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CHUGAI PHARMACEUTICAL CO., LTD.

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CHUGAI PHARMACEUTICAL CO., LTD.

1Q Results (Jan-Mar 2021) Conference Call

April 22, 2021

Event Summary

[Company Name]	CHUGAI PHARMACEUTICAL CO., LTD.
[Company ID]	4519-QCODE
[Event Language]	JPN
[Event Type]	Earnings Announcement
[Event Name]	1Q Results (Jan-Mar 2021) Conference Call
[Fiscal Period]	FY2021 Q1
[Date]	April 22, 2021
[Number of Pages]	36
[Time]	18:00 – 19:12 (Total: 72 minutes, Presentation: 40 minutes, Q&A: 32 minutes)
[Venue]	Dial-in
[Venue Size]	
[Participants]	

[Number of Speakers]	5	
	Osamu Okuda	President, CEO
	Toshiaki Itagaki	Executive Vice President, CFO
	Tetsuya Yamaguchi	Senior Vice President, Head of Project & Lifecycle Management Unit
	Shinji Hidaka	Vice President, Head of Marketing & Sales Division
[Analyst Names]*	Fumiyoshi Sakai	Credit Suisse Securities (Japan) Limited
	Akinori Ueda	Goldman Sachs Japan Co., Ltd.
	Hidemaru Yamaguchi	Citigroup Global Markets Japan Inc.
	Motoya Kohtani	Nomura Securities Co., Ltd.
	Shinichiro Muraoka	Morgan Stanley MUFG Securities Co., Ltd.
	Seiji Wakao	JPMorgan Securities Japan Co., Ltd.

*Analysts that SCRIPTS Asia was able to identify from the audio who spoke during Q&A.

Presentation

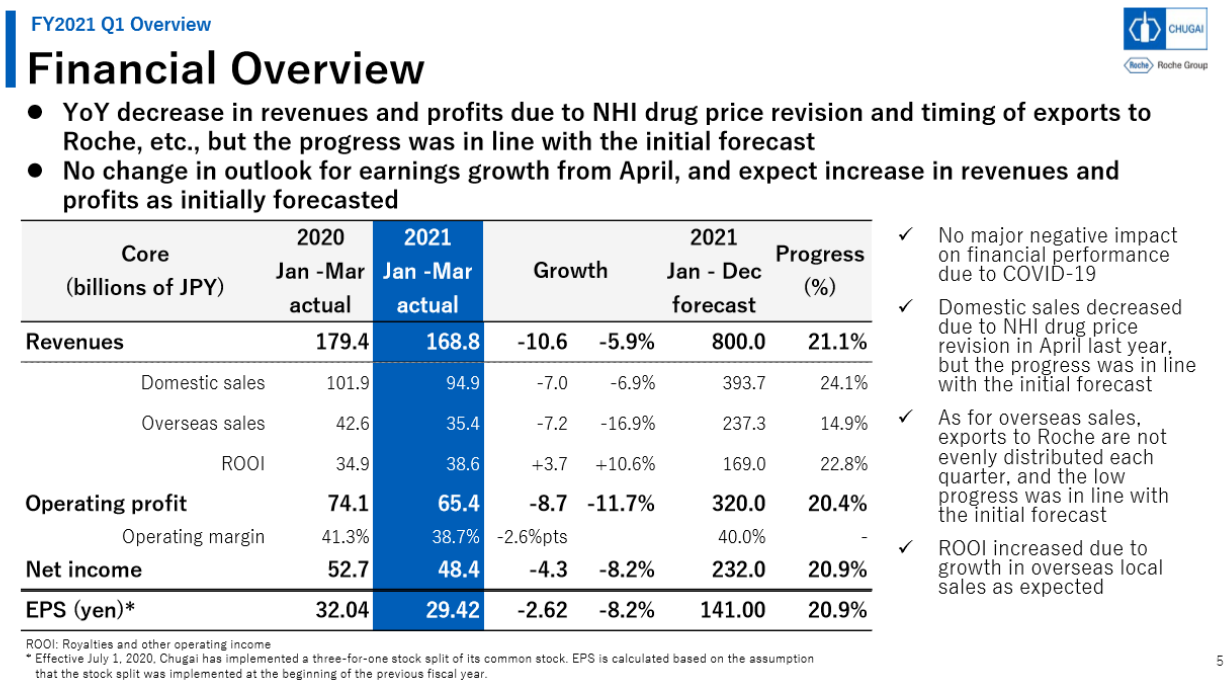
Sasai: We will now begin the CHUGAI PHARMACEUTICAL CO., LTD. Q1 2021 conference call.

Thank you very much for taking time out of your busy schedule to join us today. My name is Sasai, and I am the moderator of this session. After the presentation, there will be a 30-minute question-and-answer period, during which any questions you may have will be answered.

We will now hear from Dr. Okuda, CEO; Mr. Itagaki, CFO; and Mr. Yamaguchi, Head of Project & Lifecycle Management Unit. Please have your presentation and disclosure materials ready.

We will now begin the presentation.

First of all, Dr. Okuda will give an overall explanation of Q1 results.



FY2021 Q1 Overview

Financial Overview

- **YoY decrease in revenues and profits due to NHI drug price revision and timing of exports to Roche, etc., but the progress was in line with the initial forecast**
- **No change in outlook for earnings growth from April, and expect increase in revenues and profits as initially forecasted**

Core (billions of JPY)	2020 Jan -Mar actual	2021 Jan -Mar actual	Growth		2021 Jan - Dec forecast	Progress (%)
Revenues	**179.4**	**168.8**	**-10.6**	**-5.9%**	**800.0**	**21.1%**
Domestic sales	101.9	94.9	-7.0	-6.9%	393.7	24.1%
Overseas sales	42.6	35.4	-7.2	-16.9%	237.3	14.9%
ROOI	34.9	38.6	+3.7	+10.6%	169.0	22.8%
Operating profit	**74.1**	**65.4**	**-8.7**	**-11.7%**	**320.0**	**20.4%**
Operating margin	41.3%	38.7%	-2.6%pts		40.0%	-
Net income	**52.7**	**48.4**	**-4.3**	**-8.2%**	**232.0**	**20.9%**
EPS (yen)*	**32.04**	**29.42**	**-2.62**	**-8.2%**	**141.00**	**20.9%**

ROOI: Royalties and other operating income
* Effective July 1, 2020, Chugai has implemented a three-for-one stock split of its common stock. EPS is calculated based on the assumption that the stock split was implemented at the beginning of the previous fiscal year.

- ✓ No major negative impact on financial performance due to COVID-19
- ✓ Domestic sales decreased due to NHI drug price revision in April last year, but the progress was in line with the initial forecast
- ✓ As for overseas sales, exports to Roche are not evenly distributed each quarter, and the low progress was in line with the initial forecast
- ✓ ROOI increased due to growth in overseas local sales as expected

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Okuda: Thank you. I will now give an overview of the first quarter. Please refer to page 5 of your slides.

Revenues for the January to March period was JPY168.8 billion, down 5.9% from the same period last year. Operating profit was JPY65.4 billion, down 11.7% from the previous year, marking the start of a decline in both revenues and profits.

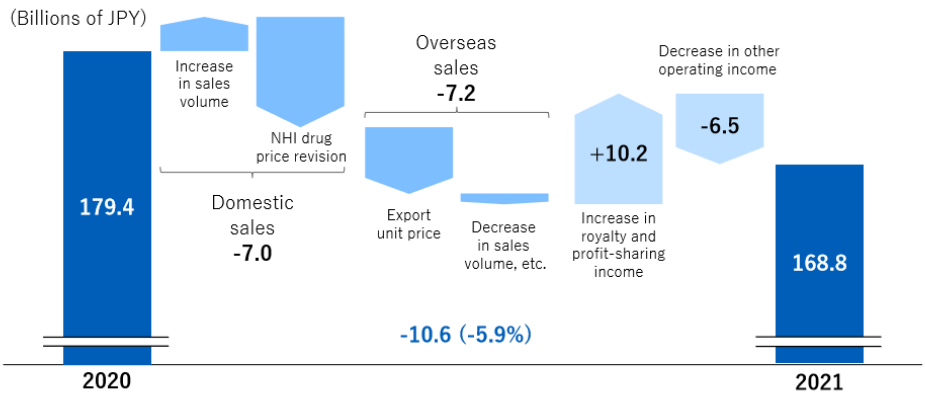
However, looking at the rate of progress toward the forecast, we are 21.1% of the way toward the JPY800 billion in revenues forecast for the current fiscal year. The figure is 20.4% for the operating profit forecast. This is almost in line with our initial expectations.

Since there is no change in the outlook for earnings growth after April, we expect to achieve the initial forecast of increased revenues and profits for the full year.

FY2021 Q1 Overview

Topline Overview

- **Domestic sales decreased due to NHI drug price revision, despite an increase in sales volume amid the impact of generic products**
- **Overseas sales decreased due to lower export unit price and timing of exports to Roche**
- **Royalty income increased due to growth in overseas local sales of in-house products**



- ✓ Domestic sales for Tecentriq, Kadcyla, and Enspryng exceeded expectations. Impact of generics on some products and impact of NHI drug price revision were significant. Overall sales declined, but progress was in line with the initial forecast.
- ✓ Overseas sales decreased due to decline in export unit price and timing of exports of Actemra to Roche as expected
- ✓ Royalty income increased due to growth in overseas local sales of Hemlibra and Actemra as expected

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Next, I will discuss the top line. Please see page 6.

In Japan, the oncology product Tecentriq is steadily penetrating the market, and Kadcyla is also performing well. In the primary area, in addition to the steady market penetration of Enspryng, sales of Hemlibra have been growing steadily.

On the other hand, sales of Avastin, Herceptin, and Edirol decreased due to the NHI price revision and the penetration of generics.

Overall sales in Japan decreased compared to the same period last year despite an increase in volume. This is due to the significant impact of the NHI price revision in April last year.

Overseas sales decreased due to a decline in export unit prices and a bias due to the export timing of Actemra.

Royalties and profit-sharing income for Hemlibra and Actemra increased, reflecting the growth in overseas local sales.

Overall, current fiscal year started from decrease in revenues, but are progressing as expected at the beginning of the fiscal year.

FY2021 Q1 Overview

R&D Overview

- **Obtained approval for multiple first-in-class products in Japan, which is expected to contribute to sales this year**
  - ✓ Polivy: Aiming for early market penetration through obtaining approval and launch for relapsed / refractory indication prior to 1st line treatment
  - ✓ FoundationOne Liquid CDx*: Preparing for launch to address diverse needs with complementary use
- **Progress of development pipelines for COVID-19**
  - ✓ Actemra: REMDACTA study did not meet its primary endpoint
    Collaborating with Roche to evaluate clinical study results obtained to date
  - ✓ Antibody Cocktail: Achieved primary endpoints in multiple Phase 3 trials conducted overseas.
    Domestic Phase 1 study initiated, scheduled to file in 2021
  - ✓ AT-527: Oral new drug candidate in-licensed from Roche, preparing for development in Japan

(As of April 22, 2021)

Approved	Actemra	Adult patients with SSc-ILD**	Mar. 2021 (US)
	Polivy	Relapsed or Refractory Diffuse Large B-cell Lymphoma	Mar. 2021
	FoundationOne Liquid CDx*	Blood-based Comprehensive Genomic Profiling Test for Solid Tumors	Mar. 2021
Filed	Enspryng	Neuromyelitis Optica Spectrum Disorder	Aug. 2019 (EU)
	nemolizumab	atopic dermatitis	Q3 2020***
	Risdiplam	Spinal Muscular Atrophy	Oct. 2020

Letters in orange: in-house projects
*FoundationOne Liquid CDx Cancer Genomic Profile **SSc-ILD: Systemic sclerosis-associated interstitial lung disease ***Filed by Maruho Co., Ltd., the licensee in Japan

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Please see page 7.

On the R&D front, we obtained approval for 2 first-in-class products that are expected to contribute to sales from this fiscal year. We have also made great progress in the development of therapeutic agents for COVID-19.

Polivy is a novel anti-cancer antibody-drug conjugate indicated for the treatment of relapsed or refractory diffuse large B-cell lymphoma. In overseas clinical trials, a higher complete response rate was observed compared to existing treatments.

Based on these results, the drug has already been approved and launched overseas and is being used by many patients. In the future, we plan to expand the indications to include first-line treatment, and we will work to achieve market penetration as soon as possible.

Secondly, our comprehensive cancer genomic profiling, FoundationOne CDx, launched in June 2019, is already in use at many core and collaborating hospitals for cancer genome medicine. We have now received approval for the FoundationOne Liquid CDx Cancer Genomic Profile, which can detect cancer gene mutations from tumor-derived DNA in the blood.

With the addition of FoundationOne Liquid CDx, a blood sample, to the existing FoundationOne CDx, which uses tumor tissue as a sample, we believe that we can meet the diverse needs of the medical field in a mutually complementary manner. This is the first cancer genomic profiling test to be approved in Japan using blood samples.

Next, we would like to provide an update on the status of our development pipeline for COVID-19, for which there is concern about the spread of mutant strains.

Actemra failed to meet its primary endpoint in the REMDACTA study, which evaluated its efficacy in combination with Remdesivir. Since we have conducted several clinical trials so far, we are currently analyzing the results of those trials in an integrated manner.

In addition, the antibody cocktail therapy developed by Regeneron Pharmaceuticals achieved its primary endpoint in several Phase III clinical trials, including prophylactic administration to outpatients and close contacts overseas. In Japan, we have just started Phase I for Japanese patients in March. We are planning to submit an application for this antibody cocktail in 2021.

Finally, AT-527. This is an oral RNA polymerase inhibitor discovered and developed by Atea Pharmaceuticals. We are now preparing to develop it in Japan.

Other new drugs under regulatory review include Enspryng in Europe; nemolizumab, which is highly effective against itching, for atopic dermatitis in Japan; and risdiplam, which can be administered orally for the intractable disease of spinal muscular atrophy and is very easy for patients to use.

That is all from me.

Sasai: We will now hear from Mr. Itagaki.

FY2021 Q1 Consolidated Financial Overview (Core)

P/L Jan - Mar (Year on Year)

(Billions of JPY)	2020	2021	Growth	
Revenues	**179.4**	**168.8**	**- 10.6**	**- 5.9%**
Sales	144.5	130.3	- 14.2	- 9.8%
Domestic	101.9	94.9	- 7.0	- 6.9%
Overseas	42.6	35.4	- 7.2	- 16.9%
Royalties and other operating income	34.9	38.6	+ 3.7	+ 10.6%
Royalty and profit-sharing income	26.4	36.6	+ 10.2	+ 38.6%
Other operating income	8.5	2.0	- 6.5	- 76.5%
Cost of sales	**-61.0**	**-55.0**	**+ 6.0**	**- 9.8%**
(cost to sales ratio)	42.2%	42.2%	-	-
Operating expenses	**-44.4**	**-48.5**	**- 4.1**	**+ 9.2%**
M&D and G&A *1	-19.4	-19.7	- 0.3	+ 1.5%
Research and development	-25.0	-28.7	- 3.7	+ 14.8%
Operating profit	**74.1**	**65.4**	**- 8.7**	**- 11.7%**
(operating margin)	41.3%	38.7%	-2.6%pts	-
Financial account balance	-1.2	0.3	+ 1.5	-
Income taxes	-20.2	-17.2	+ 3.0	- 14.9%
Net income	**52.7**	**48.4**	**- 4.3**	**- 8.2%**
EPS (JPY) *2	32.04	29.42	-2.62	- 8.2%

Domestic sales
Decrease due to NHI drug price revision and launch of generic drugs

Overseas sales
Decrease in export of Actemra

Royalty and profit-sharing income
Increase in income for Hemlibra

Other operating income
Decrease in one-time income

Cost of sales
Cost to sales ratio remained unchanged from 2020 Q1

Operating expenses
Increase of research and development expenses due to progress of projects, etc.

Operating profit
Decrease due to lower revenues, including a decrease in one-time income, and an increase in research and development expenses

*1 M&D: Marketing and distribution, G&A: General and administration
*2 Effective July 1, 2020, Chugai implemented a three-for-one stock split of its common stock. EPS are calculated based on the assumption that the stock split was implemented at the beginning of the previous fiscal year.

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Itagaki: Good evening, everyone. I am Itagaki. I would like to explain the details of the financial results.

Please go to page 9. We will look at the profit and loss results for the first quarter, comparing them to the same period last year.

Revenues totaled JPY168.8 billion, a decrease of JPY10.6 billion, or 5.9%, from the same period last year.

As for the breakdown of revenues, domestic sales declined by 6.9% due to the NHI price revision in April last year and the impact of generics.

Overseas sales decreased by 16.9% due to factors such as differences in the timing of Actemra exports and the impact of export unit prices.

Royalty and profit-sharing income increased by JPY10.2 billion, mainly due to royalty income related to Hemlibra, while other operating income only achieved JPY2 billion to a decrease in one-time income.

The decline of revenues in the first quarter is in line with expectations, and there is no change in forecast for full-year revenues growth.

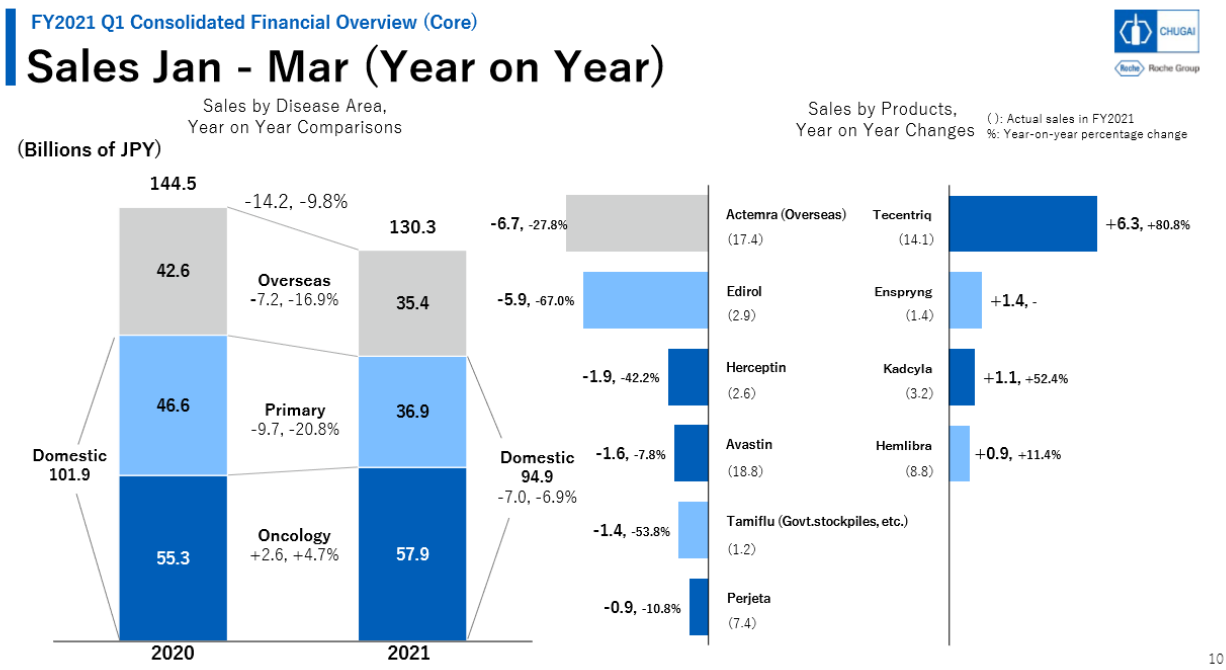
Cost of sales maintained the product cost ratio of 42.2% for the same period last year due to the higher sales composition of in-house products, although the NHI price revision in April last year increased the cost ratio of some products.

As for expenses, marketing, general, and administrative expenses increased modestly by 1.5%, and we invested aggressively in R&D. R&D expenses increased by JPY3.7 billion, an increase of 14.8%, mainly due to progress in development projects.

Incidentally, we planned to increase R&D expenses by JPY18 billion for the full year, and the rate of increase was expected to be 15.9%, so this first quarter performance was on track with the plan.

As a result, operating profit was JPY65.4 billion, a decrease of 11.7%, and the operating margin was 38.7%. Subtracting the financial account balance and corporate income tax from this figure, net income was JPY48.4 billion.

As for profits, the first quarter is expected to see a decrease in profits as expected, and together with revenues, we are forecasting an increase in both revenues and profits for the full year, and we expect to reach a record high for the fifth consecutive year.



Please see the slide on page 10. The following is a breakdown of the changes in sales.

By therapeutic area, first of all, the domestic oncology area, at the bottom of the page, grew by 4.7%. Looking at individual products on the right, Tecentriq showed a large increase of 80.8%. Sales of Kadcyla also increased due to the expansion of indications.

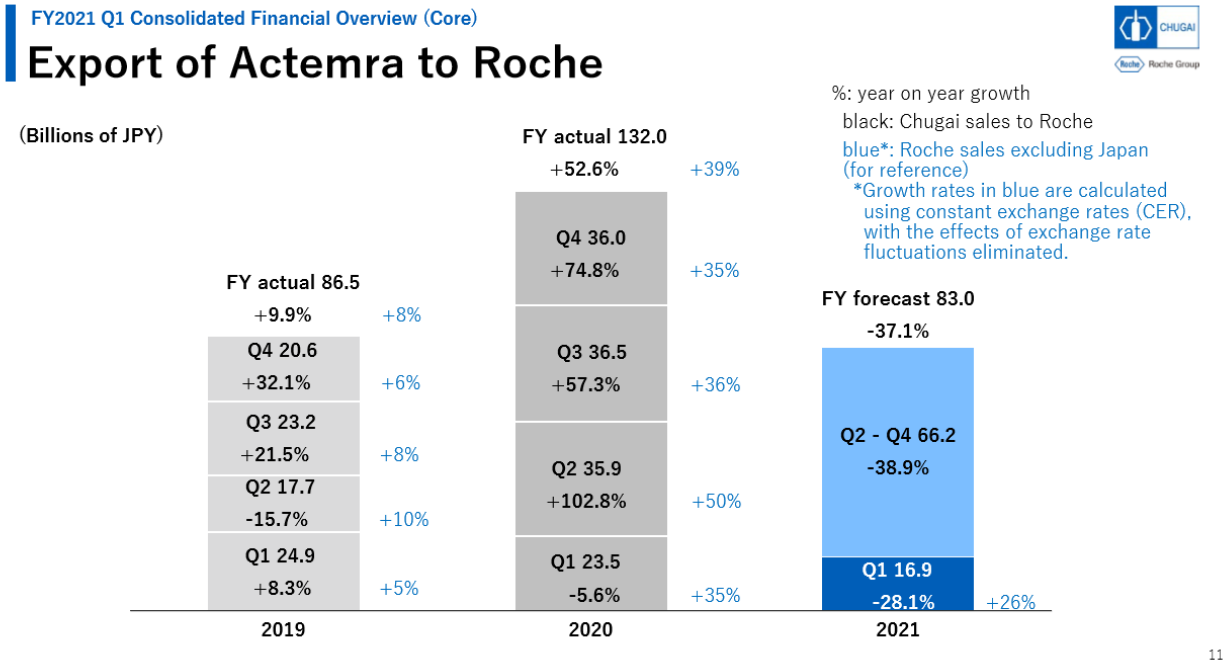
On the other hand, sales of Herceptin, Avastin, and Perjeta decreased due to the impact of last year's NHI price revision.

Next, sales in the domestic primary area declined by 20.8%. Sales of in-house products, Enspryng and Hemlibra, increased as market penetration progressed. Sales of Hemlibra grew by 11.4%. This follows the 15% NHI price reduction in April last year due to market expansion re-pricing. Sales grew by about 32% on a volume basis.

On the other hand, sales of Edirol, for which a generic version is available, decreased by JPY5.9 billion, and sales of Tamiflu, for stockpiles, also decreased by JPY1.4 billion.

Overseas, as we have already explained, sales decreased by 16.9% due to the timing of Actemra exports and the impact of export unit prices. Of the JPY6.7 billion decrease in Actemra exports, JPY6.6 billion will be made up of the decrease in exports to Roche.

The conditions for exporting Actemra to Roche are explained on the next page.



Please see page 11.

First, from left to right, 2019, 2020, and 2021 are shown in chronological order. Quarters are shown starting from the bottom.

This year's figure of JPY66.2 billion for the second quarter to the fourth quarter is based on the full-year forecast minus the first quarter results.

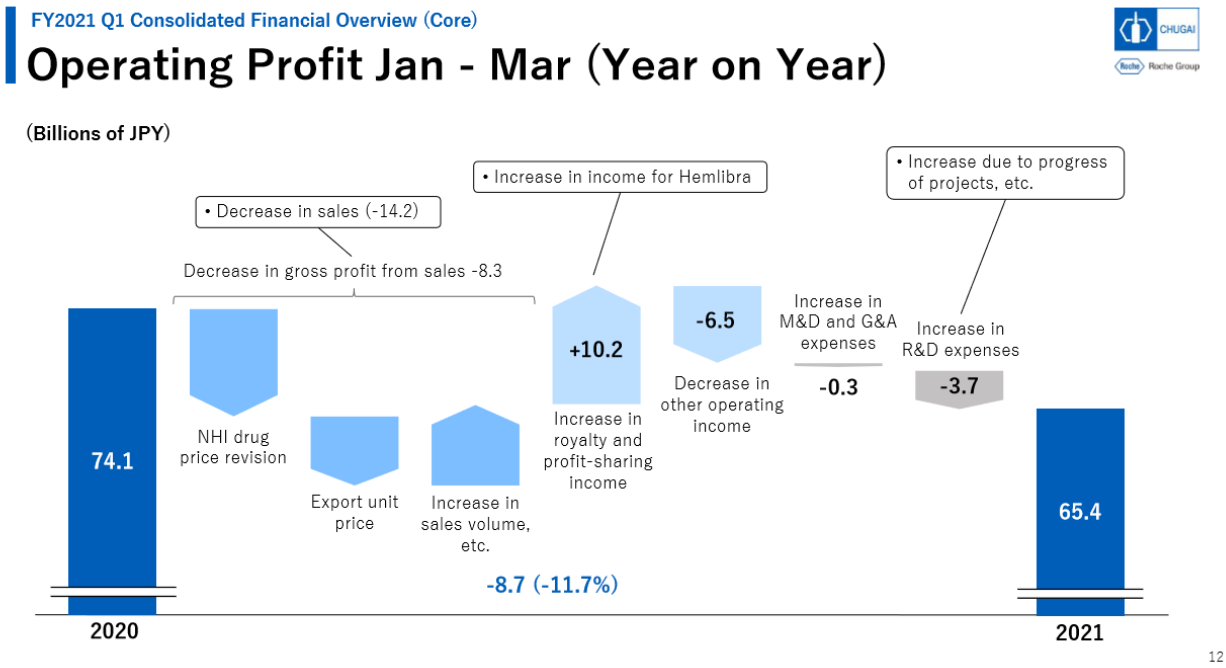
First of all, in 2020, we achieved full-year sales of JPY132 billion, up 52.6% from the previous year. On the other hand, given that growth in 2019 was 9.9%, and the demand for rheumatoid arthritis treatment is stable, we can assume that about 40 percentage points of the differential increase is due to demand related COVID-19 and the increased exports.

The next figure in blue is the percentage increase in Actemra sales by Roche. The growth rate for 2019 was 8%, and last year was 39%, which means that there was a significant demand for COVID-19 in Roche territory.

Compared to last year's market growth rate of 39% in Roche territory, the increase in exports from our company to Roche was 52.6%, which indicates that shipments were made ahead of schedule. As a result of these factors, exports in the first quarter of this year were somewhat restrained, resulting in JPY16.9 billion.

The first quarter exports were already on order when we announced our initial forecast, so the actual results of JPY16.9 billion, a 28.1% decrease from the previous year, are in line with our plan.

The full-year forecast of JPY83 billion includes only a limited amount of exports for COVID-19 demand. However, the growth rate of the first quarter in the Roche territory is still high at 26%, as you can see on the bottom right, so we expect additional exports in the second half of the year that have not been factored into our forecast.



This is page 12. The following is a waterfall graph showing the breakdown of changes in operating profit.

The second, third, and fourth bar graphs from the left show the decomposition of the JPY8.3 billion decrease in gross profit from sales.

Although sales volume has increased, the impact of the NHI price revision in Japan, and the reduction of export unit prices overseas, have had a significant impact.

Next, the increase in royalty and profit-sharing income of JPY10.2 billion directly contributed to the increase in profit.

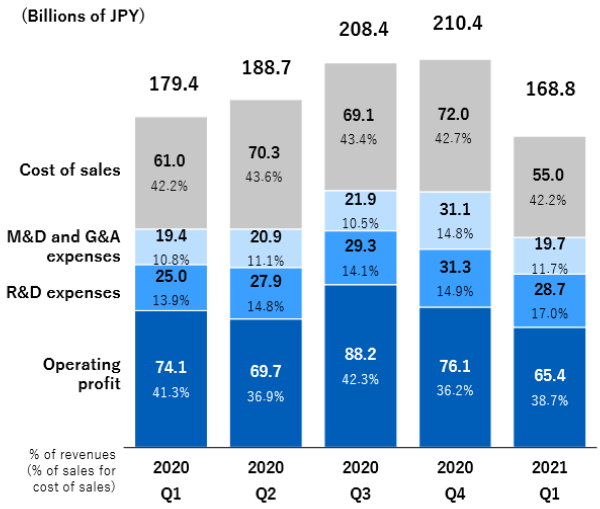
Other operating income decreased by JPY6.5 billion in reaction to the relatively large upfront payment income in the first quarter last year, which directly resulted in a decrease in profit.

Expenses increased by JPY300 million due to an increase in marketing, general, and administrative expenses. Expenses here have increased slightly, mainly due to marketing activities in China, while expenses and marketing expenses in Japan and Europe have decreased slightly.

Research and development expenses increased by JPY3.7 billion, as already explained.

FY2021 Q1 Consolidated Financial Overview (Core)

Structure of Costs and Profit by Quarter



vs. Year on Year (2020 Q1)

Cost of sales ratio: unchanged from 2020 Q1

R&D expenses: increase due to progress of projects, etc.

Operating profit: decrease of -8.7 (-11.7%)

vs. Previous Quarter (2020 Q4)

Cost of sales ratio: no significant change (-0.5%pts)

M&D and G&A expenses: decrease in line with the trend of previous years

R&D expenses: despite progress of projects, decrease according to the trend of costs incurred in previous years

Operating profit: decrease of -10.7 (-14.1%)

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From page 13, there are 3 more slides showing the quarterly trends.

First of all, this first slide shows the cost structure.

In the upper right-hand corner, you will see a comment comparing it to last year's first quarter, which I have already explained, so I will only mention how it compared to the previous quarter, as described below.

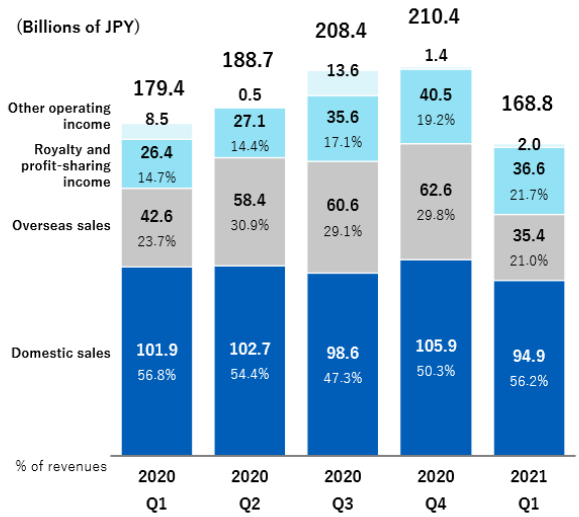
This is a comparison of the right-most 2 bars. As you can see, the previous quarter was characterized by high sales and expenses, while the first quarter is characterized by low sales and expense spending.

Although the structure of costs will not change significantly, the R&D expense ratio has increased to 17% in this first quarter. It can be seen that RED SHIFT, the strategy of TOP I 2030, is already underway.

The cost to sales ratio was in the 42% range, with no significant change.

FY2021 Q1 Consolidated Financial Overview (Core)

Structure of Revenues by Quarter



vs. Year on Year (2020 Q1)

Domestic sales: decrease due to NHI drug price revision and launch of generic drugs, etc.

Overseas sales: decrease in sales of Actemra

Royalty and profit-sharing income: increase in income for Hemlibra

Other operating income: decrease in one-time income

vs. Previous Quarter (2020 Q4)

Domestic sales: decrease due to impact from launch of generic drugs in addition to the trend in previous years

Overseas sales: decrease in sales of Actemra, Alecensa, etc.

Royalty and profit-sharing income: decrease in income for Hemlibra

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The next page, page 14, looks at the composition of revenues. Again, I will only mention the comparison with the previous quarter.

This is a comparison between the right-most 2 graphs.

First, the top block, consisting of other operating income, is event-driven and variable between quarters. In the first quarter, this figure was JPY2 billion. This is an increase of about JPY600 million from the previous quarter.

Below that, we can see that royalty and profit-sharing income declined. This was related to Hemlibra. Sales of Hemlibra by Roche have been steadily increasing, so royalty income from initial shipments, so-called “royalty 2,” has been increasing, but normal royalty income, “royalty 1,” will gradually increase in accordance with the yearly accumulated sales. In other words, it is a progressive rate. This is a contract in which the rate gradually increases, so the first quarter “royalty 1” is received at a lower rate.

As a result, there is a decrease compared to the previous quarter.

Next, overseas sales are variable due to export timing. The timing of exports of Actemra was shifted to the last year's fourth quarter, so the amount of sales decline in the first quarter was slightly larger.

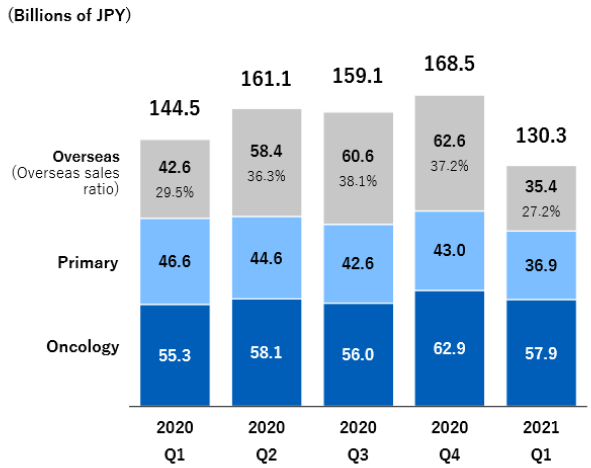
Sales of Alecensa also declined due to decline of unit export prices and shipment timing.

Lastly, with regard to domestic sales, first quarter sales are lower than the previous quarter, following the trend in previous years. The increasing impact of generics is also a factor in the decline in sales.

The bottom 2 blocks, sales, are broken down further on the next page.

FY2021 Q1 Consolidated Financial Overview (Core)

Structure of Sales by Quarter



vs. Year on Year (2020 Q1)

Overseas	Actemra: -6.7
Oncology	Tecentriq: +6.3, Kadcyla: +1.1 Herceptin: -1.9, Avastin: -1.6 Perjeta: -0.9
Primary	Edirol: -5.9, Tamiflu (Govt. stockpiles, etc.): -1.4 Enspryng: +1.4, Hemlibra: +0.9

vs. Previous Quarter (2020 Q4)

Overseas	Actemra: -19.4, Alecensa: -7.6 Enspryng: -4.0, Hemlibra: +4.0
Oncology	Avastin: -2.3, Perjeta: -1.3 Alecensa: -1.3, Herceptin: -1.0 Tecentriq: +2.1
Primary	Actemra: -1.5, Mircera: -1.2

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This is page 15.

The gray block, overseas, has decreased significantly from JPY62.6 billion in the fourth quarter last year to JPY35.4 billion in this first quarter.

As you can see in the overseas section on the lower right, Actemra decreased by JPY19.4 billion, Alecensa decreased by JPY7.6 billion, and Enspryng decreased by JPY4 billion in reaction to the relatively large initial shipment last year.

On the other hand, Hemlibra increased by JPY4 billion.

In the domestic oncology and primary areas, the impact of the NHI price revision in April last year is neutral when compared to the fourth quarters, so the reason for the decline in sales is mainly the normal trend between quarters.

Sales of Tecentriq increased by JPY2.1 billion, due in part to the expansion of its indication for the treatment of hepatocellular carcinoma.

FY2021 Q1 Consolidated Financial Overview (Core)

P/L Jan - Mar (vs. Forecast)

(Billions of JPY)	Actual 2021 Jan - Mar	Forecast 2021 Jan - Dec	Forecast Progress	2020 Progress *1
Revenues	**168.8**	**800.0**	**21.1%**	**22.8%**
Sales	130.3	631.0	20.6%	22.8%
Domestic	94.9	393.7	24.1%	24.9%
Overseas	35.4	237.3	14.9%	19.0%
Royalties and other operating income	38.6	169.0	22.8%	22.7%
Royalty and profit-sharing income	36.6	163.0	22.5%	20.4%
Other operating income	2.0	6.0	33.3%	35.3%
Cost of sales	**- 55.0**	**- 252.5**	**21.8%**	**22.4%**
(cost to sales ratio)	42.2%	40.0%	-	-
Operating expenses	**- 48.5**	**- 227.5**	**21.3%**	**21.5%**
M&D and G&A	- 19.7	- 96.0	20.5%	20.8%
Research and development	- 28.7	- 131.5	21.8%	22.0%
Operating profit	**65.4**	**320.0**	**20.4%**	**24.1%**
(operating margin)	38.7%	40.0%	-	-
Net income	**48.4**	**232.0**	**20.9%**	**24.0%**
EPS (JPY) *2	29.42	141.00	20.9%	24.0%

Domestic Sales
Progress nearly in line with forecast as total

Overseas sales
Progress nearly in line with forecast

Royalty and profit-sharing income
Progress nearly in line with forecast

Other operating income
Progress nearly in line with forecast

Cost of Sales
Cost to sales ratio nearly in line with Q1 forecast

Operating expenses
Progress nearly in line with forecast

Operating profit
Progress nearly in line with forecast

*1 Jan – Mar progress versus Jan – Dec

*2 Effective July 1, 2020, Chugai implemented a three-for-one stock split of its common stock. EPS are calculated based on the assumption that the stock split was implemented at the beginning of the fiscal year.

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Next, I would like to take a look at the progress toward the full-year forecast announced at the beginning of the fiscal year. This is page 16.

To summarize, sales, costs, and profits are all progressing roughly as expected.

First of all, the third line from the top, domestic sales, showed a progress of 24.1%, almost the same as last year. Next, overseas, the first quarter was within the firm order period, so the export performance was as planned. As for the full-year forecast, for example, Actemra has announced a forecast that does not include COVID demand, and we are not changing that assumption now, so we are making progress against the forecast as expected.

In addition, royalties, or other operating income, are not divergent from the forecast.

The cost to sales ratio is slightly higher at 42.2% in the first quarter compared to our full-year forecast of 40%, but we plan to gradually improve it as our own products grow further toward the end of the fiscal year.

As for expenses, although we were under a declared state of emergency in Japan during the first quarter, we were generally able to carry out our activities as planned, and there are no major problems with the progress of spending. As a result, the 20.4% progress in operating profit is also in line with our expectations.

FY2021 Q1 Consolidated Financial Overview (Core)

Sales Jan - Mar (vs. Forecast)

(Billions of JPY)	Actual 2021 Jan - Mar	Forecast 2021 Jan - Dec	Forecast Progress	2020 Progress *
Sales	**130.3**	**631.0**	**20.6%**	**22.8%**
Domestic	**94.9**	**393.7**	**24.1%**	**24.9%**
Oncology	**57.9**	**226.7**	**25.5%**	**23.8%**
Avastin	18.8	60.5	31.1%	25.0%
Tecentriq	14.1	49.2	28.7%	20.8%
Perjeta	7.4	31.8	23.3%	24.8%
Alecensa	6.0	27.0	22.2%	21.5%
Kadcyla	3.2	13.3	24.1%	20.6%
Herceptin	2.6	10.9	23.9%	28.3%
Gazyva	1.0	5.7	17.5%	21.7%
Rituxan	1.2	5.2	23.1%	26.4%
Xeloda	0.6	2.7	22.2%	30.6%
Rozlytrek	0.1	0.9	11.1%	0.0%
Foundation Medicine	1.0	7.2	13.9%	21.4%
Other	1.8	12.3	14.6%	22.0%

(Billions of JPY)	Actual 2021 Jan - Mar	Forecast 2021 Jan - Dec	Forecast Progress	2020 Progress *
Primary	**36.9**	**167.0**	**22.1%**	**26.4%**
Hemlibra	8.8	51.7	17.0%	23.2%
Actemra	9.2	38.5	23.9%	24.2%
Edirol	2.9	17.3	16.8%	31.7%
Mircera	3.4	11.7	29.1%	24.0%
Bonviva	2.0	8.5	23.5%	23.6%
CellCept	2.0	8.3	24.1%	24.2%
Oxarol	1.4	5.5	25.5%	21.9%
Enspryng	1.4	4.0	35.0%	0.0%
Tamiflu(Ordinary use)	-0.1	0.8	-12.5%	75.0%
Tamiflu(Govt. stockpiles, etc.)	1.2	1.2	100.0%	70.3%
Other	4.7	19.6	24.0%	25.8%
Overseas	**35.4**	**237.3**	**14.9%**	**19.0%**
Hemlibra	8.5	89.7	9.5%	33.0%
Actemra	17.4	85.3	20.4%	17.9%
Alecensa	6.0	44.2	13.6%	14.0%
Enspryng	-	3.9	0.0%	1.8%
Neutrogin	2.2	8.7	25.3%	27.8%
Other	1.2	5.4	22.2%	22.9%

* Jan – Mar progress versus Jan – Dec

17

Page 17 shows the progress of sales by product.

As I said, both domestic and overseas sales are in line with expectations, but when you look at individual products, there are differences.

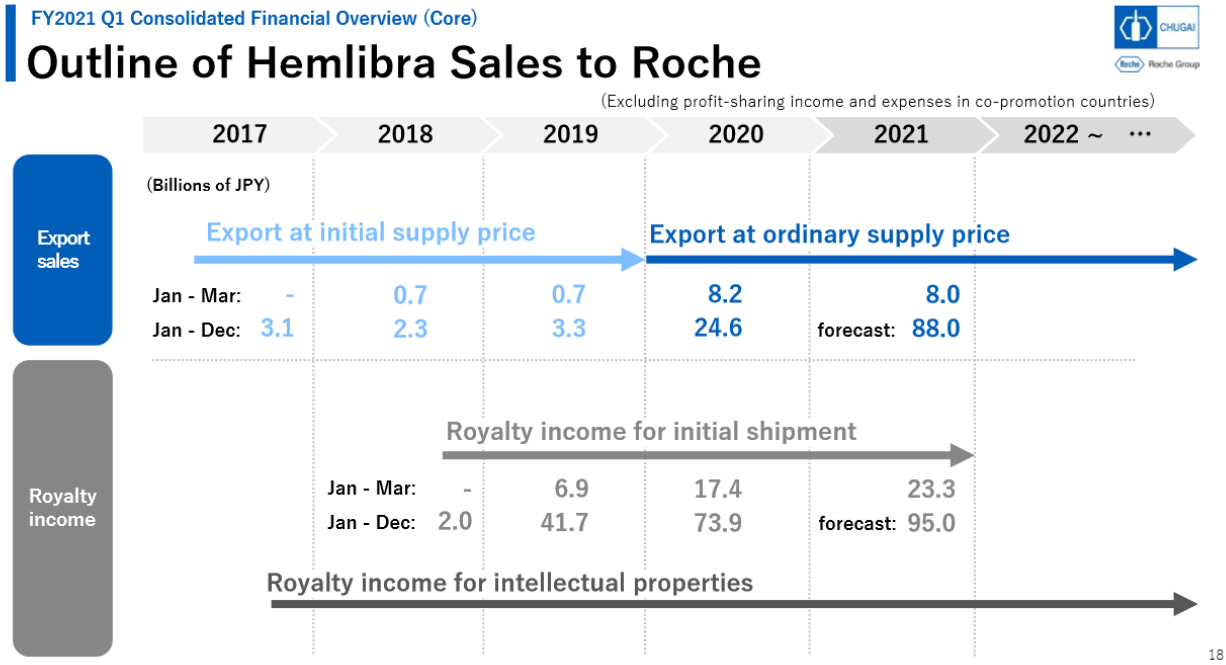
In the oncology area, Herceptin, Gazyva, Rituxan, Xeloda, and Rozlytrek, which are in the middle row on the left side, are slightly below the current forecast.

Foundation Medicine is progressing at 13.9%, but since FoundationOne Liquid CDx was approved for cancer genomic profile in March, sales are expected to increase from April.

In the primary area, Hemlibra is lagging slightly behind. In addition, Edirol is progressing at 16.8%, but we plan to increase sales because Chugai will solely be responsible for marketing from April 11.

In the oncology area, we have made good progress with the top left 2 products, Avastin and Tecentriq, which are our mainstay products, as well as Kadcyla. In the primary area, the new product, Enspryng, is performing well with a progress rate of 35%.

As for overseas sales, the rate of progress is bumpy due to the timing of exports, so comparisons with the previous year are not very helpful, but the first quarter is in line with the plan, as it is in the firm order period. Exports are expected to increase in the second quarter and beyond.



Page 18 is about Hemlibra sales to Roche.

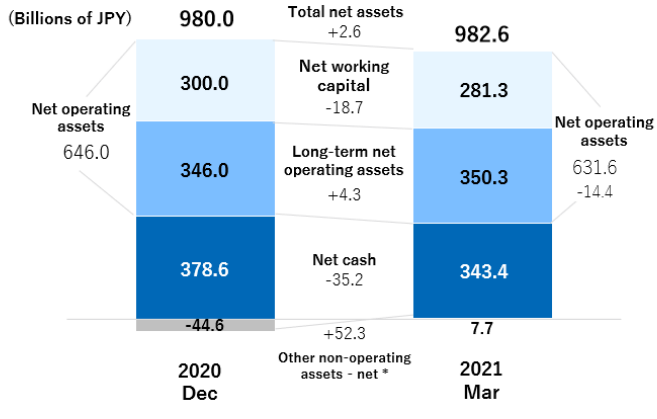
The top arrow shows export sales, and the bottom arrow shows royalty income. Both are in line with our expectations in the first quarter, and there are no changes to our full-year forecasts at this time.

In addition, royalty income related to initial shipments, or “royalty 2,” is expected to be JPY95 billion for the current fiscal year. It will come to an end at the end of the current fiscal year, as we explained at the beginning of the fiscal year.

This concludes the explanation of profit and loss.

FY2021 Q1 Consolidated Financial Overview (Core)

Financial Position (vs. 2020 Year End)



	2020 Dec		2021 Mar
Total assets	1,235.5	-90.9	1,144.6
Total liabilities	-255.5	+93.5	-162.0
Total net assets	980.0	+2.6	982.6
Ratio of equity attributable to Chugai shareholders	79.3%	+6.5%pts	85.8%

Decrease in net working capital

Decrease mainly in trade accounts receivable

Increase in long-term net operating assets

Mainly increase in Property, plant and equipment

Decrease in net cash

(Please refer to the next slide)

Increase in other non-operating assets – net

Decrease in accrued corporate tax

* e.g. deferred income tax assets, accrued corporate tax, etc.

FX rate to the JPY (end of period)

	2020 Actual	2021 Actual
1CHF	117.10	117.14
1EUR	126.89	129.30
1USD	103.19	110.37
1SGD	77.98	81.87

19

Page 19 is the balance sheet.

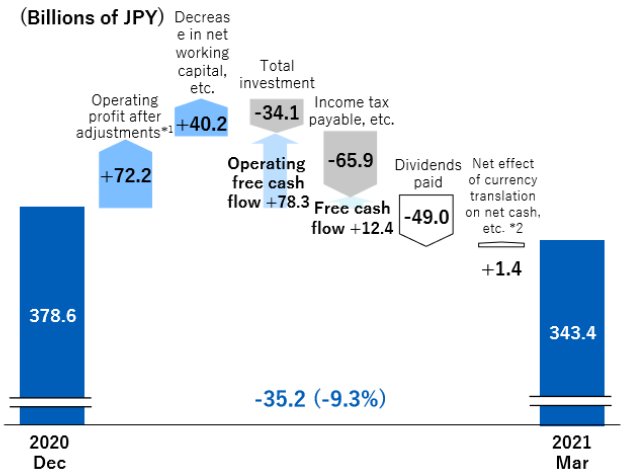
As you can see from the top of the figure on the left, net working capital decreased by JPY18.7 billion due to the collection of trade receivables, while long-term net operating assets increased by JPY4.3 billion due to investments for future growth, such as the new research center and manufacturing building.

In the first quarter, net cash decreased by JPY35.2 billion due to the payment of corporate taxes and year-end dividends, but there are no financial problems.

As you can see at the bottom of the table below, the shareholders' equity ratio increased by 6.5 percentage points to 85.8%, which is the highest level since the adoption of IFRS standards in 2013.

FY2021 Q1 Consolidated Financial Overview (Core)

Net Cash (vs. 2020 Year End)



Operating profit after adjustment *1	+72.2
Operating profit *1	+64.0
Depreciation, amortization and impairment *1	+7.3
Decrease in net working capital, etc.	**+40.2**
Total investment	**-34.1**
Property, plant and equipment	-28.9
Payment for lease liabilities	-2.2
Intangible assets	-2.9
Operating free cash flow	**+78.3**
Income tax payable, etc.	**-65.9**
Income tax payable	-63.3
Free cash flow	**+12.4**
Dividends paid	**-49.0**
End of FY 2020	-49.0
Net effect of currency translation on net cash, etc.	**+1.4**

*1 Including Non-Core (IFRS results)
*2 Net effect of currency translation on net cash, etc. = Transaction in own equity instruments + Purchase of non-controlling interests + Net effect of currency translation on net cash(*3)
*3 Results from using different types of exchange rates when consolidating overseas subsidiaries in financial statements, i.e. net cash using end of period exchange rate and free cash flows using average exchange rate. (Chugai defines this term based on International Accounting Standard (IAS) 7 and IAS 21)

20

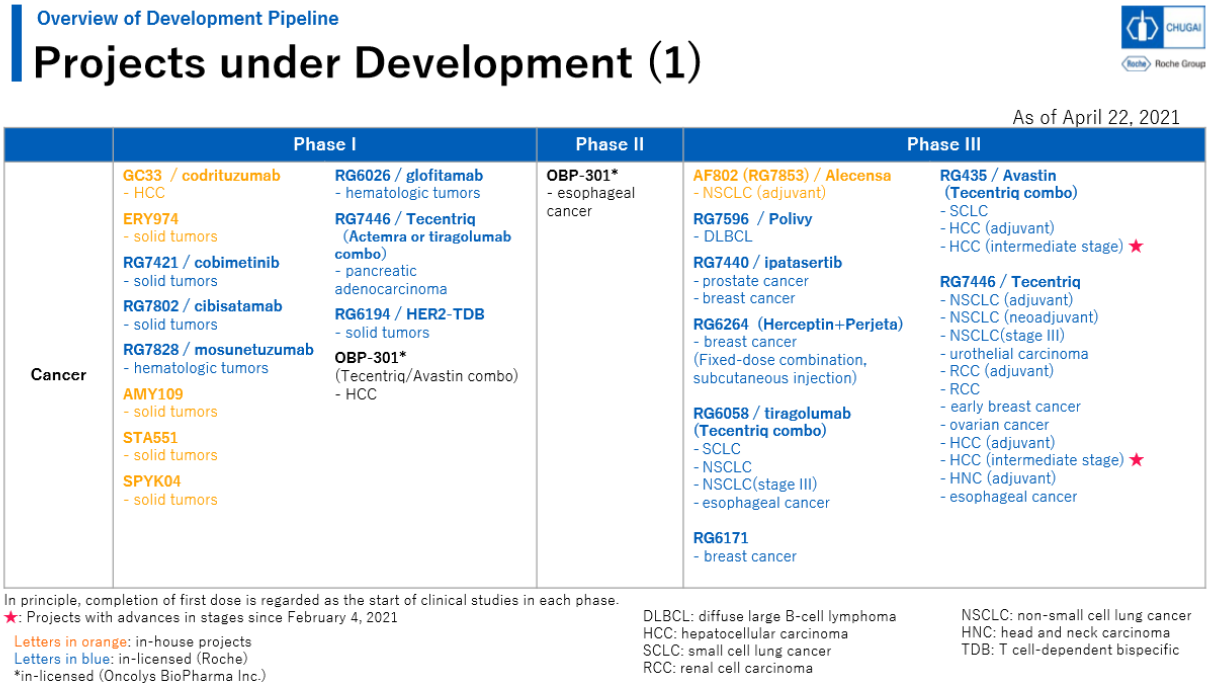
Finally, we look at the change in net cash. This is page 20.

First of all, cash inflow from operating activities was JPY72.2 billion, and after adding the decrease in working capital and subtracting investments in the construction of new laboratories and manufacturing facilities, operating free cash flow was positive JPY78.3 billion. As a result, net cash decreased by JPY35.2 billion from last year to JPY343.4 billion at the end of March.

Since we expect to increase both revenues and profits from the second quarter onward, we expect our balance sheet and cash flow to further improve.

This concludes my presentation.

Sasai: Next, we will hear from Mr. Yamaguchi, Head of Project & Lifecycle Management Unit.



Yamaguchi: My name is Yamaguchi. I would like to discuss the status of our development pipeline.

Please refer to page 27 of the slides. The first page of the development pipeline shows the development projects in the oncology area.

Products created in-house are shown in orange, Roche products in blue, and changes from the previous fiscal year are indicated with a red star.

A Phase III study has been initiated for combination Tecentriq and Avastin in patients with intermediate stage hepatocellular carcinoma.

Overview of Development Pipeline

Projects under Development (2)

PNH: paroxysmal nocturnal hemoglobinuria
nAMD: neovascular age-related macular degeneration
DME: diabetic macular edema
NMOSD: neuromyelitis optica spectrum disorder

As of April 22, 2021

	Phase I	Phase II	Phase III	Filed
Bone & Joint			NRD101 / Suvenyl (China) - knee osteoarthritis /shoulder periarthritis	
Renal	EOS789 - Hyperphosphatemia			
Autoimmune	RG7880 (IL-22 fusion protein) - inflammatory bowel disease			
Neurology	RG7935 / prasinezumab - Parkinson's disease GYM329 (RG6237) - neuromuscular disease RG6100 / semorinemab - Alzheimer's disease	RG7906 / ralmitaront - schizophrenia	RG1450 / gantenerumab - Alzheimer's disease RG6042 / tominersen - Huntington's disease	SA237 (RG6168) / Enspryng (EU) - NMOSD RG7916 / risdiplam - spinal muscular atrophy
Others	PCO371 - hypoparathyroidism AMY109 - endometriosis NXT007 - hemophilia A (PI/II) RG6413+RG6412 / casiribimab+imdevimab - COVID-19★		RG7716 / faricimab - DME - nAMD - retinal vein occlusion★ MRA (RG1569) / Actemra (JPN) - COVID-19 pneumonia ACE910 (RG6013) / Hemlibra (JPN) - Acquired hemophilia A SKY59 (RG6107) / crovalimab - PNH	

In principle, completion of first dose is regarded as the start of clinical studies in each phase.
★: Projects with advances in stages since February 4, 2021

Letters in orange: in-house projects
Letters in blue: in-licensed (Roche)

28

The second page shows development projects in other areas.

As you know, a Phase I study for casirivimab and imdevimab has commenced in Japan for COVID-19.

In addition, we have started Phase III trials of faricimab for retinal vein occlusion.

Overview of Development Pipeline

Key News Flows in Q1

As of April 22, 2021

Approved	Actemra	Adult patients with SSc-ILD	March, 2021 (US)
	Polivy	Relapsed or refractory diffuse large B-cell lymphoma	March, 2021
	FoundationOne Liquid CDx[1]	Blood-based comprehensive genomic profiling test for solid tumors	March, 2021
	FoundationOne CDx[2]	Pemigatinib: biliary tract cancer (*FGFR2* fusion genes)	February, 2021
New to pipeline	Tecentriq + Avastin	Hepatocellular carcinoma (intermediate stage: combination with TACE)	P3 study (TALENTACE)
	faricimab	Retinal vein occlusion (CRVO / BRVO)	P3 study
	casirivimab/imdevimab[3]	COVID-19	P1 study
Development Discontinued	Tecentriq	Early breast cancer (HER2+, neoadjuvant)	P3 study (IMpassion050)
Late-stage Readout	Actemra	COVID-19 pneumonia: primary endpoint not met	P3 study (REMDACTA)
	Tecentriq	Non small cell lung cancer (adjuvant): primary endpoint met	P3 study (IMpower010)
	casirivimab/imdevimab[3]	COVID-19: primary endpoint met	P3 study (2067, 2069)
Medical Conference	risdiplam	P2/3 SUNFISH study (2-year data)	March, 2021(MDA)
		P2/3 FIREFISH study (2-year data)	April, 2021(AAN)
	faricimab	Results of P3 studies (YOSEMITE, RINE / TENAYA, LUCERNE)	February, 2021(AED)
Others	AT-527	New oral treatment against COVID-19 in-licensed from Roche	February, 2021

Letters in orange: in-house projects
Letters in blue : in-licensed (Roche)

1: FoundationOne Liquid CDx Cancer Genomic Profile
2: FoundationOne CDx Cancer Genomic Profile
3: antibody cocktail

SSc-ILD: Systemic Sclerosis-associated Interstitial Lung Disease
TACE: Transarterial chemoembolization
CRVO: Central Retinal Vein Occlusion
BRVO: Branch Retinal Vein Occlusion

MDA: Muscular Dystrophy Association
AAN: American Academy of Neurology
AED: Angiogenesis, Exudation, and Degeneration

29

Next is page 29. The following is a list of major topics for the first quarter.

First of all, as announced in the press release, Actemra was approved in the United States for the treatment of systemic sclerosis-associated interstitial lung disease. It is the first biologic approved by the FDA for the treatment of this disease.

Anti-CD79b antibody-drug conjugate, Polivy, was approved for lymphoma, as mentioned earlier. We are also planning to acquire data for first line treatment this year.

FoundationOne Liquid CDx is as mentioned earlier.

Moving on to the pipeline entry, Tecentriq and Avastin were approved in September last year for the treatment of advanced unresectable hepatocellular carcinoma. We have just started a Phase III study in combination with hepatic artery chemoembolization for the earlier intermediate stage.

As for faricimab, we are participating in 2 global phase 3 trials, one for central retinal vein occlusion and the other for branch retinal vein occlusion. Retinal vein occlusion is a disease in which a vein becomes blocked by a blood clot, resulting in macular edema and vision loss.

Moving on to the discontinuation of development, the development of Tecentriq preoperative adjuvant for HER2-positive breast cancer has been discontinued due to the recommendation of the Independent Data Monitoring Committee.

As you know, combination Actemra and Remdesivir failed to meet its primary endpoint of shortening the time to hospital discharge and other endpoints in patients with severe COVID-19 pneumonia.

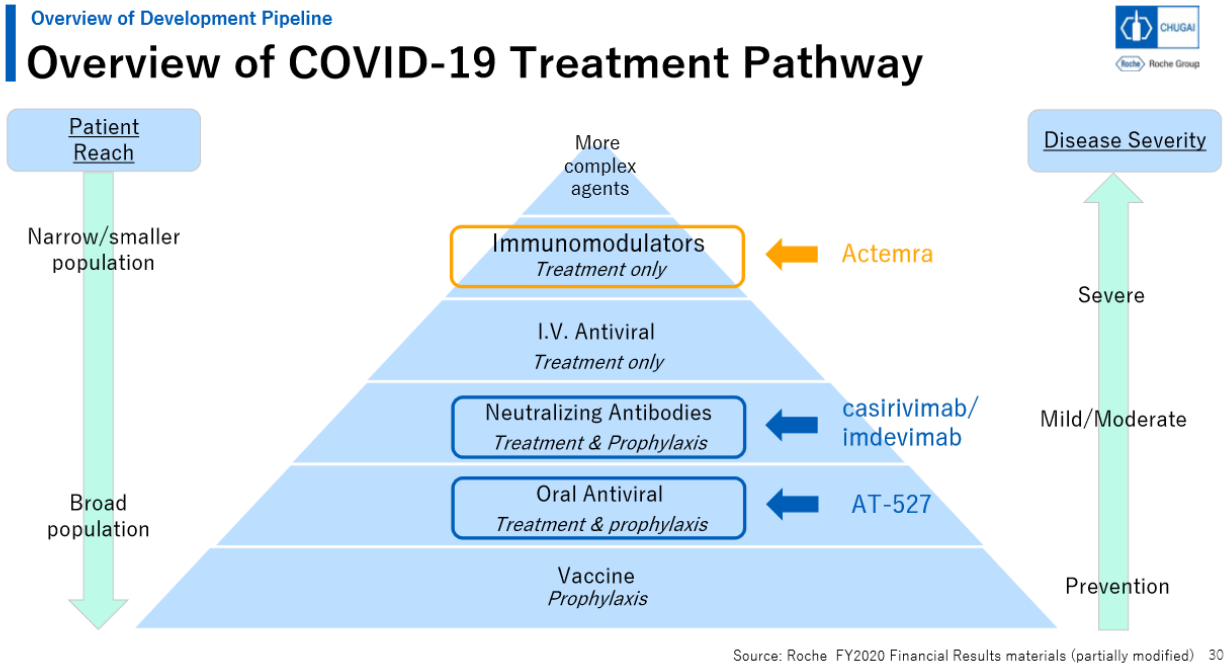
In the interim analysis of Tecentriq, a postoperative adjuvant for non-small cell lung cancer, the primary endpoint of disease-free survival was extended in stage II to IIIA. Based on the results, we will submit an application this year, one year earlier than planned.

As for casirivimab/imdevimab, as already mentioned, both the 2067 study in outpatients with COVID-19, and the 2069 study in household close contacts conducted by Regeneron, met their primary endpoints.

As for conference presentations, data was presented for risdiplam that showed continued improvement and maintenance of motor function even after 2 years of administration in 2 pivotal trials in spinal muscular atrophy.

In addition, positive results from 4 pivotal trials of faricimab in diabetic macular edema and age-related macular degeneration have been published.

As you know, AT-527 is an RNA polymerase inhibitor produced by Atea Corporation in the US, and we introduced it to Japan under a sublicense from Roche. In the future, we will develop it as an oral treatment for COVID-19.



Please see page 30. The position of various drugs in the treatment of COVID-19 is shown here. The higher up the pyramid, the higher the severity of the disease.

Our development projects include Actemra for immunomodulation in severe disease, casirivimab and imdevimab for neutralizing antibodies in mild/moderate disease, and AT-527 as an oral antiviral agent.

In the following slides, I will add some more explanation about the status of Actemra and the neutralizing antibody combination.

Overview of Development Pipeline

Summary of Clinical Trials of Actemra against COVID-19

Clinical trials sponsored by Roche / Chugai

Study	Sponsor / Region	Population	Dosing regimen	Results
J-COVACTA (Phase 3)	Chugai / Japan	Hospitalized severe patients >10	Single 8mg/kg IV dose; up to one additional dose may be given	—
COVACTA (Phase 3)	Roche / Global	Hospitalized severe patients 450	Same as above	Primary endpoint not met
EMPACTA (Phase 3)	Roche / Global	Hospitalized patients 379	Same as above	Primary endpoint met
REMDACTA (Phase 3)	Roche* / Global * collaboration with Gilead Sciences, Inc.	Hospitalized severe patients 650	Same as above** ** combination with remdesivir	Primary endpoint not met

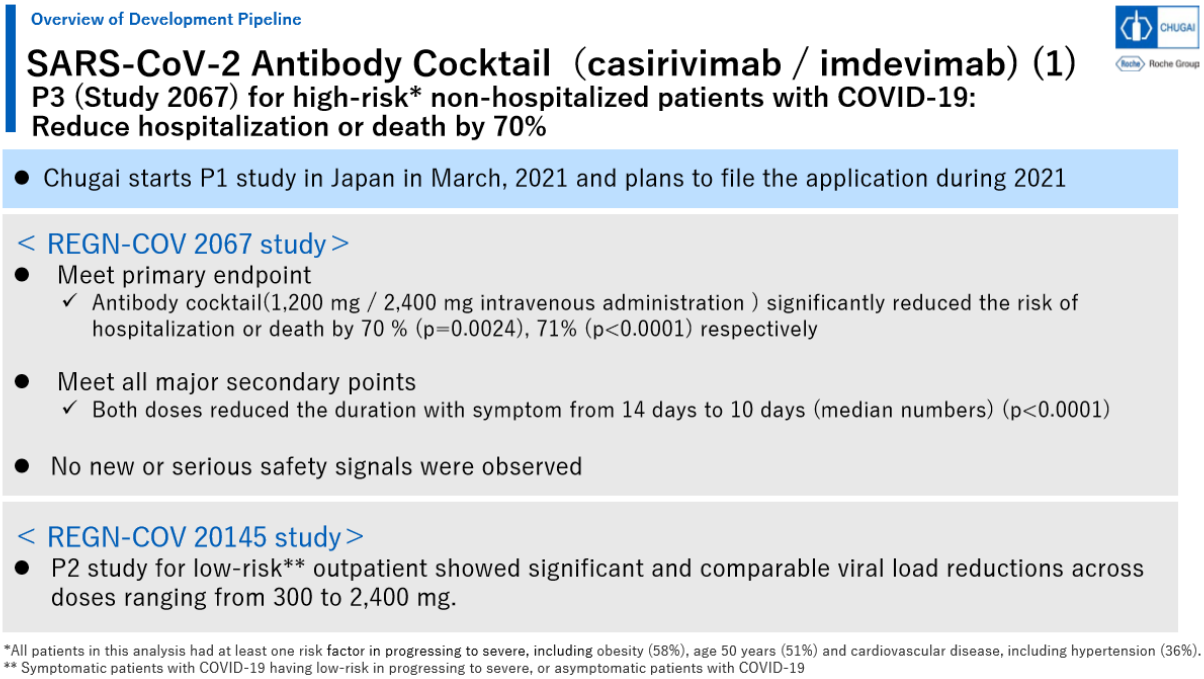
＜Next Action＞
Analyze accumulated results so far in details and evaluate overall risk / benefit profile of Actemra

31

Page 31. In this slide, we have listed an overview of the tests conducted by Chugai and Roche on Actemra.

Unfortunately, the REMDACTA study that we have presented here did not show any significant improvement in clinical symptoms. However, based on the data obtained to date, including the EMPACTA study that met its primary endpoint, we believe that the possibility that Actemra can contribute to the treatment of COVID-19 has not been ruled out.

We will work with Roche to further analyze the data from investigator initiated trials, including the RECOVERY study conducted overseas, and will consult with the authorities in each country to evaluate the overall risk-benefit profile of Actemra and determine whether or not to file an application.



Please go to page 32. Here are the results of studies conducted overseas on Regeneron's neutralizing antibody combination.

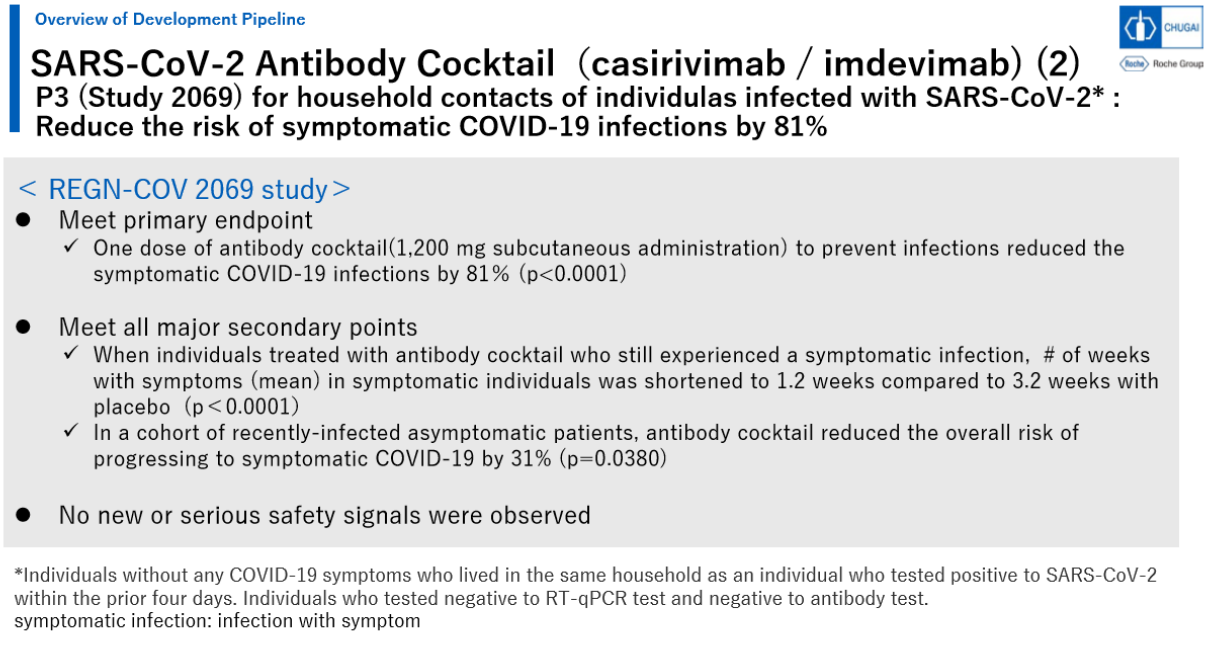
First of all, as I explained earlier, the Phase I study is already underway in Japan, and we are aiming to submit an application this year, together with overseas data.

First, the REGN-CoV-2 2067 trial. This is a Phase III study of outpatients with risk factors for severe disease, such as obesity, advanced age, and cardiovascular disease, and the primary endpoint was achieved with a 70% reduction in the risk of hospitalization or death for each of the 2 doses administered.

In addition, all major secondary endpoints were met, including the median duration of symptoms for both doses, which decreased from 14 days to 10 days.

No new safety concerns have been identified.

Below that, the 20145 trial. This is a Phase II study in patients with no risk factors for severe disease, and the dosage ranged from 300 mg to 2,400 mg, which is a low dose.

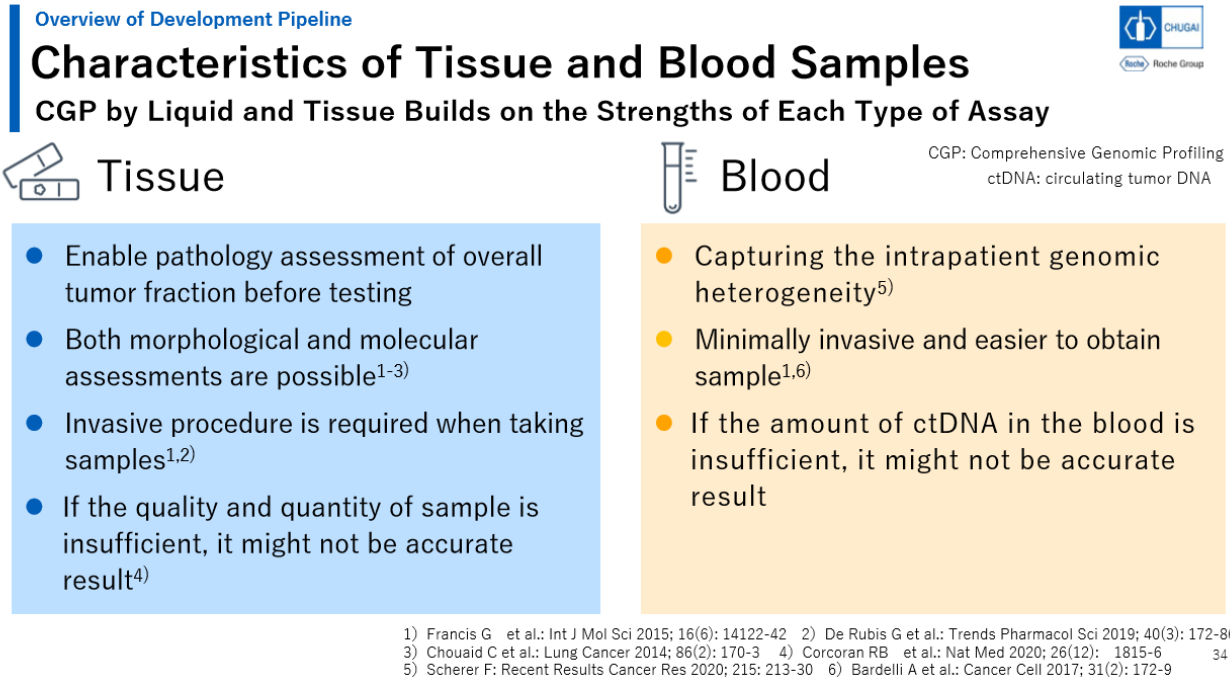


Please go to the next page, page 33. This is the 2069 trial.

This is a Phase III study for the prevention of the onset of infection in household contacts, and the route of administration is subcutaneous. The primary endpoint was achieved with a significant reduction of 81% in the risk of developing symptomatic infection.

All of the primary secondary endpoints were also met, especially in cases of symptomatic infection, where the mean duration of symptoms was reduced from 3.2 weeks to 1.2 weeks. For asymptomatic patients, i.e., those who have been infected but have not developed symptoms, the risk of becoming symptomatic is reduced by 31%.

No new safety concerns have been identified.



Let us proceed to page 34. This is an explanation of genomic profiling using the FoundationOne Liquid CDx and blood samples—in particular, the difference from the FoundationOne CDx test using tissue samples.

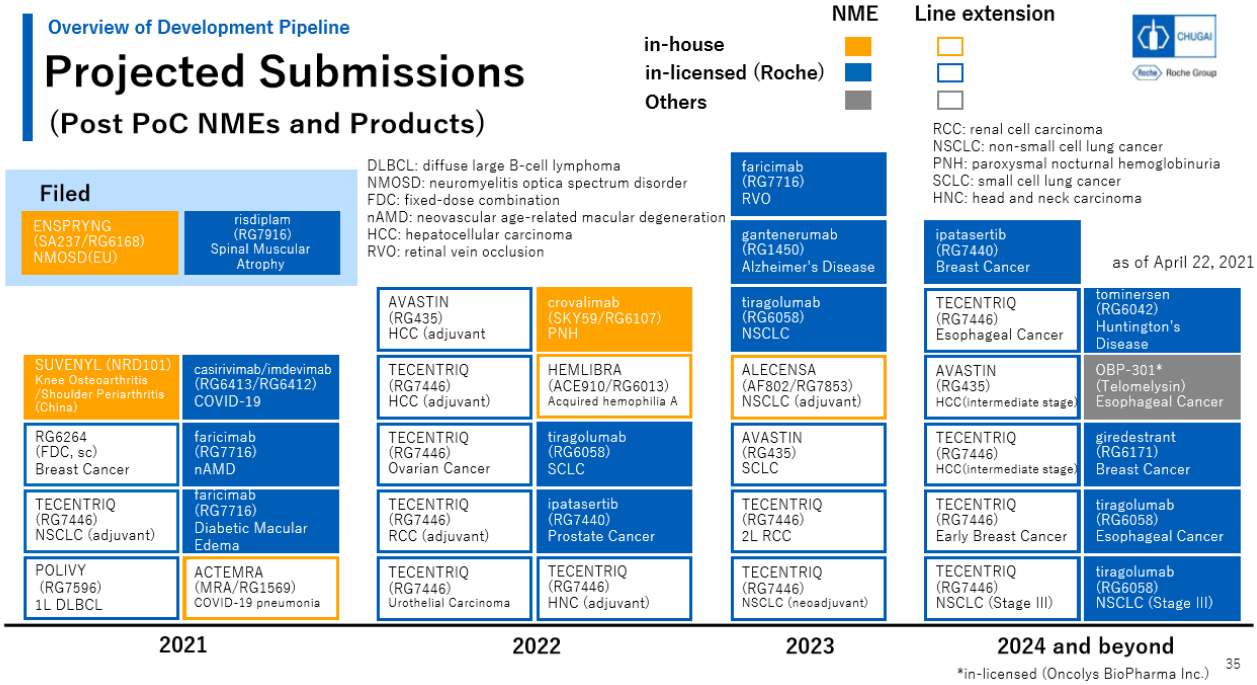
When using tissue specimens, it is natural to be able to actually see the tumor cells, and both morphological and molecular evaluations can be performed in parallel.

On the other hand, the collection of specimens requires invasive procedures, and in some cases, test results cannot be obtained because specimens of the quality and quantity required for genomic profiling cannot be collected.

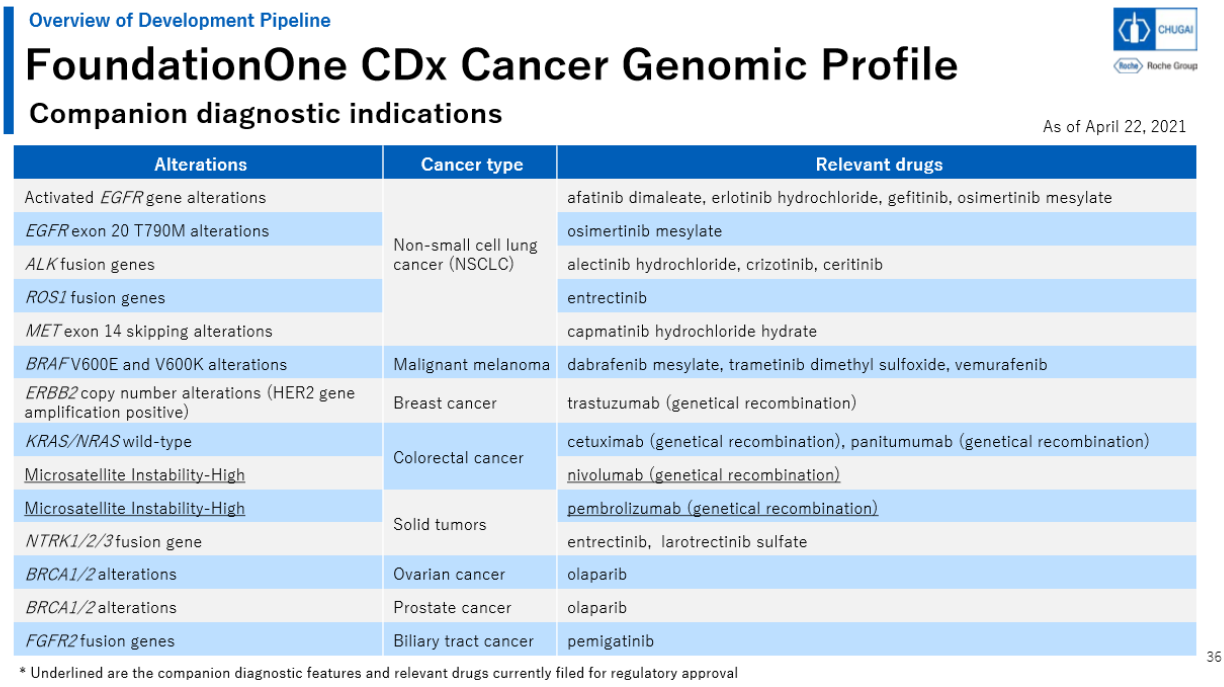
On the other hand, when blood specimens are used, it means that specimen collection is easy, and tests can be performed when necessary. Furthermore, it is thought to be possible to capture the heterogeneity of cancer genomic information more broadly throughout the body.

On the other hand, if the amount of circulating tumor DNA is insufficient, the test results will naturally be inaccurate.

We believe that both inspection methods will be used in a complementary manner.



The next slide shows the schedule of future applications. Previously, we have presented a column for “2023 and beyond,” but we are now using “2024 and beyond.”



Alterations	Cancer type	Relevant drugs
Activated *EGFR* gene alterations	Non-small cell lung cancer (NSCLC)	afatinib dimaleate, erlotinib hydrochloride, gefitinib, osimertinib mesylate
EGFR exon 20 T790M alterations		osimertinib mesylate
ALK fusion genes		alectinib hydrochloride, crizotinib, ceritinib
ROS1 fusion genes		entrectinib
MET exon 14 skipping alterations		capmatinib hydrochloride hydrate
BRAF V600E and V600K alterations	Malignant melanoma	dabrafenib mesylate, trametinib dimethyl sulfoxide, vemurafenib
ERBB2 copy number alterations (HER2 gene amplification positive)	Breast cancer	trastuzumab (genetical recombination)
KRAS/NRAS wild-type	Colorectal cancer	cetuximab (genetical recombination), panitumumab (genetical recombination)
Microsatellite Instability-High		nivolumab (genetical recombination)
Microsatellite Instability-High	Solid tumors	pembrolizumab (genetical recombination)
NTRK1/2/3 fusion gene		entrectinib, larotrectinib sulfate
BRCA1/2 alterations	Ovarian cancer	olaparib
BRCA1/2 alterations	Prostate cancer	olaparib
FGFR2 fusion genes	Biliary tract cancer	pemigatinib

* Underlined are the companion diagnostic features and relevant drugs currently filed for regulatory approval

Page 36 shows the companion diagnostic functionality of FoundationOne CDx.

With the approval of pemigatinib for biliary tract cancer and FGFR2, companion diagnostics are now available for 8 cancer types, 14 genes, and 18 drugs.

Overview of Development Pipeline

FoundationOne Liquid CDx Cancer Genomic Profile

Companion diagnostic indications

As of April 22, 2021

Alterations	Cancer type	Relevant drugs
Activated *EGFR* gene alterations	Non-small cell lung cancer (NSCLC)	afatinib dimaleate, erlotinib hydrochloride, gefitinib, osimertinib mesylate
EGFR exon 20 T790M alterations		osimertinib mesylate
ALK fusion genes		alectinib hydrochloride, crizotinib, ceritinib
ROS1 fusion genes		entrectinib
NTRK1/2/3 fusion gene	Solid tumors	entrectinib

37

On the last page, we have added a list of companion diagnostic features that have been approved for FoundationOne Liquid CDx.

At the time of its release, it is possible to make companion diagnoses for 2 cancer types, 6 genetic mutations, and 8 drugs.

This concludes my presentation.

Sasai: Thank you.

Question & Answer

Sasai: We will now take your questions.

When it is your turn to ask a question, I will call your name. Please let us know your company name and your name before asking your questions.

Please note that the audio of your questions, along with the presentation, will be posted on our website at a later date. Also present today is Mr. Hidaka, Vice President, Head of Marketing and Sales Division.

We will now take your questions.

First of all, Mr. Wakao of JPMorgan Securities Japan.

Wakao: This is Wakao from JPMorgan Securities Japan. Thank you.

My first question is about the slide on page 11. You explained that there is a possibility that exports of Actemra to Roche will go up in the second half of the year, but Roche seems to have some inventory right now, so I was wondering if you could give me some hints on how much of an upward swing there will be, taking into account Roche's inventory.

Looking at Roche's overseas sales of Actemra, excluding Japan for the January to March period, for example, the figure is CHF695 million.

If overseas sales of Actemra were to reach the same level as the previous fiscal year, or in other words, about CHF2.5 billion, the full-year results for the previous fiscal year here would be JPY132 billion in exports to Roche. However, if overseas sales were to reach the same level as the previous fiscal year, how much would it be after taking inventory into account?

Itagaki: Thank you very much, Mr. Wakao.

First of all, what will be the scale and duration of the COVID-19 epidemic in Roche's territory, and what will be the future status of development and use of vaccines and therapeutic agents?

As you pointed out, there were many uncertainties about what the inventory situation would be at Roche and in the market, and we would manufacture the products according to Roche's orders and export them. There were a lot of unknowns at the start of the year. Therefore, we have not reflected COVID-19 demand into the forecast. That was the basis for our forecast.

However, the results from Roche for the first quarter were up 26% compared to last year. This excludes both the impact of foreign exchange rates and sales of Chugai, which will be tied to Chugai’s exports, and is 26% higher than Roche's first quarter last year.

To begin with, Roche's first quarter performance last year itself grew by 35% compared to the previous year. As I said, if things continue as they are, in the second quarter and beyond, perhaps in the second half of the year, we will see a continuation of that trend, and we will see additional exports. That is what I think is going to happen.

We can at least achieve the full-year target of JPY83 billion. As for the guidance, there are still many uncertainties, so I cannot give you a specific number. I honestly do not know, but I am confident that we can achieve the forecast.

Wakao: If the sales level were to be the same as the previous fiscal year, should we not think that the export sales level would be the same JPY130 billion level? Does this mean that inventory export should be taken into account to some extent?

Itagaki: Yes, you are right. The inventory part will be affected to some extent this year, so I think it is better to take that into consideration.

Wakao: Understood.

My second question relates to the production of Actemra. I believe Roche recently outsourced the production of Actemra API to Novartis, and from what I read here, your company's production capacity will also be insufficient, so can I assume that Roche is outsourcing the production to Novartis? Or is this not related to your Company at all?

Also, where is the production of Actemra within the Roche Group at this point in time, and what is the allocation of production? Also, it would be very helpful if you could tell us the status of your capacity.

Itagaki: First of all, for Actemra, we make the API in Japan, formulate it, and export it to Roche. At the same time, Genentech's plant on the West Coast makes the API, and we purchase it, formulate it, and sell it.

With regard to COVID-19, from the first quarter to the second quarter of last year, we transferred technology to another facility in the U.S., in Hillsboro, so that it can be formulated there, as well. We are taking measures to prepare for any potential disruptions.

However, there was a very large demand during the last year, and our manufacturing capacity was sufficient to handle it. This year, too, there is no such concern in that sense, but Roche has decided to outsource the production to Novartis. I think that decision was made.

However, in terms of the overall scheme, we purchase APIs from the Roche Group as a whole, including those that have been manufactured externally, and formulate them. There will be no big-picture impact on our ability to generate export sales or receive royalties.

Wakao: Understood. Thank you.

Lastly, for NXT007, I think it has been about 2 years since the Phase I/II study started in 2019.

Also, I think you mentioned that the half-life of this NXT007 is longer than that of Hemlibra, and I think the current maximum duration for Hemlibra is once every 4 weeks. Have you obtained any data that would allow us to expect a longer administration period than this? This is my last question. Thank you.

Tetsuya Yamaguchi: My name is Yamaguchi. Thank you for your question.

We are not able to discuss the next update at this time. As you mentioned, we are developing both drugs in relation to Hemlibra.

Wakao: Thank you very much. That is all.

Sasai: Next, Mr. Muraoka from Morgan Stanley MUFG Securities, please go ahead.

Muraoka: Hello. Morgan Stanley, Muraoka. Thank you.

I would like to reconfirm what you said about the Novartis outsourcing from Roche. This was not related to Chugai but decided by Roche.

When Roche starts to buy APIs from Novartis, does that mean that exports and royalties will be completed between Roche and Novartis, without passing through the Chugai P&L? That was not clear to me.

Also, I would like to reconfirm what was said earlier. Basically, your company's view is that, even after seeing the 26% increase in Roche's sales in the first quarter, the supply can be maintained under the current scheme, is that correct?

Itagaki: Roche and Genentech outsourced the production of APIs to Novartis under the responsibility of the Roche Group. Genentech will purchase the APIs that we have ordered and then deliver them to Chugai, so in terms of transactions between Chugai and the Roche Group, there will be no change.

In terms of capacity, we have a good track record from last year, and we are completely relieved that we now have more options to build in various places.

Muraoka: I am sorry to keep asking. For example, if Genentech orders through Novartis, the amount of outsourcing to Genentech will increase further, but as a result, it will still be reflected in your company's export income and export profit. Is that correct?

Itagaki: Yes.

Muraoka: I understand. Thank you.

Also, with regard to the business results, you have repeated several times that both revenues and profits decreased in the first quarter, but that revenues and profits will increase from the second quarter onward.

I do not doubt what you are saying about the second quarter, but does that mean that you are expecting continued increases in revenues and profits in the third and fourth quarters?

Itagaki: Regarding Q2 and beyond, we are not saying that there will be YoY increases in all quarters. Since there are various timings for exports, I think it would be better to understand that we are anticipating increased revenues and profits in the remaining 9 months of the fiscal year.

Muraoka: I understand. Thank you.

Lastly, going back to the Actemra case, the risk from biosimilars has been increasing following Biogen. I think there was a discussion on the Roche call yesterday about Fresenius in 2022 or 2023.

What are your thoughts on the possibility of export negotiations, taking into account the risk of such biosimilars from the second half of this fiscal year? Or do you think that that will become a factor in negotiations with Roche a little later?

Itagaki: Naturally, we are aware that there are 4 companies that have already developed biosimilars of Actemra and are working to bring them to market. As for the timing, we cannot say when because of our patents.

As for exports, although we are negotiating with Roche, we are still in the position of receiving orders, so that is still a long way off. As for the price, we do not have any information to disclose at this time, especially in relation to biosimilars. Please wait a little longer.

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

Sasai: Next, Mr. Sakai from Credit Suisse Securities, please go ahead.

Sakai: My name is Sakai. Let me ask you 2 questions briefly.

Regarding the situation with Hemlibra, Roche has already released figures, but I heard that it has grown by 33%, and its market share is steadily increasing.

I believe that your company's exports of Hemlibra for this fiscal year have not deviated greatly from your assumptions, considering that there are moving parts in terms of royalty one and royalty 2, and the export value. One point I would like to make sure is that I was under the impression that these first quarter Roche sales were seeing an increased pace.

The other thing is that there is no export of Enspryng at this time, but the initial shipment of Enspryng was only for the first indication, which I think includes one for the European approval. Is it correct to say that it has been released?

Even though it may not be as big as Hemlibra, I wonder if we will see another adjustment in the cost of exports or something like that in the future, as we saw with Hemlibra. Now that the drug has been approved in Europe, I think there may be a lot of potential for expanding the indications for the drug. I would be grateful if you could give us some indication of the possibility at this point. These are my 2 questions.

Itagaki: First, about the exports of Hemlibra.

The growth rate for the first quarter announced by Roche yesterday was 33%, as Mr. Sakai mentioned. In terms of regions, the US, which happens to be the same, has a 33% share. Roche discloses its US market share and patient market share for each quarter, and up until now, it has been increasing by around 2% or 3% points per quarter, but from last year's Q4 to this year’s Q1, it has increased by 5% points. So, I think the market penetration has increased significantly.

However, on the other hand, there is still a minor COVID-19 impact for Roche, so I think there is still a lot of room for growth. However, we have included this in our export forecasts, so you can assume that this is within our expectations.

As for the export of Enspryng, this first quarter is zero. Last year, we received approval from the US, and although we have yet to receive approval from Europe, we have been exporting our initial shipments, especially in last year's Q4.

It is within our expectation that this first quarter will be zero, not as a reaction to the previous quarter, but because of the timing of export shipments. I will not comment on expansion of indications.

Tetsuya Yamaguchi: This is Yamaguchi.

As for the expansion of indications, since this is an anti-IL-6 receptor antibody, we will aggressively conduct development activities for additional indications for autoimmune diseases in which IL-6 is involved, with the aim of making it a major product. We would like to disclose more information as development progresses.

Sakai: I understand. Thank you very much.

Sasai: Thank you very much. Next, Mr. Yamaguchi from Citigroup Global Markets Japan, please go ahead.

Hidemaru Yamaguchi: My name is Yamaguchi. Thank you. I would like to confirm 2 points about Hemlibra.

I think you mentioned that the royalty rate changes progressively during the term, but I was wondering if you had mentioned this before. In other words, the first question is whether there will be a structure in which royalties will increase with each passing term, or rather each quarter, or whether such fluctuations will occur within a year.

One more thing: the domestic volume of Hemlibra has grown considerably, even after the NHI price revision, but you mentioned that it is still a little weak compared to the company's forecast. These are my 2 questions about Hemlibra.

Itagaki: I would like to answer the first point, and Mr. Hidaka will take the second point.

This is the first time today that I have disclosed that the Hemlibra royalty rate from Roche is progressive. That has not been disclosed before. However, given that the fluctuation might be a source of confusion for people looking at the figures, I thought it was best to make that clear. I will not say anything about the structure of any others.

Second point, Mr. Hidaka.

Hidaka: My name is Hidaka. Thank you for your question.

As for the impact of the COVID-19 this year, we originally had a plan that included the possibility that the coronavirus pandemic would come to an end. However, due to the current COVID-19 situation, the recovery has not been as complete as expected.

As larger hospitals, where new cases of the Hemlibra had not been admitted to date, are now admitting these patients, I think we are seeing a bright sign.

Hidemaru Yamaguchi: Understood.

Secondly, in the area of Actemra, the UK's physician-led program is positive, but other programs continue to be negative in terms of top line, so I understand very well what you mean about risk-benefit.

You may suggest that I direct this question to Roche, but one thing I have been thinking about is whether it is time to file for the program now that it is pretty much ready to be filed for and scheduled for this year.

Also, is there always a link between global and domestic actions? In other words, if Roche files overseas, you will file domestically, and if Roche does not file overseas, you will not file domestically.

Tetsuya Yamaguchi: Thank you very much.

It is true that we cannot deny the fact that the data is not very consistent.

On the other hand, in the Roche-led trials, from the early stage of the COVID epidemic up to now, as in the case of REMDACTA, treatment methods for COVID have changed considerably, and concomitant medications have also changed considerably.

On the other hand, as you know, we believe that RECOVERY or REMAP-CAP has good potential for actual clinical use, and we are currently conducting detailed analysis of individual patients in collaboration with Roche.

We will mainly consult with the authorities in Japan, the US and EU in detail in the future, so we cannot deny the possibility that the actual acceptance or unacceptance of the application may differ depending on the opinion of the authorities.

Under such circumstances, we believe that there is no need or stage to change our original plan to file this year, and we would like to continue on that basis.

Hidemaru Yamaguchi: Understood. Thank you. That is all.

Sasai: Next, Mr. Ueda from Goldman Sachs, please go ahead.

Ueda: I am Ueda from Goldman Sachs. First of all, I would like to ask you about the export of Alecensa.

Earlier, you mentioned the price revision and the timing of exports, but while Roche's exports are growing, can we assume that the reason for the negative YoY growth is largely due to the timing of the volume? Can you tell us whether the price level has changed to such an extent that it will completely change from the trend of Roche's sales in the future?

Itagaki: Thank you, Mr. Ueda. This is Itagaki.

Yesterday, Roche announced that Alecensa sales are up by 14%, which of course is due to the first line in the US. In addition to the very high share of new patients in the EU, the growth rate of the international market is 44%, and especially in China, the sales have grown significantly since it was placed on NRDL, the reimbursement list. On the other hand, prices have been falling.

Our export prices to Roche have been revised since January, based on the weighted average of Roche's global retail prices last year, so the unit price of exports has dropped, especially with the expansion of the international market. As you know, in terms of volume, exports from Chugai have increased by more than 30% compared to the previous year, but on the other hand, unit prices have fallen, and this has been offset.

Ueda: Thank you very much.

Secondly, regarding the domestic trend of Hemlibra, as you mentioned earlier, while Roche's business is growing very fast in Europe and the US, in Japan, even taking into account the impact of the repricing, it seems that there is not much growth compared to the second half of last year.

As you mentioned earlier, can you tell us if this is due to the COVID-19 situation or if there are any different trends in Japan?

Hidaka: This is Hidaka.

There are differences between Japan and other countries. Japan has been relatively sensitive to changes due to the coronavirus pandemic. This is because of educational hospitalization or hospital appointments taking place for several weeks in a row.

In particular, large hospitals are converting beds to coronavirus care beds during periods when the coronavirus infections are particularly prevalent, so I think they are relatively susceptible.

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

Sasai: We still have a few more questions, but this will be the last one.

Mr. Kohtani of Nomura Securities, please go ahead.

Kohtani: I am Kohtani from Nomura Securities.

The first question is about Actemra's patent. When I asked about Actemra on the Roche call, the answer was, “ask Chugai, we don’t own it,” and your answer this time was that you could not say much.

Your company has a patent for intravenous injection and subcutaneous injection, and I believe you have the patent for subcutaneous injection until 2030 and beyond. Until that part expires, it will probably be difficult for others to enter the market because subcutaneous injection is quite common in the US and Europe.

Tetsuya Yamaguchi: This is Yamaguchi.

I am sorry, but we are unable to discuss patent information. As the development of biosimilars and other products moves forward, we want to protect our intellectual property to the maximum extent possible. Under these circumstances, we will take appropriate measures in the future.

That is all.

Kohtani: Secondly, on page 31, there is a clinical trial of Actemra for COVID-19.

Since there were only 4 items in the presentation, it seems as if REMDACTA and COVACTA will be very important. Is there any mention of a decrease in the use of Actemra after March 12? In short, after REMDACTA was released. I wanted to ask you about that first.

Tetsuya Yamaguchi: I will take this question.

Currently, we are not aware of any decline in the use of Actemra following release of the REMDACTA study. It is our understanding that use continues as before in clinical settings.

Kohtani: In that case, I think what medical professionals are probably using the RECOVERY trial as a reference. This trial had 4,100 patients. There are about 6 other randomized trials that have been done here, but they are all very small. The number of deaths is probably less than 100, and while there are such trials, this one has a very large number of patients.

Furthermore, the paper states that when all 8 trials are considered together, allocation tocilizumab associated with a 13% proportional reduction in 28-day mortality rate 0.87, P=0.005. From that, I think that expectations of Actemra have increased considerably after the RECOVERY trial.

Tetsuya Yamaguchi: First of all, based on the RECOVERY study, and also the REMAP-CAP, the recommendations of the National Health Service in the UK and in Europe regarding Actemra are currently being maintained. We do not recognize changes on these situations due to REMDACTA results. As you pointed out, Actemra is still being used on the front line.

With the infection situation, the first quarter was very significant, so we do not have an answer as to whether or not the RECOVERY results have boosted results.

Kohtani: I understand. Thank you very much.

Sasai: Thank you very much.

We still have a lot of questions, but the time has come, so this concludes the first quarter conference call.

If you still have questions, please contact the Media Relations Group or the Investor Relations Group of the Corporate Communications Department, as usual. Contact information can be found in the presentation materials.

Once again, thank you very much for taking time out of your busy schedule to join us today. Thank you for your time.

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