I will answer. At the time of public funding, the prescription rate of three oral drugs for all COVID-19 positive patients was 22-23%. Approximately half of them have been using Xocova, and it has only been one month, so we have not fully read the impact of the up to JPY9,000 co-payment, but the decline has not been as expected.

I think a think tank called INES released a press release in August, and it said that patients' willingness to take medication would be reduced by about one-tenth if they had to pay 10,000 yen out of pocket. However, it has not fallen that far and is now about halfway down. We are not yet able to read how much of this is due to public funding and how much is due to the overall drop in patients, since we have very few fixed-point observations right now, but contrary to our expectations, it may not have dropped that much.

In the future, for example, since public subsidies are still available from local governments for children, they can be used free of charge. As I have said this many times, the drugs for influenza is 92% to 93%. On the other hand, the rate of COVID-19 treatment, which is also an antiviral drug, is still at 10%, so we would like to increase the overall treatment rate as soon as possible, including safety and Long COVID data, and promote the necessity of treatment to increase the prescription rate.

If doctors realize the antiviral efficacy in their clinical settings, they are proactively use it to their patients. We are hoping to accumulate such cases in Japan to increase the treatment rate in the future.

Ueda : Thank you very much. Second, I would like to know about the COVID-19 vaccines. I would like to know why it was not approved this time and the background of why it would be evaluated for the trial in Vietnam. Can you also tell us about the data disclosure in the vaccine for this XBB 1.5 variant, as well as your outlook and timeline for its approval?

Uehara : First of all, we are in a situation where the original strain vaccine has been disapproved and is under continuing reviewing. We are not aware of all the discussions within authorities, but our understanding is that the existing neutralizing antibody data alone is not sufficient at the stage of approval, and they would like to evaluate the efficacy of this vaccine together with the data from the already completed Phase III trials on prevention of disease onset.

Therefore, we are providing data that has already been completed. Our opinion is that the data is not that disappointing, and we hope that it will be used for a reasonable discussion.

Furthermore, as for the future of XBB1.5, we have already produced a vaccine for the Wuhan strain and are now in the process of producing a vaccine for the mutant strains. This winter, we will be taking data to compare neutralizing antibody titers in a Phase III, or clinical trial. When such data is obtained, we will be able to proceed with the application for approval, so our approximate target is to have our vaccine available for use at the timing of next year's fall/winter vaccination.

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

Kyokawa : Mr. Hashiguchi.

Hashiguchi : My name is Hashiguchi from Daiwa Securities. Thank you for your time today. I would like to know your approach to R&D and SG&A expenses. Compared to the results of H1, I believe that you plan to increase by about 40% in H2. You introduced what factors would cause the increase, and based on those factors, I received that, first of all, SG&A expenses will increase more in the next fiscal year.

So, if you are talking about the cost of preparation for the development of Xocova overseas, is it correct to understand that it will increase more once the results of Phase III are available and more certainty is obtained? Of course, if sales come with it, it would not be a problem at all. Also, as for R&D expenses, can we have the opposite outlook for this, that the Phase III trial of Xocova overcomes the challenges and it will decrease in the next fiscal year? I would be interested to know your thoughts on the future as well.

Teshirogi : Thank you for the question. Additional remarks will be received from Hanasaki or John. As you say, SG&A expenses, especially for Ensitrelvir in Asia and Ensitrelvir in the US, as well as some in Europe, will increase depending on how soon sales accompany them. Therefore, we would like to invest with the idea that an increase in SG&A expenses equals an increase in the top line, assuming that SG&A expenses will not first increase one or two years in advance.

In addition, since our forecast for R&D expenses is based on sales growth, we would like to increase R&D expenses in line with sales growth, and at the same time, we would like to work on new projects.

As for the composition, I am sure that the Ensitrelvir part will decrease. This SCORPIO-HR, a large Phase III, and the subsequent PEP is also of a certain size, so that part will decrease as this becomes the end, but for us, we are also preparing for Phase III of the S-309309.

Also, the Apnimed joint venture that was just mentioned by John is quite an interesting structure, which John can mention again later, but Sleep Apnea, as you know and maybe you can understand, has no animal model. Therefore, we will look at animals or preclinical studies to see if this mechanism should work, but we will not know if this combination will work until we start Phase IIa because there are no animals with Sleep Apnea.

Apnimed's strengths include the hospital setup there and the MD setup, and I think probably no other company in the world has that setup better than they do, so the more the research progresses well and the more compound groups that go into Phase IIa and Phase IIb, the sooner we can get there and get into clinical trials.

How we can best use our R&D expenditures, which are around 20% of sales, including the anti-obesity drugs, S-005151, and the Apnimed I mentioned earlier, is a major point for us. Naturally, John and Uehara are not happy with the approximately JPY113 billion that we have this time, and they want us to spend more, so we are trying to figure out how to manage that while there are many things we want to do.

Regarding SG&A expenses, Mr. Hanasaki globally or Mr. Iwasaki domestically, if you have any.

Hanasaki : My name is Hanasaki and I am in charge of overseas business. As Teshirogi said, we will use SG&A expenses while looking at our sales. In the case of the US, in particular, SCORPIO-HR is in progress, and we plan to control SG&A expenses, or sales force expenses, in a stepwise manner while confirming the various responses from the authorities and their events.

Hashiguchi : Thank you very much. I would like to make one more point. You introduced the process for obtaining approval for the COVID-19 vaccine, but can you give us any update on the production capacity, which has been an issue in the past, and how much can you supply if the approval is granted on this schedule?

Teshirogi : I think the final endorsement will come from Hanasaki, since he is in charge of the entire production and supply chain.

The UNIGEN facility, which has also received government money, is finally starting to show signs of operation in our own way, and we would naturally like to consider producing there when XBB 1.5 is successful. One batch is large, and we can supply 5 to 10 million people in one batch, so I think we are well on our way to supplying that unit next winter.

Hanasaki : I am Hanasaki, in charge of supply. We started trial and commercial vaccine production with 500 L tank in UMN in Akita. As Teshirogi mentioned, we are currently improving various steps of vaccine production, such as cultivation and purification, at the UNIGEN plant in Gifu. In that sense, to some extent, the prospects for S-268019 have become clear, and we are now preparing to scale up commercial production for next year's fall/winter season.

Hashiguchi : Thank you very much. That's all.

Kyokawa : Mr. Matsubara from Nomura.

Matsubara : My name is Matsubara from Nomura Securities. Thank you very much for your explanation. I ask two things about the pipeline.

The first is that S-309309 does not act directly on GLP-1, for example, reduction in adverse events of nausea and vomiting, and then the reduction in muscle mass that is now being mentioned, which I am aware is not here, is that correct? Also, if that is not the case, I would think that a combination with DPP-4 or other drugs would be better than the combination with GLP-1 mentioned here, but what is your perception there?

Uehara : Thank you for your question. No such events have occurred so far for Phase I. Naturally, no such events have occurred in animal toxicity studies, so our drug is so far free of muscle weakness and various gastrointestinal disorders associated with its mechanism of action.

As for the future approach of combining the two, we are now in the process of exploring what is really the most appropriate approach. We are in the process of repeating experiments with various non-clinical data. Combination with GLP-1, even if we consider GLP-1, is it an add-on to GLP-1, or is it used for those who cannot use it because of adverse events, such as when it is lowered with GLP-1 but switched because it is too high, or because it causes adverse events. I believe that GLP-1 can be used in a variety of ways, and theoretically it is possible to combine GLP-1 with various mechanisms of action, such as DPP-4, as you mentioned.

Since it is a normal body's natural tendency for muscle mass to decrease if dietary suppression occurs, there is a possibility of combining a drug with a mechanism of action that does not cause such a decrease while also maintaining muscle mass. We are in a situation where we are keen to add various evidences and develop them.

Matsubara : I understand very well. As an addition, when I look at MGAT2 inhibition, I often see papers that show it can reduce inflammation and fibrosis and help with NASH, but what about your company's expansion of such indications?

Uehara : There are many obese people who have fatty liver and NASH. In this Phase II trial, we will be conducting an exploratory evaluation by scanning various liver parameters, etc., so if weight loss or some other positive effects can be obtained from this drug or its mechanism of action, such a development is one possibility.

Matsubara : I understand very well. Secondly, I heard that it is difficult to find patients with refractory ulcers with regard to recruitment for epidermolysis bullosa with redasemtide, what is the current status of enrolment?

Uehara : We face difficulties, and we have confirmed a few cases out of the total of three we plan to enroll, but the remaining cases are still in the process of being registered.

Matsubara : Looking at page 26 of the document, I believe the application will be for Q3 of FY2024. I believe this is a 52-week patient follow-up, so I'm wondering if it would be difficult to complete patient enrollment here by now.

Uehara : At this point, we have not completed case enrollment in Phase IIb itself, so the timeline is a bit of hard. However, the number of patients we are targeting is not that large, so as soon as we find good patients, we will be able to proceed with the process.

Matsubara : I understand very well. Thank you.

Kyokawa : BofA Securities Mr. Mamegano.

Mamegano : My name is Mamegano from BofA Securities. Thank you. I would like to ask a question about domestic infectious diseases.

Regarding H1, I think that Xocova has made good progress, quite good, but your plan for H2 has also been increased from JPY 21.5 billion to 44.2 billion, this is for COVID-19 and influenza. I would like to know more about the breakdown. I think you originally said that you were expecting it in H2 Xofluza, but I think the background to this increase, and I know that COVID-19 has been decreasing recently, and you mentioned earlier that it is being used more than expected.

Teshirogi : We have told you since the beginning of the year that we would not disclose the breakdown this time.

The reason is that the flu is flaring up tremendously right now, but I wonder if this will really last until November or January, or if we will suddenly have a type B outbreak. Originally, in fact, the basic idea that we are aiming for in our business model is to hedge risk to the business by expanding the scope of coverage in terms of the number of viruses.

If it is a single virus, we cannot make any sales at all when it is not expected, but RSV now is moving to Phase IIa, and among these viruses, including RSV, influenza A and B, and COVID-19, we want to consistently make a certain amount of sales among those that are spreading. This is our original business direction.

As for H2, it is true that we had created a business plan that overreacted considerably to the public expenditure after October, including COVID-19, so I think that part will go a little further, and the influenza will be quite strong, at least when we look at the single month of October. Rapiacta is also moving quite well.

However, the breakdown is not to be disclosed by us at this time.

Mamegano : Thank you very much. Another point of interest is Xocova in Asia. This time, you are a bit conservative and said that you would withdraw it once. From what you said, I thought there was no need to think so negatively, but I believe that your company's mid-term plan is designed to generate sales for FY2025 or FY2030, so is it safe to assume that there will be no impact on that plan?

Teshirogi : I think so. Since you are an analysts, I think you can probably handle that, but from our point of view, it is very difficult to read how foreign countries interpret Japan's emergency approval. I think there are

various people who are thinking, although they are not saying it out loud, that official approval in Japan must come first, or that approval by FDA or EMA must come first.

I am sure that if it happens, everything moves all of the sudden. Therefore, we have not changed our outlook for FY2024 and beyond.

Mamegano : Thank you very much.

Kyokawa : Mr. Sakai.

Sakai : This is Sakai from UBS Securities. I think it was in a professional journal, and I think there was a bit of a problem with the administration of Xocova to pregnant women. The share of usage of Xocova has increased from less than 20% to just under 23% in Q1, and you need to further increase this share. With the official approval of Xocova coming next year, how is Xocova being used by health care providers?

With all the talk about teratogenicity and the problem of administration to pregnant women, how can such a phenomenon occur? I am a little concerned about how your MRs and others are responding to this situation.

Teshirogi : Thank you. I would rather talk about it, so I would like to hear from Iwasaki about how they are doing sales, and then from Uehara, who is responsible for the safety management, about what they are doing in terms of safety management.

Iwasaki : We have been aware of this since before the launch. Therefore, we have created an explanatory document for patients and always inform them of the contraindications at the time of delivery, such as at a briefing session. In terms of the actual patient flow, the doctor or co-medical staff will ask the patient if she is pregnant before the consultation, and of course, this is also confirmed in the consent document. We have also informed them in the consent document that it is contraindicated.

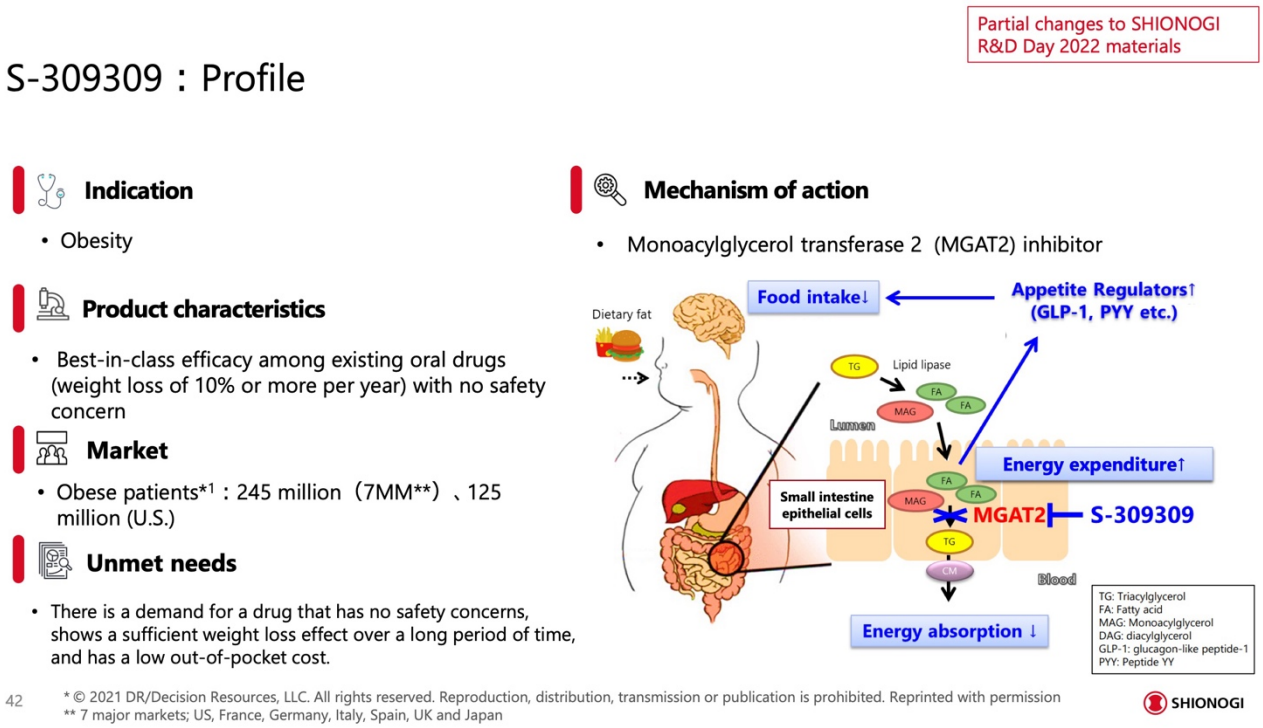
After a prescription is issued, it goes to a dispensing pharmacy, and the pharmacist explains the situation to the dispensing pharmacy before delivering it to the patient. We have them explain to us when they make such materials and deliver them to both hospitals and dispensing pharmacies. We are also in the process of providing thorough information on this type of safety data as it is updated.

Uehara : In addition, as part of our safety policy, we take steps to prevent such use by issuing warnings whenever possible. However, there are some cases in which the patient must take the medication, so we have established a hotline for the Center for Child Health and Development to provide appropriate follow-up medical consultation for such patients.

There are so many drugs in the world that cause teratogenicity in animal experiments. In this context, our company will alert you whenever possible. In addition, we are trying to create an environment that is as safe as possible for people to use the product by providing appropriate follow-up services in the event that someone has taken it.

Teshirogi : Overall we take this very seriously. In fact, we all meet together first thing every Monday morning to track all of the cases, how many were received this week, what kind of communication was made to the child health and development centers, and what week each one of them is currently in. We are doing all of this in collaboration with the Ministry of Health, Labor and Welfare and the Center for Child Health and Development, and we have received high evaluations from the Safety Investigation Committee for our efforts to this point.

I think it is such a serious issue for the Company, and we are trying to see to it that not even a single case is overlooked, including by top management.



Sakai : Thank you. The other question, sorry to be extremely basic, but there are a variety of obesity drugs in S-309309, GLP-1 frenzy. I'm not a specialist in this, so I'm not sure, and when I look at the chart on page 42, I can't help but think of the orlistat curse, but of course, this is different in mechanism, just the pathways that come into play are the same, I think. So I'm not sure what kind of differentiation or what kind of effect you can draw there.

Uehara : Actually, this drug does not inhibit lipid absorption and thereby cause diarrhea. The drug is designed to stop the pathway where triglycerides are broken down in the cells, made into triglycerides once more, and placed on chylomicrons, so it is not a drug that allows lipids to flow directly into the digestive tract in the lumen. Therefore, although similar in mechanism of action, they are completely different drugs.

In fact, animal studies have shown a clear weight loss effect, and what percentage control it can be demonstrated in humans depends on the results, which we would be happy to discuss again depending on the results.

Keller : Administration of S-309309 changes lipid metabolism. The fatty acids are already in the epithelium of the digestive tract, they are not being expelled. Once absorbed, it changes the metabolism in the cell. It does not pass through the digestive tract.

Akahane : I am Akahane from Tokai Tokyo Research Institute. I'm looking at pages 29 and 30, and I'm afraid I'm being persistent, but it's S-309309. Certainly, GLP-1 is a social problem, so I understand that it is very growing as you show in the graph, and if you look at page 30, the dose dependence is very good even for a layman, but on the other hand, three obesity drugs have been approved in the US, but they are not doing very well.

I also asked the details about Eisai's Belviq to Eisai, but in the case of Belviq, that was because it was carcinogenic. I think the market is very large, but it is very negative or weak against side effects, and the hurdle for approval is that the difference from placebo must be at least 5% or 36% and more.

What I was wondering this time is that you gave us a lot of details in the previous session, but this time, if the combination of GLP-1 is already available, is it your understanding that the market is large but the hurdle for

approval is high and that rather than a monotherapy , it will be used in combination with GLP-1, which has been on the market from the beginning, and that is the strategy for development? Or are you writing this way because GLP-1 happens to be the topic of discussion? I don't know if you will be able to develop and sell the product in the future, but what kind of strategy do you have in mind right now?

Teshirogi : Our understanding is that there are many things we really don't know about anti-obesity drugs. As I may have told you before, we are also in a situation where we really don't have any data at all on whether a single mechanism can keep the weight off by blocking it all the time.

We believe that while there are many reasons for essentials, such as hypertension, and one mechanism cannot successfully control high blood pressure, a combination of several mechanisms will be important to control the important disease of obesity, and in that regard the first point is that it is better to have many mechanisms.

And then, as John said a little bit, if you are on GLP-1 and you lose a certain amount of weight, say 25%, at this point, if you stop, you will gain it right back. The doctors have a great deal of interest in how to maintain the weight that has been lost. If possible, I believe that MGAT2 would be one way to meet the need for a therapeutic agent that is not so expensive, safe, and capable of maintaining weight for a long period of time.

In this context, I believe that there is even a possibility of a change in the regulatory requirements for GLP-1 when several GLP-1 products are released, so we are still thinking about how to maximize the value of this drug, either as a single agent or in combination with other drugs.

Also, we have been approached by various companies to partner or work together with us. However, we have not yet discussed the possibility of doing the first two phases on our own, but if these companies find the results of the second phase interesting, we may be able to collaborate with them on a development strategy.

Akahane : I understand very well. Are you saying that S-309309 is very effective in rebounding?

Teshirogi : I don't know yet, including that part, but I think it is a very difficult issue whether any anti-obesity drug can really keep that condition after termination. Recently, even with GLP-1, some papers have begun to appear that 100 does not return after termination, for example, seven out of 10 drops return, but the remaining three may not. However, this is not endorsed. We recognize that this is just the beginning.

Akahane : I understand very well. Thank you.

Kyokawa : Mr. Wada.

Wada : I am Wada, SMBC Nikko Securities. Thank you. I too would like to ask about S-309309. I have two questions.

First, I would like to know where you decided to doze for Phase II, as I think I see a PK and a clean dose dependency in Phase I. I would first like to ask if you can see where it is hitting you in the head to some extent. What do you think?

Uehara : Thank you for your question. At this time, the dosage is undisclosed, but the dosage is set to show the required drug effect in animal studies. Therefore, we have set three doses that are sufficiently higher than these doses, and we are conducting clinical trials within this Phase I profile, specifically, within the range where the safety has been sufficiently confirmed.

Wada : Thank you very much. On another point, I would also like to ask about something like mechanism of action and positioning. My understanding was that it was more like suppressing the upstream of GLP-1 or promoting the secretion of GLP-1 by suppressing MGAT2, and that this would be effective. If so, I was

wondering if the effects of GLP-1 would overlap, and I would like to know how you see the differentiation between the two in the non-clinical setting.

Specifically, you have previously shown us data on mice for the combined effect during the R&D briefing, but there is no mention of the dosage of the GLP-1 formulation, nor what the drug is. I would like to know if that is where we are seeing the upside after properly administering a dose of GLP-1 drugs that work well enough in mice.

Uehara : Thank you for your sharp question. As you understand, one mechanism of action is that GLP-1 signaling is a feedback of the results of the mechanism of action, but as far as nonclinical data are concerned, the results are not as to whether agonistic effects on GLP-1 are the key to weight loss in direct MGAT2 inhibition.

The GLP-1 signal is only one part of the mechanism, but the actual absorption inhibition, the process of stopping re-generation, and various other complex signals such as modulation of energy metabolism are involved, which together cause weight loss.

In fact, we are still repeating various experiments, nonclinical models. However, it is a mechanism of action that has more than enough potential to further lower the weight lowered by GLP-1, and we would like to bring such data back to you.

Kyokawa : Mr. Yamaguchi from Citigroup Global Markets, please.

Yamaguchi : This is Yamaguchi from Citigroup Global Markets. Thank you. Two points on S-309309, briefly, first. First, I'm afraid I would like you to disclose some detailed data, but it used to be the top line in one to three of FY2023, and now it is in Q1 of FY2024. Is this specifically a slight shift from one to three to four to six next year? Or, since it was originally the top line, has that remained the same? What do you think about that?

Teshirogi : That is correct, as Mr. Yamaguchi said, and we decided in April to June because it would be more realistic to include a full month of follow-up. Enrollment is now over, so we can now draw a line between when the last patient out and the 30-day follow-up, measured precisely 24 weeks from that point, so we have changed it to four to six, which we think is realistic.

Yamaguchi : I understand. I think Phase I is being done with healthy people, have those people also lost their appetites? Were there any suggestions regarding such efficacy?

Uehara : In Phase I, we actually evaluated the drug in a certain number of obese Healthy Volunteers to see the blood levels in obese patients. Naturally, we weigh the patients on a daily basis, but the reality is that in the Phase I environment, where patients are hospitalized and on a regular diet, it is difficult to evaluate the effectiveness of the program because there are many patients whose weight comes down nicely.

However, there are some interesting trends in the action of the drug, such as the movement of biomarkers, so we hope that this does not mean that the drug is not effective at all.

Yamaguchi : Have you also asked about appetite? Did they feel somewhat less hungry, or was there anything in particular?

Uehara : Not particularly.

Yamaguchi : I understand. While you mentioned that you will be starting Phase III, you also mentioned that you might work with some other party in Phase II. I had thought on my own that if you were to try to do this drug business plan globally, Phase III would be in partnership with some other party, as has been the case up to now, but I guess that plan depends on the data, but has it been decided yet?

Teshirogi : That's right. We still have to decide whether we will put the entire project in Phase IIb or two projects in Phase III at once, but in any case, it will cost a considerable amount of money, and our current position is to wait and see the results of Phase II before deciding on the best form of implementation.

Yamaguchi : I understand. One more thing, you told us about OSA's joint venture. I believe this company already has about two trials running, and it was mentioned that they are not covered this time, but is there any option or possibility for your company to develop or enter into development and sales in the future, including those agents?

Keller : This program is independent with respect to the structure of the JV. The mechanism of the JV, and then the compound, will be different from what we have now. We will of course be working very closely with Apnimed, and for the JV programs, we have chosen what we think is the best together.

Teshirogi : As for Shionogi, are completely open to the possibility of our participation after the results of AD109 in Phase III. If they obtain great results, I hope that Apnimed would first think of us as a potential partner, so we would like to think about it at that time. At this stage, at that level, our goal is to get JV programs into clinical trials as soon as possible.

Yamaguchi : Thank you very much. Finally, of these four approaches, I think most drugs are now basically about managing physical obstruction of the upper airway. I think that your company is trying to take a new approach, so, now it is mostly CPAP, but have you decided on an approach that would combine or replace it?

Keller : We will pursue a number of approaches at the same time, often in combination. We will then consider which is best for each patient based on their sleep patterns and other characteristics. So, as for combinations, we will test three or four at first. At this stage, we expect to have two programs in the development pipeline, and a significant pipeline of discovery programs, maybe four to six.

Kyokawa : Then, the next question will be the last. Mr. Wakao of JPMorgan Securities, please.

Wakao : I'm Wakao from JPMorgan. Please tell just one thing. Regarding S-309309, what is your assumption of its weight loss potential in monotherapy? I would like to know what level you are looking at as an expectation.

When I looked at the results of the animal experiments, I could not figure out what this was because the reduction was different for A and B of GLP-1, but I assumed from this chart that if anything, the weight loss capacity was lower than GLP-1. However, I think you are doing a lot of things including animal testing again, so I wonder if you could comment on whether it is as good as GLP-1 as your company's expectation at this point in time.

Teshirogi : I think there are some questions as to whether 25% is really the weight loss potential we should be looking for with the combination of GLP-1 injection and GIP. We have disclosed several times that we are targeting 8% to 10% for the oral formulation, and we think that this level is reasonable, both in terms of combining mechanisms and in terms of maintaining those who have truly lost weight through some action.

However, on the other hand, if there is only a 5% or 3% weight loss, I think it will be difficult to develop in the future, so I don't know if somewhere around 8 to 10 is the highest dosage or the middle dosage, but once you get there, I think there are enough ways to build various programs from there.

Wakao : Thank you very much. What about in terms of vs. oral GLP-1? I think it is difficult to compare with the injectable GLP-1 because the weight loss is very high but compared to the oral GLP-1 in the market now, it is just a little less than that, with 8 to 10, so.

Teshirogi : I think oral GLP-1 is also a really difficult weight loss reading to balance with side effects. The amount of GLP-1 that keeps weight loss really tolerable is about 8 to 10 in our opinion, and from that point of view, it should be about equal weight loss capacity.

At the moment, ours is very safe and I don't think that is a concern, so I think it is a difficult question to answer, including whether we are comparing apples to apples in that area.

Wakao : I understand. Thank you.

Kyokawa : This concludes the results briefing for Q2 of FY2023 of SHIONOGI. Thank you very much for your time today.

Teshirogi : Thank you.

[END]