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**CHUGAI PHARMACEUTICAL CO., LTD.**

 A member of the Roche group

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

Conference on FY 2023.12 Q1 Financial Results

April 27, 2023

## Event Summary

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<b>[Company Name]</b>	CHUGAI PHARMACEUTICAL CO., LTD.	
<b>[Company ID]</b>	4519-QCODE	
<b>[Event Language]</b>	JPN	
<b>[Event Type]</b>	Earnings Announcement	
<b>[Event Name]</b>	Conference on FY 2023.12 Q1 Financial Results	
<b>[Fiscal Period]</b>	FY2023 Q1	
<b>[Date]</b>	April 27, 2023	
<b>[Number of Pages]</b>	34	
<b>[Time]</b>	19:30 – 20:31 (Total: 61 minutes, Presentation: 35 minutes, Q&A: 26 minutes)	
<b>[Venue]</b>	Webcast	
<b>[Venue Size]</b>		
<b>[Participants]</b>		
<b>[Number of Speakers]</b>	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 Division
	Toshiya Sasai	Head of Corporate Communications Department
<b>[Analyst Names]*</b>	Shinichiro Muraoka	Morgan Stanley MUFG Securities
	Seiji Wakao	JPMorgan Securities
	Motoya Kohtani	Nomura Securities
	Hidemaru Yamaguchi	Citigroup Global Markets
	Kasumi Haruta	Credit Suisse Securities

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

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# Presentation

**Sasai:** Good evening, everyone. Thank you very much for joining us for the financial results briefing for FY2023 Q1. I am Sasai from Corporate Communications, and I will be facilitating today's session. Thank you.

Today we will be conducting a financial results presentation via Zoom webinar. The meeting agenda is shown on the web page and on page three of the presentation materials. Our presentation will follow the contents of the presentation materials.

Questions will be taken in batches after all presentations have been completed. The Q&A is expected to last approximately 30 minutes.

Dr. Okuda will now give an overview of Q1 of FY2023.

## FY2023 Q1 Overview



# Financial Overview

- Increases in revenue and profits were mainly driven by good penetration of new/mainstay products and steady growth of exports to Roche
- Excluding COVID-19-related drug impact, full-year revenue and profit are expected to increase, with no changes to the initial forecast

Core (billions of JPY)	2022 Jan -Mar actual*	2023 Jan -Mar actual	Growth		2023 Jan - Dec forecast	Progress (%)
<b>Revenue</b>	<b>268.4</b>	<b>312.2</b>	<b>+43.8</b>	<b>+16.3%</b>	<b>1,070.0</b>	<b>29.2%</b>
Domestic sales	161.7	192.7	+31.0	+19.2%	541.7	35.6%
Overseas sales	81.0	98.8	+17.8	+22.0%	378.3	26.1%
Other revenue	25.7	20.7	-5.0	-19.5%	150.0	13.8%
<b>Operating profit</b>	<b>98.9</b>	<b>105.4</b>	<b>+6.5</b>	<b>+6.6%</b>	<b>415.0</b>	<b>25.4%</b>
Operating margin	36.8%	33.8%	-3.0pts	-	38.8%	-
<b>Net income</b>	<b>70.6</b>	<b>78.4</b>	<b>+7.8</b>	<b>+11.0%</b>	<b>306.0</b>	<b>25.6%</b>
<b>EPS (yen)</b>	<b>42.91</b>	<b>47.66</b>	<b>+4.75</b>	<b>+11.1%</b>	<b>186.00</b>	<b>25.6%</b>

- Domestic sales grew mainly due to the supply of Ronapreve to the government and the good market penetration of new/mainstay products despite the impact of NHI drug price revision and generics. Domestic sales excl. Ronapreve maintained steady growth at 111.5 billion yen (+ 10.5%)
- Overseas sales increased mainly due to Alecensa and Actemra exports to Roche
- Other revenue decreased due to the termination of royalty income from initial shipments of Hemlibra

\* Starting from FY2023, Chugai has excluded income from disposal of product rights from revenue. In conjunction with this change, the results for FY 2022 have been restated accordingly.

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**Okuda:** Hello. I will provide a summary of results for Q1 of 2023. Please see page five.

Revenue increased 16.3% YoY, while operating profit and net income rose 6.6% and 11%, respectively. Exports to Roche of in-house developed products, new and mainstay products in domestic market remain solid.

Our core businesses in Japan and overseas are growing steadily. We expect both sales and income to increase as expected for the full year, excluding the impact of COVID-19 related therapies.

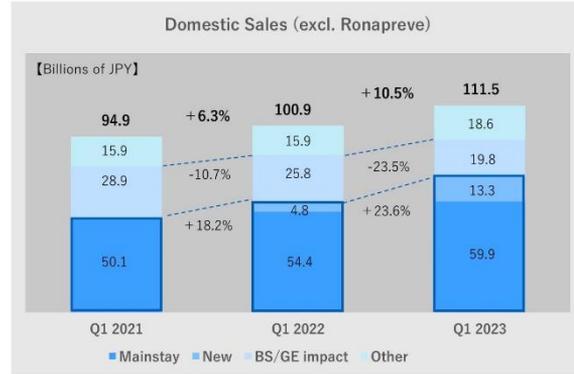
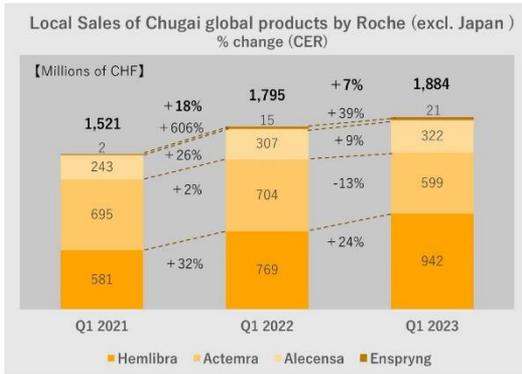
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## Progress of Q1 Sales of Chugai Global Products and Domestic Sales

- Local sales of Chugai global products by Roche are steadily penetrating the market, mainly due to Hemlibra
- Domestic sales increased by the good performance of new/mainstay products, surpassing the negative impacts of biosimilars/generic drugs



Hemlibra: Patient Share in Hemophilia A in Japan

Q4 2021	Q1 2022	Q2 2022	Q3 2022	Q4 2022	Q1 2023
24.7%	26.3%	27.3%	28.5%	29.2%	30.0%

Mainstay products: Tecentriq, Hemlibra, Actemra, Perjeta, Alecensa, Enspryng, Kadcyla  
 New products: Polivy, Evrysdi, Vabysmo  
 Products impacted by BS/GE: Avastin, Herceptin, Rituxan, Edrol, Oxarol, CellCept

Next, I will explain the trends in Q1 global sales of our in-house products and domestic sales compared to the previous two fiscal years.

See the graph on the left. This shows local sales trends by Roche for four of our in-house global products.

The bar graph, from the bottom, shows the results of Hemlibra, Actemra, Alecensa, and Enspryng. Compared to FY2022, sales of Actemra declined by a double-digit percentage due to a decrease in COVID-19 demand.

Meanwhile, sales of Hemlibra and other products have steadily increased, with total sales up 7% YoY and steady market penetration.

The graph on the right shows domestic sales, excluding Ronapreve.

The total increase in sales of mainstay and new products offset the decline in sales resulting from competition with generics. Overall domestic sales grew steadily, up 10.5% YoY.

Hemlibra's patient share in the US and Europe grew steadily, up 1% from the previous quarter to 37%, and in Japan, to 30.0%.

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## Updates of In-house Developed Late-stage Products

Crovalimab and nemolizumab sequentially achieved primary endpoints in the pivotal studies

Product	Expected indication	Pivotal Study	Medical conference	Expected file/launch year
 Initiated by Roche	PNH	COMMODORE2 met primary endpoints and the other P3 study COMMODORE1 supported the favorable benefit-risk profile in February 2023	To be presented at EHA 2023 (June 8-11)	To be filed in H1 2023 (JP/US/EU) * In China, filed in 2022
 Initiated by Galderma	Atopic dermatitis	Two P3 studies (ARCADIA1/2) met all co-primary endpoints and key secondary endpoints in Q1 2023	To be presented in H2 2023	To be launched in H2 2024 (US)
 Initiated by Eli Lilly and Company	Prurigo nodularis	OLYMPIA2 met all primary endpoints and all key secondary endpoints. The other P3 study OLYMPIA1 is on track.	Results of OLYMPIA 2 were presented as a late-breaking presentation at AAD in March 2023	To be launched in H2 2024 (US)
	Type 2 diabetes	P3 study scheduled to start in H1 2023	–	–
	Obesity	P3 study scheduled to start in H1 2023	–	–

EHA : European Hematology Association    AAD : American Academy of Dermatology Association

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This covers R&D updates. Please see page seven.

Our in-house developed late-stage products are showing steady progress. Crovalimab has shown positive results in two global Phase III trials in paroxysmal nocturnal hemoglobinuria. Detailed study results will be presented at the European Hematology Congress in June. Regulatory submissions are scheduled to be filed in Japan, the US, and Europe in H1 of this fiscal year.

Nemolizumab is being developed for atopic dermatitis and prurigo nodosa by Galderma, an overseas licensee.

For atopic dermatitis, two Phase III trials have met all primary endpoints and detailed results will be presented later this year.

Detailed results of the OLYMPIA 2 trial in prurigo nodosa were also presented at the late-breaking session of the American Academy of Dermatology in March. Mr. Yamaguchi will discuss this later. Both indications are expected to be launched in the US in H2 of FY2024.

Finally, Eli Lilly and Company is developing orforglipron globally. Our development code is OWL833. This is scheduled to start separate Phase III trials for type 2 diabetes and obesity in H1 of this fiscal year.

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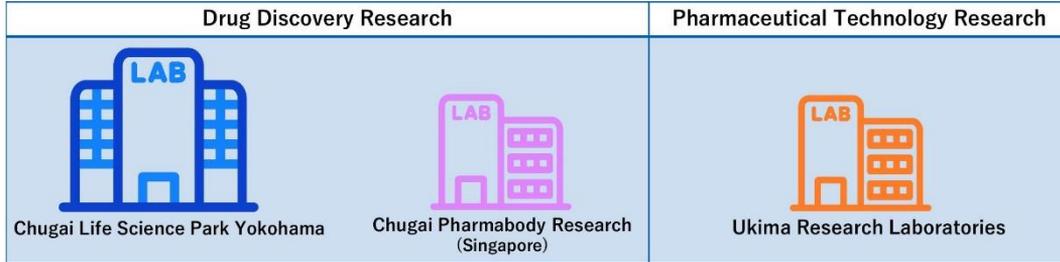
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## Research Facilities for Drug Discovery and Pharmaceutical Technology

Chugai Life Science Park Yokohama started full operation in April, integrating Fuji Gotemba and Kamakura Research Laboratories



■ Progress toward relocation of the research laboratories

Research laboratory	Site area	Buyer	Planned disposition date
Fuji Gotemba research lab.	142,285m <sup>2</sup>	Yoshicon Co., Ltd.	2023 Q4 (as-is)
Kamakura research lab. South side site	53,945m <sup>2</sup>	HASEKO Corporation	2023 Q3 (as-is)
Kamakura research lab. North side site	35,359m <sup>2</sup>	Takasago International Corporation	2025 Q4 (vacant site)

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Next, I will present the status of our drug discovery and pharmaceutical research bases.

In drug discovery research, the Chugai Life Science Park Yokohama (Chugai LSP Yokohama), which integrated the Fuji Gotemba research laboratories and the Kamakura research laboratories, began full operation in April. Chugai LSP Yokohama will work with Chugai Pharmabody Research in Singapore to maximize our drug discovery capabilities. Pharmaceutical technology research will continue to be handled by the Ukima Research Laboratories.

The timescale for disposition of the Fuji Gotemba laboratories and the Kamakura research laboratories is also shown in the lower platform of this slide.

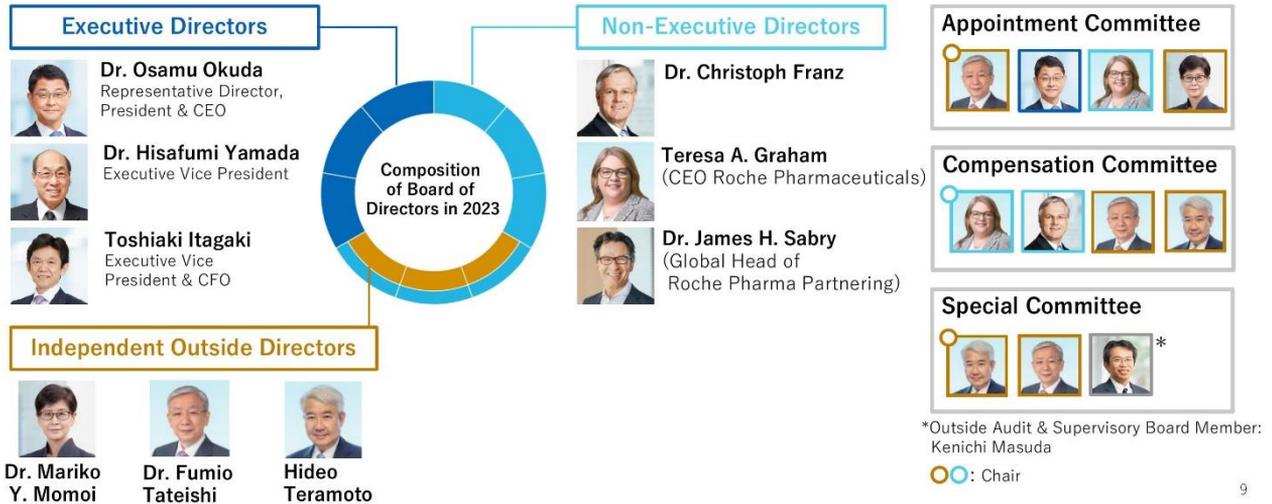
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# Composition of Board of Directors (as of April 1, 2023)

Diverse personnel composition from Chugai, outside the company, and Roche



This is page nine. Next, I would like to introduce the composition of our Board of Directors.

Three new members have been appointed, and we are now operating under a new structure. As a non-executive director, Ms. Teresa A. Graham joined from Roche to chair the Compensation Committee.

Dr. Fumio Tateishi and Mr. Hideo Teramoto joined as independent outside directors, assuming the positions of Chair of the Nominating Committee and the Special Committee, respectively.

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# Early Retirement Incentive Program

<b>Background</b>	<ul style="list-style-type: none"> <li>Increased difficulty in developing new drugs, promotion of measures to curb medical/pharmaceutical expenses in Japan and overseas, expansion of market penetration of generic drugs and biosimilars and other factors, further accelerated the severe business environment</li> <li>Change in business activities associated with the advancement of digital technology</li> </ul>												
<b>Purpose</b>	<ul style="list-style-type: none"> <li>Swift response to the drastically changing business environment and our management issues, and implement structural reform toward strategic resource allocation</li> <li>Support for employees who retire early and seek new opportunities due to diversified views on work and lifestyles</li> </ul>												
<b>Outline</b>	<table border="0"> <tbody> <tr> <td style="padding-left: 20px;">➤ Eligible employees</td> <td>Employees aged 40 or over [Detailed criteria are specified separately]</td> </tr> <tr> <td style="padding-left: 20px;">➤ Application period</td> <td>From April 3 to April 21, 2023</td> </tr> <tr> <td style="padding-left: 20px;">➤ Retirement date</td> <td>June 30, 2023</td> </tr> <tr> <td style="padding-left: 20px;">➤ Number of applicants</td> <td>374 employees</td> </tr> <tr> <td style="padding-left: 20px;">➤ Incentives</td> <td>(i) Special additional allowance on top of regular retirement allowance (ii) Reemployment support services</td> </tr> <tr> <td style="padding-left: 20px;">➤ Impact on financial performance</td> <td>Special additional allowance and other expenses related to this program of approximately JPY 10.4 billion will be reported as Non-Core item *Negligible impact on the forecast for FY2023 consolidated core results</td> </tr> </tbody> </table>	➤ Eligible employees	Employees aged 40 or over [Detailed criteria are specified separately]	➤ Application period	From April 3 to April 21, 2023	➤ Retirement date	June 30, 2023	➤ Number of applicants	374 employees	➤ Incentives	(i) Special additional allowance on top of regular retirement allowance (ii) Reemployment support services	➤ Impact on financial performance	Special additional allowance and other expenses related to this program of approximately JPY 10.4 billion will be reported as Non-Core item *Negligible impact on the forecast for FY2023 consolidated core results
➤ Eligible employees	Employees aged 40 or over [Detailed criteria are specified separately]												
➤ Application period	From April 3 to April 21, 2023												
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➤ Number of applicants	374 employees												
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➤ Impact on financial performance	Special additional allowance and other expenses related to this program of approximately JPY 10.4 billion will be reported as Non-Core item *Negligible impact on the forecast for FY2023 consolidated core results												

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This is the last slide from me. I would like to explain the early retirement incentive program announced in today's press release.

We implemented the early retirement incentive program in order to promptly respond to our management issues in the drastically changing business environment, to promote structural reforms, and to support employees who are considering a new career by retiring early due to the diversification views on work and lifestyles. A total of 374 applicants responded.

The JPY10.4 billion special additional allowance will be recorded as a non-core item.

That is all from me.

**Sasai:** Now, Mr. Itagaki will give an overview of the consolidated financial results for Q1.

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## P/L Jan – Mar (Non-core adjustment)

(Billions of JPY)	IFRS results	Non-core items		Core results	Non-core items	
		Intangible assets	Others		Intangible assets	Others
<b>Revenue</b>	<b>312.2</b>			<b>312.2</b>		
Sales	291.5			291.5		
Other revenue	20.7			20.7		
Cost of sales	-151.3	+0.3		-151.0		
Research and development	-42.9	+4.9	+1.9	-36.1		
Selling, general and administration	-21.0		+0.0	-21.0		
Other operating income (expense)	1.3		+0.0	1.3		
<b>Operating profit</b>	<b>98.3</b>	<b>+5.2</b>	<b>+1.9</b>	<b>105.4</b>		
Financial account balance	1.4			1.4		
Income taxes	-26.2	-1.6	-0.6	-28.3		
<b>Net income</b>	<b>73.5</b>	<b>+3.6</b>	<b>+1.3</b>	<b>78.4</b>		
<b>EPS (JPY)</b>	<b>44.67</b>			<b>47.66</b>		

		(Billions of JPY)
<b>Intangible assets</b>		
Amortization		+0.5
Impairment		+4.7
<b>Others</b>		
Restructuring expenses, etc.		+1.9

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**Itagaki:** Thank you. This is a detailed presentation of the financial figures. See page 12.

The adjustment items remain the same as before, as shown on the right.

Impairment losses amounted to JPY4.7 billion. This includes the previously announced impairment loss due to the termination of the license agreement with TWOCELLS COMPANY for knee cartilage regeneration cell therapy products.

If you look at the adjustment in operating profit, we have added back JPY7.1 billion, which means that the core result is JPY105.4 billion. From here, the explanation will focus on non-core results.

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# P/L (2022 Jan – Mar) Renaming and Reclassification

(Billions of JPY)	2022 Actual
<b>Revenue</b>	<b>268.6</b>
Sales	242.7
Domestic	161.7
Overseas	81.0
Royalties and other operating income	25.9
Royalty and profit-sharing income	25.2
Other operating income	0.7
<b>Cost of sales</b>	<b>- 114.1</b>
(cost to sales ratio)	47.0%
<b>Operating expenses</b>	<b>- 55.6</b>
M&D and G&A	- 22.7
Research and development	- 32.9
<b>Operating profit</b>	<b>98.9</b>
(operating margin)	36.8%
<b>Net income</b>	<b>70.6</b>
<b>EPS (JPY)</b>	<b>42.91</b>

Blue text :renamed categories

0.2 billion JPY

Income from disposal of product rights is reclassified to the new category "Other operating income (expense)"

0.0 billion JPY

Income and expenses associated with operating activities that were previously included in "G&A" but could not be classified into functional expense categories such as gain (loss) on sale of land and buildings, etc., is reclassified to the new category "Other operating income (expense)"

(Billions of JPY)	2022 Actual
<b>Revenue</b>	<b>268.4</b>
Sales	242.7
Domestic	161.7
Overseas	81.0
Other revenue	25.7
Cost of sales	- 114.1
(cost to sales ratio)	47.0%
Research and development	- 32.9
Selling, general and administration	- 22.7
Other operating income (expense)	0.2
<b>Operating profit</b>	<b>98.9</b>
(operating margin)	36.8%
<b>Net income</b>	<b>70.6</b>
<b>EPS (JPY)</b>	<b>42.91</b>

For 2022 results in the following slides, categories are after renaming and reclassification.

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See page 13. As already indicated in the previous announcement of financial results, we have changed or reclassified the presentation starting from this fiscal year.

For comparison, we have made the same reclassification for the previous fiscal year's Q1 results. As you can see here, revenue is down JPY200 million, but operating profit remains the same. The previous year's figures used in the following slides are after this reclassification.

# P/L Jan – Mar (Year on Year)

(Billions of JPY)	2022	2023	Growth	
<b>Revenue</b>	<b>268.4</b>	<b>312.2</b>	+ 43.8	+ 16.3%
Sales	242.7	291.5	+ 48.8	+ 20.1%
Domestic	161.7	192.7	+ 31.0	+ 19.2%
Overseas	81.0	98.8	+ 17.8	+ 22.0%
Other revenue	25.7	20.7	- 5.0	- 19.5%
Cost of sales	-114.1	-151.0	- 36.9	+ 32.3%
(cost to sales ratio)	47.0%	51.8%	+4.8%pts	-
Research and development	-32.9	-36.1	- 3.2	+ 9.7%
Selling, general and administration	-22.7	-21.0	+ 1.7	- 7.5%
Other operating income (expense)	0.2	1.3	+ 1.1	+ 550.0%
<b>Operating profit</b>	<b>98.9</b>	<b>105.4</b>	+ 6.5	+ 6.6%
(operating margin)	36.8%	33.8%	-3.0%pts	-
Financial account balance	-0.8	1.4	+ 2.2	-
Income taxes	-27.5	-28.3	- 0.8	+ 2.9%
<b>Net income</b>	<b>70.6</b>	<b>78.4</b>	+ 7.8	+ 11.0%
<b>EPS (JPY)</b>	<b>42.91</b>	<b>47.66</b>	+4.75	+ 11.1%

## Domestic sales

Increase due to sales growth of new products as well as mainstay products

## Overseas sales

Increase in sales of Alecensa and Actemra

## Other revenue

Decrease due to end of royalty income for initial shipping inventory of Hemlibra

## Cost of sales

Cost to sales ratio higher due to a change in product mix, impact from foreign exchange, etc.

## Research and development

Increase due to investments in research and early development, including start of operation of Chugai Life Science Park Yokohama, progress of development projects, etc.

## Selling, general and administration

Decrease in various expenses

## Other operating income (expense)

Increase in income due to gain on sales of property, plant and equipment, etc.

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Now look at the next page, page 14. The following table compares the results of the current period with those of the previous period.

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Revenue was JPY312.2 billion, an increase of 16.3%.

Domestic sales, including Ronapreve, grew 19.2% due to strong sales of new products and mainstay products. Overseas sales grew 22% due to an increase in sales of Alecensa and Actemra.

Other revenue decreased by 19.5% due to the termination of royalty income related to the initial shipment of Hemlibra, the so-called Royalty 2.

The cost of sales increased 4.8% to 51.8% due to changes in the product mix and the impact of foreign exchange rates.

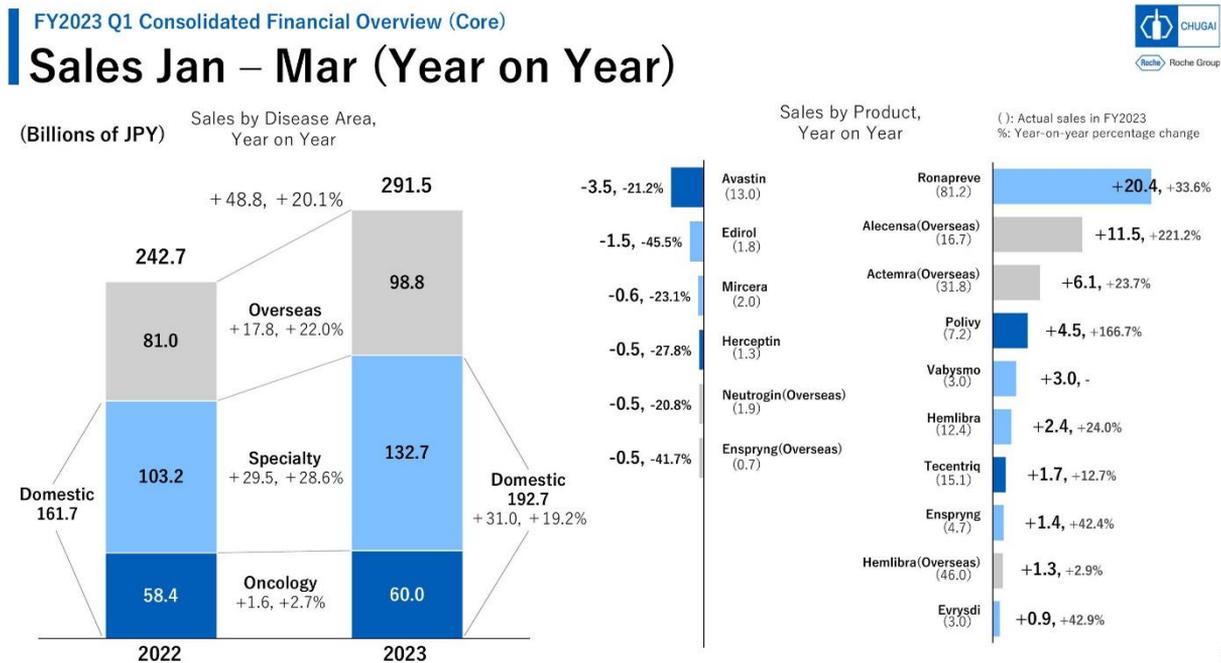
R&D expenses increased by 9.7% due to the amortization of the new laboratory in Yokohama and the progress of development projects.

On the other hand, SG&A expenses decreased in such areas as overhead costs.

Other operating income included a gain on the sale of land, resulting in a income of JPY1.3 billion.

As a result, operating profit was JPY105.4 billion, an increase of 6.6%, and the operating margin was 33.8%.

After subtracting financial account balance, income taxes, and other similar items, net income increased by 11% to JPY78.4 billion. We have seen a record high for Q1 in terms of sales, operating profit, and net income.



Next, on page 15 is a breakdown of changes in sales of manufactured goods.

From the bottom left, sales in the domestic oncology area grew 2.7%. Sales grew for the individual products on the right side, such as Polivy and Tecentriq, in dark blue. The impact of biosimilars on sales of products, such as Avastin and Herceptin, was absorbed.

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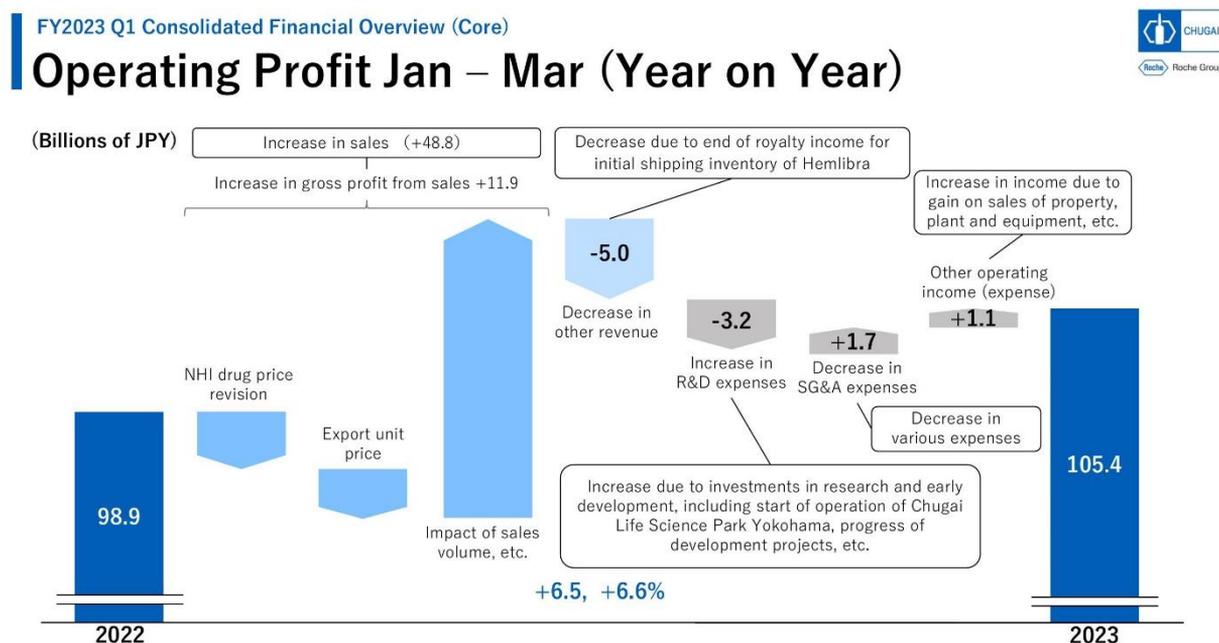
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Next, in the specialty area, there has been a 28.6% increase in revenue. The top right-hand column shows an increase of JPY20.4 billion for Ronapreve, which is a very large contribution to the total sales. Even if we exclude Ronapreve, the increase in revenue in the specialty area is JPY9.1 billion, an increase of 21.5%.

Looking at individual products, sales of Vabysmo, Hemlibra, and Enspryng are also growing.

Overseas sales remained strong, with a 22% increase in total sales. Alecensa, Actemra, and Hemlibra all saw higher exports YoY. There are various reasons for this, including the timing of shipments.



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The next page, page 16, shows the breakdown of changes in operating profit.

The second to fourth bars from the left provide a factor breakdown of the increase in gross profit. First, there is a negative impact from the price revision and the unit price of exports. These were absorbed by the increase in volume, resulting in a net increase of JPY11.9 billion.

Next, other revenue is negative JPY5 billion. Of this, JPY8.1 billion is included in the negative Royalty 2, so other income is up JPY3.1 billion from the previous year.

Changes in R&D, SG&A, and other operating income are as shown here.

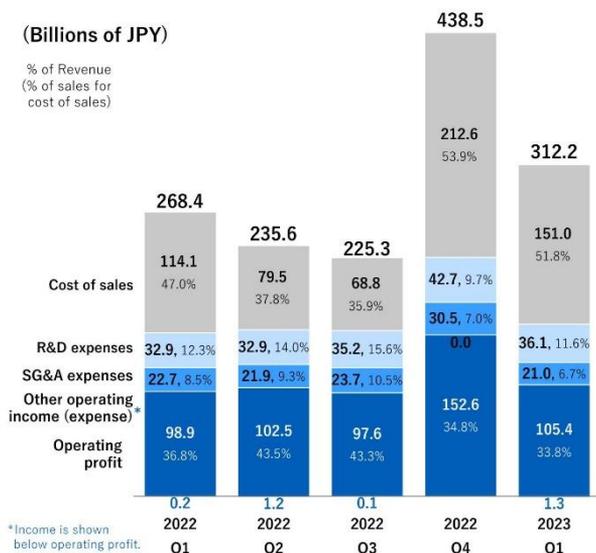
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# Structure of Costs and Profit by Quarter



## Year on Year (2022 Q1)

**Cost of sales ratio:** higher due to a change in product mix, impact from foreign exchange, etc.

**R&D expenses:** increase due to investments in research and early development, including start of operation of Chugai Life Science Park Yokohama, progress of development projects, etc.

**SG&A expenses:** decrease in various expenses

**Other operating income (expense):** increase in income due to gain on sales of property, plant and equipment, etc.

**Operating profit:** +6.5 billion JPY, +6.6%

## Quarter on Quarter (2022 Q4)

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

**R&D expenses:** decrease in line with the trend of previous years

**SG&A expenses:** decrease in line with the trend of previous years

**Other operating income (expense):** increase in income due to gain on sales of property, plant and equipment, etc.

**Operating profit:** -47.2 billion JPY, -30.9%

Next, page 17. The next three slides cover quarterly trends.

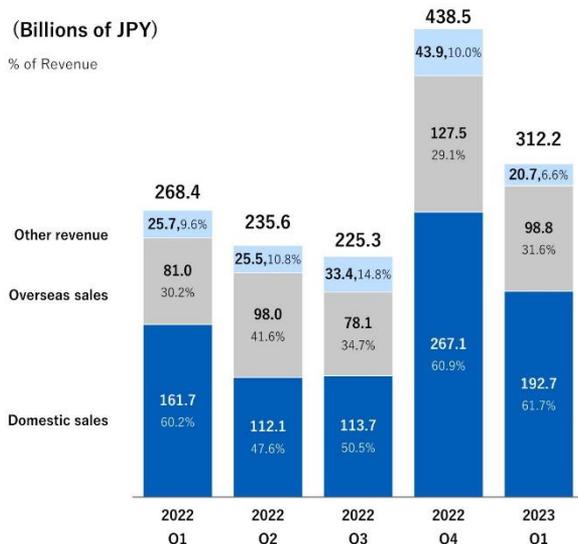
As you can see, sales in the preceding Q4 were much higher YoY. The quarterly trends are a little bumpy due to the timing of government deliveries of Ronapreve.

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## Structure of Revenue by Quarter



### Year on Year (2022 Q1)

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

**Overseas sales:** increase in sales of Alecensa and Actemra

**Other revenue:** decrease due to end of royalty income for initial shipping inventory of Hemlibra

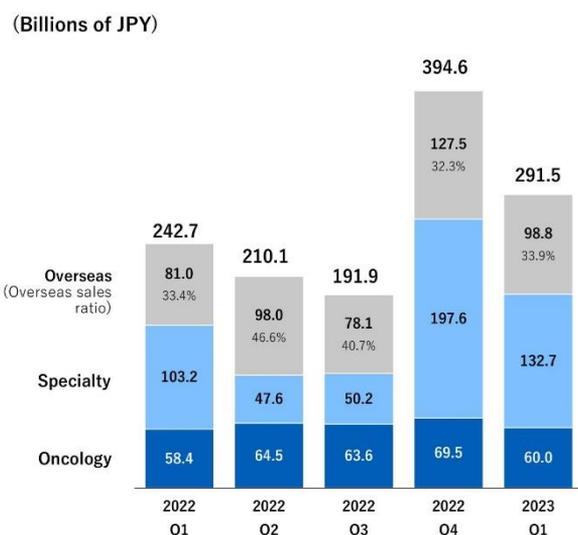
### Quarter on Quarter (2022 Q4)

**Domestic sales:** significant decrease in line with the trend of previous years and sales of Ronapreve

**Overseas sales:** significant decrease in sales of Actemra and Hemlibra

**Other revenue:** decrease in income related to Hemlibra and Alecensa

## Structure of Sales by Quarter



### Year on Year (2022 Q1)

<b>Oncology</b>	Polivy:	+4.5	Tecentriq:	+1.7
	Avastin:	-3.5		
<b>Specialty</b>	Ronapreve:	+20.4	Vabysmo:	+3.0
	Hemlibra:	+2.4	Enspryng:	+1.4
	Edirol:	-1.5		
<b>Overseas</b>	Alecensa:	+11.5	Actemra:	+6.1
	Hemlibra:	+1.3		

### Quarter on Quarter (2022 Q4)

<b>Oncology</b>	Avastin:	-3.6	Tecentriq:	-2.0
	Alecensa:	-1.4	Perjeta:	-1.2
<b>Specialty</b>	Ronapreve:	-61.6	Hemlibra:	-1.7
	Actemra:	-1.6		
<b>Overseas</b>	Actemra:	-18.5	Hemlibra:	-12.7
	Alecensa:	+3.2		

Ronapreve sales were JPY60.8 billion in Q1 last year, then JPY142.8 billion for Q4 of last year, and now JPY81.2 billion for Q1 of this year. Besides these factors, there are no other major changes to mention.

Due to the limited time available today, I will skip the explanation of these quarterly transition slides.

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## P/L Jan – Mar (vs. Forecast)

(Billions of JPY)	Actual	Forecast		2022
	2023 Jan - Mar	2023 Jan - Dec	Progress	Progress*
<b>Revenue</b>	<b>312.2</b>	<b>1,070.0</b>	<b>29.2%</b>	<b>23.0%</b>
Sales	291.5	920.0	31.7%	23.4%
Domestic	192.7	541.7	35.6%	24.7%
Overseas	98.8	378.3	26.1%	21.1%
Other revenue	20.7	150.0	13.8%	20.0%
Cost of sales	- 151.0	- 405.0	37.3%	24.0%
(cost to sales ratio)	51.8%	44.0%	-	-
Research and development	- 36.1	- 165.0	21.9%	22.9%
Selling, general and administration	- 21.0	- 100.0	21.0%	23.0%
Other operating income (expense)	1.3	15.0	8.7%	14.3%
<b>Operating profit</b>	<b>105.4</b>	<b>415.0</b>	<b>25.4%</b>	<b>21.9%</b>
(operating margin)	33.8%	38.8%	-	-
<b>Net income</b>	<b>78.4</b>	<b>306.0</b>	<b>25.6%</b>	<b>22.2%</b>
<b>EPS (JPY)</b>	<b>47.66</b>	<b>186.00</b>	<b>25.6%</b>	<b>22.2%</b>

### Domestic sales

Overall progress nearly in line with forecast  
(2023 progress excluding Ronapreve: 24.2%  
2022 progress excluding Ronapreve: 22.4%)

### Overseas sales

Progress nearly in line with forecast

### Other revenue

Progress nearly in line with forecast

### Cost of sales

Cost to sales ratio nearly in line with Q1 forecast

### Research and development

Progress nearly in line with forecast

### Selling, general and administration

Progress nearly in line with forecast

### Other operation income (expense)

Progress nearly in line with forecast

\* Jan-Mar progress versus Jan-Dec actual

20

We will jump to page 20. Page 20 shows progress against the full year forecast.

The progress rate of revenue is 29.2%, which is 6.2% better than last year.

The Q1 progress for domestic sales, excluding Ronapreve, is 24.2%, which is 1.8% less than last year's figure.

This 1.8% difference in progress is also due to the timing of overseas sales shipments and other factors. Including these factors, revenue progress is generally in line with our expectations.

There is no particular discrepancy with the plan in terms of cost at this point, so the project is on track to meet our expectations.

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## Sales Jan – Mar (vs. Forecast)

(Billions of JPY)	Actual	Forecast		2022	(Billions of JPY)	Actual	Forecast		2022
	2023 Jan - Mar	2023 Jan - Dec	Progress	Progress *		2023 Jan - Mar	2023 Jan - Dec	Progress	Progress *
<b>Sales</b>	<b>291.5</b>	<b>920.0</b>	<b>31.7%</b>	<b>23.4%</b>	<b>Specialty</b>	<b>132.7</b>	<b>288.4</b>	<b>46.0%</b>	<b>25.9%</b>
<b>Domestic</b>	<b>192.7</b>	<b>541.7</b>	<b>35.6%</b>	<b>24.7%</b>	Ronapreve	81.2	81.2	100.0%	29.8%
<b>Oncology</b>	<b>60.0</b>	<b>253.3</b>	<b>23.7%</b>	<b>22.8%</b>	Hemlibra	12.4	53.7	23.1%	20.3%
Tecentriq	15.1	67.7	22.3%	22.0%	Actemra	9.9	44.3	22.3%	23.1%
Avastin	13.0	48.1	27.0%	24.4%	Enspryng	4.7	21.6	21.8%	19.8%
Polivy	7.2	31.6	22.8%	17.4%	Vabysmo	3.0	17.4	17.2%	0.0%
Perjeta	7.5	31.0	24.2%	22.9%	Evrysdi	3.0	14.1	21.3%	18.3%
Alecensa	6.6	28.2	23.4%	21.8%	Mircera	2.0	7.6	26.3%	24.1%
Kadcyla	3.8	14.1	27.0%	22.7%	CellCept	1.6	6.7	23.9%	22.8%
Herceptin	1.3	4.9	26.5%	25.4%	Edirol	1.8	5.2	34.6%	29.5%
Gazyva	0.8	4.5	17.8%	25.0%	Other	13.1	36.7	35.7%	24.6%
Rituxan	0.9	3.7	24.3%	22.7%	<b>Overseas</b>	<b>98.8</b>	<b>378.3</b>	<b>26.1%</b>	<b>21.1%</b>
Foundation Medicine	1.9	8.3	22.9%	22.5%	Hemlibra	46.0	185.2	24.8%	23.1%
Other	1.9	11.2	17.0%	25.2%	Actemra	31.8	121.4	26.2%	19.7%
					Alecensa	16.7	50.4	33.1%	12.8%
					Enspryng	0.7	3.8	18.4%	42.9%
					Neutrogen	1.9	7.3	26.0%	27.6%
					Edirol	0.0	0.5	0.0%	0.0%
					Other	1.8	9.7	18.6%	22.6%

\* Jan - Mar progress versus Jan - Dec actual

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On the next page, we will look at progress on an individual product basis.

The oncology area in Japan is shown on the left, the specialty area in Japan is on the top right, and overseas products are on the bottom right. All of these products are generally progressing in line with initial forecasts. Referring to individual products, in oncology, Alecensa is doing well, while sales of Kadcyla and Gazyva are struggling a little. In the specialty area, Edirol is doing well.

However, we have only just completed Q1, and we will continue to move forward to achieve our forecast.

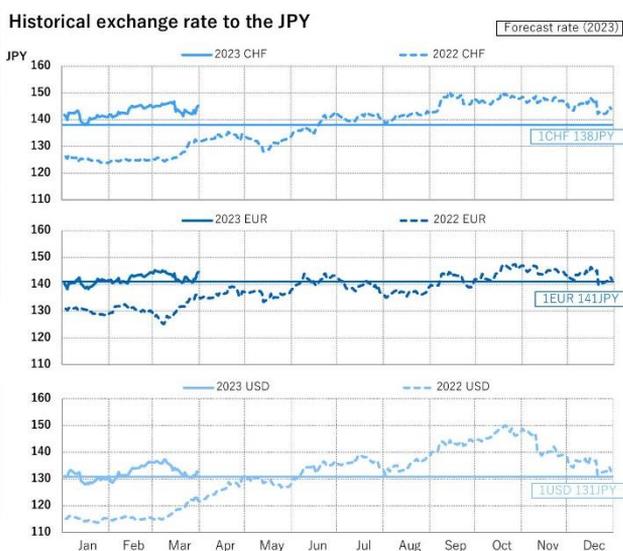
## Impact from Foreign Exchange Jan – Mar

(Billions of JPY)	vs. 2022 Actual rate	vs. 2023 Forecast rate
<b>Revenue</b>	<b>+11.9</b>	<b>-1.3</b>
Sales	+10.5	-0.6
Other revenue	+1.4	-0.7
<b>Cost of sales</b>	<b>-13.0</b>	<b>-0.0</b>
<b>Other than above*1</b>	<b>-0.9</b>	<b>-0.1</b>
<b>Operating profit</b>	<b>-2.0</b>	<b>-1.4</b>

Exchange rate (JPY)	2022 Jan - Mar Actual rate*2	2023 Jan - Mar Actual rate*2
1CHF	121.27	137.05
1EUR	130.68	141.96
1USD	111.13	132.79

\*1 Total of R&D expenses, SG&A expenses and other operating income (expense)  
\*2 Weighted average of the exchange rates used to record foreign currency transactions included in categories from revenue to operating profit



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Next, page 22. This slide shows the foreign exchange impact.

The dotted line in the graph on the right shows that the yen depreciated from January to December last year.

This year's hedging related to foreign currency transactions was recorded as a hedge over the past year. If the average of the hedges recorded is, say, Swiss francs, then JPY138 is the average hedge rate, which is the assumed rate.

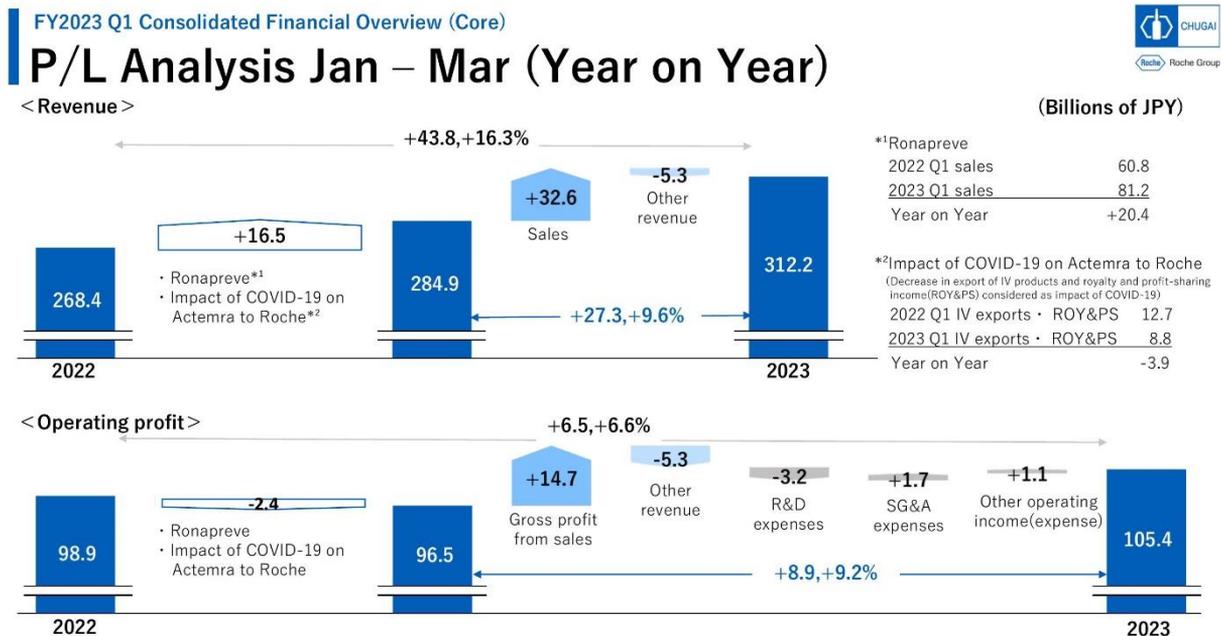
Individual hedges were taken during H1 of last year, with the yen slightly stronger than the assumed rate, and hedges were taken during H2, with the yen weaker than the assumed rate.

Therefore, the hedges used in Q1 of this year are those with a slightly higher yen than the assumed rate. If you look at the table on the left, for the assumed rate for Q1 against the yen, you will see a JPY1.3 billion unfavorable difference in earnings.

However, after one year, this full year, if all hedges are used, there will be no difference from the assumed rate, so I think it is correct to say that this difference is temporary.

On the other hand, if we look at the actual exchange rate of the previous year, the yen has weakened compared to the previous year's rate, so revenue is positive and cost of sales is negative.

However, the cost of sales was down JPY13 billion compared to the actual rate. This is due to the large impact of the depreciation of the yen on Ronapreve purchased last year, and the Ronapreve hedge on sales this year.



23

Let's move on to page 23. This is an analysis that takes into account how COVID-19 has affected revenues and profits in Q1.

If you look at the top right, in Q1, the government delivery of Ronapreve is JPY81.2 billion, a positive effect of JPY20.4 billion YoY.

In addition, the impact of Actemra IV exports means that there is a negative JPY3.9 billion YoY.

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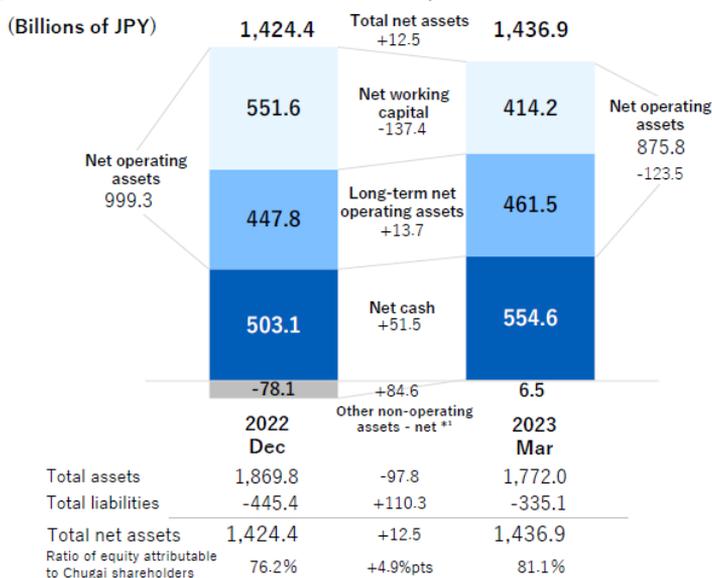
If you add these together, the total revenue impact is JPY16.5 billion. If you exclude the effect of COVID-19 drugs in Q1, how does it look compared to the previous year? If not excluded, we would see a revenue increase of 16.3%, but excluding the effect, we would see an increase of 9.6%.

Looking at operating profit in the same way, the core business increased by 6.6%, but the profit increase was 9.2%, so we can see from this slide that revenues and profits of the core business continue to be strong.

FY2023 Q1 Consolidated Financial Overview (Core)



## Financial Position (vs. 2022 Year End)



### Decrease in net working capital

Decrease in trade accounts receivable including Ronapreve

### Increase in long-term net operating assets

Increase in property, plant and equipment due mainly to the investment in manufacturing building for APIs\*2 (FJ3) at Fujieda Plant

### Increase in net cash

(See next slide)

### Increase in other non-operating assets – net

Increase due mainly to a decrease in accrued corporate tax

\* 1 E.g., deferred income tax assets, accrued corporate tax, etc.  
 \* 2 APIs: active pharmaceutical ingredients

See page 24. Here is the balance sheet situation.

If you look at the second line from the bottom on the left, total net assets increased by JPY12.5 billion from the end of the previous period to JPY1.4369 trillion.

The underlying shareholder equity ratio is 81.1%, which is a very robust financial position.

Net cash increased by JPY51.5 billion to JPY554.6 billion at the end of March, as shown in the middle of the chart.

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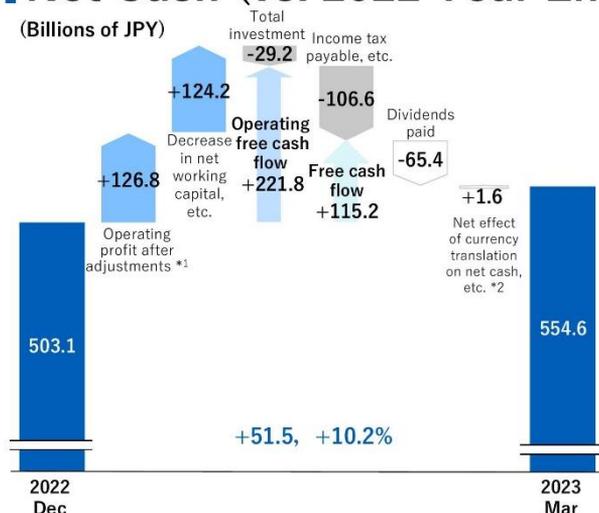
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# Net Cash (vs. 2022 Year End)

(Billions of JPY)



<b>Operating profit after adjustment *1</b>	<b>+126.8</b>
Operating profit *1	+98.3
Depreciation, amortization and impairment *1	+13.4
<b>Decrease in net working capital, etc.</b>	<b>+124.2</b>
Trade accounts receivable, accounts payable and inventory of Ronapreve	+56.6
<b>Total investment</b>	<b>-29.2</b>
Property, plant and equipment	-27.2
Payment for lease liabilities	-2.0
Intangible assets	-
<b>Operating free cash flow</b>	<b>+221.8</b>
<b>Income tax payable, etc.</b>	<b>-106.6</b>
Income tax payable	-95.6
<b>Free cash flow</b>	<b>+115.2</b>
<b>Dividends paid</b>	<b>-65.4</b>
<b>Net effect of currency transaction on net cash, etc. *2</b>	<b>+1.6</b>

\*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)

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The next page shows the breakdown of changes in net cash. This is page 25.

The first is cash flow from operating activities, the second one from the left. Adjusted operating profit, which is the amount of profit after adjustment for non-cash expenses, such as depreciation and amortization, is JPY126.8 billion. A decrease in working capital of JPY124.2 billion contributes to an increase in net cash.

This is due to the fact that payments related to Ronapreve, delivered to the government at the end of last year, remained as accounts receivable at the end of last year and have been collected in cash.

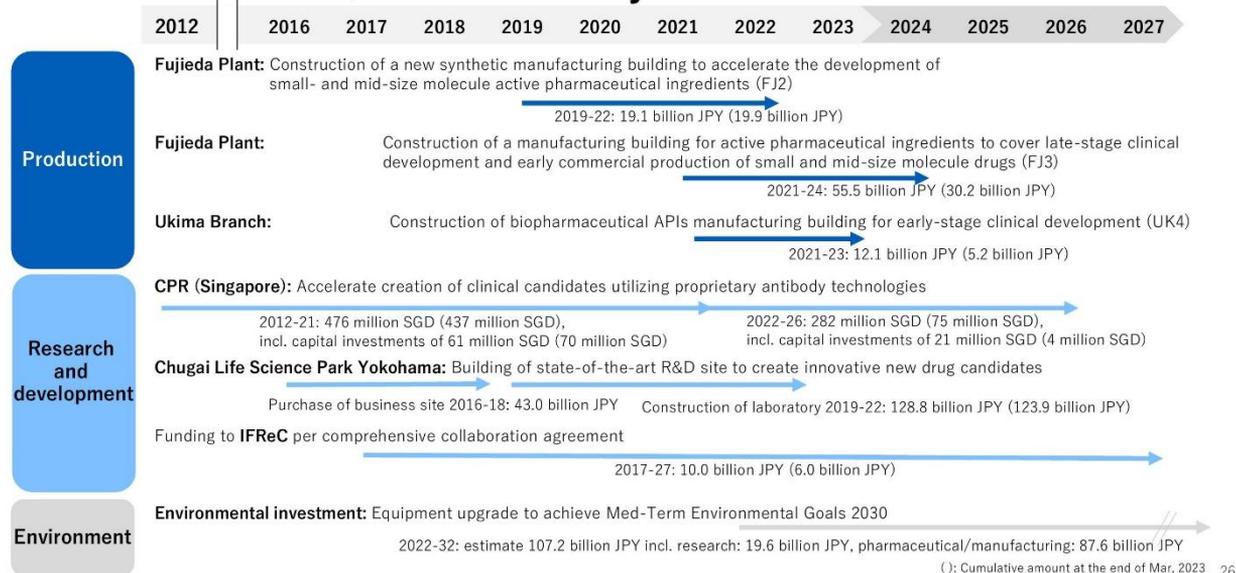
After deducting JPY29.2 billion in capital investment and other payments, operating free cash flow was a positive JPY221.8 billion, and after deducting last year's income tax payment and year-end dividend payment, net cash increased by JPY51.5 billion over the three-month period to JPY554.6 billion at the end of March.

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# Current Status / Plan for Major Investments



Next, page 26. Major investments have not changed. The actual amounts in these brackets have been updated since the end of last year.

Six months have passed since the completion of the Chugai Life Science Park Yokohama, and it has been in full operation since this April.

The bottom of the page is a column titled "Environment." This column includes information on investments in environmental measures, which we already explained at last year's ESG meeting. We are currently estimating that we will invest JPY107.2 billion in environmental conservation until 2032.

That is all from me.

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

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Approved	<b>Actemra/RG1569</b>	COVID-19 in hospitalized adult patients (Taiwan, Import drug license)	April 2023
Filed	<b>Actemra/RG1569</b>	Cytokine release syndrome induced by cancer treatment	February 2023
	<b>Vabysmo</b>	Macular Edema Associated with Retinal Vein Occlusion (RVO)	April 2023
New to pipeline	<b>Gazyva</b>	Pediatric nephrotic syndrome	P3(March 2023)
	<b>Vabysmo</b>	Angioid streaks	P3(March 2023)
	<b>giredestrant</b>	Breast cancer [1L-3L] (in combination with everolimus)	P3(April 2023)
	<b>GYM329/RG6237</b>	Facioscapulohumeral muscular dystrophy (FSHD)	P2(March 2023)
	<b>SAIL66</b>	CLDN6 positive solid tumors	P1(April 2023)
Readout in pivotal study	<b>crovalimab/RG6107</b>	Lupus nephritis (LN)	P1(February 2023)
	<b>crovalimab/RG6107</b>	Paroxysmal nocturnal hemoglobinuria (PNH) / COMMODORE1, COMMODORE2	February 2023
	<b>nemolizumab</b>	Atopic dermatitis / ARCADIA1, ARCADIA2	March 2023

Letters in orange : in-house projects (global development) Letters in blue : in-licensed from Roche (development and distribution in Japan)

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**Tetsuya Yamaguchi:** Thank you. Let's start from page 28.

First, we have two slides showing the highlights of Q1.

The approved projects and the filed projects have already been announced. In particular, an application has been filed today in Japan to expand the indications of Vabysmo to include macular edema associated with retinal vein occlusion.

There are six pipeline entries. As a new in-house project, SAIL66 has started Phase I trial. CLDN6-positive solid tumors will be targeted. We can't disclose detailed information on the mechanism of action at this time.

GYM329, an in-house developed product, has entered a Phase II study for facioscapulohumeral muscular dystrophy, and crovalimab has entered a Phase I study for lupus nephritis.

Simultaneous development of in-house products in multiple diseases is progressing well.

For Roche products, studies have been initiated for Gazyva for pediatric nephrotic syndrome, Vabysmo for angioid streaks, and giredestrant for breast cancer, in combination with everolimus, respectively.

The top-line presentations on crovalimab and nemolizumab, will be discussed later.

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## Q1 Topics (2/2)



As of April 27, 2023

Category	Product	Study/Indication	Date
Medical conference	Vabysmo	BALATON / COMINO (RVO): Angiogenesis, Exudation, and Degeneration 2023	February 2023
	nemolizumab	OLYMPIA 2 (PN): American Academy of Dermatology (AAD) 2023	March 2023
	Tecentriq	IMbrave050 (HCC adjuvant): American Association for Cancer Research (AACR) 2023	April 2023
Literature publication	AMY109	Non-clinical efficacy data: Science Translational Medicine	February 2023
Others	Enspryng/RG6168	Forerunner Designation / AIE, MOGAD	March 2023
	Vabysmo	Orphan drug designation / Angioid streaks with neovascularization	March 2023
	gMSC*1	Termination of license agreement with TWOCELLS	April 2023
Development discontinued	ipatasertib	Prostate cancer (1L) (IPATential150 study in combination with abiraterone)	
	Tecentriq	Renal cell carcinoma (2L) (CONTACT-03 study in combination with cabozantinib)	

Letters in orange : in-house projects (global development) Letters in blue : in-licensed from Roche (development and distribution in Japan) Letters in black : others

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Coming to conference presentations, the OLYMPIA 2 study of nemolizumab in prurigo nodularis has been presented by Galderma, as mentioned earlier. I will talk about that later.

Enspryng, one of our in-house products, has received a forerunner designation for autoimmune encephalitis and myelin oligodendrocyte glycoprotein antibody-associated disease. In addition, Vabysmo received orphan drug designation for angioid streaks with neovascularization.

The development of ipatasertib and Tecentriq for one indication each has been discontinued.

## 2023: Key R&D Milestones



Underlined and bolded are new progress since February 2, 2023

	Product	Indication/Study name	Progress
Projects to be approved	Actemra	Systemic sclerosis with interstitial lung disease (SSc-ILD) (EU)	
	Hemlibra	Moderate hemophilia A (EU)	✓
	crovalimab	PNH (China)	
	RG6264 (PER/HER FDC)	HER 2 positive Breast cancer/Colorectal cancer	
P3/Pivotal readouts	Alecensa	ALINA Study: NSCLC [adjuvant]	
	crovalimab	<b>COMMODORE 1/2 study: PNH</b>	✓
	nemolizumab	<b>ARCADIA 1/2 study: Atopic dermatitis</b>	✓
	Tecentriq + Avastin	IMbrave050 study: HCC [adjuvant]	✓
	Tecentriq	<b>IMpassion030: eBC [adjuvant]</b>	✗
	Tecentriq	IMvoke010 study: HNC [adjuvant]	
	Tecentriq+ tiragolumab	SKYSCRAPER-01 study: NSCLC [1st line]	
	mosunetuzumab+Polivy	SUNMO study*: r/r aNHL	
delandistrogene moxeparovovec	EMBARC study: Duchenne muscular dystrophy (DMD)		

Letters in orange : in-house projects (development in global) Letters in blue : in-licensed from Roche (development and distribution in Japan)

\* Readout expected in 2023-2024

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This is the progress of key R&D milestones this year.

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As mentioned above, positive study results were obtained for crovalimab and nemolizumab. On the other hand, IMpassion030 trial for Tecentriq breast cancer(adjuvant) was discontinued early on the recommendation of an Independent Data Monitoring Committee.

Overview of Development Pipeline



## Primary Endpoints Met (crovalimab/nemolizumab)

### Two in-house projects achieved primary endpoints in multiple Phase 3 studies

crovalimab	nemolizumab
<p><b>COMMODORE 1, COMMODORE 2 (PNH)</b></p> <p><b>COMMODORE 2:</b> Non-inferiority study with standard therapy in patients with PNH who had not previously been treated with a complement inhibitor met its two primary endpoints. Verified non-inferiority to standard therapy.</p> <p>[Primary endpoints]</p> <ul style="list-style-type: none"> <li>• Transfusion avoidance</li> <li>• Hemolytic control (LDH level; ongoing RBC destruction)</li> </ul> <p><b>COMMODORE 1:</b> P3 study in patients with PNH who switched to crovalimab from an existing complement inhibitor. Efficacy and safety supported the favorable benefit-risk profile of the COMMODORE 2.</p> <ul style="list-style-type: none"> <li>• The results of COMMODORE 1/2 will be presented at EHA2023</li> <li>• Filed in China with COMMODORE 3 results</li> </ul>	<p><b>ARCADIA 1, ARCADIA 2 (Atopic dermatitis)</b></p> <p>Both ARCADIA 1 and ARCADIA 2 in patients with moderate to severe atopic dermatitis (adolescent to adult) met primary and key secondary endpoints</p> <ul style="list-style-type: none"> <li>• Nemolizumab in combination with TCS (topical steroid) was evaluated in comparison to placebo, administered subcutaneously every 4 weeks</li> <li>• Improved skin lesions, itching, sleep disturbances</li> <li>• Presentation at a conference in late 2023, launch planned in H2 2024 (US)</li> </ul> <p><b>OLYMPIA 1, OLYMPIA 2 (Prurigo Nodularis )</b></p> <ul style="list-style-type: none"> <li>• OLYMPIA 2 study met all primary and all key secondary endpoints. The other P3 study OLYMPIA 1 is on track.</li> <li>• Details of the OLYMPIA 2 study are on the next slide.</li> <li>• To be launched in H2 2024 (US)</li> </ul>

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This is the status of achievement of the primary endpoints for crovalimab and nemolizumab.

As you can see on the left, the COMMODORE 1 study was conducted in patients with PNH who switched from existing complement inhibitors to crovalimab, while COMMODORE 2 was a non-inferiority study of crovalimab versus standard therapy in patients with PNH who had not previously been treated with a complement inhibitor.

The COMMODORE 2 study has verified non-inferiority in the primary endpoints of transfusion avoidance and hemolytic control.

The efficacy and safety data from the COMMODORE 1 study also support the favorable benefit-risk profile of COMMODORE 2.

As announced, the data will be presented at the European Hematology Congress this June. We are currently working on an application schedule in the middle of this year for Japan, the U.S., and Europe.

Both studies, ARCADIA 1 and ARCADIA 2, were conducted in patients with moderate to severe atopic dermatitis, in combination with topical steroids and subcutaneous administration of nemolizumab every four weeks and were compared with placebo.

Both studies showed improvement in the primary endpoints of IGA 0/1 and EASI-75 achievement.

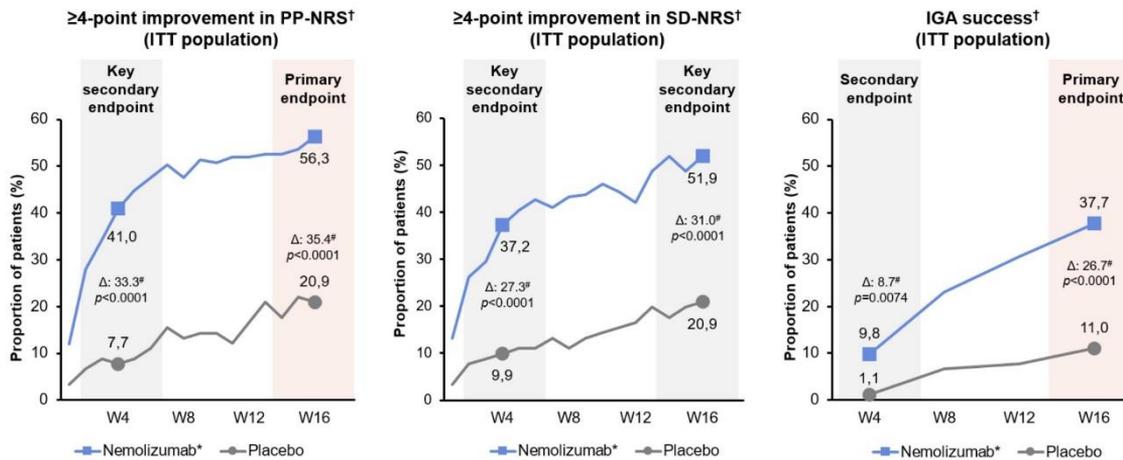
In addition, Galderma announced improvement in some of the key secondary endpoints, such as skin lesions, itching, and sleep disturbance. As for the data, the status of the presentation at the conference later this year and the planned U.S. launch in H2 of FY2024 is as stated.

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Overview of Development Pipeline

# Significant Improvements in itch, sleep disturbance and skin lesions at Weeks 4 and 16



CMH, Cochran-Mantel-Haenszel; ITT, intention-to-treat; PP-NRS, peak pruritus Numerical Rating Scale; SD-NRS, sleep disturbance Numerical Rating Scale; W, week. Baseline was defined as the last non-missing weekly value before the first dose of the study drug. Data presented here are of non-responder imputation (missing result at a visit was considered non-response). If a subject received any rescue therapy, the data at/after receipt of rescue therapy were considered of non-responders. \*Nemolizumab is an investigational drug and Galderma has not received approval for any indication in any country. <sup>†</sup>Weekly average PP-NRS/SD-NRS score was considered, and the values were calculated as average of 7 consecutive days up to the target study day (excluding) and set to missing if <4 days data are available. \*Unadjusted proportion differences are presented. Unadjusted p-values for between-group comparisons are from the CMH test. Presented at American Academy of Dermatology Annual Meeting (March 17-21) All rights reserved

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Next, I would like to show you the results of the OLYMPIA 2 study of nemolizumab for prurigo nodularis, as I mentioned earlier. This was presented at the American Academy of Dermatology annual meeting in March.

The primary endpoint was at 16 weeks, but including the secondary endpoint at four weeks, statistically significant differences were obtained compared to the placebo group in PP-NRS, which evaluates itching, and IGA, which is an overall evaluation.

The application based on results of OLYMPIA 2, together with OLYMPIA 1, which is currently underway, is planned to submit and to obtain approval for this indication in the U.S. in H2 of next year.

Overview of Development Pipeline

# In-house Product Sales in 2022 and Marketability of crovalimab/nemolizumab



Sales in 2022

## Actemra®

- ✓ Launched in 2005
- ✓ Global Sales 2,701mCHF\*

## Alecensa®

- ✓ Launched in 2014
- ✓ Global Sales 1,513mCHF\*

## Hemlibra®

- ✓ Launched in 2018
- ✓ Global Sales 3,823mCHF\*

## Enspryng®

- ✓ Launched in 2020
- ✓ Global Sales 192mCHF\*

\*Data from Roche financial results

## crovalimab related markets in 2028

PNH: 3,090mUSD	No. of Patients PNH: 12,500
SCD: 3,876mUSD	
aHUS:1,652mUSD	

To be filed for approval in H1 2023 in Japan, US, and EU (PNH). Subcutaneous and self-injectable formulation with small dosing volume enables administration at home. Shorter dosing time may provide benefits to patients and medical professionals.

Market size: Evaluate's sales estimates based on marketed and developed products (obtained PoC in principle) in each market. Patient number: Based on data provided by Evaluate. Total number of patients in EU5, US, JP, and Canada. Evaluate-provided patient count data is not available for SCD, aHUS, and PN.

## nemolizumab related markets in 2028

Atopic dermatitis:  
20,543mUSD

Prurigo nodularis:  
No market data



No. of Patients  
Atopic dermatitis:  
48.05million  
Prurigo nodularis:  
No data

To be launched in the U.S. in the second half of 2024. Since pruritus is strongly and rapidly suppressed by inhibition of IL-31 receptor A, early improvement of patient's QOL is expected. Significant improvement in dermatitis is also demonstrated in multiple phase III clinical studies. Aiming for differentiation with features not demonstrated in other drugs.

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I will continue with an explanation of the marketability of crovalimab and nemolizumab.

First of all, a few words about products already launched by Chugai, Actemra, Alecensa, Hemlibra, and Enspryng. These are all growing steadily in the global market, with total market sales amounting to CHF8.229 billion last year.

These are followed by crovalimab and nemolizumab, global in-house products. The data provided by Evaluate Pharma shows the estimated size of the target market for both drugs in 2028 for the indications currently under development.

First, for the indications for which crovalimab is being developed, the estimated market size is USD3.09 billion for PNH, USD3.876 billion for sickle cell disease, and USD1.652 billion for aHUS.

The number of patients is estimated at 12,500 for PNH. Although there are no patient estimates for sickle cell disease or aHUS, there are currently 100,000 patients with sickle cell disease in the U.S. based on the scientific publication. According to a Japanese registry estimate, there are 200 patients with aHUS in Japan. We intend to carefully research this in the future.

Also, as written below, we would like to differentiate crovalimab by providing benefits to patients and the medical community as a subcutaneous and self-injectable formulation with small dosing volume enables administration at home.

On the right side, the indication for which nemolizumab is being developed is atopic dermatitis, with an estimated market size of USD20.5 billion and an estimated 48.05 million patients.

Although we do not have an estimate for prurigo nodularis, we estimate that there are more than 50,000 patients in Japan.

As indicated, the atopic dermatitis market is expected to become increasingly competitive with the development of treatments with various modes of action, such as IL-4 and IL-13 antibodies, OX40 antibodies, JAK inhibitors, and PDE inhibitors. Of these, nemolizumab is the only IL-31 receptor inhibitor. It is expected to suppress pruritus strongly and promptly and improve quality of life at an early stage. Since it has also been confirmed to improve dermatitis, we are planning to differentiate our products with features not found in other agents.

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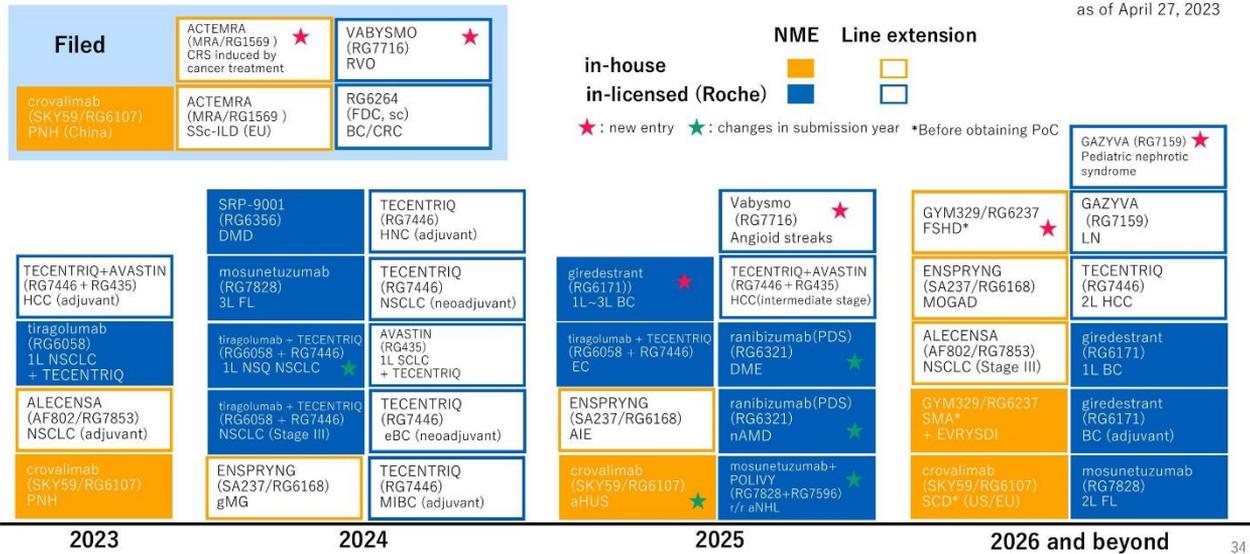
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# Projected Submissions (Post PoC NMEs and Products)



as of April 27, 2023



This is the schedule for future applications.

Those marked with a red star are new additions, and those marked with a green star are projects where the year of application has changed.

Also, Projects previously disclosed as 2025 and beyond will be disclosed as 2025 or 2026 and beyond. We have included some reference materials with the presentation papers today.

This concludes my presentation.

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## Question & Answer

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**Sasai [M]:** I would now like to move on to the Q&A session. Mr. Hidaka, Executive Vice President, Head of Marketing and Sales Division, will also be present for the Q&A session.

We sincerely appreciate your cooperation in limiting the number of questions to two per person to ensure that we receive as many questions as possible.

Please note that an audio recording of your questions, along with the presentation, will be posted on our website at a later date.

We will now take your questions. When it is your turn to ask a question, we will call your name. Please state your name and affiliation before asking your question.

Now, on to your first question. Morgan Stanley Securities, Mr. Muraoka, please go ahead.

**Muraoka [Q]:** Hello. Morgan Stanley, Muraoka. Thank you very much. I am looking at page five of the supplemental material just now. I see that progress of other operating income, under the royalties' section, and other operating income (expense), between SG&A and operating profit, are far behind the Company's full year plan.

I think that the figures in the upper part of operating profit have probably been achieved with transfer of the marketing authorization regarding Bonviva in April, but in the line just below royalties, other operating income, this is delayed and is zero. I assume that the 17.0 billion should be attainable if the applications for crovalimab and nemolizumab go ahead. Is that a reasonable assumption?

**Itagaki [A]:** Itagaki here. We have not disclosed how much or by what means, but we have included items such as milestone revenues in the full year forecast, and I think it is correct to understand that the relevant event has not occurred in Q1.

**Muraoka [Q]:** So, you are not behind schedule, and things are going well?

**Itagaki [A]:** Yes. It is not behind schedule.

**Muraoka [Q]:** Is that also true of the operating incomes below royalties and SG&A?

**Itagaki [A]:** That's what I mean.

**Muraoka [Q]:** Okay. Thank you very much. Also, regarding the Actemra biosimilar, the Biogen financial statement of yesterday or the day before says that the review is still going on as scheduled. Am I correct in understanding that no settlement has been made yet regarding this?

**Okuda [A]:** Okuda here. Thank you for your question. We are not in a position to comment on the status of the settlement with respect to Biogen. Thank you.

**Muraoka [Q]:** Is it correct to say that there is something taking place in this area and you are not able to comment on it?

**Okuda [A]:** As you know, we will tell you when something happens and we are able to announce or publicize it, but at this point, we are unable to comment on anything.

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**Muraoka [Q]:** I remember you saying before that biosimilars are nothing to worry about in 2023 and that we don't need to worry so much in 2024 either. Has there been any change in that?

**Okuda [A]:** We have been saying for some time that we do not expect any major impact in 2023, this year. We do not offer any comment on 2024 and beyond.

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

**Sasai [M]:** Thank you very much. Next, Mr. Wakao from JPMorgan Securities.

**Wakao [Q]:** My name is Wakao from JPMorgan. Thank you very much. I would like to ask about crovalimab and nemolizumab.

First of all, I am concerned about the competitive environment for crovalimab, especially given the iptacopan data that Novartis announced in the past few days.

In light of this, iptacopan seems to be a good choice for existing drugs, so I think it is becoming a little difficult to see how strong the once-per-four-week subcutaneous administration of crovalimab is. Based on the iptacopan results, how do you see the PNH potential of crovalimab?

I'm wondering how conservatively I should consider this area. Any comments would be appreciated. Thank you.

**Tetsuya Yamaguchi [A]:** Yes, thank you, Mr. Wakao. Yamaguchi here. As you have just pointed out, the iptacopan trial result was good.

I have heard that the enrolled patient number was around 40, so I think it is necessary to accumulate more information, of course. However, I think that this was a good demonstration of the potential of the project.

Since this study was conducted on patients with some residual anemia symptoms, it will be interesting to see if similar results can be obtained in patients without anemia symptoms.

On the other hand, I have heard that iptacopan is to be administered orally twice a day regardless of the study results. In other words, in terms of blood half-life, crovalimab is administered subcutaneously once every four weeks, which means that the therapeutic effect remains very stable.

PNH is a very serious disease, and from the viewpoint of medication compliance, we believe that SC administration of crovalimab, which maintains a stable drug effect, remains a strong proposition.

Furthermore, I understand that the C5 antibody is currently the standard of care and a very well-established treatment, so it may take some time to establish the evaluation of factor B inhibition.

**Wakao [Q]:** Yes, thank you. Second, with nemolizumab, I think the results of the clinical trial have been very good, as per the initial concept.

On the other hand, it is a unique product that is quite different from existing drugs, so I am not sure how well it will be accepted in the market.

From this point of view, the itch suppression is a key issue. You mentioned earlier that the competitive environment is very intense. I have heard that there is a big demand for itch suppression in the domestic market, given the appreciation for Mitchga.

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Do you have any information, qualitative or otherwise, that would indicate the potential for this drug to be accepted?

If there is nothing in particular, we will have to look at the track record. While the trial results are solid, it seems necessary to scrutinize the potential closely. Any more information you can provide about this would be helpful. That is all.

**Tetsuya Yamaguchi [A]:** Yes, thank you. As for the results of the trial, we will need to look at the announcement ahead of time, and we will certainly need to look at that carefully.

It has been shown to have an extremely rapid effect on itching, at least in prurigo nodularis. In the case of Mitchga, this is extremely anecdotal, but we have heard of patients who were suffering from itching who, after receiving Mitchga, experienced an extremely rapid and immediate disappearance of the itching. People have described this as transforming their everyday lives.

In this sense, we believe that there are definitely patients within the patient segment who suffer from this itchiness, and we believe that we can position ourselves in such an appropriate segment.

Thank you.

**Wakao [M]:** Thank you very much. I look forward to seeing the detailed data in your conference presentation. That is all.

**Sasai [M]:** Thank you very much. Next, Nomura Securities, Mr. Kohtani.

**Kohtani [Q]:** Kohtani, Nomura Securities. I would like to make two points about crovalimab. First, as you can see on page 33, crovalimab has the potential to be a very important drug, and I am very grateful for that. I think that the results of APPOINT-PNH trial for iptacopan were the best data I could think of.

We do not know the results of the COMMODORE 1 or COMMODORE 2 trials yet, so I would like to ask your opinion on the APPOINT-PNH trial. After all, the LDH value was [inaudible] after 24 weeks and [inaudible] transfusion-free after 24 weeks, The FACIT-Fatigue score also improved by 10.6 points, which means that this is superior in every way compared to the 301 trial of Ultomiris.

Naturally, due to the difference in mechanism, C5 antibodies cannot suppress extravascular hemolytic damage, so I do not think crovalimab is superior to iptacopan in terms of the ratio of breakthrough hemolytic damage and prevention of transfusion.

As you said, iptacopan has the problem of adherence, and crovalimab has the advantage of subcutaneous administration, but looking at this data, I still think iptacopan looks pretty amazing. In light of this, how do you see the market potential of crovalimab? This is my first question.

**Tetsuya Yamaguchi [A]:** Yes, thank you, Mr. Kohtani. I am aware of the data you just mentioned, and I think it is true that it very clearly shows effectiveness.

The problem is that the data is from patients with residual anemia symptoms, as I mentioned earlier, and the enrolled patient number is about 40, so we need to look at the data with caution.

That and whether oral twice daily or subcutaneous once every four weeks would be better would be the major points.

Of course, this is not a uniform patient segment, and we believe that there will inevitably be a segment of patients for whom crovalimab is a good choice.

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**Kohtani [Q]:** What you are saying, is that APPOINT-PNH is taken in selected patients with residual anemia disorder, so we have to be careful when comparing it to the Ultomiris and crovalimab trials?

**Tetsuya Yamaguchi [A]:** It is my understanding that a new trial of iptacopan has been started in patients with hemoglobin levels of 12 g/dL or higher. In my personal opinion, data from such patients is also necessary.

**Kohtani [Q]:** Okay. Second point, I think crovalimab's biggest opportunity actually is sickle cell disease, and this one is the most problematic for the development of vaso-occlusive crisis, or VOE. This is a very painful condition. To begin with, these patients are at high risk of death, and as I understand it, there are no drugs available today to prevent VOE.

Since infection is the leading cause of death in sickle cell disease patients, I think many studies have shown that C5 is probably involved, but I wonder if that is enough to start a Phase II trial.

I would like to ask you about the probability of success in SCD. When your company started this Phase II study, did you conduct animal experiments to specifically confirm the mechanism by which C5 is really involved in the development of vaso-occlusive crisis, or did you simply conduct the study based on the results of this kind of research? Please tell us how confident you are about the potential in this area. That is all.

**Tetsuya Yamaguchi [A]:** Thank you very much. Currently, there is no solid clinical evidence for use in sickle cell disease. We are now in Phase II of development and are in the process of establishing a proof of concept.

This study is being led by Roche, and if we obtain better results, Phase III study will be initiated. As we show that the number of patients in Asia is small anyway, we are waiting for the results of Phase II at this stage.

**Kohtani [M]:** Okay. That is all from me.

**Sasai [M]:** Yes, thank you. Next, Mr. Yamaguchi from Citigroup.

**Hidemaru Yamaguchi [Q]:** Thank you very much. Hemlibra is growing in Japan and globally in various ways, but following the coronavirus pandemic, the number of patients being hospitalized and having treatments changed is beginning to grow, especially in Japan. How much switching activity is currently taking place in this area? It was mentioned before that there was no sign of any ceiling in the market penetration rate. I would be grateful if you could say something about the current situation, and whether a ceiling has come into view. Thank you.

**Okuda [A]:** Thank you for your question, Mr. Yamaguchi. Okuda here. First of all, I would like to answer from the global perspective. Regarding the influence of the coronavirus pandemic, which was back at the start of 2020, we saw a reduction in medication switching in the US. Since then, over time, we have seen an increase in the rate of switching. The rate of increase of patients starting Hemlibra has returned to normal.

As Roche also announced, we are seeing continuous growth, with 21% growth in the US, 27% in Europe, and 38% in other areas internationally.

Mr. Hidaka can comment on the situation in Japan.

**Hidaka [A]:** Thank you. As for the domestic situation, coronavirus-related restrictions on hospital visits and new introductions are indeed gone now.

I think the current situation is that penetration is gradually progressing with patient understanding.

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Another point is that Hemlibra has expanded indications for acquired hemophilia A, so the market penetration here has also been a positive factor for the Company's performance.

**Hidemaru Yamaguchi [Q]:** Okay. Thank you very much. One more point. Regarding Vabysmo, I get the impression it is increasing steadily, but the degree of penetration was low because it is still in a growth phase. Even looking at QoQ change, I can't say that it is growing that much. Could you comment on the current status of Vabysmo? It seems that it is getting a lot of attention globally, but what is the situation in Japan?

**Hidaka [A]:** Thank you. Naturally, on an annual basis, the rate of progress naturally appears low because we forecast the sales will go up steadily.

In the beginning, there were still many switch cases, switching from other drugs, but gradually more and more naive cases, so-called first-use cases, are being seen.

At the recent meeting of the Japanese Society of Ophthalmology, there was a session on Vabysmo in which a summary of the clinical results of its use to date was presented.

In particular, there was an announcement that about half of the cases in which the drug was used as a switch drug could be administered for a longer period of time. While the clinical data are being continuously presented and accumulated, we will work to thoroughly penetrate the drug in the market.

**Hidemaru Yamaguchi [Q]:** While there is a steady increase for the full year, I don't know if we can say that it is sufficient. Can you comment any more on the pace of increase? Is it enough?

**Hidaka [A]:** Yes, it is.

**Hidemaru Yamaguchi [M]:** Thank you. That is all.

**Sasai [M]:** Yes, thank you very much. Next, the Nikkan Yakugyo, Osakabe, please go ahead.

**Osakabe [Q]:** The Nikkan Yakugyo, Osakabe. I would like to ask you about the early retirement program. Although it has already been mentioned in the release, I would like to ask you to explain again about the management issues in the business environment.

**Okuda [A]:** Okuda here. Thank you for your question. In terms of management issues, as global healthcare financial pressures increase enormously, measures to curb healthcare and drug costs are accelerating.

In addition, with the entry of generics and biosimilars into the market, the business environment and market conditions in which our company operates have entered a very difficult phase.

In order to realize the high goals of doubling R&D output and launching one global product per year, as set forth in our growth strategy "TOP I 2030," which we started a little over two years ago, we believe that we need to make some very significant changes. That is a key management issue.

In order to continue drug discovery at a global level, we need structural changes allowing a strategic asset allocation with a RED SHIFT. To move CHUGAI PHARMACEUTICAL forward, we need to focus on our organizational capabilities and on pursuing the highest quality of human resources. To confront these management issues, we have implemented this early retirement incentive program.

**Osakabe [Q]:** Thank you. I understand that 374 people have applied for this program. What is the distribution of these people across business areas or roles?

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**Okuda [A]:** Thank you for your question. The breakdown of those 374 persons is not disclosed. We apologize for the inconvenience and ask for your understanding.

**Osakabe [M]:** Understood. Thank you very much.

**Sasai [M]:** Thank you very much. Next, Ms. Haruta, Credit Suisse Securities, please go ahead.

**Haruta [Q]:** My name is Haruta from Credit Suisse Securities. Just one question for confirmation. In the full year guidance, the export of Hemlibra to Roche was to optimize inventories, and while we had expected a decrease in sales for the current fiscal year, we have seen positive results in Q1. Please tell us about any changes in the situation and the outlook for Q2 and beyond.

**Itagaki [A]:** Itagaki. The full year forecast is based on the assumption that exports will be suppressed to some extent in order to optimize Roche-side inventories.

At this point, there is no change in the forecast for the full year. The impact of inventory optimization is not something that occurs in a specific month or quarter, so there may be some variability in the results for a single quarter due to demand conditions, the timing of our shipments, and various other factors. At this point, our full year forecast remains unchanged. The current Q1 progress is also in line with our internal plan.

**Haruta [M]:** Understood. Thank you very much.

**Sasai [M]:** Yes, thank you. This is the end of the financial results briefing. If you have additional questions, please contact the Corporate Communications department.

Thank you very much for joining us today. Thank you.

[END]

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