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**CHUGAI PHARMACEUTICAL CO., LTD.**

 A member of the Roche group

## **CHUGAI PHARMACEUTICAL CO., LTD.**

1Q Results (Jan - Mar 2022) Conference Call

April 25, 2022

## Event Summary

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[Company Name]	CHUGAI PHARMACEUTICAL CO., LTD.	
[Company ID]	4519-QCODE	
[Event Language]	JPN	
[Event Type]	Earnings Announcement	
[Event Name]	1Q Results (Jan - Mar 2022) Conference Call	
[Fiscal Period]	FY2022 Q1	
[Date]	April 25, 2022	
[Number of Pages]	35	
[Time]	18:00 – 19:06 (Total: 66 minutes, Presentation: 40 minutes, Q&A: 26 minutes)	
[Venue]	Dial-in	
[Venue Size]		
[Participants]		
[Number of Speakers]	5	
	Dr. Osamu Okuda	President, CEO
	Toshiaki Itagaki	Director, Executive Vice President, CFO
	Tetsuya Yamaguchi	Executive Vice President, Head of Project & Lifecycle Management Unit
	Shinji Hidaka	Executive Vice President, Head of Marketing & Sales Div.
	Toshiya Sasai	Head of Corporate Communications Dept.
[Analyst Names]*	Fumiyoshi Sakai	Credit Suisse Securities (Japan) Limited
	Seiji Wakao	JPMorgan Securities Japan Co., Ltd.
	Hidemaru Yamaguchi	Citigroup Global Markets Japan Inc.
	Shinichiro Muraoka	Morgan Stanley MUFG Securities Co., Ltd.

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

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# Presentation

**Sasai:** Good evening. Thank you very much for joining us for the CHUGAI PHARMACEUTICAL CO., LTD., FY2022 Q1 conference call. I am Sasai of Corporate Communications, and I will be the moderator today.

During the presentation, your connections will be set to listening only. After the presentation, there will be a 30-minute Q&A period during which any questions will be answered.

First, we will hear from Dr. Okuda, President and CEO; Mr. Itagaki, CFO; and Mr. Yamaguchi, Head of Project & Lifecycle Management. Please have your presentation and disclosure materials on hand.

We will now get started with the presentations. Dr. Okuda will provide an overview of Q1 performance.

## FY2022 Q1 Overview

### Financial Overview



- Significant YoY increase in revenues and profits due to an increase in new products such as RON and exports to Roche etc.
- No change in the earnings forecast after April, and full-year revenues and profits are expected to increase in line with the initial forecast

Core (billions of JPY)	2021	2022	Growth		2022	Progress (%)
	Jan - Mar actual	Jan - Mar actual			Jan - Dec forecast	
Revenues	168.8	268.6	+99.8	+59.1%	1150.0	23.4%
Domestic sales	94.9	161.7	+66.8	+70.4%	646.3	25.0%
Overseas sales	35.4	81.0	+45.6	+128.8%	385.2	21.0%
ROOI	38.6	25.9	-12.7	-32.9%	118.5	21.9%
Operating profit	65.4	98.9	+33.5	+51.2%	440.0	22.5%
Operating margin	38.7%	36.8%	-2.6%pts		38.3%	-
Net income	48.4	70.6	+22.2	+45.9%	312.5	22.6%
EPS (yen)*	29.42	42.91	+13.49	+45.9%	190.00	22.6%

ROOI : Royalties and other operating income  
RON: Ronapreve  
HEM: Hemlibra

- The effect of changing situations in Russia/Ukraine had no major negative impact on performance and limited impact on development activities
- The RON supply to the government based on the 2021 contract contributed significantly. Its 2022 contract has been signed in line with the initial forecast
- Overseas sales increased significantly mainly due to HEM exports to Roche as expected
- Significant decline in ROOI associated with the initial shipment of HEM as expected
- Litigation settlement with Alexion recognized 91.9 billion yen as non-core revenue

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**Okuda:** Hello. I will now give a summary of Q1. Please see page five of the slides.

Revenues increased approximately 60% YoY. Operating profit and net income each grew approximately 50%. Increased revenues and profits marked a strong start to the year. For the full year, we expect an increase in both revenues and profits, with no change in our assumptions from the beginning of the period. The situation in Ukraine has no significant negative impact on our business performance.

Regarding Ronapreve, the remainder of last year's contracted amount has all been delivered in the January to March period of this year. In addition, a new contract for FY2022 has been signed with the government. Here, there are no major changes from the assumptions made at the beginning of the period regarding the volume of deliveries through the end of December of this fiscal year.

Regarding the settlement with Alexion, it is recognized as non-core revenue as it is a non-recurring item.

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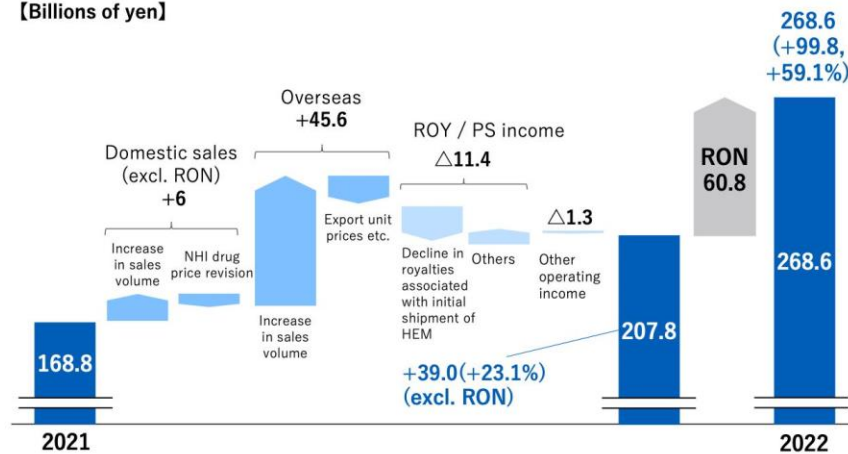
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# Topline Overview

- Domestic sales (excl. RON) increased due to an increase in new products and sales volume\*
- Overseas sales increased significantly as volume growth exceeded the decline in export unit prices
- A decrease in royalty income was offset by an increase in overseas sales as expected

[Billions of yen]



- Domestic sales (excl. RON) increased as sales growth in new products Polivy, Evrysdi, and Enspryng exceeded the impact of generics and NHI drug price revision as expected
- Overseas sales increased significantly due to the full-scale HEM exports to Roche at regular shipment unit price as well as ACT exports as expected
- Regular royalties of HEM and ACT increased due to growth in overseas local sales despite a decrease in royalty income from initial shipments of HEM as expected

\* Among them, the domestic patient share of HEM is as below.

'22Q1 27.9%, '21Q4 26.2%, '20Q4 20.7%, '19Q4 14.8%, '18Q4 2.1%

ACT: Actemra ROY: royalty PS: profit share

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Next, I will explain the details of the topline. See slide six.

Sales in the domestic market, excluding those of Ronapreve, increased due to the steady penetration of new products such as Polivy and Evrysdi. This absorbed the negative impact of the NHI drug price revision and other factors.

Overseas, export sales increased significantly due to the stepping up of Hemlibra export at regular shipment price, as well as the contribution of Actemra exports.

Royalty-related incomes declined on a YoY basis due to lower initial shipment royalties from Hemlibra.

Combined domestic, foreign, and royalty sales revenue increased 23%, or JPY39 billion. In addition, we also saw a contribution to overall sales by Ronapreve. This resulted in a significant increase in sales to start the year, as we had expected.

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## R&D Overview

- **A full-scale entry into the ophthalmology field is expected to contribute revenue growth for Chugai**
  - **Vabysmo:** Obtained approval for nAMD and DME. Achieved 16 week-interval administration for the first time as an intravitreal injection. Information provision activities conducted by in-house medical reps. GP3 studies for the additional indication of RVO are ongoing
  - **RG6321 (PDS):** Started domestic P1 / 2 study as a new development product in the ophthalmology field
  - **Roche's ophthalmology pipeline :** 9 NME\*<sup>1</sup>
- **Delivering new value with specialized partners in the skin diseases area**
  - **Mitchga®'s domestic approval:** Maruho obtained approval for pruritus associated with atopic dermatitis. Business scheme: Manufactured by Chugai and sold by Maruho
  - **Expected to improve QoL:** The first drug targeting IL-31, which is the cause of pruritus. Promptly reduced pruritus in domestic P3 study
  - **Overseas:** Galderma\*<sup>2</sup> is conducting GP3 studies for atopic dermatitis and prurigo nodularis, and a GP2/3 study for chronic kidney disease associated pruritus
- **Protecting the rights of unique drug discovery technologies that lead to competitive advantage**
  - **Recycling antibody technology:** Settlement agreement signed with Alexion for a patent infringement lawsuit

PDS: Port Delivery System with ranibizumab, nAMD: neovascular age-related macular degeneration, DME: diabetic macular edema, RVO: retinal vein occlusion

NME: new molecular entity

\*1 As of February 3, 2022 \*2 Galderma retains exclusive global license for the development and marketing excluding Japan and Taiwan  
Mitchga® is a registered trademark of Maruho Co., Ltd. in Japan.

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Next, I will discuss the key points in R&D. See slide seven.

In March, Vabysmo was approved for age-related macular degeneration and diabetic macular edema. This is our first full-scale entry into the ophthalmology field. We are covering information provision activities in major markets exclusively through in-house MRs.

There is the expanded indication for Vabysmo to include RVO, RG6321, and Roche has an extensive ophthalmology pipeline. Chugai will use these to focus on the ophthalmology area.

Next, I would like to talk about nemolizumab, a drug discovered in-house. Maruho, out-licensed in Japan, received approval for pruritus associated with atopic dermatitis. We will manufacture the products and Maruho will market them.

Overseas, Galderma is conducting late-stage clinical trials for multiple indications.

Finally, the settlement with Alexion mentioned at the beginning of this talk relates to our proprietary recycling antibody technology. We hold a number of patents that give us a competitive advantage in relation to antibodies and small- and mid-size molecules. We will continue to focus on protecting our key asset, intellectual property rights.

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## Progress Toward Relocation of the Research Laboratories

### ■ Chugai Life Science Park Yokohama

- **Features:** Aiming to dramatically improve research productivity by consolidating all drug discovery research functions and utilizing robotics / AI etc.
- **Construction work:** Progress as planned (scheduled to complete in October 2022 and start operation in April 2023)

### ■ Kamakura research lab. / Fuji Gotemba research lab.: Progress toward closure is as follows.

#### Overview of Chugai Life Science Park Yokohama

Core research lab. under construction in Totsuka-ku, Yokohama city, Kanagawa  
 • Building area: 35,210m<sup>2</sup>  
 • Total floor area: 119,960m<sup>2</sup>

Focusing on global warming countermeasures, regional disaster prevention, and biodiversity conservation, aiming for environmental performance certification

In addition to making environmental agreements with Yokohama city, we emphasize coexistence with the local community



	Contractor	Contract name	Site area	Contract period	Planned disposition date
Kamakura research lab. North side site	TAKASAGO INTERNATIONAL CORPORATION	Real estate sales contract	35,359m <sup>2</sup>	March 2022	Late 2025 (vacant site)
Kamakura research lab. South side site	Haseko Corporation	Real estate sales contract	53,945m <sup>2</sup>	March 2022	September 2023 (as-is)
Fuji Gotemba research lab.	TBD	TBD	142,285m <sup>2</sup>	TBD	TBD

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Next, I would like to talk about the relocation of our research facilities. See slide eight.

Construction of the Chugai Life Science Park Yokohama is progressing smoothly toward completion in October 2022, and full-scale operation in April 2023. We plan to introduce the new institute to the press and institutional investors in time for its completion in October or official launch next year.

In addition, two existing laboratories are preparing for closure, and a buyer has been decided for the Kamakura laboratory.

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## Response to the Transition to the New Market Category "Prime Market"

### ■ Establishment of Special Committee

- At the request of the revised Corporate Governance Code for companies listed on the Prime Market, we selected to establish a Special Committee (established on March 29, 2022)
  - ✓ Deliberate and consider important transactions and acts etc. that may conflict with the interests of the parent company Roche and minority shareholders
  - ✓ The Special Committee consists of three or more members consisting of only independent outside directors and independent outside corporate auditors, including one independent outside director who also serves as a outside member of the Compensation Committee

Name	Role	Position in our company
Yoichiro Ichimaru	Chairman* <sup>1</sup>	independent outside director* <sup>2</sup>
Masayuki Oku	member	independent outside director* <sup>2</sup>
Kenichi Masuda	member	independent outside corporate auditor* <sup>2</sup>

\*1 Selected by mutual election of committee member

\*2 Designated as an independent officer pursuant to the regulations of the Tokyo Stock Exchange, Inc., to which notification has been made.

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Next, I will talk about our work in the area of corporate governance. See slide nine.

As required by the revised Corporate Governance Code pertaining to Prime Market listed companies with controlling shareholders, we have elected to establish a Special Committee.

The Committee will deliberate and review important transactions and actions that may conflict with the interests of Roche, the parent company, and minority shareholders, and strive to further strengthen corporate governance.

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## Introduction of New Management Members (Supervisory Responsibility)

As of April 1, 2022

			
<b>Dr. Osamu Okuda</b> Representative Director, President & CEO Supervisory responsibility for Corporate Planning, Partnering, External Affairs, and Audit	<b>Dr. Hisafumi Yamada</b> Director, Executive Vice President Supervisory responsibility for Project & Lifecycle Management (R&D), Research, Translational Research, Clinical Development, and Pharmaceutical Technology	<b>Toshiaki Itagaki</b> Director, Executive Vice President & CFO Supervisory responsibility for Finance & Accounting, Corporate Communication and Purchasing Head of Finance Supervisory Div.	<b>Tetsuya Yamaguchi</b> Executive Vice President Supervisory responsibility for Project & Lifecycle Management (Marketing), Drug Safety, Medical Affairs, and Foundation Medicine Head of Project & Lifecycle Management Unit
			
<b>Junichi Ebihara</b> Executive Vice President Supervisory responsibility for Legal Affairs, Intellectual Property, General Affairs, Risk Management, Compliance, and Quality and Regulatory Compliance	<b>Shinji Hidaka</b> Executive Vice President Supervisory responsibility for Marketing & Sales Head of Marketing & Sales Div.	<b>Yoshiyuki Yano</b> Executive Vice President Supervisory responsibility for Human Resources and Environment, Health, and Safety Head of Human Resources Management Dept.	<b>Satoko Shisai</b> Executive Vice President Supervisory responsibility for Digital Transformation Head of Digital Transformation Unit

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Finally, we would like to introduce our management team.

Under the strong leadership of Honorary Advisor Nagayama and Senior Advisor Kosaka, we have entered into a strategic alliance with Roche. By focusing on innovation, we have grown significantly to become one of the top R&D-driven pharmaceutical companies in Japan.

Going forward, we will promote TOP I 2030 and aim for further growth under the new eight-member management team shown here. Each individual has a different leadership style, as well as different knowledge, experience, and skills. As speedy and appropriate management decisions are required to address complex and diverse issues, the team will lead Chugai's management by taking advantage of the diversity of the eight members and sharing various opinions.

**Sasai:** Next, Mr. Itagaki will present an overview of the consolidated financial results.

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# IFRS and Core Results Jan – Mar

(Billions of JPY)	IFRS results	Non-core items		Core results
		Intangible assets	Others	
<b>Revenues</b>	<b>360.6</b>		<b>-91.9</b>	<b>268.6</b>
Sales	242.7			242.7
Royalties and other operating income	25.9			25.9
Other revenue	91.9		-91.9	-
Cost of sales	-114.4	+0.3		-114.1
<b>Operating expenses</b>	<b>-59.1</b>	<b>+0.2</b>	<b>+3.4</b>	<b>-55.6</b>
M&D and G&A	-25.3		+2.6	-22.7
Research and development	-33.9	+0.2	+0.8	-32.9
<b>Operating profit</b>	<b>187.0</b>	<b>+0.4</b>	<b>-88.5</b>	<b>98.9</b>
Financial account balance	-0.8			-0.8
Income taxes	-54.4	-0.1	+27.0	-27.5
<b>Net income</b>	<b>131.8</b>	<b>+0.3</b>	<b>-61.5</b>	<b>70.6</b>
<b>EPS (JPY)</b>	<b>80.09</b>			<b>42.91</b>

## Non-Core items

(Billions of JPY)

### Intangible assets

Amortization	+0.3
Impairment	+0.2

### Others

Lump-sum income from settlement agreement with Alexion Pharmaceuticals, Inc.	-91.9
Restructuring expenses, etc.	+3.4

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**Itagaki:** Itagaki here.

Now, please go to page 12. First, we will look at the non-core adjustment.

To calculate core results, we add or subtract what we consider to be non-recurring items to or from IFRS results. In this Q1, that non-core adjustment is performed as described on the right.

First, intangibles, in this case, refer to the upfront and milestone payments that accompany in-license. They are recorded on the balance sheet as intangible assets and amortized over a certain period of time after launch. If a product has to be discontinued or written down before it is put on the market, it will be written down. These are treated as non-core expenses. Q1 had costs of JPY300 million and JPY200 million, respectively.

The other two are the settlement and business restructuring fees. As previously announced, the lawsuit with Alexion has been settled for an upfront payment of USD775 million. Since the settlement payment is a non-recurring item, it is recorded in other income and converted to yen as a non-core adjustment of JPY91.9 billion. The office reorganization expenses are the accelerated depreciation expenses for the two laboratories, which will be incurred in conjunction with the consolidation of the Gotemba Research Center and the Kamakura Research Center into a new research center in Yokohama in 2023.

As a result of these adjustments, core operating profit will be JPY98.9 billion, compared to JPY187 billion in IFRS actual operating income. In the slides that follow, I would like to explain the core results.

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## P/L Jan - Mar (Year on Year)

(Billions of JPY)	2021	2022	Growth	
<b>Revenues</b>	<b>168.8</b>	<b>268.6</b>	<b>+ 99.8</b>	<b>+ 59.1%</b>
Sales	130.3	242.7	+ 112.4	+ 86.3%
Domestic	94.9	161.7	+ 66.8	+ 70.4%
Overseas	35.4	81.0	+ 45.6	+ 128.8%
Royalties and other operating income	38.6	25.9	- 12.7	- 32.9%
Royalty and profit-sharing income	36.6	25.2	- 11.4	- 31.1%
Other operating income	2.0	0.7	- 1.3	- 65.0%
<b>Cost of sales</b>	<b>-55.0</b>	<b>-114.1</b>	<b>- 59.1</b>	<b>+ 107.5%</b>
(cost to sales ratio)	42.2%	47.0%	+4.8pts	-
<b>Operating expenses</b>	<b>-48.5</b>	<b>-55.6</b>	<b>- 7.1</b>	<b>+ 14.6%</b>
M&D and G&A *	-19.7	-22.7	- 3.0	+ 15.2%
Research and development	-28.7	-32.9	- 4.2	+ 14.6%
<b>Operating profit</b>	<b>65.4</b>	<b>98.9</b>	<b>+ 33.5</b>	<b>+ 51.2%</b>
(operating margin)	38.7%	36.8%	-1.9pts	-
Financial account balance	0.3	-0.8	- 1.1	- 366.7%
Income taxes	-17.2	-27.5	- 10.3	+ 59.9%
<b>Net income</b>	<b>48.4</b>	<b>70.6</b>	<b>+ 22.2</b>	<b>+ 45.9%</b>
<b>EPS (JPY)</b>	<b>29.42</b>	<b>42.91</b>	<b>+13.49</b>	<b>+ 45.9%</b>

### Domestic sales

Significant increase due to sales growth of new products as well as mainstay products

### Overseas sales

Significant increase in sales of Hemlibra and Actemra

### Royalty and profit-sharing income

Significant decrease in royalty income for initial shipping inventory of Hemlibra

### Other operating income

Decrease in one-time income

### Cost of sales

Cost to sales ratio higher due to a change in product mix, etc.

### Operating expenses

Increase due to business taxes and increased activities of overseas subsidiaries  
Increase of research and development expenses due to progress of projects, etc.

### Operating profit

Growth mainly due to increase in sales

\* M&D: Marketing and distribution, G&A: General and administration

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Please see page 13. We will look at the profit and loss results for Q1, comparing them to the previous period.

Revenue was JPY268.6 billion, an increase of 59.1%. Sales in the domestic market increased by 70.4% due to strong sales of new and mainstay products. Overseas sales also grew strongly at 128.8% due to increases in Hemlibra and Actemra.

Royalty and profit-sharing income were down 31.1% due to lower royalty revenues related to initial shipments of Hemlibra. Other operating income were also limited to JPY0.7 billion due to a decrease in one-time income.

The cost to sales ratio was 47%, a 4.8 percentage point deterioration year on year, mainly reflecting a change in the product mix. M&D and G&A expenses increased by JPY3 billion due to higher business taxes and increased activities of overseas subsidiaries. R&D expenses also increased by JPY4.2 billion due to progress in research themes.

As a result, operating profit was JPY98.9 billion, up 51.2%, and operating margin was 36.8%. After subtracting financial account balance and income tax, the net income was JPY70.6 billion, an increase of 45.9%.

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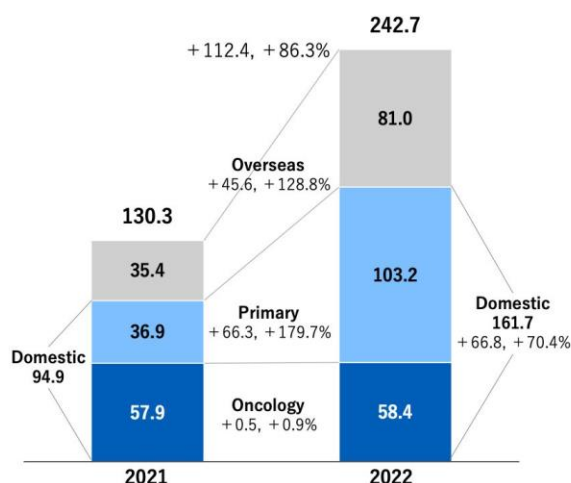
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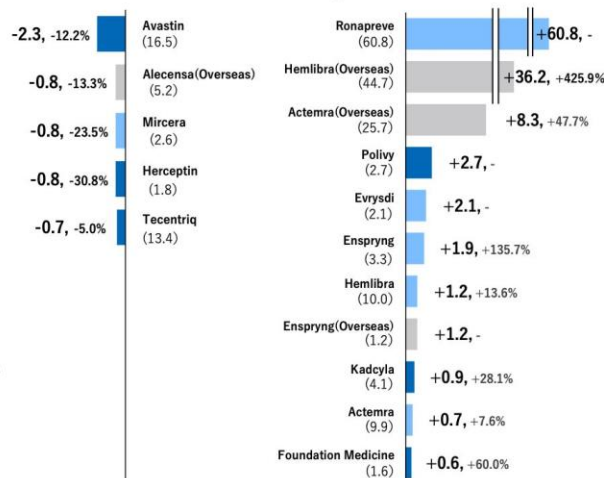
# Sales Jan - Mar (Year on Year)

(Billions of JPY) Sales by Disease Area,  
Year on Year Comparisons



Sales by Products,  
Year on Year Changes

( ): Actual sales in FY2022  
%: Year-on-year percentage change



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Moving on to page 14.

The breakdown of the change in product sales is as follows: oncology, primary, and overseas sales all increased in each therapeutic area.

In the oncology area in Japan, sales grew by 0.9%. The each product was shown in dark blue on the right side. Polivy, which was launched in May last year, Kadcyla, which is performing well due to its expanded indications, and Foundation Medicine, to which FoundationOne Liquid was added, increased sales.

On the other hand, sales of Avastin and Herceptin decreased due to biosimilars. Tecentriq sales decreased due to the impact of a drop in drug price of an approximately 11% by NHI prices revision based on market expansion in last August.

In the domestic primary area, sales increased by 179.7%. Looking at the products shown in light blue, sales of Ronapreve, which received special approval in last July, totaled JPY60.8 billion. Sales of Evrysdi, which was launched in August last year, totaled JPY2.1 billion. Sales of in-house products, such as Enspryng, Hemlibra, and Actemra, are also growing steadily.

Sales for Mircera decreased by JPY0.8 billion.

The overseas also posted a significant revenue growth of 128.8%. Hemlibra overseas exports were 5.2 times higher year on year, as initial shipping inventories have run their course and shipments at regular unit prices have begun in earnest. Overseas Sales of Actemra also increased by 47.7%. We will look at the details on the next page.

Exports of Enspryng, which began in the second half of last year, amounted to JPY1.2 billion. Exports of Alecensa decreased by JPY0.8 billion due to a decline in unit prices, although the export volume itself increased.

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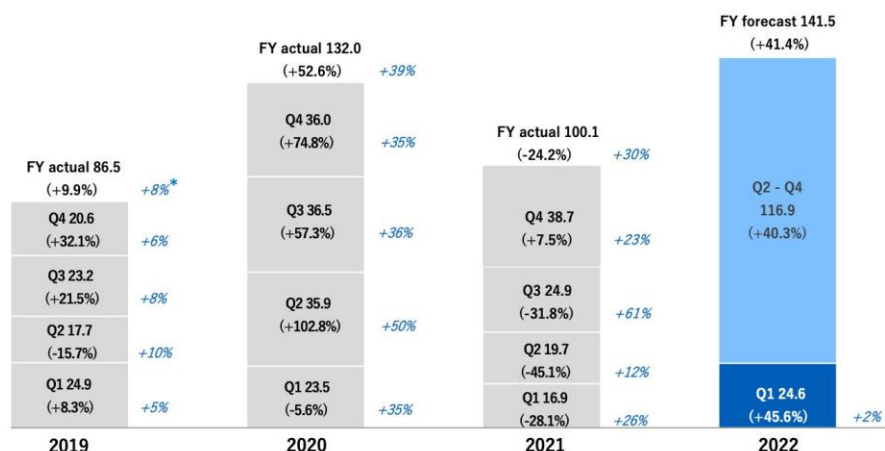
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# Export of Actemra to Roche

(Billions of JPY)

%: year on year growth  
 black: Chugai sales to Roche  
 blue\*: Roche sales excluding Japan (for reference)  
 \*Growth rates in blue are calculated with the effects of exchange rate fluctuations eliminated.



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Page 15 covers exports of Actemra to Roche. We are gaining familiarity with this picture.

The figures are stacked chronologically from left to right and quarterly from the bottom. The blue numbers written on the side show the percentage increase in Actemra sales in the Roche territory.

First of all, if you look at last year's full year results, our exports decreased by 24.2% year on year, while Roche territory sales grew 30%. There are two reasons for the negative growth in our exports. The first point is that we shipped too much in 2020 ahead of schedule, and the first half of last year saw a reaction to this. The second point is that exports were somewhat outpaced by demand in the second half of last year due to production capacity issues.

Since we have been able to expand our production capacity since then, this fiscal year we will make up for the supply-demand shortage that occurred in the second half of last year. Therefore, for the current fiscal year, the forecast of Actemra export to Roche is JPY141.5 billion, an increase of 41.4% year on year.

As you can see at the bottom of the right-hand side, exports to Roche in Q1 totaled JPY24.6 billion, an increase of 45.6%. This is almost in line with our forecast.

Incidentally, Roche's Q1 growth rate, as written on the right, is 2%, excluding Japan. Q1 results for last year, which are used as a comparison, are themselves a very high launch pad.

If you look at Roche's Q1 results in chronological order, 2020 saw a 35% increase, and 2021 saw a 26% increase. If we take 2019 as the base, last year's results are 1.7 times larger. Compared to that, the 2% increase in Q1 of this fiscal year, I think we can say that we are maintaining a high enough level.

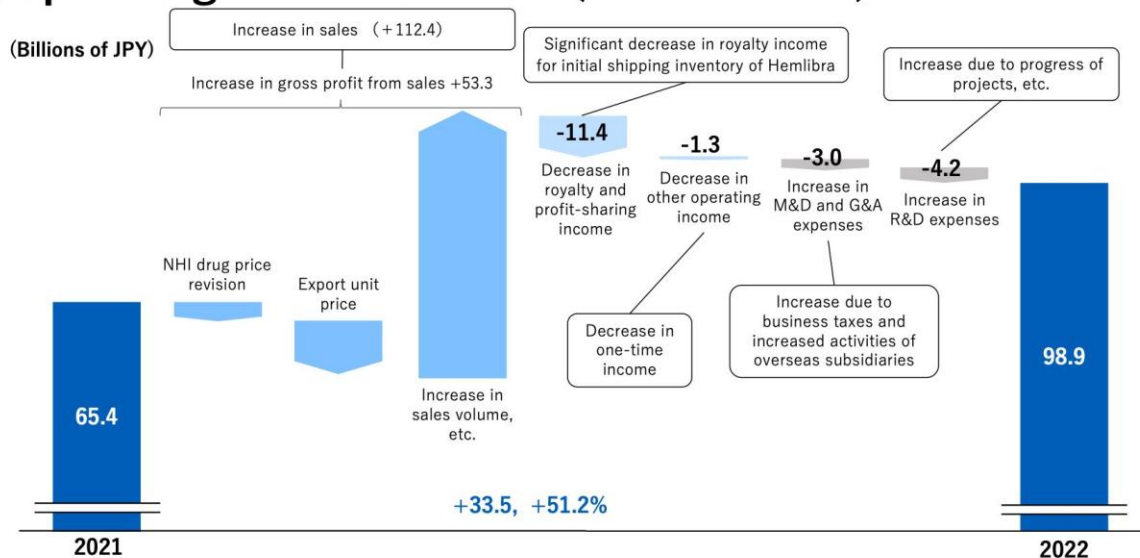
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## Operating Profit Jan - Mar (Year on Year)



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Next, page 16. This is a breakdown of the increase in operating profit.

The second through fourth bars on the left show the elemental decomposition of the increase in gross profit. The negative impact of price revisions and export unit prices was absorbed by volume growth, resulting in a net increase of JPY53.3 billion.

Next, royalty and profit-sharing income decreased by JPY11.4 billion. Of this amount, royalties on initial shipments of Hemlibra, or Royalty 2, were negative JPY15.2 billion, although this figure is not shown in the above slide.

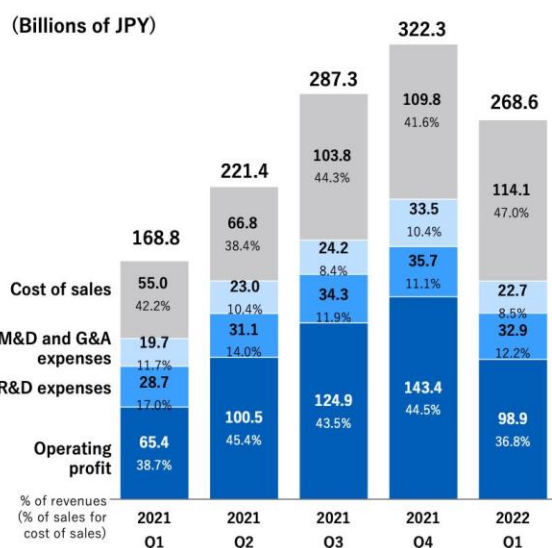
Other operating income, M&D and G&A expenses, and R&D expenses are as shown.

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# Structure of Costs and Profit by Quarter



## vs. Year on Year (2021 Q1)

Cost of sales ratio: higher due to a change in product mix, etc.

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

Operating profit: increase of +33.5 (+51.2%)

## vs. Previous Quarter (2021 Q4)

Cost of sales ratio: higher due to a change in product mix, etc.

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

Operating profit: decrease of -44.5 (-31.0%)

17

Starting on page 17, there are three more slides showing quarterly trends. On each page, the upper right-hand side of the page compares results to the previous year's Q1, and the lower right-hand side compares results to the previous year's Q4. I have already explained the comparison with the same period of the previous year, so I will skip the explanation in the next three slides.

This is the first slide. This slide looks at the cost structure, starting with the cost ratio.

This is up from Q4 due to a change in product mix. Although costs are lower than in Q4, this is consistent with the trend in previous years. COVID-19 has not particularly had an effect.

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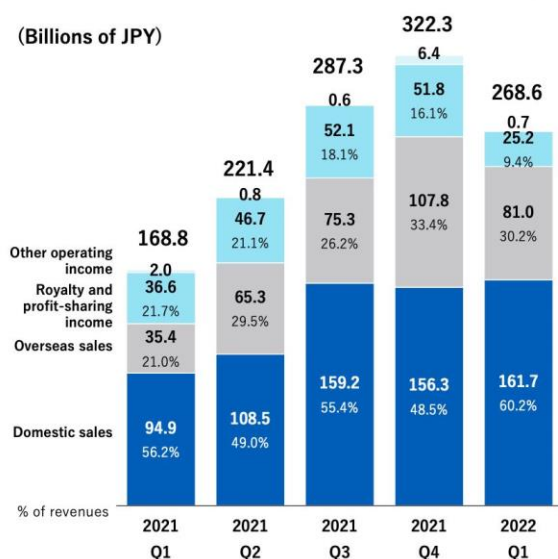
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## Structure of Revenues by Quarter



### vs. Year on Year (2021 Q1)

Domestic sales: significant increase due to sales growth of new products as well as mainstay products

Overseas sales: significant increase in sales of Hemlibra and Actemra

Royalty and profit-sharing income: significant decrease in royalty income for initial shipping inventory of Hemlibra

### vs. Previous Quarter (2021 Q4)

Domestic sales: decrease in line with the trend of previous years, increase in sales of Ronapreve

Overseas sales: decrease mainly due to variance in timing of exports from quarter to quarter, etc.

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

18

The next page, page 18, shows the revenue composition.

Sales in the domestic market, which tend to be high in Q4 and then drop in the following Q1, were up JPY5.4 billion this quarter. The reason for this Q1 result is the recording of JPY60.8 billion of Ronapreve sales in Q1.

The figure for overseas revenue is down JPY26.8 billion from the preceding Q4. In my previous explanation of the financial results, I had mentioned that the acceptance inspection time for Hemlibra on the Roche side was accelerated, and that last year's final sales achieved above our forecast ahead of JPY15.1 billion. The impact of this is seen in this Q1. Adjusting for the JPY15.1 billion due to the timing of the acceptance inspection, we see a slight increase in Q1 result compared to the preceding Q4 result.

Q1 royalty and profit-sharing income decreased by JPY26.8 billion from Q4. This is mainly due to the JPY11.4 billion decrease in initial shipment royalties on Hemlibra and a decrease in regular shipment royalties.

The royalty rate on exports usually increases in steps as Roche's sales accumulate, so Q1 will naturally be less than Q4.

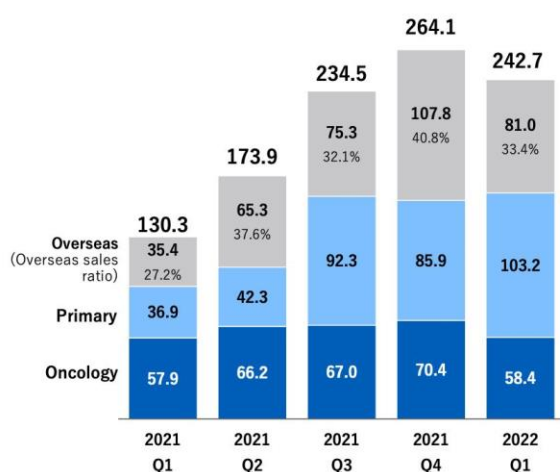
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# Structure of Sales by Quarter

(Billions of JPY)



## vs. Year on Year (2021 Q1)

<b>Oncology</b>	Polivy:	+2.7	Avastin:	-2.3
<b>Primary</b>	Ronapreve:	+60.8	Evrysdi:	+2.1
	Enspryng:	+1.9		
<b>Overseas</b>	Hemlibra:	+36.2	Actemra:	+8.3

## vs. Previous Quarter (2021 Q4)

<b>Oncology</b>	Avastin:	-4.6	Tecentriq:	-2.7
<b>Primary</b>	Ronapreve:	+26.2	Hemlibra:	-2.3
	Edirol:	-1.6	Actemra:	-1.5
<b>Overseas</b>	Actemra:	-13.6	Hemlibra:	-7.8
	Alecensa:	-6.6		

19

The last slide of the quarterly trends, page 19, shows sales by product category.

Compared to last year's Q4, the lower right-hand corner shows that only Ronapreve was the only product with increased revenue, increasing by JPY26.2 billion. Other products decreased in revenue. These trends are the same as in previous years, with higher Q4 and lower Q1.

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## P/L Jan - Mar (vs. Forecast)

(Billions of JPY)	Actual	Forecast		2021
	2022 Jan - Mar	2022 Jan - Dec	Progress	Progress*
<b>Revenues</b>	<b>268.6</b>	<b>1,150.0</b>	<b>23.4%</b>	<b>16.9%</b>
Sales	242.7	1,031.5	23.5%	16.2%
Domestic	161.7	646.3	25.0%	18.3%
Overseas	81.0	385.2	21.0%	12.5%
Royalties and other operating income	25.9	118.5	21.9%	19.6%
Royalty and profit-sharing income	25.2	114.0	22.1%	19.6%
Other operating income	0.7	4.5	15.6%	20.4%
<b>Cost of sales</b>	<b>- 114.1</b>	<b>- 460.0</b>	<b>24.8%</b>	<b>16.4%</b>
(cost to sales ratio)	47.0%	44.6%	-	-
<b>Operating expenses</b>	<b>- 55.6</b>	<b>- 250.0</b>	<b>22.2%</b>	<b>21.1%</b>
M&D and G&A	- 22.7	- 100.5	22.6%	19.6%
Research and development	- 32.9	- 149.5	22.0%	22.1%
<b>Operating profit</b>	<b>98.9</b>	<b>440.0</b>	<b>22.5%</b>	<b>15.1%</b>
(operating margin)	36.8%	38.3%	-	-
<b>Net income</b>	<b>70.6</b>	<b>312.5</b>	<b>22.6%</b>	<b>15.5%</b>
<b>EPS (JPY)</b>	<b>42.91</b>	<b>190.00</b>	<b>22.6%</b>	<b>15.5%</b>

### Domestic Sales

Overall progress nearly in line with forecast

### 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

\* Jan - Mar progress versus Jan - Dec

20

Next, the forecast ratio. See page 20.

As noted to the right, cost of sales, expenses, and profit are all generally progressing as expected. However, we have also included last year's progress rate here. Compared to that, this year's progress, especially in revenues, has been better. I will say a few words about this.

First of all, the progress of sales in the domestic is better than last year due to the impact of Ronapreve, which was 18.3% last year and 25% this year. Excluding Ronapreve, the progress was 21.5% last year and 22.6% this year. Excluding Ronapreve, the trend of progress is almost the same.

Next, overseas. The difference in progress rate was affected by the bumpy export timing of Hemlibra. We will confirm this on the next page.

Progress in terms of ROOI is faster than last year because the Royalty 2 will converge toward the end of the period this year. This is why we are seeing a better rate of progress in Q1 this year.

This is why we are seeing better progress in earnings compared to the previous fiscal year. We have factored this into our plans, so overall, the progress is almost as planned.

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## Sales Jan - Mar (vs. Forecast)

(Billions of JPY)	Actual	Forecast		2021	(Billions of JPY)	Actual	Forecast		2021
	2022 Jan - Mar	2022 Jan - Dec	Progress	Progress *		2022 Jan - Mar	2022 Jan - Dec	Progress	Progress *
<b>Sales</b>	<b>242.7</b>	<b>1,031.5</b>	<b>23.5%</b>	<b>16.2%</b>	<b>Primary</b>	<b>103.2</b>	<b>385.8</b>	<b>26.7%</b>	<b>14.3%</b>
<b>Domestic</b>	<b>161.7</b>	<b>646.3</b>	<b>25.0%</b>	<b>18.3%</b>	Ronapreve	60.8	199.0	30.6%	0.0%
<b>Oncology</b>	<b>58.4</b>	<b>260.5</b>	<b>22.4%</b>	<b>22.1%</b>	Hemlibra	10.0	51.8	19.3%	21.2%
Avastin	16.5	69.4	23.8%	23.2%	Actemra	9.9	41.9	23.6%	21.3%
Tecentriq	13.4	62.0	21.6%	22.7%	Enspryng	3.3	16.7	19.8%	14.4%
Perjeta	7.4	33.7	22.0%	23.0%	Edrol	3.3	10.8	30.6%	13.0%
Alecensa	6.3	28.7	22.0%	21.7%	Mircera	2.6	10.2	25.5%	23.6%
Polivy	2.7	16.2	16.7%	0.0%	Evrysdi	2.1	8.8	23.9%	0.0%
Kadcyla	4.1	16.0	25.6%	20.4%	CellCept	1.8	7.4	24.3%	23.8%
Herceptin	1.8	8.3	21.7%	26.5%	Bonviva	1.7	7.0	24.3%	24.4%
Gazyva	1.0	5.4	18.5%	22.2%	Oxarol	1.4	5.1	27.5%	22.6%
Rituxan	1.0	4.1	24.4%	23.5%	Other	6.3	27.1	23.2%	7.9%
Foundation Medicine	1.6	9.1	17.6%	19.6%	<b>Overseas</b>	<b>81.0</b>	<b>385.2</b>	<b>21.0%</b>	<b>12.5%</b>
Other	2.6	7.5	34.7%	22.4%	Hemlibra	44.7	186.0	24.0%	7.4%
					Actemra	25.7	144.4	17.8%	16.9%
					Alecensa	5.2	34.1	15.2%	12.0%
					Enspryng	1.2	4.6	26.1%	0.0%
					Neutrogen	2.4	8.8	27.3%	24.2%
					Other	1.9	7.4	25.7%	19.4%

\* Jan - Mar progress versus Jan - Dec

21

The sales forecast ratios for individual products are shown on page 21.

Progress on individual products is also generally in line with expectations, although there are a few products whose progress to the full-year forecast is below 20% such as Polivy, Gazyva, Foundation Medicine, and Hemlibra. Firstly, we anticipate an increase in sales of these products toward the end of this fiscal year, so the low progress rate in Q1 is as expected.

In addition, since overseas exports depend on the timing of shipments, it would be difficult to judge the situation solely by looking at the progress rate here. However, we saw firm order transactions in Q1 at the time the plan was formulated at the beginning of the fiscal year.

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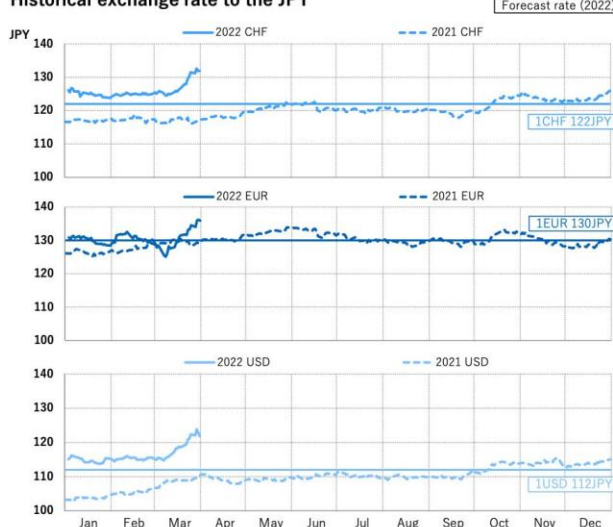
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## Impact from Foreign Exchange (vs. Forecast)

(billions of JPY)	FX impact 2022 (FX impact vs. Assumption)	
Revenues	Sales	-1.2
	Royalties and other operating income	+0.4
Cost of sales & Operating expenses	Cost of sales	-0.1
	Operating expenses	-0.1
Operating profit		<b>-1.0</b>

Market average exchange rate(JPY)	2021 Actual	2022 Assumption	2022 Actual
1CHF	117.08	122.00	125.78
1EUR	127.65	130.00	130.43
1USD	105.83	112.00	116.17

Historical exchange rate to the JPY



22

Next is page 22. This slide shows the impact of exchange rate fluctuations. We usually put this in the appendix, but since the yen has been weakening considerably recently, I would like to bring it to the main part of this presentation to discuss it a little more.

As shown in the graph on the right, the current level of the yen itself is about 10% weaker than the rate during the first quarter. This is shown at the top of the graph against the Swiss franc.

If you look at the left, in this Q1, there is a negative impact of JPY1.2 billion in sales compared to the forecast. However, since almost 100% of the export sales in Q1 were hedged, some may question whether this makes any difference. The assumed exchange rate against the Swiss franc for Q1 was JPY122. In fact, many of the hedges used were for slightly appreciated yen.

To begin with, hedges are taken throughout the year, and spread out over the previous year, so there is a variation in the exchange rate of each held. The assumed rate itself is an average of these rates, so depending on which hedge is actually used, and at what timing, each transaction will be plus or minus as planned differences. However, if all the exchange reservation are used up, there will be no difference from the forecast for the full year, so we hope you understand that this is a temporary difference.

However, it should be noted that 80% of the main foreign transactions are hedged, and therefore, for transactions that are not hedged, gains or losses will be affected by market exchange rate movements.

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# Financial Position (vs. 2021 Year End)

(Billions of JPY)

	1,188.0	Total net assets +52.5	1,240.5	
	370.1	Net working capital +54.0	424.1	
Net operating assets 772.6	402.4	Long-term net operating assets +8.5	410.9	Net operating assets 834.9 +62.3
	472.0	Net cash -40.2	431.8	
	-56.5	+30.3	-26.2	
	2021 Dec	Other non-operating assets - net *	2022 Mar	
Total assets	1,538.7	+46.2	1,584.9	
Total liabilities	-350.7	+6.3	-344.4	
Total net assets	1,188.0	+52.5	1,240.5	
Ratio of equity attributable to Chugai shareholders	77.2%	+1.1%pts	78.3%	

## Increase in net working capital

Increase mainly in accounts receivable relating to settlement agreement with Alexion Pharmaceuticals, Inc. despite decrease in trade accounts receivable, etc.

## Increase in long-term net operating assets

Increase mainly in property, plant and equipment, etc.

## Decrease in net cash

(See next slide)

## Decrease in other non-operating assets – net

Decrease mainly in accrued corporate tax

\* E.g., deferred income tax assets, accrued corporate tax, etc.

23

This concludes the explanation of profit and loss. Page 23 is a slide covering the balance sheet.

If you look at the second line from the bottom on the left, you will see the total net assets. As of the end of this March, the balance stood at JPY1.2405 trillion, an increase of JPY52.5 billion from the end of the previous fiscal year.

The breakdown above shows that assets increased by JPY46.2 billion, while liabilities increased by only JPY6.3 billion. This resulted in 1.1% points increase in the shareholders' equity ratio to 78.3%, shown at the bottom.

Net cash was JPY40.2 billion, a decrease from the end of the previous fiscal year, with a balance of JPY431.8 billion. We will see the changes in balance on the next page.

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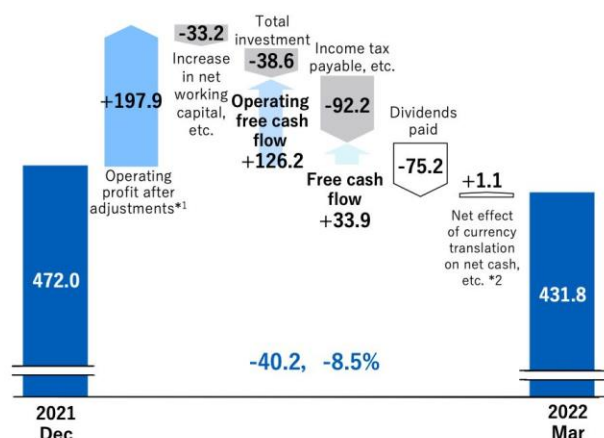
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# Net Cash (vs. 2021 Year End)

(Billions of JPY)



Operating profit after adjustment <sup>*1</sup>	+197.9
Operating profit <sup>*1</sup>	+187.0
Depreciation, amortization and impairment <sup>*1</sup>	+7.5
Increase in net working capital, etc.	-33.2
Total investment	-38.6
Property, plant and equipment	-34.1
Payment for lease liabilities	-1.8
Intangible assets	-2.6
<b>Operating free cash flow</b>	<b>+126.2</b>
Income tax payable, etc.	-92.2
Income tax payable	-85.5
<b>Free cash flow</b>	<b>+33.9</b>
Dividends paid	-75.2
Net effect of currency transaction on net cash, etc. <sup>*2</sup>	+1.1

\*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)

24

Page 24 shows the cash movement from the end of last year to the end of March.

First, there was a cash inflow of JPY197.9 billion from operating activities. After deducting a JPY33.2 billion increase in net working capital and JPY38.6 billion in payments for the construction of new laboratories and manufacturing facilities, operating free cash flow was a positive JPY126.2 billion. We cashed out JPY92.2 billion in income taxes and JPY75.2 billion in year-end dividends, resulting in a JPY40.2 billion decrease in net cash. This leaves a balance of JPY431.8 billion.

Tax and dividend payments in Q1 are significant, so it is customary for cash to decrease, and there is no particular problem here. We expect the change in net cash to be positive in Q2 because of the receipt of JPY91.9 billion in settlement proceeds.

That is all from me.

**Sasai:** Next, Mr. Yamaguchi will explain the status of our development pipeline.

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## Q1 Topics



Letters in orange : in-house projects (global development)

Letters in blue : in-licensed from Roche (development and distribution in Japan)

As of April 25, 2022

Approved	Mitchga	pruritus associated with atopic dermatitis	March 2022
	Vabysmo	age-related macular degeneration associated with subfoveal choroidal neovascularization and diabetic macular edema (DME)	March 2022
	Perjeta/Herceptin	advanced or recurrent HER2-positive colon cancer or rectal cancer not amenable to curative resection that has progressed after cancer chemotherapy	March 2022
Filed	Actemra	<u>COVID-19 in hospitalized adults - under Priority Review by the U.S. FDA</u>	April 2022 (acceptance of filing)
	Gazyva	<u>chronic lymphocytic leukemia (CLL) - combination with acalabrutinib</u>	March 2022
Pipeline entry	SKY59/crovalimab	<u>Sickle cell disease (US and EU)</u>	P2 study (March 2022)
	RG6321/ranibizumab(PDS)	neovascular age-related macular degeneration (nAMD) and DME	P1/2 study (March 2022)
	RG7828/mosunetuzumab	follicular lymphoma (3 <sup>rd</sup> Line)	P1 study (March 2022)
Development discontinued	RG7992	non-alcoholic steatohepatitis (NASH)	
Readout in pivotal study	SKY59/crovalimab	COMMODORE 3 (China) met co-primary endpoints in PNH	P3 study (Q1 2022)
	RG6058/tiragolumab	SKYSCRAPER-02 did not meet its co-primary endpoint of PFS in SCLC	P3 study (March 2022)
Medical conference	Vabysmo	YOSEMITE/RHINE studies (DME)	AED (February 2022)
	Evrysdi	SUNFISH/RAINBOWFISH studies (Spinal muscular atrophy)	MDA (March 2022)

Underlined are disclosed due to changes in pipeline entry rule

PDS: Port Delivery System with ranibizumab AED: Angiogenesis, Exudation and Degeneration MDA: Muscular Dystrophy Association

26

**Tetsuya Yamaguchi:** Yamaguchi here.

Please see page 26. This is an introduction to new topics since the last financial announcement.

First, in terms of approvals, three products were approved in March. Mitchga has been approved for pruritus associated with atopic dermatitis by Maruho, the company to which we licensed the drug. In addition, Vabysmo was approved for two indications: age-related macular degeneration and diabetic macular edema. The indications for Parjeta/Herceptin have been expanded to include HER2-positive advanced or recurrent colorectal cancer.

An application was filed in the US for Actemra in COVID-19 pneumonia and was designated for priority review. Actemra for use in COVID-19 pneumonia has been approved or filed in approximately 40 countries around the world. In addition, we have obtained pre-certification from the WHO. We have submitted an application to expand the indications of Gazyva for use in combination with acalabrutinib in chronic lymphocytic leukemia. From this presentation onward, we are disclosing development studies by major out-licensing partners and combination studies. Additions are indicated with an underline due to the change in disclosure method.

Next, the pipeline. Roche has initiated a Phase II study for crovalimab in sickle cell disease. As for ranibizumab (PDS), we have started domestic Phase I/II trials for age-related macular degeneration and diabetic macular edema.

In late-stage development top-line announcements, a Phase III study for crovalimab in China for paroxysmal nocturnal hemoglobinuria, PNH, met their primary endpoints. The study will evaluate control of hemolysis and transfusion avoidance in a single group of 50 patients for up to 24 weeks. Data will be presented at an upcoming conference. On the other hand, the anti-TIGIT antibody tiragolumab unfortunately failed to meet its primary endpoint in the global Phase III small cell lung cancer study.

As for conference presentations, we presented Vabysmo data from the diabetic macular edema Phase III trial at two years, and Evrysdi presented data from the SMA Phase III trial at three years. All of these achieved good results.

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# Mitchga® (nemolizumab)

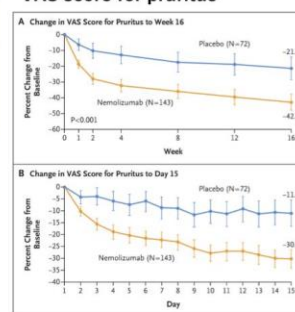
- Maruho received regulatory approval for pruritus associated with atopic dermatitis (AD)
- IL-31 is known to play a role in pruritus and skin inflammation associate with multiple skin diseases including AD, and Mitchga is the first antibody drug targeting IL-31 receptor A
- Pruritus in AD affects QoL significantly by raising barriers in patients' lives, such as poor sleep quality and concentration
- Mitchga® is expected to improve QoL through a rapid improvement of pruritus as well as sleep disturbance

Results from P3 study in Japan\*1

Outcome Measures (at week 16)	Primary endpoint	Secondary endpoint			Safety
	mean percent change in the VAS*2 score for pruritus	mean percent change in the EASI*3 score	DLQI*4 score 4 or less (proportion)	ISI*5 score 7 or less (proportion)	Adverse Event
nemolizumab (n=143)	-42.8%	-45.9%	40%	55%	71%
placebo (n=72)	-21.4%	-33.2%	22%	21%	71%
Difference between two groups (95%CI)	-21.5%pts (-30.2, -12.7), P < 0.001	-12.6%pts (-24.0, -1.3)	17%pts (2, 31)	33%pts (17, 48)	-

\*1 conducted by licensee Maruho \*2 VAS (Visual Analogue Scale) provides a range of scores from 0-100 (0: no pruritus, 100: expected max pruritus)  
 \*3 EASI (Eczema Area and Severity Index) is a validated scoring system that grades the physical signs of atopic dermatitis/eczema.  
 \*4 DLQI (Dermatology Life Quality Index) is designed to measure the health-related quality of life of patients suffering from a skin disease (0-30 point).  
 \*5 ISI (Insomnia Severity Index) is an instrument to assess sleep by patients' subjective views (0-28 point). 7 points or less corresponds to "no clinical insomnia."  
 Mitchga® is a registered trademark of Maruho Co., Ltd. in Japan.  
 Source: Kenji Kabashima et al. NEJM 2020; 383: pp141-150.

Mean percent change in the VAS score for pruritus



27

Maruho has obtained approval for this product, Mitchga.

Mitchga is an anti IL-31 receptor A antibody developed by Chugai. It directly suppresses pruritus by inhibiting the function of the pruritogenic cytokine IL-31. In March, Maruho, out-licensed in Japan, obtained a manufacturing and marketing approval for the treatment of pruritus associated with atopic dermatitis, ahead of other companies in the world.

In a Phase III study conducted by Maruho in Japan, the primary endpoint of the pruritus VAS showed rapid improvement in pruritus from the day after dosing. In addition, the ISI, a sleep assessment index, also saw great improvement.

By reducing itchiness, which is the most painful symptom of atopic dermatitis, the treatment is expected to improve concentration and sleep disturbance, improve QoL, and reduce dermatitis by breaking the itch/scratch cycle.

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## Vabysmo®

- First anti VEGF-A/anti Ang-2 bispecific antibody in ophthalmology, approved for neovascular age-related macular degeneration (nAMD) and diabetic macular edema (DME)
- Vabysmo® achieved a maximum 16-week dosing interval for the first time in P3 study and showed potential to reduce injection frequency and treatment burden
- Estimated number of patients in Japan: nAMD about 0.88 million<sup>\*1</sup>, DME about 0.71 million<sup>\*2</sup>
- Vabysmo® continued to be generally well-tolerated. Adverse events in the study eye that occurred at a frequency of 0.5% or greater included intraocular inflammation (e.g. uveitis), intraocular pressure increased, retinal pigment epithelial tears, and vitreous floaters.

Proportion of patients in global P3 studies who achieved a treatment duration of up to 16 weeks interval at 1 year or at 2 years <sup>\*3</sup>

Indication	study	at 1 year	at 2 years
nAMD	TENAYA	45.7%	Not presented
	LUCERNE	44.9%	Not presented
DME	YOSEMITE	52.8%	60.0%
	RHINE	51.0%	64.5%

VEGF-A: vascular endothelial growth factor A  
Ang-2: Angiopoietin-2

<sup>\*1</sup> Miho Yasuda; The Hisayama Study. New Ophthalmology 2016;33:1247-51. <sup>\*2</sup> Yau JW, et al. Diabetes Care 2012;35:556-64.  
<sup>\*3</sup> Source: Heier JS, et al. The Lancet. 2022; 399:729-740 Wykoff CC, et al. The Lancet. 2022; 399:741-755 Angiogenesis, Exudation and Degeneration 2022

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Vabysmo is our first full-scale entry into the ophthalmology field.

We obtained a manufacturing and marketing approval for nAMD and DME as the first anti VEGF-A/anti Ang-2 bispecific antibody in the field of ophthalmology.

In addition to inhibition of angiogenesis by VEGF-A, Ang-2 inhibition improves vascular stability and effectively suppresses vascular leakage and inflammation.

In the four Phase III studies, approximately half of the patients achieved 16-week dosing intervals at one year of treatment. At two years of DME, approximately 60% of patients achieved 16-week dosing intervals. The safety profile is also generally favorable. We expect to be able to reduce the treatment burden by decreasing the frequency of administration to the eye.

The number of patients in Japan suffering with nAMD is estimated to be approximately 880,000. The figure for DME is 710,000. The peak annual sales in the domestic market, including retinal vein occlusion disease, which is under development, is expected to exceed JPY30 billion.

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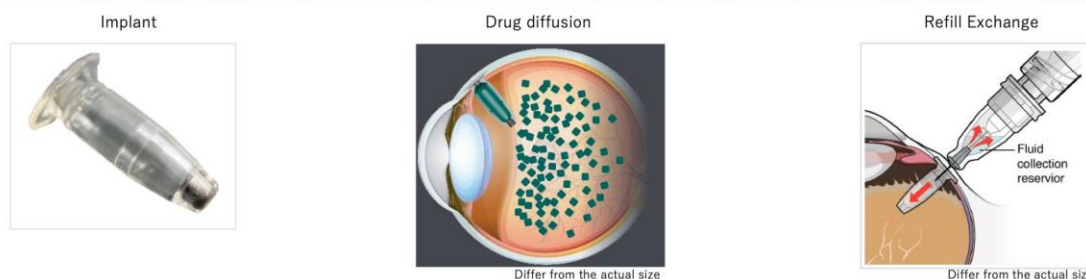
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## Port Delivery System with Ranibizumab<sup>1</sup> (PDS)

- PDS is an implant that enables long and continuous drug delivery
  - PDS maintains visual acuity and controlled retinal thickness as effectively as monthly ranibizumab injections
- In US, Genentech received the FDA approval in October 2021 for the indication of neovascular age-related macular degeneration (nAMD) and commercializes the product under SUSVIMO™<sup>2</sup>. Global phase III trials are ongoing for diabetic macular edema (DME) and diabetic retinopathy.
  - In Japan, local phase I/II trial is ongoing in nAMD and DME patients with every 24 -week refills.



1. Ranibizumab is a Fab-fragment of a recombinant humanized monoclonal antibody against vascular endothelial growth factor-A (VEGF-A) that is already marketed and supplied worldwide as Lucentis® for intravitreal administration.  
2. Dosage and administration in US: The recommended dose of SUSVIMO (ranibizumab injection) is 2 mg(0.02 mL of 100 mg/mL solution) continuously delivered via the SUSVIMO implant with refills every 24 weeks (approximately 6 months).

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We are pleased to introduce the Port Delivery System, PDS, for ranibizumab, a newly initiated clinical trial.

Ranibizumab is marketed worldwide under the name Lucentis for intravitreal administration. PDS will be a device and drug system in which an implant filled with a specialized high concentration ranibizumab formulation is placed in the vitreous chamber.

The implant, which is refilled with the formulation every six months, is expected to release the drug slowly into the vitreous chamber at an appropriate rate for long-lasting effect. We expect to improve maintenance of vision by reducing the administration burden to patients and improving treatment compliance.

In conducting the study, we provide training to the investigators on implant placement techniques to ensure safety. Regarding nAMD the product launched in the US last year. We have applied for approval in the EU.

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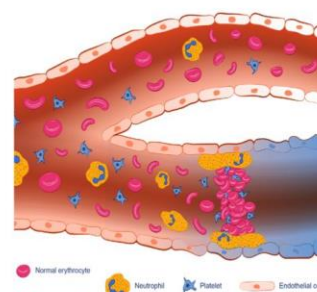
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## Crovalimab : Sick cell disease (SCD)

Exploring the potential role of complement inhibition with crovalimab in the treatment of SCD

- SCD is a genetic disorders caused by mutations in *HBB*, which encodes hemoglobin subunit  $\beta$
- Hemoglobin molecules that include mutant hemoglobin subunit  $\beta$  can polymerize, which cause sickling of red blood cells
- Sickled erythrocyte results in chronic hemolysis and anemia, painful vaso-occlusive crises, and multi-system end-organ damage that accumulates over time
- Prevalence of SCD is highest in sub-Saharan Africa, India, the Middle East, and the Mediterranean region and is increasing globally due to migration patterns. It is rare in Japan
- Elevation in markers of complement activation have been reported in SCD\*

\* Tampaki A et al. Blood rev 2021;100805.



Source: materials from Roche

### Crovalimab Clinical Development

Study	Main Objective
CROSSWALK-a	evaluating the safety and the preliminary efficacy for an acute vaso-occlusive painful crisis, which is a major unmet need in SCD, with single-dose treatment Primary endpoint: safety
CROSSWALK-c	evaluating the efficacy of sustained, longer-term complement inhibition in prevention of vaso-occlusive crises and end-organ damage Primary endpoint: VOC rate, up to 48 weeks

VOC: Vaso-occlusive crises

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This slide introduces crovalimab in sickle cell disease, for which Roche has initiated a Phase II study in the US and Europe.

Crovalimab is an anti-C5 recycling antibody developed by Chugai. Although Chugai does not plan to develop the product for this indication, we are providing this explanation because we expect to receive royalty income in the future.

Sickle cell disease is caused by a genetic mutation of hemoglobin. The polymerization of the mutated hemoglobin deforms erythrocytes into a sickle shape. The disease can be fatal, causing chronic hemolysis, anemia, painful vascular occlusive disease, and in the long term, multiple organ damage. It is found in Africa, India, the Middle East, and the Mediterranean. Tens or hundreds of thousands of patients have been reported in the United States and Europe. On the other hand, there have been almost no reports of the disease in Japan.

In sickle cell disease, elevated complement activation markers have been reported. We expect C5 inhibition to inhibit hemolysis and thrombus formation.

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This is the schedule for future applications.

The red stars are the ones we have added. In addition to what has already been explained, due to a change in the disclosure method, we have added the European Hemlibra item for mild to moderate hemophilia A. For application in 2023, there is Tecentriq non-small cell lung cancer in combination with cabozantinib, and Tecentriq with lenvatinib and sorafenib for hepatocellular carcinoma.

The green star indicates a change in the year of application. This is Tecentriq and urothelial carcinoma. The application has been pushed back to 2023 due to a delay in the occurrence of OS-rated events.

We can see the status of the development pipeline on pages 33 to 34, the progress of third-party licensing projects on page 35, the companion diagnostic function of the cancer genome profile of FoundationOne CDx on page 36, the companion diagnostic function of Liquid CDx on page 37, and the major clinical trials that will be initiated soon on page 38. Please refer to the appropriate section.

That is all from me.

**Sasai:** That concludes the presentation section.

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## Question & Answer

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**Sasai [M]:** I would now like to begin the question-and-answer session. We will take questions in the order of receipt until the scheduled finishing time.

We sincerely appreciate your cooperation in limiting the number of questions to two per person so that as many people as possible can ask questions.

When it is your turn to ask a question, I will call your name. Please mention your company name and name when asking questions. An audio recording of the session will be posted on our website at a later date along with the presentation. Thank you. Also present today is Mr. Hidaka from Sales. Thank you.

First, Mr. Wakao from JPMorgan, please go ahead.

**Wakao [Q]:** Thank you very much. This is Wakao from JPMorgan.

First, could you comment on the outlook Q2 and beyond with respect to export sales of Actemra and Hemlibra? You mentioned that both Actemra and Hemlibra are in line in terms of firm orders with respect to Q1 figures for export sales. Please comment on the outlook for Q2 and beyond, based on these Q1 Roche sales.

Regarding Actemra, I have the impression that Q1 sales have peaked out a bit compared to the previous quarter. Is this in line with your expectations? Also, you seem to be doing well with respect to Hemlibra, could this have an impact on export sales in Q2 and beyond? This is my first question.

**Itagaki [A]:** This is Itagaki.

Regarding Actemra exports, Roche is also announcing its Q1 financial results today. Global Actemra growth is 3%. As I mentioned earlier, the launch pad has already been growing at a very high-rate last year and the year before, growing at a CAGR of about 20% over three years.

Therefore, our exports are in the context of the fact that they are still being used in clinical practice in severe cases of COVID-19. In addition, due to some restrictions in the manufacturing process last year, Roche and the market inventories during the period were insufficient for exports. We are planning to gradually fill the shortage. Based on this assumption, our current projection is that shipments will steadily increase toward the end of the fiscal year.

Hemlibra, by the same token, still shows a very high growth rate, with Roche's global growth of 30%, or 32% excluding Japan. In the exports of these products, there is almost no initial shipment inventories in Roche side. As a result, shipments at normal prices have been gradually coming in since about the second half of last year. They are now in full swing, and in terms of last year, about 5.5 times as many exports have occurred in this Q1.

The progress rate is 24.2%, and if you consider that this is one quarter of the total, you can see from the outside that we are almost on schedule.

We can consider the growth rate compared to last year in terms of volume and unit price. The unit price of Hemlibra, as well as Alecensa, has been declining since last year, so the YoY growth rate is even higher when viewed on a volume basis. The growth rate is 452%, but the reality is that the growth rate is about 600% on a volume basis. We expect to steadily increase sales and exports in Q2 and beyond toward the full-year forecast.

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**Wakao [Q]:** I understand. Thank you very much. Looking at Actemra's quarterly sales in Europe and the US, I was slightly concerned because there was a slight slowing trend. Based on your current explanation, I understand that they will basically remain in line with your company's plans for Q2 and beyond. Thank you very much.

Second question. Please tell us about the settlement regarding the patent lawsuit with Alexion. Is this result close to what your company was aiming for this time? The amount of the settlement is very large, so I think it was a good result for your company. On the other hand, as for Ultomiris, which could be a competitor of crovalimab, there has been no sales injunction or anything, so I am wondering if there has been any impact on the future development strategy of crovalimab.

**Tetsuya Yamaguchi [A]:** I will answer this question. The development of crovalimab has proceeded under the assumption that Alexion's drug is available on the market, so there have been no changes that would affect the development side of the project. The impact has also been proceeding on the assumption that ravulizumab is present. That is all.

**Wakao [Q]:** Thank you very much. I think the PNH clinical trials for crovalimab in the US and Europe will be finished by the end of this year. The timing of the application in China is listed in the calendar, but the timing of the application in the US and Europe is not clear. Is there any background to why this has not been announced yet? Is it correct to say that an application will be filed?

**Tetsuya Yamaguchi [A]:** I think it was in the applications for the following year. Elsewhere, the global application for PNH is set in 2023. We have stated that the application is scheduled to be filed in 2022 for China.

**Wakao [Q]:** Thank you very much. Sorry, I didn't look at it properly. The Chinese results of crovalimab, when will the contents of this be announced?

**Tetsuya Yamaguchi [A]:** We are planning to release specific figures at a future conference, so at this point we are unable to release them.

**Wakao [M]:** I understand. Thank you very much. That is all.

**Sasai [M]:** Thank you very much.

Next, Morgan Stanley, Muraoka, please go ahead.

**Muraoka [Q]:** Morgan Stanley, this is Muraoka. Thank you very much.

Regarding Hemlibra, you may say that I should ask Roche, but I know sales are going well, and the US and EU side of the business, which was in the Roche document today, has a 34% patient share. I know it's a detailed question, but the QoQ, that's only a 1% point increase. It has been increasing at a rate of 2% points all this time and now it is down to 1% point. Maybe it's to do with rounding, but it seems to me that although sales are strong, the growth in market share has slowed down a bit. I would be helpful if you could explain the background.

**Okuda [A]:** Okuda here.

The numbers are, as you point out, 33% for last year's Q4 and 34% for this year's Q1, so the increase is 1% point. However, I believe there is a rounding element, so I think it would be premature to say that sales are slowing based on this one number alone. I would like to see the transition during Q2 and Q3.

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**Muraoka [Q]:** So it's not that the competitive environment has slowed the growth a bit, or that the growth has not been as strong as in the past in relation to the market?

**Okuda [A]:** Indeed. I am sure you are all aware of the competitor products, but I understand that the situation has not changed in any way during this Q1.

**Muraoka [Q]:** I understand. Thank you very much.

As for the exchange rate, as Mr. Itagaki explained earlier, I believe that 80% of the contracts are already booked and the average is at JPY122. Am I correct in understanding that with the yen weakening this much, if the momentum continues toward the second half of the fiscal year, there is a possibility that the benefits of a weaker yen will have a significant effect on earnings in the second half of the fiscal year?

**Itagaki [A]:** About 80% of the exchange rate portion is done on a first-come, first-served basis. Later transactions will be exposed, and with the exchange rate in the market at that time. Under the assumption that the yen is weak, if you net both sales and purchases, it is normal for sales to have more exposure on the net. If the yen were weaker, it would normally be a positive factor for the plan.

For this year only, a certain large hedge for Ronapreve's purchase from Roche was not conducted, because the contract was not finalized as of last year, although we have incorporated into the plan. Therefore, since Ronapreve's purchases are at the stage of exposure, the depreciation of the yen for this part is negative against the plan because it is a purchase. When all such positive and negative factors are taken into account, the current view is that there is a higher likelihood of a negative outcome rather than a positive one, as you mentioned.

**Muraoka [Q]:** So, you are saying that Ronapreve's cost ratio will get worse with each passing period if this exchange rate change continues.

**Itagaki [A]:** Yes. This Q1 is fixed in the part of last year's contract, so that part is fine. I cannot disclose that much, but this later part is based on the assumption that the government delivered price is constant compared to last year, and the purchase price is higher in yen terms as the yen weakens.

**Muraoka [M]:** I understand. Thank you very much. That is all.

**Sasai [M]:** Thank you very much.

Next, Mr. Yamaguchi of Citigroup, please go ahead.

**Hidemaru Yamaguchi [Q]:** I am Yamaguchi from Citi. Thank you very much.

The first question is about Ronapreve. I am sorry to be persistent, but I was told that there will be a new order in April. In the case of other companies, we have seen cases of cancellations of vaccines during the course of the year. In the case of your company, is it correct to assume that the possibility of such cancellations is low due to the new contract? Are there still some areas that remain as possibilities? Thank you.

**Tetsuya Yamaguchi [A]:** I am Yamaguchi.

Although I am unable to go into the details of the contract, I understand that the government has decided to prepare Ronapreve for government procurement based on the uncertainty of the sensitivity to future mutations.

In light of this situation, we consider the possibility of cancellation to be low. Of course, accurate descriptions of the cancellation policy are included in the contract. I think that is what I can say now.

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**Hidemaru Yamaguchi [Q]:** Thank you very much.

One more question, Vabysmo has been approved and will be launched to market. I think there are probably some sales included in the other sales section, but since there are existing products where Vabysmo will be included later, do you plan to launch the product in a style that basically takes in new patients? Or is there some basic sales strategy that you can tell us about that you think you can take from existing products because the interval of administration is longer?

**Hidaka [A]:** I am Hidaka from Sales. Thank you for your question.

I think there are elements of both. We are expecting new patients, of course, but we are also expecting a certain amount of switching, especially in the advantage of interval, depending on the patient's needs. That is all.

**Hidemaru Yamaguchi [Q]:** So basically, it is both.

**Hidaka [A]:** Yes, that's right.

**Hidemaru Yamaguchi [M]:** I understand. Thank you very much. That's all from me.

**Sasai [M]:** Thank you very much.

Next, Mr. Sakai from Credit Suisse Securities.

**Sakai [Q]:** My name is Sakai from Credit Suisse.

First, I would like to ask you about Hemlibra. At the end of last year, the EU and US share was 34% and Japan's share was about 26%. It seems that Factor VIII is still being used in a significant portion of the market. Although the COVID-19 pandemic has had an impact, do you anticipate that conversion or switching is likely to accelerate in the future? Looking at Roche's financial results for Q1 of this fiscal year, I have the impression that growth is a bit sluggish. I wouldn't say it is a peak, but what is your view on this?

**Hidaka [A]:** This is Hidaka. I would like to answer in terms of domestic sales.

On page six, the market share is shown on the bottom right. In Q1 of 2022, the figure is 27.9%, which is a gain of 1.7% points compared to Q4 last year. As you can see, the range of gain is a little larger than in the past, and there is a sense that the number of new patients has increased a little. This has been especially true since the release of epidemic prevention measures, so there is still plenty of room for growth in the future.

**Okuda [A]:** Okuda here.

As explained earlier, the situation at Roche was 33% in Q4 last year, and then 34%, which is up 1% point. A previous questioner asked if this was a slowdown in sales, but since the 1% point is in the range of rounding, it is too early to judge this at this point. It is necessary to look at the Q2 and Q3 results to see the change.

**Sakai [Q]:** So, it is my understanding that there is still plenty of room for further switching from Factor VIII?

**Okuda [A]:** Yes, that's right.

**Sakai [Q]:** Finally, I would like to ask about Ronapreve. We know that this is government procurement, but it has already been disclosed that it is not very effective against Omicron. What is the impact of this, and should it be considered in the future? I understand that the contract and other details remain unchanged at present.

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**Tetsuya Yamaguchi [A]:** I am Yamaguchi.

Currently, use in Omicron's BA.1 variant is not recommended in the administrative communication due to its significant decrease in neutralizing activity. We are currently looking at the BA.2 variant, and we will be examining the neutralizing activity or the possibility of neutralizing this variant.

On the other hand, we have heard that the use of antibodies from other companies has been suspended in the US, I think because of reduced activity with BA.2. Our current research situation is that there are considerable differences among the variants of Omicron.

We continue to measure and look at the possibility of activity against various mutations.

**Sakai [M]:** I understand. Thank you very much.

**Sasai [M]:** Thank you very much.

Next, Mr. Saito of the Nikkei Shimbun.

**Saito [Q]:** This is Saito from Nihon Keizai Shimbun.

Regarding Ronapreve, I understand that the contract for the current fiscal year is as agreed, but are negotiations underway for FY2023? You mentioned earlier that the supply has been secured as a reserve against future mutations. What are your thoughts on the current supply possibilities for the next fiscal year and beyond? Thank you.

**Tetsuya Yamaguchi [A]:** This is Yamaguchi.

As you are already aware, Ronapreve is under discussion in the government's single-year budget. We have concluded a contract for the current fiscal year through March of next year. At present, we are not sure of the status looking further into the future.

**Saito [M]:** I understand. Thank you very much.

**Sasai [M]:** Thank you very much.

Next, Mr. Kamio from Mix.

**Kamio [Q]:** I'm Kamio from Mix.

I would like to ask about the organizational changes that come into effect on July 1. In sales, you mentioned that you are reorganizing from an area-centered structure to a two-field structure of oncology and specialty. Could you give some more information on the background behind that decision?

**Hidaka [A]:** This is Hidaka.

We have decided to set two categories: oncology and specialty. As we have already announced, there has been a considerable increase in the number of specialty areas in primary care, such as ophthalmology and neurology, which we have entered. The number of areas in which we have entered has increased, so we have changed our structure to pursue more specialization. In order to change the structure, we have divided oncology and specialty into two separate fields.

Of course, the MRs and managers will be working with fewer items, so we anticipate that this will lead to more specialized strategic planning and execution.

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**Kamio [Q]:** In relation to what you just said, in the specialty field, are you going to subdivide and place the activities quite a bit, like the ophthalmology or neurology?

**Hidaka [A]:** No, we are currently planning to do that part in the form of a so-called specialty batch.

**Kamio [M]:** Thank you very much.

**Sasai [M]:** Thank you very much.

As there are no further questions, we will now conclude the Q1 conference call. If you have any further questions, please contact the corporate communications department.

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

[END]

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