1st Quarter of Fiscal 2019 Financial Results

Conference Call

Moderator: Ladies and gentlemen, thank you for waiting. We are now ready to start a conference call on the financial results for the first quarter of the fiscal year ending March 31, 2020 of SHIONOGI & CO., LTD.

The opening remarks will be given by Mr. Kyokawa. Mr. Kyokawa, please.

Kyokawa: Good afternoon, my name is Kyokawa from SHIONOGI. I would like to extend my sincere gratitude for your attendance at our conference call today. Thank you very much.

First of all, I would like to introduce you three speakers. First, Ms. Takuko Sawada, Director and Executive Vice President.

Sawada: Good afternoon, everyone. My name is Sawada. It's a pleasure to be here today.

Kyokawa: Next, here is Dr. Kohji Hanasaki, Senior Executive Officer and Head of Corporate Strategy Division.

Hanasaki: Good afternoon, my name is Hanasaki.

Kyokawa: Lastly, Dr. Kenji Matsuo, General Manager of Finance & Accounting Department.

Matsuo: Good afternoon, my name is Matsuo.

Kyokawa: At 1:00 p.m. today, we disclosed the presentation materials for the financial results. The overview of the financial results shown on pages 3 to 10 as indicated in the Agenda will be explained by Mr. Matsuo, General Manager of Finance & Accounting Department. The Actions and Progress in the latter part of the material, will be discussed in detail by Mr. Hanasaki, the Head of Corporate Strategy Division.

Now, Mr. Matsuo gives the explanation, first.

Financial Results (Consolidated)

(Unit: B yen)

	FY2019 Forecasts Full year	FY2019 Forecasts 1H	FY2019 Apr.-Jun. results	FY2019 Progress vs. forecasts	FY2018 Apr.-Jun. results	Y on Y Change (%)	Y on Y Change (B yen)
Sales	365.5	159.0	**79.2**	49.8%	88.5	(10.5%)	(9.3)
Operating income	147.0	52.0	**29.0**	55.7%	27.6	4.7%	1.3
Ordinary income	170.5	63.0	**32.4**	51.4%	37.9	(14.6%)	(5.5)
Profit attributable to owners of parent	133.0	49.0	**24.4**	49.8%	31.9	(23.4%)	(7.5)

- Sales and each profit measure have smoothly progressed toward 1H forecasts
- Operating income was higher than that in Apr.-Jun. FY2018

Exchange Rate (average)	FY2019 forecasts	FY2019 Apr.-Jun. results
USD ($) – JPY (¥)	110.0	109.91
GBP (£) – JPY (¥)	145.0	141.18
EUR (€) – JPY (¥)	130.0	123.50

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Matsuo: Let me explain the overview of the financial results for the first quarter of FY 2019.

On page 4, please see the summary of the consolidated financial results. The column fields indicate, from the left hand to the right hand, the full-year forecasts, the forecasts for the first half, the first quarter results for the April-June period, and the progress ratio to forecasts for the first half period of FY2019. For reference purpose, we have shown the results for the April-June period of FY2018 and the year-on-year change rates and amounts in billions of yen.

First of all, net sales resulted in 79.2 billion yen, representing 49.8% in the progress versus forecasts for the first half period, which was lower than the previous fiscal year by 10.5%. The amount decreased by 9.3 billion yen year on year.

Meanwhile, operating income was 29 billion yen, representing 55.7% in the progress versus forecasts, which rose 4.7% year on year, or an increase of 1.3 billion yen.

Ordinary income was 32.4 billion yen, and the progress versus forecast was 51.4%, representing a year-on-year fall of 14.6%, which means a decrease of 5.5 billion yen.

Profit attributable to owners of parent ended at 24.4 billion yen, representing a progress of 49.8% versus forecast, which stands for a year-on-year decrease of 23.4%, or a decrease of 7.5 billion yen.

Please note that the year-on-year decreases are attributable to temporary rises in the same period last year, and that net sales and other profits grew steadily in line with the forecasts for the first half of the current fiscal year.

Furthermore, one-time expenditures for strategic business investments were accounted for as cost in the previous fiscal year. Therefore, in the absence of such factor, operating income increased on a year-on-year basis in the period under review.

As to the average foreign exchange rates, as you can see in the table at the lower right, the US dollar remained almost flat while sterling pound and euro are weakening against Japanese yen.

Statement of Income

(Unit: B yen)

	FY2019 Forecasts Full year	FY2019 Forecasts 1H	FY2019 Apr.-Jun. results	Achievement (%)	FY2019 Apr.-Jun. results	Y on Y Change (%)	Y on Y Change (B yen)
Sales	**365.5**	**159.0**	**79.2**	49.8	88.5	(10.5)	(9.3)
	14.6	16.0	16.1		13.5		
Cost of sales	**53.5**	**25.5**	**12.7**	49.9	11.9	6.9	0.8
Gross profit	**312.0**	**133.5**	**66.5**	49.8	76.6	(13.2)	(10.1)
	45.1	51.3	47.4		55.3		
SG&A expenses	**165.0**	**81.5**	**37.5**	46.1	49.0	(23.3)	(11.4)
	31.6	35.5	32.4		27.4		
Selling & administrative expenses	**115.5**	**56.4**	**25.7**	45.5	24.3	5.8	1.4
	13.5	15.8	15.0		27.9		
R&D expenses	**49.5**	**25.1**	**11.9**	47.3	24.7	(51.9)	(12.8)
Ordinary R&D expenses *	**49.5**	**25.1**	**11.9**	47.3	13.7	(13.2)	(1.8)
Strategic investment	**-**	**-**	**-**	-	11.0	-	(11.0)
	40.2	32.7	36.6		31.2		
Operating income	**147.0**	**52.0**	**29.0**	55.7	27.6	4.7	1.3
Non-operating income & expenses	**23.5**	**11.0**	**3.4**	31.3	10.3	(66.6)	(6.9)
	46.6	39.6	40.9		42.9		
Ordinary income	**170.5**	**63.0**	**32.4**	51.4	37.9	(14.6)	(5.5)
Profit attributable to owners of parent	**133.0**	**49.0**	**24.4**	49.8	31.9	(23.4)	(7.5)

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* Ordinary R&D expenses: Total R&D expenses excluding strategic investment

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Now, we move on to page 5. Here is the summary of the Profit and Loss Statements. It shows that net sales for the first quarter was 79.2 billion yen, a progress of 49.8%, and a year-on-year comparison was a decrease of 9.3 billion yen.

The year-on-year decrease is mainly attributable to a reaction against the milestone income associated with Xofluza we received from Roche in the same period last year. Against this decrease, the increase in domestic sales of prescription drugs reflecting growth in strategic products and new products, growth in sales in overseas subsidiaries, and an increase in royalties received from HIV franchise, etc. contributed to the reduction of the decreased profits. I will explain the details of these factors later.

Cost of sales in the first quarter was 12.7 billion yen, accounting for 49.9% of the forecast. On a year-on-year basis, cost of sales increased by 0.8 billion yen. As a result, gross profit was 66.5 billion yen, representing a decrease of 10.1 billion yen year on year.

Meanwhile, selling, general and administrative expenses were 37.5 billion yen, representing 46.1% in the progress, and a decrease of 11.4 billion yen year on year.

The breakdown is as follows: Selling & administrative expenses were 25.7 billion yen, representing an increase of 1.4 billion yen year on year. R&D expenses were 11.9 billion yen, a decrease of 12.8 billion yen year on year.

The year-on-year decrease in R&D expenses is mainly attributable to a decrease caused by reaction against the strategic business investments amounting to 11.0 billion yen in the previous fiscal year.

Ordinary R&D expenses decreased by 1.8 billion yen year on year, which we consider are in line with what we had expected.

As a result, operating income was 29.0 billion yen, representing 55.7% in the progress of the forecast for the first half. On a year-on-year basis, operating income increased by 1.3 billion due to a decrease in R&D expenses despite a year-on-year decline in net sales.

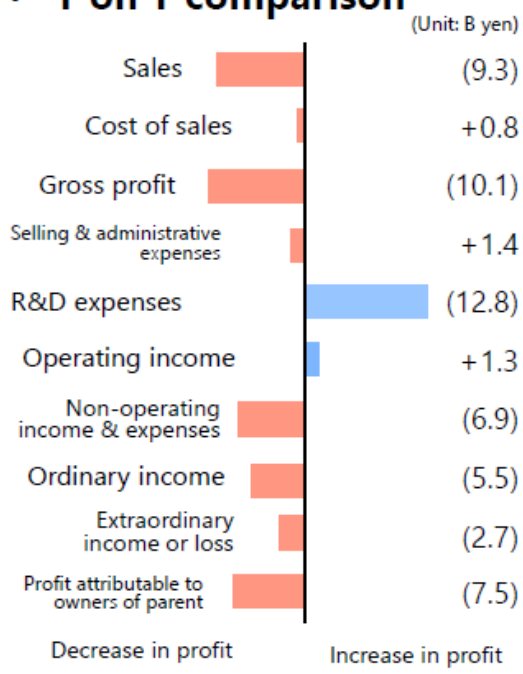
Non-operating income stood at 3.4 billion yen, a year-on-year decrease of 6.9 billion yen. As to dividend from ViiV, we had received one-time dividend in addition to ordinary dividend in the previous fiscal year. Therefore, dividend received had been higher than usual. In the current fiscal year, the year-on-year decrease was recorded as a result of the impact of such extraordinary dividend received.

Furthermore, the impact of recent fluctuations in foreign exchange rates is also attributable to the year-on-year decrease. In sum, ordinary income was 32.4 billion yen, a decrease of 5.5 billion yen year on year.

Profit attributable to owners of parent was 24.4 billion yen, a decrease of 7.5 billion yen year on year. The year-on-year decrease is attributable to the impact of gains on sale of the Nanjing factory of C&O in China which was accounted for as extraordinary gains in the same period last year.

Y on Y Comparison and Main Variation Factors (Statements of Income)

- **Y on Y comparison**



Main Variation Factors (Y on Y)

- **Sales**
  - FY2018: Income from Roche for Xofluza™*
- **Cost of sales**
  - Sales growth of drugs
- **SG & A expenses**
  - **Selling & administrative expenses**
    - › Increase according to sales growth of drugs
  - **R&D expenses**
    - › FY2018: Strategic investment (11.0 B yen)
- **Non-operating income & expenses**
  - FY2018: One-time dividend from ViiV
  - Exchange-rate fluctuations
- **Extraordinary income or loss**
  - FY2018: Sale of the Nanjing factory of C&O in China

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* Royalty income from Roche as milestones of R&D achievement

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Now page 6 summarizes the main factors of year-on-year changes in the profit and loss statements for your reference.

As I mentioned earlier, the decrease in sales is attributable to a significant fall in milestone income associated with Xofluza which we had received from Roche in the same period last year. But the decrease in profit was partly offset by the expansion of sales of drugs in Japan and abroad, and growth of royalty income from HIV franchise. In the aspect of costs, operating income turned profitable thanks to the decrease in R&D expenses on the back of the impact of strategic investments in the previous fiscal year despite increases in selling and administrative expenses.

As to non-operating income and expenses, the impact of changes in foreign exchange rates are becoming gradually apparent. On the other hand, the impacts of the factors which occurred in the previous fiscal year such as one-time dividend from ViiV, and gains on sale of the Nanjing factory of C&O in China which were recorded as extraordinary income are attributable to the decrease in profits in the current fiscal year.

On the next page, I will explain about sales by business segment.

Sales by Segment

(Unit: B yen)

	FY2019 Forecasts* Full year	FY2019 Forecasts* 1H	FY2019 Apr.-Jun. results	FY2019 Achievement (%)	FY2018 Apr.-Jun. results	Y on Y Change (%)	Y on Y Change (B yen)
Prescription drugs	144.1	53.7	26.7	49.7	25.4	5.0	1.3
Overseas subsidiaries/export	31.4	16.0	10.6	66.6	9.9	7.4	0.7
Shionogi Inc.	9.9	6.3	5.2	83.3	6.1	(14.0)	(0.9)
Mulpleta®	1.0	0.25	0.15	61.2	-*	-	0.2
C&O	14.6	6.8	3.8	55.2	2.3	61.1	1.4
Contract manufacturing	14.3	9.1	2.4	27.0	2.8	(12.1)	(0.3)
OTC and quasi-drug	9.7	4.6	2.1	44.5	1.6	29.4	0.5
Royalty income	163.6	74.3	36.9	49.6	48.3	(23.6)	(11.4)
HIV franchise	126.5	61.3	29.7	48.5	24.5	21.4	5.2
Crestor®	22.0	11.0	5.6	50.5	5.5	1.1	0.1
Others	15.1	2.1	1.6	79.1	18.3	(91.0)	(16.7)
Others	2.4	1.2	0.54	45.0	0.58	(5.9)	(0.0)
Total	**365.5**	**159.0**	**79.2**	**49.8**	88.5	**(10.5)**	**(9.3)**

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*The full-scale promotion was initiated in Dec. 2018.

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Page 7 shows sales by business segment. First, in the domestic prescription drugs segment, sales for the April-June period were 26.7 billion yen, and the achievement ratio was 49.7%, representing a year-on-year increase of 5.0%, or 1.3 billion yen. This was attributable to steady growth in sales of our strategic products including Cymbalta and Intuniv. I will show you the breakdown of sales by product later.

Next, sales in the overseas subsidiaries and export were posted at 10.6 billion yen, with the achievement ratio of 66.0%, increasing 0.7 billion yen year on year.

Specifically, Shionogi Inc. in the United States, recorded sales reaching 5.2 billion yen and the achievement ratio of 83.3%, but on a year-on-year basis, sales decreased 14%, or 0.9 billion yen.

Associated with the business alliance with BioDelivery Sciences International Inc. in the United States concerning joint sales activities of Symproic, which was announced in April 2019, we received one-time payment. On the other hand, we had also received one-time payment from Purdue Pharma L.P. in the United States during the same period last year. Therefore, sales decreased year on year due to the impact of those payment received.

In China, C&O Pharmaceutical Technology recorded year-on-year sales increase of 61.1%, or 1.4 billion yen, due to steady growth in sales of Rabeprazole.

In the contract manufacturing segment, sales were 2.4 billion yen, a decrease of 0.3 billion yen year on year.

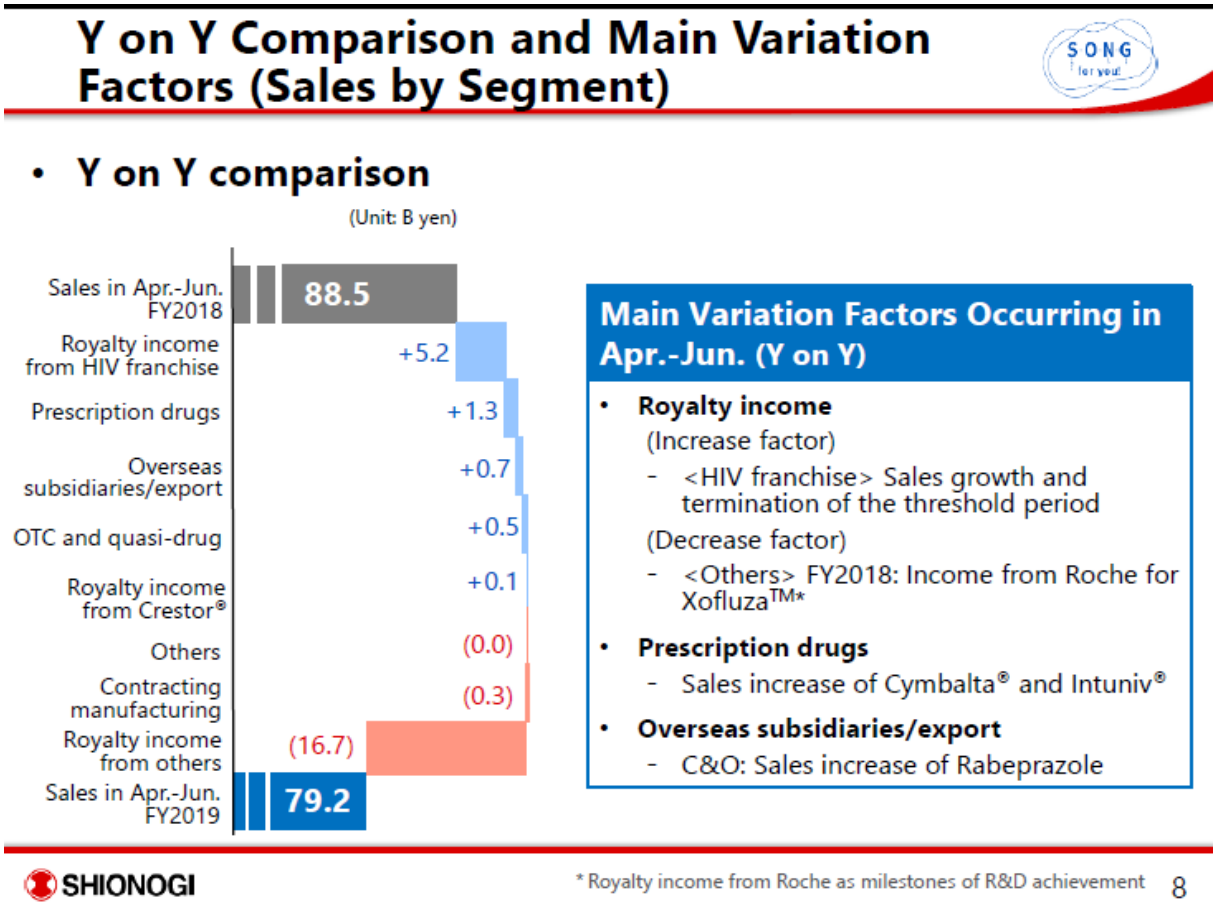
In the OTC and quasi-drug segment, sales were 2.1 billion yen, an increase of 0.5 billion yen year on year.

Royalty income totaled 36.9 billion yen, a year-on-year decrease of 11.4 billion yen. The breakdown is as follows: HIV franchise was 29.7 billion yen, a year-on-year increase of 5.2 billion yen. This was attributable to the robust expansion of global sales of Tivicay, Triumeq and Juluca in ViiV, and the increase in the amount received upon the termination of the threshold period.

The royalty income on Crestor sales remained flat year on year, at 5.6 billion yen.

The royalty income from Others was 1.6 billion, a sharp fall of 16.7 billion yen year on year. This decline reflects the impact of a milestone income arising from the acceptance of the New Drug Application for Xofluza in the United States in the same period last year. The significant decrease amounting to 16.7 billion yen was mainly attributable to the year-on-year decrease in net sales.

In sum, sales in all segments totaled 79.2 billion yen, a year-on-year decrease of 9.3 billion yen.



Page 8 outlines the year-on-year comparison and main variation factors in sales by segment. As you may have noticed it, this significant decrease in income from Roche for Xofluza represents the major factor of decrease in royalty income.

In contrast, royalty income from HIV franchise, sales of domestic prescription drugs, overseas subsidiaries/export, and OTC and quasi-drug expanded to offset part of the significant decrease in sales, reducing the decrease in sales.

On the next page, I will explain about domestic sales of prescription drugs by product.

Sales of Prescription Drugs in Japan

(Unit: B yen)

	FY2019 Forecasts Full year	FY2019 Forecasts 1H	FY2019 Apr.-Jun. results	FY2019 Achievement (%)	FY2018 Apr.-Jun. results	Y on Y Change (%)	Y on Y Change (B yen)
Cymbalta®	29.3	13.0	6.7	51.6	6.1	10.3	0.6
Intuniv®	13.6	4.6	1.8	39.9	1.1	65.6	0.7
Xofluza®	28.0	0.28	0.00	0.0	0.03	(100.0)	(0.0)
Rapiacta®	2.6	0.05	0.00	2.6	0.01	(89.4)	(0.0)
Brightpoc® Flu	1.8	0.18	0.01	5.1	0.01	97.7	0.0
Total of strategic products	75.7	18.2	8.6	47.1	7.3	18.1	1.3
OxyContin® franchise	6.7	3.6	1.7	46.7	2.0	(15.5)	(0.3)
Symproic®	2.3	1.1	0.53	48.6	0.31	70.6	0.2
Actair®	0.27	0.12	0.06	45.8	0.04	42.1	0.0
Mulpleta®	0.33	0.17	0.03	19.7	0.05	(31.2)	(0.0)
Pirespa®	6.9	3.5	1.7	49.8	1.4	26.2	0.4
Total of new products	92.2	26.7	12.6	47.3	11.0	14.4	1.6
Crestor®	10.0	5.2	2.4	46.9	2.6	(7.8)	(0.2)
Irbetan® franchise	4.9	2.6	1.2	47.0	1.9	(35.5)	(0.7)
Others	36.9	19.2	10.4	54.0	9.8	5.8	0.6
Prescription drugs	**144.1**	**53.7**	**26.7**	**49.7**	25.4	**5.0**	**1.3**

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Page 9 shows sales of domestic prescription drugs. First of all, in the strategic product sector, sales of Cymbalta were 6.7 billion yen, representing a 51.6% achievement of the forecasts for the first half of the current fiscal year. Sales continued to grow from the previous fiscal year, increasing 10.3% year on year, or 0.6 billion yen.

Sales of Intuniv stood at 1.8 billion yen, a year-on-year increase of 65.6%, or 0.7 billion. This product has grown steadily. The achievement ratio to the forecast for the first half remained at 39.9%, but the forecast figure was set with an emphasis on the second quarter. Therefore, we consider the achievement ratio is in line with our expectation. The influenza-related product group showed no significant moves since the period under review is a non-epidemic season.

Sales of strategic products totaled 8.6 billion yen, a year-on-year increase of 18.1%, or 1.3 billion yen, representing steady growth.

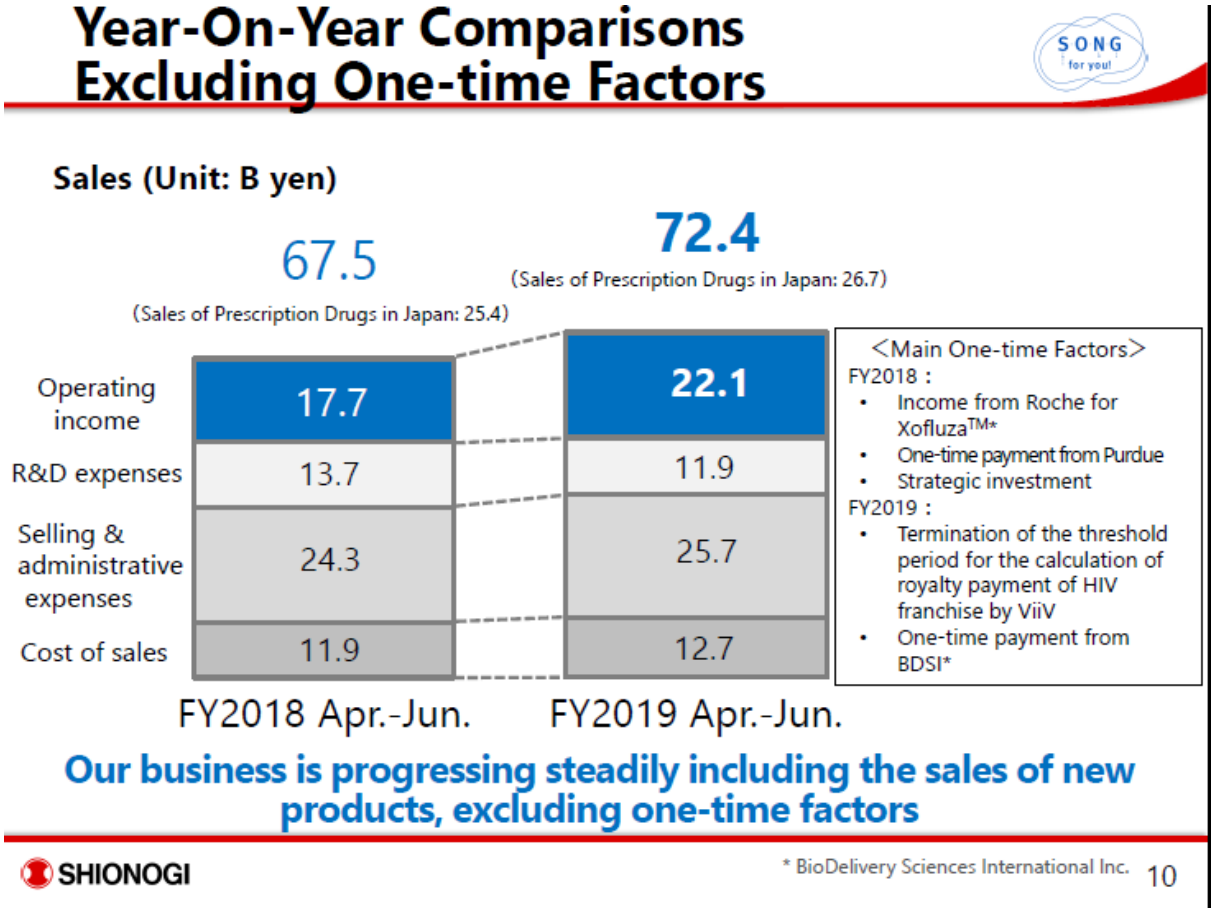
On the other hand, OxyContin franchise has been under the pressure of generic drug, and sales remained at 1.7 billion yen, a year-on-year decrease of 0.3 billion yen, representing 46.7% in achievement ratio.

Sales of new products including Symproic, Actair, Mulpleta and Pirespa totaled 12.6 billion yen, an increase of 14.4% year on year, or 1.6 billion yen.

While Crestor and Irbetan franchise had been the factors of significantly decreased sales up to the previous fiscal year affected by the prevalence of generic drugs, the year-on-year effects in the period under review have been shrinking since the their prevalence has become saturated.

In sum, sales of domestic prescription drugs were 26.7 billion yen. The year-on-year increase of 1.3 billion yen was attributable to the steady growth in sales of the strategic products such as Cymbalta and Intuniv.

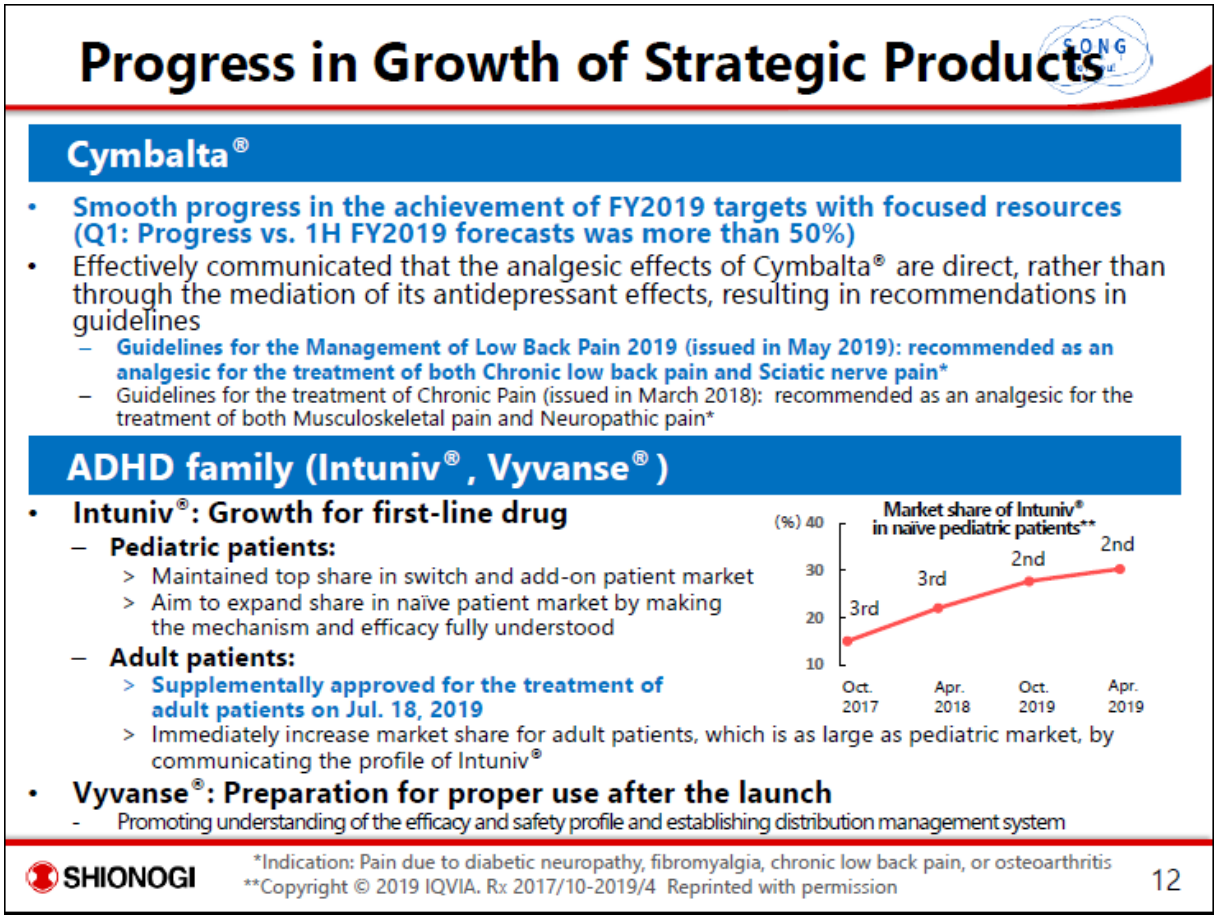
Going forward, we will endeavor to further expand sales of strategic products and new products with the aim of continuing to increase sales by our own efforts and products.



Now, we are going onto page 10, the last page of the overview of financial results. This chart illustrates the year-on-year comparisons excluding one-time factors. As I explained earlier, we had one-time factors in the first quarter of FY2018 and the first quarter of FY2019, respectively, as shown in the box in the right.

Let us exclude these one-time factors to compare the respective results on a real business. Then, we can see that sales including the expansion of new products grew, and we could secure the increased operating income. Therefore, we consider that our business has been advancing steadily.

That is all I have to say about the overview of the financial results for the first quarter of FY2019.



Hanasaki: Next, Mr. Hanasaki will explain about our actions and progress in the first quarter of FY2019.

Page 12 shows the progress of the strategic products for growth. In the previous fiscal year, we concentrated resources for sale of Xofluza which was in its first full-year marketing. In the first quarter under review, we also put a significant emphasis on Cymbalta and ADHD family by increasing resources.

Sales of Cymbalta achieved more than 50% versus the forecasts for the first quarter of FY2019 towards the achievement of the full-year budget for the FY2019 by means of concentration of resources.

In the Guidelines for the Treatment of Chronic Pain issued in March 2018, Cymbalta was recommended for treatment of both musculoskeletal pain and neuropathic pain. Furthermore, in the Guidelines for the Management of Low Back Pain 2019, the SNRI class was recommended as an analgesic for the treatment of both chronic low back pain and sciatic nerve pain. Therefore, we consider this drug is effective for chronic low back pain consisting of various pains including sciatic nerve pain.

We will endeavor to firmly provide the value of this drug by appealing the mechanism and clinical evidence supporting those recommendations of the Guidelines, which means direct, rather than through the mediation of its antidepressant effects, analgesic effects.

Next, I will explain about Intuniv of the ADHD family. First, for pediatric patients, we maintained top share in switch and add-on patient market, and we also pursue the top share of Intuniv in naïve pediatric patients from the present second place, as you see in the chart in the right

hand. To this end, we will appeal that Intuniv has different mechanisms from other drugs while emphasizing its effects.

On the other hand, we received supplemental approval for adult patients on June 18. Since approximately 50% of ADHD patients are adults, we expect we will be able to obtain higher share in the adult patient market.

We have been working for this purpose for almost one month, and found that approximately one-third of our target institutions have already adopted this product, and the adoption of this product has increased steadily.

Speaking of Vyvanse of which we received approval in March, it has been designated as raw material for the stimulant under the drug restriction category. Therefore, we are now preparing for post-sale proper use by establishing strict distribution management systems which should be understood very well, and by communicating the effects of this drug and safety information.

Progress in Growth of Strategic Products

XOFLUZA™

- BLOCKSTONE study:
  XOFLUZA™ showed a significant prophylactic effect against influenza infection after a single oral dose in people exposed to an infected family member during a 10 days observation period.
- Collection and analysis of the data regarding PA/I38 variants for 2019/2020 season.

Status	Clinical assessments	(★) Data to be shown prior to 2019/2020 flu season	Presentation schedule
Ongoing	**Additional analysis for the completed clinical studies** • Including next generation sequencing	Additional analysis on PA/I38 variants for the completed clinical studies (CAPSTONE-1, CAPSTONE-2, pediatric studies). (★)	**CAPSTONE-1: ECCMID (done)** **CAPSTONE-2 and pediatric study: OPTIONS X**
Ongoing	**Post exposure prophylaxis**	Assessing prophylactic efficacy of baloxavir and the risk of transmission of PA/I38 variants. (★)	**OPTIONS X or IDWeek**
Ongoing	**Drug susceptibility surveillance**	Resistance monitoring in the clinical setting. (★)	**OPTIONS X**
Ongoing	**Global pediatric patients**	Assessing safety, efficacy and pharmacokinetics of baloxavir compared with oseltamivir, including the emergence of PA/I38 variants. (★)	**OPTIONS X**
Ongoing	**Pediatric studies at higher doses**	Assesses safety, PK and efficacy at higher dose.	To be determined
Ongoing	**Severely ill & hospitalized patients**	Explores combination therapy with NAIs and multiple dosing in hospitalized patients.	To be determined
Planned	**Reduced transmission**	Clinical assessment for reduced transmission to household contacts from patients treated with baloxavir and possible risk of transmission of PA/I38 variants.	To be determined

Status	Non-clinical assessment		Presentation schedule
Ongoing	**Transmission study in ferret models**	Explores effect of baloxavir on transmission and assess risk of transmission of I38 variants in ferrets	To be determined

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ECCMID: Apr.13-16, 2019
OPTIONS X: Aug. 29-Sep 1, 2019
IDWeek: Oct. 2-9, 2019

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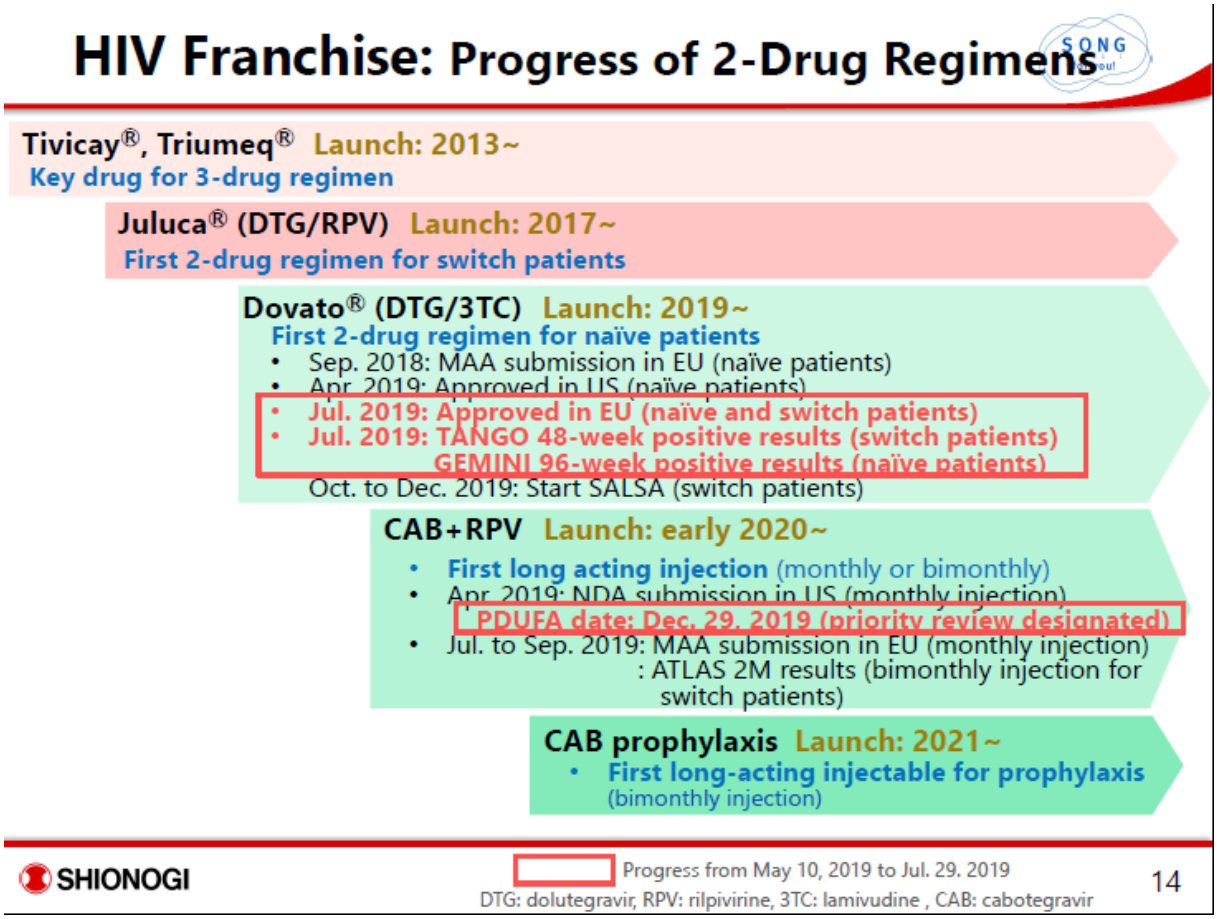
Next, page 13 shows the progress in Xofluza. As announced on June 4 in the form of immediate release, we met the primary endpoint of the phase III (BLOCKSTONE) study, and confirmed the preventive effects by treating with Xofluza during a 10-day observation period after a single dose.

Toward the winter season of this year, we will promote understanding of safety profile, and collect and analyze data from various clinical and non-clinical assessments concerning PA/I38 variants and conduct presentations at medical societies or announce them in paper. We expect that the safety profile of this drug and the characteristics of the variants will be understood for proper use.

As to the four ongoing clinical assessments with a star mark, we plan to announce the relevant data before the winter season of 2019.

Specifically, we will conduct a presentation at a medical society in August on the additional analysis on PA/I38 variants, which we indicate as OPTIONS X here, for the completed clinical studies. We will also present OPTION X in August or IDWeek in October on the effects of the preventive treatment tests and the data of the infection of the variants to a household member. Furthermore, we plan to present OPTION X on the surveillance tests and Roche plans to present the global pediatric patients test conducted by Roche.

In addition, we will announce the data of ongoing tests or tests in preparation as soon as they are ready.



Next, page 14 introduces the details of HIV franchise.

Conventionally, we used to conduct 3-drug regimen such as Tivicay and Triumez, but we are now shifting to 2-drug regimen.

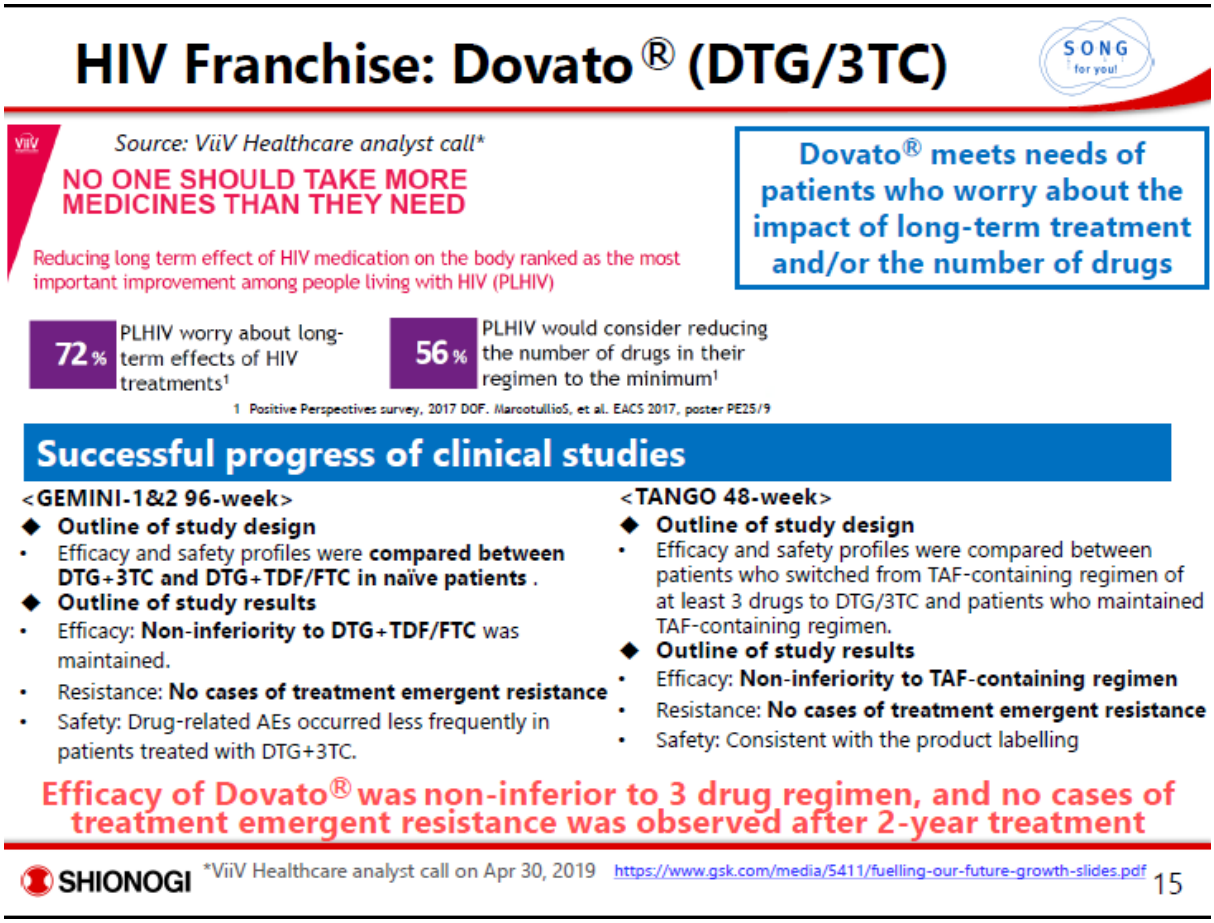
The first drug is Juluca, which was launched in 2017 and now shows robust growth in the United States.

As the second 2-drug regimen, we have Dovato. This drug was approved in the United States in April 2019, and has shown good market performance. In July, we have received approvals in EU for both naïve and switch patients. And the results of TANGO and GEMINI tests were reported in July 2019. I will explain the details in the next page.

Moreover, we have two kinds of 2-drug regimen following Dovato: Cabotegravir and Rilpivirine as the first long acting injection drugs. They were already applied for review in the United

States in April, and designated as priority review. The PDUFA date is December 29, 2019. We will also apply for review in EU in July to September.

We expect that this HIV franchise will become one of the growth drivers by growing from 3-drug regimen to 2-drug regimen, and to injectable and prophylaxis.



Page 15 shows the overview of the test result of Dovato in the HIV franchise. Among HIV-infected patients, 72% of them worry about the impact of long-term treatment while 56% worry about the number of drugs they are taking. Dovato meets needs of those patients and is characterized by its less expensive price.

With respect to clinical studies of this drug, the data of the GEMINI-1 & 2, 96-week test was reported as you can see in the left. As to the outline of study design, the results of comparison of the efficacy and safety profiles were compared between DTG+3TC, and DTG+TDF/FTC in naïve patients were reported, and non-inferiority to DTG+TDF/FTC was maintained. And, no cases of treatment emergent resistance to Dovato were observed. From the viewpoint of drug-related adverse events, such events occurred less frequently in patients treated with DTG+3TC.

On the other hand, the 48-week data of TANGO test was reported. This test was conducted to compare efficacy and safety profiles between patients who maintained TAF-containing regimen of more than 3 drugs and patients who switched to DTG/3TC. The results indicated non-inferiority to TAF-containing regimen, no cases of treatment emergent resistance, and safety consistent with the product labelling.

As a consequence, efficacy of Dovato was non-inferior to 3-drug regimen, and no cases of treatment emergent resistance was observed after 2-year treatment. For further details of these data, please refer to page 28 of the Appendix.

And for details of sales and year-on-year comparisons, and other data of domestic prescription drugs, please refer to the Appendix.

I conclude my explanations here. Thank you for your attention.

Kyokawa: We conclude the presentation. Thank you very much.

Q＆A

Kyokawa: I would now like to move onto Q&A.

MC: I would like to introduce the first questioner. The first question is from Mr. Yamaguchi of Citigroup Global Markets Japan. Mr. Yamaguchi, please go ahead.

Mr. Yamaguchi: Thank you. I have three questions.

I apologize that my first question is rather nitpicky. The year-on-year comparison excluding one-time factors that you have shown us was very clear and easy to understand. On the other hand, can the 6.9 billion-yen difference between your operating income without one-time factors of 22.1 billion yen for Q1 FY2019 and your actual results, which I think was a little less than 29 billion yen, be mostly explained by the payment from BDSI and the termination of threshold period for the royalty payment of HIV alone? I just felt that the difference was rather large.

Matsuo: I would like to answer that question. As you have pointed out, the difference can mostly be explained by those two factors.

Mr. Yamaguchi: I see. I understand. My second question is about the royalties for HIV. I have two sub-questions.

One is about the threshold that you were talking about. My memory is not exactly clear, but I think you explained at the Q1 results presentation last year that the threshold was the amount of sales up to which you will not receive royalty, and over which you will receive royalty. This is my understanding of the threshold. The threshold had appeared in the past, in Q1. However, my memory is that it disappeared from Q1 FY2018. Or, is my understanding wrong and did the threshold disappear this year, in FY2019?

Hanasaki: For last year, the threshold remained.

Mr. Yamaguchi：So, is it right to understand that the threshold started to disappear last year but still remained and this year it completely disappeared?

Hanasaki: That is correct.

Yamaguchi: So, I guess the reason for the royalty in Q1 to be a little above the trend of sales is that the net royalty is rising due to termination of threshold period?

Hanasaki: Yes. That is correct.

Mr. Yamaguchi: I see. The other question is about dividends, for HIV.

This is always difficult to forecast from the outside. Last year it was around 9 billion yen. This year it is 4 billion, and 5 billion in extraordinary dividends. Now it is Q1, but for the future, for Q2, Q3, and Q4—I heard that in the past there were some fluctuations but the figure gradually leveled. For the future outlook, do you know at the moment how the remaining figures will be? If you know, please tell us your outlook.

Hanasaki: This time there is a little impact from the pound. The dividend we received in Q1 was a little small, but we expect the annual dividend to end at our forecast figure.

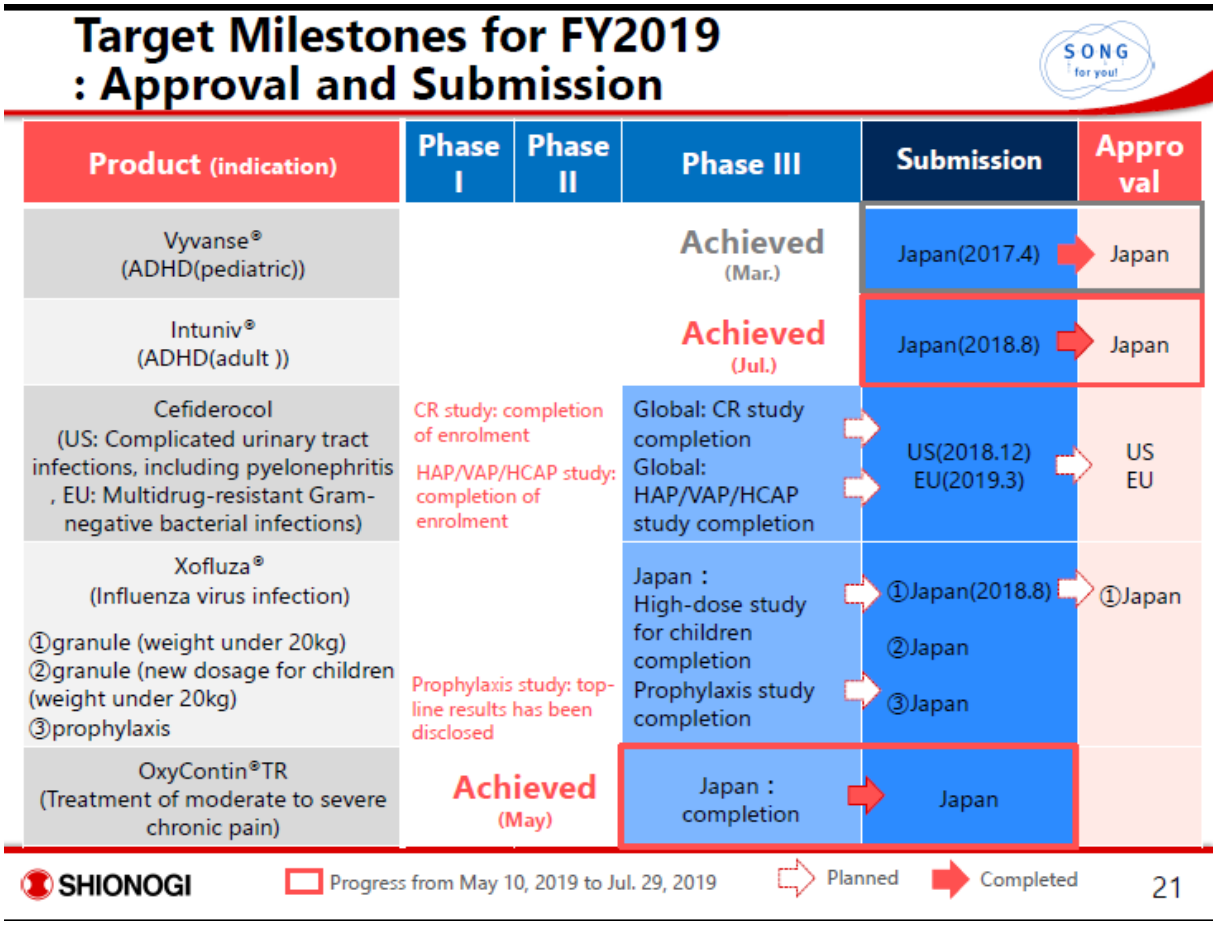
Mr. Yamaguchi: Which means that the dividend for Q1 was a little lower due to the strength of the yen?

Hanasaki: Yes.

Mr. Yamaguchi: I understand. Lastly, this is a little way off or about the past, and has nothing to do with the short-term Q1. It is about the Crestor hill. It is now FY2019, but in a chart that I saw before, royalties were expected to decline from around FY2020 or FY2021. Can I confirm how the profit guidance was at the time?

Matsuo: I would like to answer that question. Our recognition of royalties for Crestor is until FY2020. Royalties are expected to gradually decrease from FY2021.

Mr. Yamaguchi: They will see a gradual drop from there, from FY2021. I see. Thank you. That will be all from me.



MC: The next question will be from Ms. Kumagai of JP Morgan Securities. Ms. Kumagai, please ask your question.

Ms. Kumagai: This is Kumagai of JP Morgan.

I only have one question. I would like to ask for an update on the review of cefiderocol in the United States. What is the future timeline, including advisory committee (ad com)?

Also, when about is the timing of your announcement of the CR study data?

Sawada: I would like to answer that question.

About cefiderocol, the enrolling of patients in CR study has been completed, which we have mentioned in the Appendix. When we talk about this, both the FDA and the EMA naturally want to see the data. Due to this reason, the approval is expected to be delayed from our

initial plan. However, we still expect the product to be approved by the end of the year, and the adcom is also planned.

Ms. Kumagai: When will the CR study data be shown?

Sawada: We are planning announcement during ID Week, but since that is an academic meeting, we are not sure if we can make the announcement as we have intended. Therefore, the announcement is still unfixed.

Ms. Kumagai: I understand. Thank you.

MC: The next question is by Mr. Sakai of Credit Suisse Securities. Mr. Sakai, please go ahead.

Mr. Sakai: Hello. I have two quick questions.

One is about Xofluza. I would like to confirm if there have been any updates.

Sawada: I would like to answer that question again. We held a meeting with the National Institute of Infectious Diseases the PMDA in attendance. There we discussed that information should be shared more smoothly in the future by including both parties.

I have heard that the Institute will update their surveillance data on a timely basis.

Mr. Sakai: I see. Then, does the situation remain to be the Institute releasing data?

Sawada: That is correct.

Mr. Sakai: I understand. So, your future response is to submit data at a new timing. That is, the data that you have compiled.

Sawada: As for our data, we intend to announce it, including at an appropriate academic meeting, as soon as we have completed compiling.

Mr. Sakai: So, you will present it at an academic meeting.

Sawada: Yes.

Mr. Sakai: I see. Thank you.

I have one more question, which I am afraid is a very qualitative one. In HIV drugs, there was Juluca, and this time it is Dovato. They are 2-drug regimens, and I understand that you and ViiV have high expectations toward these drugs, but I have seen a report stating that some HIV specialists are relatively cautious about switching from a 3-drug regimen to a 2-drug regimen, according to a study.

Perhaps it is not appropriate to ask for your company's comments on a 3-drug regimen and a 2-drug regimen. But I would like to ask for your comment from your company's standpoint not exactly about the shift to a 2-drug regimen but how the review of the regimen has solidified, or if it is being solidified, at the clinical site, in view of the current situation at ViiV.

Sawada: Again, let me answer that question.

It is indeed a very difficult question, and we believe it is important to achieve results of follow-ups on a longer-term. In that sense, we have not recognized the emergence of resistant viruses at the 96-week point, in addition to the 48-week point. We believe that the confirmation of non-inferiority against the so-called 3-drug combination therapy is a strong data.

In addition, we believe it is important to follow this up on a long term to further establish this therapy in the future, and that this oral administration data will ultimately improve the value of the long acting 2-drug combination.

Mr. Sakai: I understand. Thank you.

MC: The next question is from Mr. Hashiguchi of Daiwa Securities. Mr. Hashiguchi, please go ahead.

Mr. Hashiguchi: Hello, this is Hashiguchi. I have two questions.

The first question is about your business results—page 9 of your material. The sales of your prescription drugs were 26.7 billion yen for April–June, of which “Others” accounted for around 40%, or 10.4 billion yen. The progress rate here is high compared to the forecasts in the first half. Is there anything you could tell us as the reason for this in a few words?

Hanasaki: Thank you for your question. I would like to answer.

One reason is the growth of Flumarin. Demand for Flumarin grew, leading to a small increase in sales, due to the external environment where the supply of Cefazolin was suspended. This is one of the components of “Others.”

Mr. Hashiguchi: So, that component was quite large, I suppose.

Hanasaki: That is one of the factors. Some of the other products have also grown, including in year-on-year terms.

Mr. Hashiguchi: I understand. Thank you.

My second question is about cefiderocol. It was mentioned earlier that it will probably be approved by the end of the year, but can you tell us about your preparations for the sale? How much do you intend to sell by yourself? Even if you will partner with another company or will sell by yourself, many options are possible, such as you will prepare by yourself or take in infrastructure that has already been established to some degree from outside. Can you comment on how much options you have narrowed down to at the moment and made specific preparations?

Hanasaki: I would like to answer that question. For cefiderocol, especially in the United States and Europe, our strategy is to specialize in infectious diseases. In this sense, cefiderocol is in a very important position. Therefore, we are making preparations for a system where we will sell and deliver the product by ourselves.

Mr. Hashiguchi: I think there are many ways, such as using internal resources or acquiring a company with marketing infrastructure that is established to some degree and building up on that. What about this point?

Hanasaki: We will think of many options, but basically, we hope to establish a system where we can sell properly by ourselves.

Mr. Hashiguchi: I understand. That will be all from me. Thank you.

MC: The next question is from Mr. Kotani of Nomura Securities. Mr. Kotani, please.

Mr. Kotani: My question is mainly about HIV. First of all, about Dovato and the TANGO test. I am comparing it with the TAF-base regimen, but when the data was released, the discontinuation, especially due to side effects, was 3.3% for the dolutegravir group and 0.3% for the TAF regimen, which I was quite surprised to see. Come to think of it, it is a switch from TAF, so naturally there would be many side effects in dolutegravir. Is this understanding correct, that it will not be such a large concern?

Furthermore, about “Discontinues for other reasons,” which was mentioned in the presentation. The percentage was 5.9% for TAF and 3.3% for dolutegravir, but is it necessary to consider seriously? This is my first question.

Sawada: Let me answer that question. Regarding your first question, you are right. As you can see when you compare GEMINI and TANGO, the difference between TAF and TDF is strongly indicated in the expression of adverse events. We believe this is related to the change from TAF to 3TC, and do not consider it as a significant problem in particular.

Mr. Kotani: So, the difference due to this “Discontinues for other reasons” is not so important, and perhaps is simply the loss of patients?

Sawada: We believe it is mainly a follow-up problem or a compliance problem, and that it is not particularly due to safety of effectiveness.

Mr. Kotani: I understand. Looking at the results of TANGO, there was, of course, no emergence of resistance. Honestly speaking, this was no surprise. As for dolutegravir, I think its chemical structure can address a slight mutation. This is actually preaching to the choir. I am not surprised at all to see is no resistant virus.

What I would like you to explain is about the markers of renal toxicityand about bones. This is where you want to differentiate. There seemed to have been side effects around there with Tenofovir. About creatinine, I don’t think it is that good, since dolutegravir is currently increasing. However, creatinine has always increased a little with dolutegravir. Please explain about these areas.

And also about bones. Could you explain what the situation is like now, regarding bio markers such as osteocalcin.

Sawada: As you have mentioned, we have acknowledged apparent fluctuations in creatinine since the beginning of the development of dolutegravir. However, we had confirmed that there was hardly any impact on the renal function itself, but creatinine is on the rise now.

If you look at both TANGO and GEMINI, you will see that the results of Dovato this time is exactly in between. If you consider that it is exactly midway between the 3-drug combination therapy using TDF and the 3-drug combination therapy using the TAF-based regimen, we think that the effect of NRTI, which is being combined, is manifesting itself a little, rather than dolutegravir.

If we can differentiate here, I think that will be quite difficult in that case with the TAF regimen.

Mr. Kotani: I see. Lastly, about cabotegravir. I half-remember President Teshirogi and GSK saying that cabotegravir could be used or could penetrate to probably 20% of patients.

The priority review has been designated and many data have been obtained. Is the expectation toward cabotegravir unchanged, or is it larger or smaller? Could you tell us about this point, please. That will be all from me.

Sawada: ViiV has not made an official announcement so we cannot say without permission. However, if we consider that, for example, Merck is developing a preparation that is long-acting, and Gilead is also developing a long-acting injection, including capsid inhibitors, we think that other companies are expecting the trend to go toward this direction.

If it is confirmed that there is no problem in terms of effectiveness in this 2-drug combination therapy and is promoted, we think that a 2-drug injection, especially a long-acting one, will be accepted by the market quite well.

Mr. Kotani: I understand. That will be all from me. Thank you.

MC: The next question is from Mr. Wakao of Mitsubishi UFJ Morgan Stanley Securities. Mr. Wakao, please ask your question.

Mr. Wakao: Hello. My name is Seiji Wakao. I am an analyst at Mitsubishi UFJ Morgan Stanley Securities. I have two questions for you.

My first question concerns the upfront payment from BDSI in line with the terms of the agreement between the two companies. Your April press release stated that an initial US$20 million would be paid at the time the contract was signed and an additional US$10 million would be paid within six months. During the April-June period, it is correct to assume that you only received a US$20 million payment?

Hanasaki: The amount we received is the total US$30 million.

Mr. Wakao: Thank you. At the time of the press release, I believe the payment had not been in the forecasts. The release stated that the impact from this payment would be marginal. Is it correct to understand that the impact from the monetary amount, including the US$30 million and subsequent royalty income, is insignificant? Or is this conversely a negative factor?

Hanasaki: This has already been included in the forecasts.

Mr. Wakao: So it is correct to understand that this was already included in your initial forecasts.

Hanasaki: Correct.

Mr. Wakao: Thank you.

Next, I would like an update on Cymbalta. I believe sales were off to a brisk start in the first quarter. However, given rumors that Eli Lilly plans to revise its sales structure and focus on cancer drugs in the current fiscal year, and also in light of Daiichi Sankyo's mirogabalin, at the time of your earnings presentation for full fiscal year results, you were slightly conservative on your outlook for Cymbalta. It seems you said you were uncertain as to how Cymbalta would perform in the market.

I believe that sales were fairly brisk in the first quarter. However, in the second quarter onward, should we look for impact from Eli Lily's change to its sales structure or from Tarlige sales? Or was your forecast too conservative? Can you please elaborate on this?

Hanasaki: Regarding our partnership with Eli Lilly, we plan to firmly cooperate together. In addition, some competing product has appeared in the market. As was explained earlier, the guidelines for the Management of Low Back Pain were released in May 2019. By properly conveying this evidence to doctors, we believe our sales will likely progress in line with our forecast.

Mr. Wakao: Thank you. So the negative factors you mentioned at your FY2018 earnings presentation are not surfacing. Is it correct to assume that sales will trend briskly in FY2019 given that the drug was named in the guidelines?

Hanasaki: Yes, that is correct.

Mr. Wakao: Thank you. I have no more questions.

MC: The next question is from Mr. Muraoka from Morgan Stanley MUFG.

Mr. Muraoka: Hello. My name is Shinichiro Muraoka. I am from Morgan Stanley MUFG.

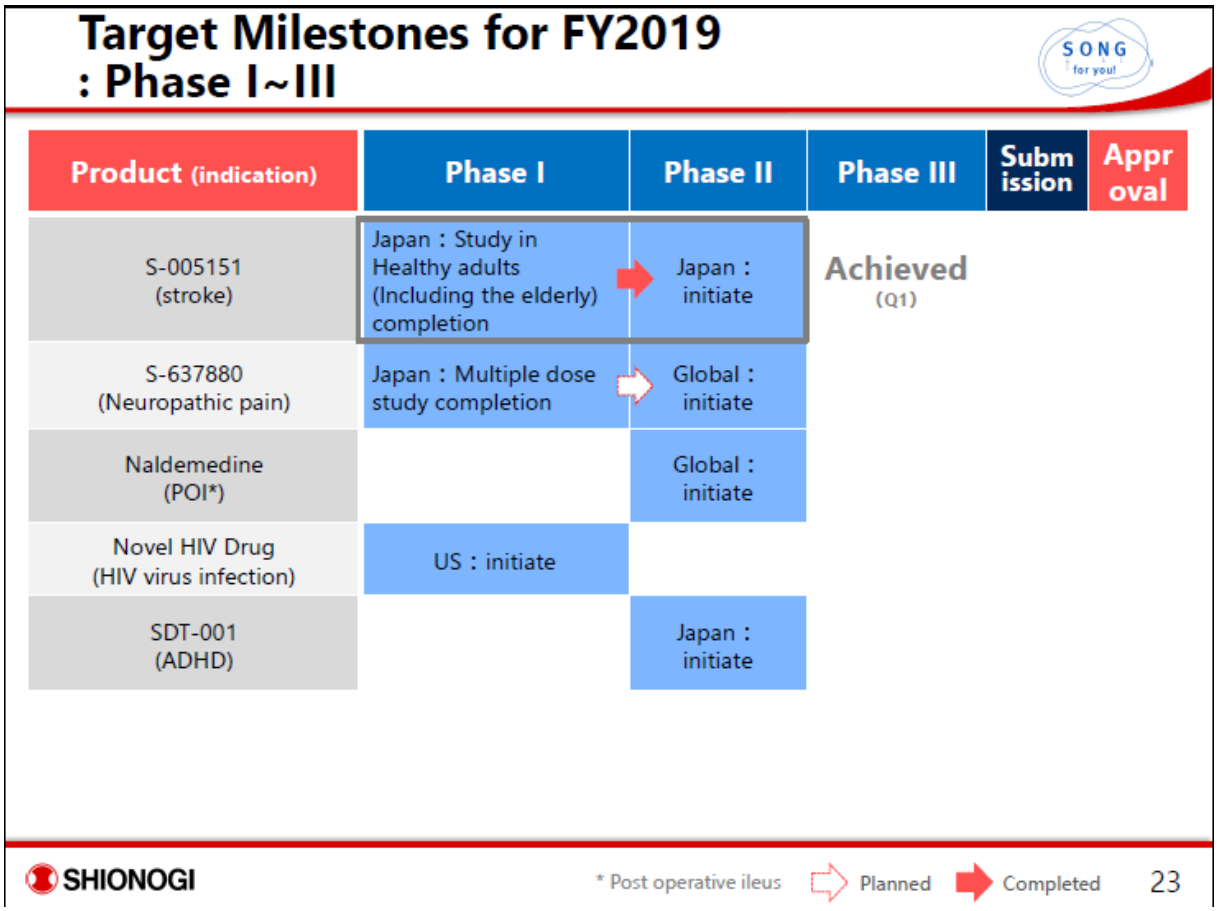
Speaker: Please go ahead.

Mr. Muraoka: I would like to get Ms. Sawada's opinion on R&D.

Earlier, I believe there was talk about Merck also embarking on a long-acting drug. Merck presented its findings at an academic conference. This implant drug of NRTTI (nucleoside reverse transcriptase translocation inhibitor) appears that this drug can be used in combination with cabotegravir. I think that a very innovative drug can be developed. Is this scientifically possible? Would the two drugs not interact well?

Sawada: We have not taken data on the combined usage of these two drugs so I cannot comment. Naturally there is always the possibility that this would work.

Mr. Muraoka: I see. Thank you.

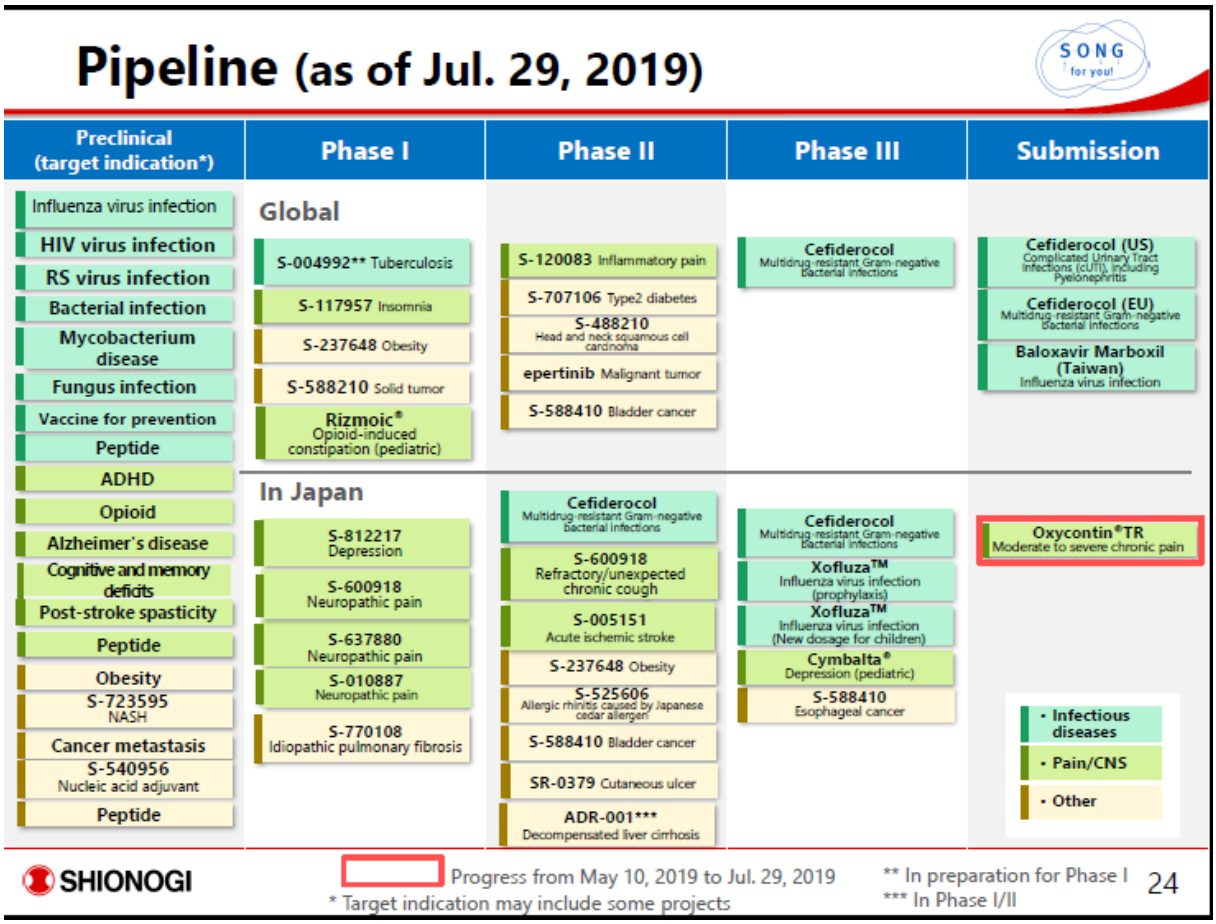


Mr. Muraoka: This question pertains to the early stage drug pipeline. This is on slide 23. S-005151 for strokes. I believe this is a HMGB1 peptide. You completed Phase 1 and have gleaned results for use on healthy adults, including seniors. Phase 2 is scheduled to start. One question is what type of results did you obtain? Also, I would like to know when do you expect to complete Phase 2?

Sawada: I am sorry but the timing of completion has not been disclosed so I hope you will forgive me for not getting into this today.

Phase 1 study for for epidermolysis bullosa was completed. But, epidermolysis bullosa is relatively prevalent in young people, and stroke is relatively prevalent in elderly people Also, since you are familiar with the content of S-005151, it was necessary for us to confirm whether the response was the same for elderly people as it was for healthy adults. The trial

was conducted on elderly people. It was confirmed that there was no problem for use on elderly people so we commenced our Phase II trial.



Mr. Muraoka: Thank you. I have one more question. Is this for use in the early stage?

ADR-001 is in the development pipeline table. This was discovered by Rohto using mesenchymal stromal cell (MSC) to treat cirrhosis of the liver. This is currently in Phase I/II, which just started. When you do estimate trials will be completed? If this is successfully completed, what will be your next step?

Sawada: This has not been disclosed by Rohto Pharmaceutical Co., Ltd. therefore I cannot discuss the details. This drug is in the category of regenerative medicine. If we obtain extremely positive results, it is possible that filing will be relatively quick. I believe that this will depend on the results.

Mr. Muraoka: Since the treatment is being used to treat cirrhosis of the liver, it is correct to assume that it is being tested on patients in fairly severe condition?

Sawada: Yes, that is correct. In any case, the trial is focusing on treatment of cirrhosis of the liver, not liver fibrosis.

Mr. Muraoka: I understand. Thank you. That is all from me.

MC: The next question is from Mr. Akahane from Tokyo Tokai Research Institute. Mr. Akahane, please go ahead.

Mr. Akahane: Thank you.

Speaker: Please go ahead.

Mr. Akahane: I have one point I would like to confirm about your earnings.

It is on Slide 10. As was discussed earlier, excluding one-time factors, earnings performance was extremely brisk. Earnings performance was also very favorable, after factoring out R&D cost. Is this due to the problem that the supply of Cefazolin was suspended?

Hanasaki: Yes, that is correct.

Mr. Akahane: This is not included in one-time factors, correct?

Hanasaki: Yes, it is not included in one-time factors.

Mr. Akahane: Was the impact fairly substantial? Your operating profit grew 4.9 billion yen so does that mean the impact was not that considerable?

Hanasaki: The impact of Cefazolin supply was very minor.

Mr. Akahane: I see. So you posted a high achievement rate. What area exhibited the largest growth based on its true strength, excluding royalty income?

Hanasaki: I think this would be sales.

Mr. Akahane: It appears that Cymbalta boasted the best sales.

Hanasaki: Yes. As shown in the table on Slide7, fluctuations in sales performance reflects, a rise in sales of prescription drugs of 1.3 billion yen year-on-year, a growth in sales at overseas subsidiaries and exports of 70 million yen, and an increase in sales of OTC and quasi-drugs of 50 million yen.

Mr. Akahane: So it is not misleading to assume that trends will largely be the same in Q2.

Hanasaki: That is right. In prescription drugs, we have created a forecast for the second quarter onward in which we estimate further growth for Cymbalta and Intuniv. We are working toward this goal therefore, at the very least, we aim to keep in line with our sales forecast.

Akahane: I understand. Thank you.

MC: We have not other questions. Mr. Kyokawa, could you please do the closing remarks.

Kyokawa: I would like to thank everyone. I have one thing I would like to say. Starting from this quarter, we plan to upload a transcript of our conference call to our website. Anyone who is unable to participate in the conference call, can read about it on our website. The Japanese version will be uploaded tomorrow and the English version will be uploaded on Friday.

Thank you once again.

Speaker: Thank you.

MC: This concludes Shionogi’s conference call for the first quarter of the fiscal year ending March 2020.

Thank you for taking time out of your busy schedule to participate.

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