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CHUGAI PHARMACEUTICAL CO., LTD.



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CHUGAI PHARMACEUTICAL CO., LTD.

Conference on FY 2022.12 3Q Financial Results

October 24, 2022

Event Summary

[Company Name]	CHUGAI PHARMACEUTICAL CO., LTD.	
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[Participants]		
[Number of Speakers]	5	
	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]*	Hidemaru Yamaguchi	Citigroup Global Markets
	Seiji Wakao	JPMorgan Securities
	Motoya Kohtani	Nomura Securities
	Shinichiro Muraoka	Morgan Stanley MUFG Securities
	Fumiyoshi Sakai	Credit Suisse Securities
	Miki Sogi	Sanford C. Bernstein

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

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Presentation

Sasai: Ladies and gentlemen, thank you for joining us for this briefing for Q3 of the fiscal year ending December 31, 2022. I am Sasai from Corporate Communications, and I will be facilitating today's session. Thank you.

Today, we will be conducting an information session via Zoom webinar.

Conference on FY2022.12 3Q Financial Results



Agenda

- | | | |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------|
| <div style="border: 1px solid blue; border-radius: 50%; width: 40px; height: 40px; display: flex; align-items: center; justify-content: center; margin: 10px 0;">01</div> | FY2022 Q3 Overview | Dr. Osamu Okuda
<small>President & CEO</small> |
| <div style="border: 1px solid blue; border-radius: 50%; width: 40px; height: 40px; display: flex; align-items: center; justify-content: center; margin: 10px 0;">02</div> | FY2022 Q3 Consolidated Financial Overview (Core) | Toshiaki Itagaki
<small>Director, Executive Vice President & CFO</small> |
| <div style="border: 1px solid blue; border-radius: 50%; width: 40px; height: 40px; display: flex; align-items: center; justify-content: center; margin: 10px 0;">03</div> | Overview of Development Pipeline | Tetsuya Yamaguchi
<small>Executive Vice President, Head of Project & Lifecycle Management Unit</small> |

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Please see the web page and page three of the presentation materials for today's meeting agenda. You can follow the contents of the briefing there.

Questions will be taken after all presentations have been completed. The Q&A session is expected to last 30 minutes. Please note that your audio will be muted during the presentation.

Now, without further ado, Dr. Okuda will provide Q3 FY2022 overview.

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Financial Overview

- Increases in revenues and profits driven by favorable penetration of new products and growth of exports to Roche, which significantly outperformed the decrease in ROOI
- As core businesses in Japan and overseas are growing steadily, the company will continue aiming to achieve its initial forecast

Core (billions of JPY)	2021 Jan - Sep actual	2022 Jan - Sep actual	Growth		2022 Jan - Dec forecast	Progress (%)
Revenues	677.5	729.5	+52.0	+7.7%	1,150.0	63.4%
Domestic sales	362.6	387.6	+25.0	+6.9%	646.3	60.0%
Overseas sales	176.0	257.1	+81.1	+46.1%	385.2	66.7%
ROOI	138.8	84.9	-53.9	-38.8%	118.5	71.6%
Operating profit	290.7	299.0	+8.3	+2.9%	440.0	68.0%
Operating margin	42.9%	41.0%	-1.9pts	-	38.3%	-
Net income	209.7	213.0	+3.3	+1.6%	312.5	68.2%
EPS (yen)	127.45	129.48	+2.03	+1.6%	190.00	68.1%

- Domestic sales grew as expected due to the favorable market penetration of new products and the steady performance of Hemlibra despite the impact of the NHI drug price revision and other factors. Ronapreve is scheduled to be delivered to the government by the end of the year as initially forecasted
- Overseas sales increased mainly due to Hemlibra and Actemra exports to Roche. Progress on the export of Actemra was delayed due to manufacturing timing
- Regarding ROOI, royalties associated with initial shipment of Hemlibra significantly decreased. Progress was more favorable than expected
- Costs and operating expenses partially increased due to factors including high energy prices caused by the Russian/Ukraine situation. Limited impact on development activities

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Okuda: This is Q3 overview.

Please see slide five.

Revenues increased 7.7% YoY, while operating profit and net income rose 2.9% and 1.6%, respectively. Continuing from H1, new products in Japan and exports to Roche have been strong. Our core businesses in Japan and overseas are growing steadily, and we will continue aiming to achieve our initial forecast for the full year.

As for Ronapreve, as planned, there were no deliveries to the government during the July to September period. In addition, there is no change in our assumption from the beginning of the fiscal year for delivery volume through December of this fiscal year.

The situation in Ukraine had no significant negative impact on our business performance. However, as the situation has become more protracted, some costs and expenses have increased due to higher energy prices and other factors.

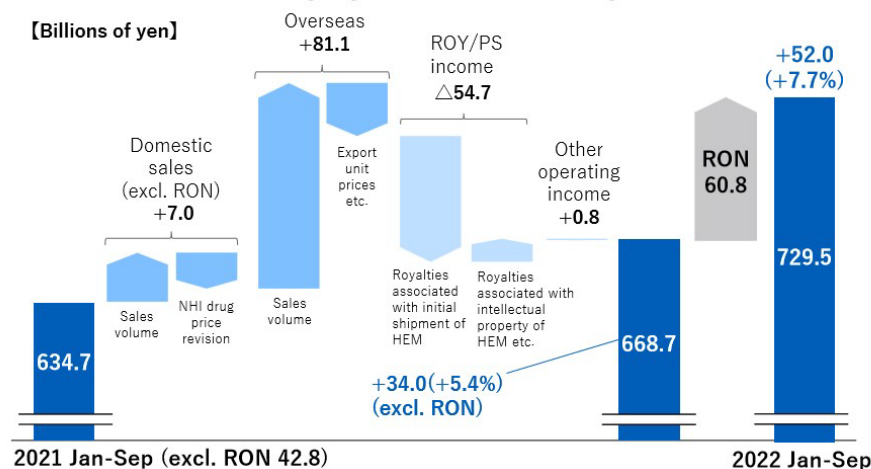
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Topline Overview

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



- Domestic sales (excl. Ronapreve) increased as market penetration of new products such as Evrysdi, Polivy, and Enspryng, and sales growth in Hemlibra exceeded the impact of generics and NHI drug price revision
- Overseas sales increased significantly due to the full-scale Hemlibra exports to Roche at regular shipment unit price and the contribution of Actemra exports
- Royalties associated with overseas' local sales of Hemlibra increased despite a substantial decrease in royalties associated with initial shipment of Hemlibra

Hemlibra: Trends of domestic hemophilia A patient share
 '22Q3 28.5%, '22Q2 27.3%, '22Q1 26.3%,
 '21Q4 24.7%, '20Q4 20.0%,
 '19Q4 14.4%, '18Q4 2.2%

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Next, I will explain the topline in detail. Please see slide six.

Excluding Ronapreve, domestic sales increased due to steady growth of new products such as Evrysdi and Polivy. Increased sales by volume absorbed the negative impact of the NHI drug price revision and other factors.

Overseas, export sales increased significantly due to the full-scale export of Hemlibra at regular shipping unit prices, as well as the contribution of Actemra exports.

Royalty-related revenues declined sharply YoY due to substantial decrease in royalties associated with initial shipment of Hemlibra.

Combined revenue from domestic and overseas sales and royalties increased by JPY34 billion. In addition, Ronapreve contributed to an overall increase of JPY52 billion in revenue.

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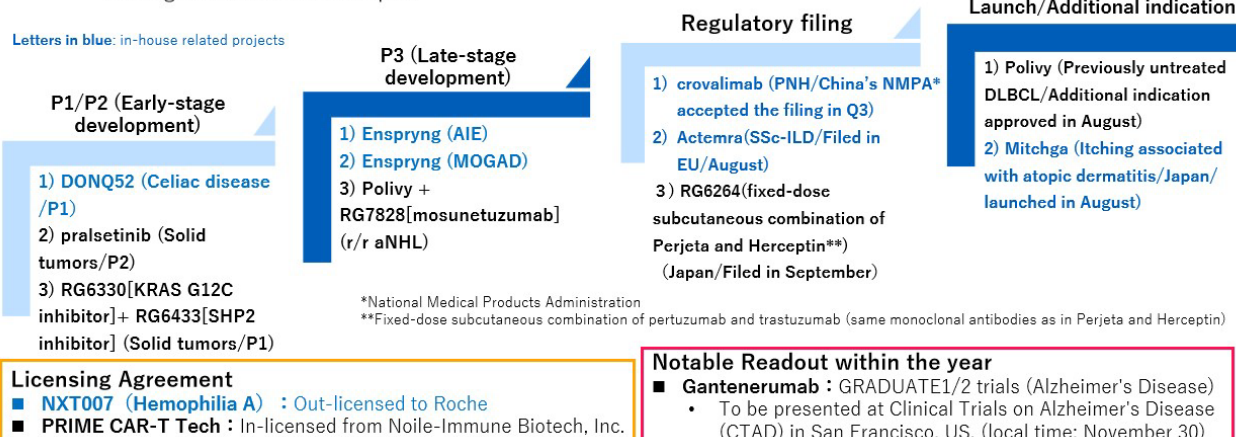
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R&D Overview

■ Steady progress in R&D, including in-house projects

- Progress in early-stage in-house projects including out-licensing of NXT007 to Roche and initiation of DONQ52 development
- Multiple phase III studies were initiated. The regulatory filing for crovalimab was accepted in China, and Mitchga has launched in Japan



The following are the key points in R&D. Please see slide seven.

In general, research and development, including in-house development projects, are progressing well. Blue letters indicate in-house related projects. Mr. Yamaguchi will explain the details of the development pipeline later, so I will focus on the key points here.

First, we out-licensed NXT007 to Roche, which we expect to be the next-generation Hemlibra. We will be accelerating further research and development with Roche in the future.

As for the early-stage development of in-house projects, Phase I trial had been initiated for DONQ52, a novel antibody for the treatment of celiac disease. In late-stage development, Phase III trials have begun for the use of Enspryng in autoimmune encephalitis and MOGAD.

The application for approval, launch, and expansion of indications are also progressing smoothly. As already announced in our press release, an application for crovalimab has been filed in China for the indication of PNH and has received priority review. As for Polivy, which is steadily penetrating the market in Japan, an indication expansion was approved and launched in August for the treatment of untreated DLBCL.

Then there is Mitchga, which was licensed out to Maruho and received approval in March, and which was launched in Japan in August. The market penetration of Mitchga is progressing well, with early improvement in pruritus seen in patients who have had an inadequate response to existing therapies.

Finally, here are some notable readouts during the year. Gantenerumab, which is being developed for the indication of Alzheimer's disease, is scheduled for readout by the end of this year.

That's all from me.

Sasai: Next, Mr. Itagaki will give an overview of the consolidated financial results for Q3.

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IFRS and Core Results Jan - Sep

(Billions of JPY)	IFRS results	Non-core items		Core results
		Intangible assets	Others	
Revenues	821.5		-91.9	729.5
Sales	644.7			644.7
Royalties and other operating income	84.9			84.9
Other revenue	91.9		-91.9	-
Cost of sales	-263.3	+0.9		-262.4
Operating expenses	-174.3	+0.5	+5.7	-168.1
M&D and G&A *	-69.9		+2.8	-67.1
Research and development	-104.4	+0.5	+2.9	-101.0
Operating profit	383.8	+1.4	-86.2	299.0
Financial account balance	-1.9			-1.9
Income taxes	-110.0	-0.4	+26.3	-84.1
Net income	272.0	+1.0	-59.9	213.0
EPS (JPY)	165.29			129.48

Non-Core items

(Billions of JPY)

Intangible assets

Amortization	+1.1
Impairment	+0.3

Others

Lump-sum income related to settlement agreement with Alexion Pharmaceuticals, Inc., etc.	-90.7
Restructuring expenses, etc.	+4.5

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

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Itagaki: My name is Itagaki.

Now, please see page nine.

There is a large difference between the IFRS results on a full basis and the core results used in this explanation. The reason for this is that the JPY90.7 billion, which is the net of the business tax portion of the JPY91.9 billion in settlement income from Alexion, which has been explained in previous financial statements, has been adjusted as non-recurring transaction. Otherwise, as in the past, amortization of intangible assets and impairment losses, such as office reorganization costs, are excluded from the IFRS results.

As a result of such non-core adjustments, revenue and profit levels were reduced by JPY84.8 billion to JPY299 billion in core results. From the slides that follow, the explanation will be based on these core results.

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P/L Jan - Sep (Year on Year)

(Billions of JPY)	2021	2022	Growth	
Revenues	677.5	729.5	+ 52.0	+ 7.7%
Sales	538.7	644.7	+ 106.0	+ 19.7%
Domestic	362.6	387.6	+ 25.0	+ 6.9%
Overseas	176.0	257.1	+ 81.1	+ 46.1%
Royalties and other operating income	138.8	84.9	- 53.9	- 38.8%
Royalty and profit-sharing income	135.4	80.7	- 54.7	- 40.4%
Other operating income	3.4	4.2	+ 0.8	+ 23.5%
Cost of sales	-225.7	-262.4	- 36.7	+ 16.3%
(cost to sales ratio)	41.9%	40.7%	-1.2%pts	-
Operating expenses	-161.1	-168.1	- 7.0	+ 4.3%
M&D and G&A	-66.9	-67.1	- 0.2	+ 0.3%
Research and development	-94.1	-101.0	- 6.9	+ 7.3%
Operating profit	290.7	299.0	+ 8.3	+ 2.9%
(operating margin)	42.9%	41.0%	-1.9%pts	-
Financial account balance	-1.9	-1.9	0.0	-
Income taxes	-79.2	-84.1	- 4.9	+ 6.2%
Net income	209.7	213.0	+ 3.3	+ 1.6%
EPS (JPY)	127.45	129.48	+2.03	+ 1.6%

Domestic sales

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

Increase in one-time income

Cost of sales

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

Operating expenses

Increase due to progress of development projects and impact of yen depreciation on costs denominated in foreign currencies, etc.

Operating profit

Growth mainly due to increase in sales

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Please see page 10. We will compare the P&L results with those from the previous fiscal year.

Sales revenue increased JPY729.5 billion, or 7.7%.

By breakdown, domestic sales increased 6.9% due to strong sales of new products and mainstay products. Overseas sales also grew by 46.1% with significant increases in Hemlibra and Actemra.

Royalty and profit-sharing income declined 40.4% due to lower royalty income related to initial shipments of Hemlibra.

Other operating income increased by JPY0.8 billion to JPY4.2 billion due to one-time income.

This is the manufactured products cost of sales ratio. This figure improved by 1.2% to 40.7%, mainly due to changes in the product mix.

Expenses are subject to increase due to the depreciation of the yen. In addition, R&D expenses, in particular, increased by 7.3%, due in part to steady progress in development themes.

As a result, operating income was JPY299 billion, up 2.9%, and operating margin was exactly 41%.

After subtracting the financial account balance and corporate income tax, quarterly profit increased by JPY213 billion, or 1.6%.

As a result, we were able to achieve a record high cumulative Q3 results, with sales and profits increasing for the sixth consecutive quarter.

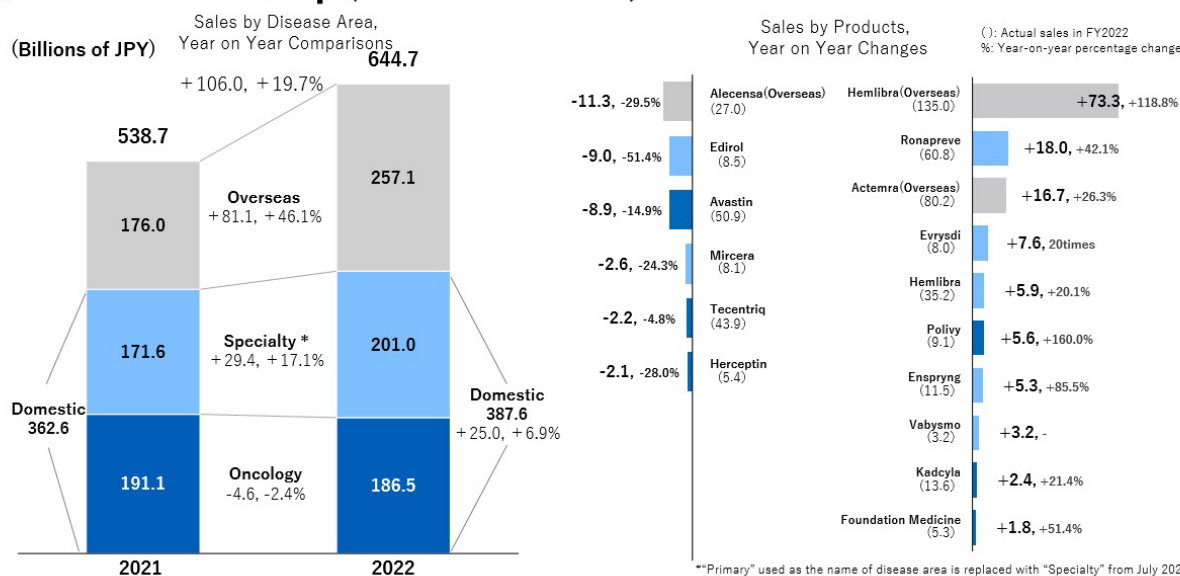
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Sales Jan - Sep (Year on Year)



Please see page 11. The following is a breakdown of changes in sales of products.

First of all, by disease area, domestic oncology, which is shown in the lower left-hand column, showed a 2.4% decrease in sales. Looking at the products shown in dark blue on the right, first, Avastin and Herceptin declined due to biosimilars.

Tecentriq sales have also declined due to an 11% decrease in NHI drug prices. This was a result of the re-pricing for market expansion in August last year.

On the other hand, sales of Polivy, which was launched in May last year, Kadcyla, for which the indication was expanded, and Foundation Medicine, to which FoundationOne Liquid was added, are increasing.

Next is the specialty area. Revenue increased by 17.1%. In terms of individual products, sales of Ronapreve increased by JPY18 billion, and sales of Evrysdi, which was launched in August last year, increased by JPY7.6 billion. Sales of our own Hemlibra and Enspryng products are also growing steadily.

Vabysmo, which was launched in May of this year, has already achieved sales of JPY3.2 billion and is steadily penetrating the market. Products that experienced declines in sales included Edrol and Mircera.

Overseas sales remained strong with a 46.1% increase in total sales. As shown at the top right, exports increased by a factor of 2.2, or JPY73.3 billion, compared to the same period last year. Actemra's overseas sales were also positive, up 26.3%, or JPY16.7 billion. More details are shown on the next page.

The sales of Alecensa overseas decreased by JPY11.3 billion due to a decrease in shipment volume as Roche's safety stock buildup ran its course last year.

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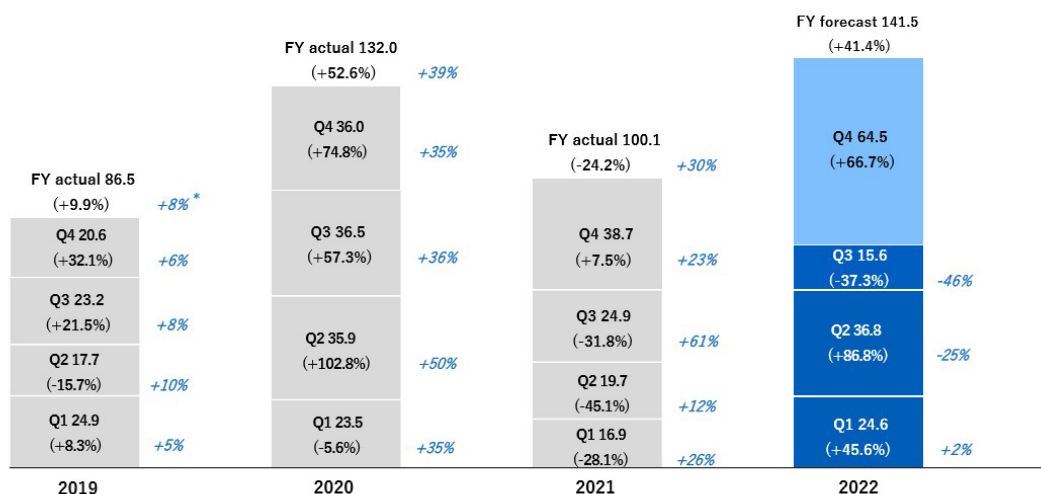
Export of Actemra to Roche

(Billions of JPY)

%: Year-on-year percentage change
 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 12 shows Roche exports of Actemra. The YoY comparison of global sales by Roche is shown in blue on the right.

As you can see, the rate of decline in Q2 and Q3 has been significant, indicating that demand associated with COVID-19 is settling down.

On the other hand, we announced at the beginning of the fiscal year that we anticipate a JPY141.5 billion, or 41.4%, increase in our full-year forecast. This plan is based on the assumption that the amount of Roche inventory, which was in short supply due to the sudden demand associated with the COVID-19 last year, will be returned to an appropriate level, so it will not be affected by the current global sales trend. In fact, Roche's shipping request to us is unchanged from the original plan at this time.

Against this backdrop, a review of the results for the current fiscal year shows that exports increased rapidly in H1 but have suddenly declined to JPY15.6 billion in Q3.

This is due to supply chain delays in Q3. We were only able to ship about half of the originally planned shipment. The cause of the delay has already been resolved, and the portion delayed in Q3 will be shipped in Q4. However, the delay in shipping that has already occurred will be postponed, and part of the Q4 portion will be delayed into Q1 of next year.

As a result, the top segment of the bar graph for this fiscal year shows a forecasted balance of JPY64.5 billion, which is not expected to be achieved.

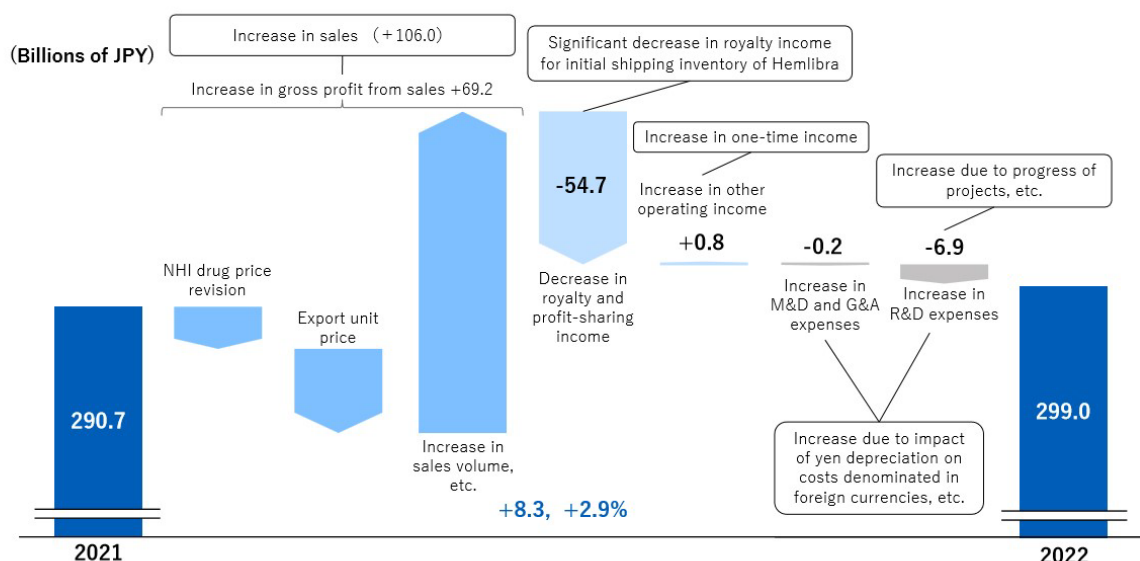
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Operating Profit Jan - Sep (Year on Year)



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On page 13, the percentage increase in operating profit, the second to fourth bars on the left break down the elements of gross profit.

The negative impact of the NHI price revision and export unit prices was absorbed by the increase in sales by volume, resulting in a net change of JPY69.2 billion.

Next is royalty and profit-sharing income, which decreased by JPY54.7 billion. Of this amount, there is a negative of JPY67 billion for the initial shipment of Hemlibra, the so-called Royalty 2, which means that other royalties have increased by JPY12.3 billion.

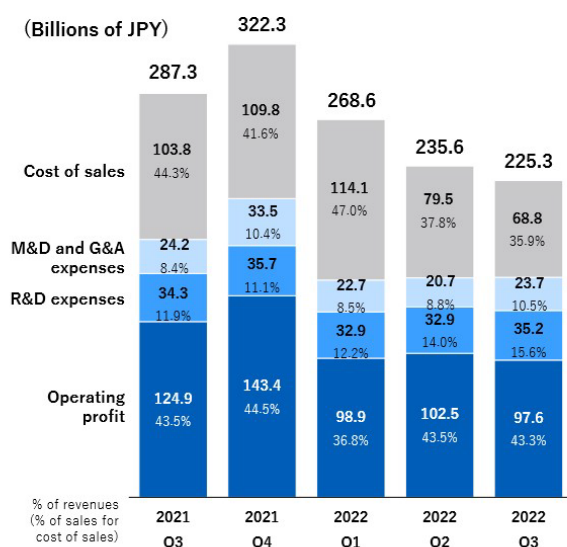
Other operating income, SG&A and R&D expenses are as shown.

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Structure of Costs and Profit by Quarter



Year on Year (2021 Q3)

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

R&D expenses: increase due to impact of yen depreciation on costs denominated in foreign currencies and progress of projects, etc.

Operating profit: -27.3, -21.9%

Quarter on Quarter (2022 Q2)

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

M&D and G&A expenses: increase due to gain on sales of property, plant and equipment in the second quarter, etc.

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

Operating profit: -4.9, -4.8%

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Now, starting on page 14, we will continue with three slides of quarterly trends.

The first slide is a look at the cost structure. On the right side are comments on YoY and QoQ comparisons, respectively.

For both of these, the cost ratio has improved, the SG&A or R&D expense ratio has increased, and the operating income ratio has decreased slightly.

The first of these that require additional explanation is the cost ratio. The first three periods, from Q3 of the previous fiscal year to Q1 of this fiscal year, all recorded cost ratios above 40%. Ronapreve delivery to the government was made during this period, and this contributed the most to the cost ratio.

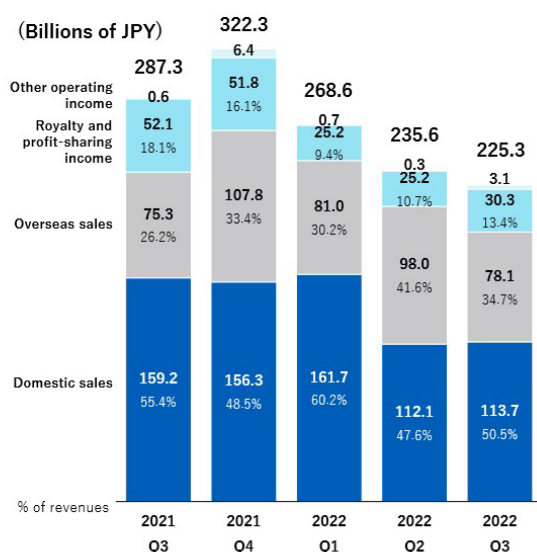
As you know, Ronapreve is a sublicense from Regeneron through Roche, so it is a product with a high cost ratio. In Q2 and Q3 of this year, there was no government delivery of Ronapreve, which means that the cost ratio will return to the 30% range. However, we expect the cost ratio to rise again because of the scheduled delivery of Ronapreve in Q4.

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Structure of Revenues by Quarter



Year on Year (2021 Q3)

Domestic sales: decrease due to the absence of supply of Ronapreve to the government, etc.

Overseas sales: significant increase in sales of Hemlibra

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

Quarter on Quarter (2022 Q2)

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

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

Royalty and profit-sharing income: Increase in royalty income related to intellectual property rights of Hemlibra

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Page 15 shows the revenue composition.

The reasons for the changes in revenue are stated on the right side.

The first point is that domestic sales, which included government deliveries of Ronapreve, were high during these three quarters.

Second, with the start of Hemlibra shipments at the regular price, overseas sales are gradually increasing in terms of revenue amount and as a proportion of overall revenues.

The third point is that the shipment delay affecting Actemra in Q3 resulted in a small decrease in that quarter for overseas sales in absolute and relative terms.

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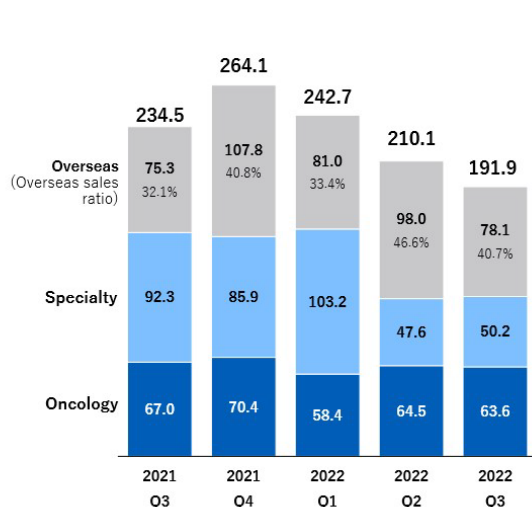
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Structure of Sales by Quarter

(Billions of JPY)



Year on Year (2021 Q3)

Oncology	Avastin:	-3.9	Herceptin:	-0.6
	Polivy:	+0.9	Kadcyla:	+0.6
Specialty	Ronapreve:	-42.8	Ediol:	-7.4
	Evrysdi:	+2.7	Hemlibra:	+2.5
	Vabysmo:	+2.3	Enspryng	+1.8
Overseas	Hemlibra:	+15.5	Actemra:	-8.8
	Alecensa:	-4.8		

Quarter on Quarter (2022 Q2)

Oncology	Avastin:	-1.0	Polivy:	+0.6
Specialty	Vabysmo:	+1.4	Hemlibra:	+1.0
Overseas	Actemra:	-20.9	Hemlibra:	-2.3
	Alecensa:	+3.0		

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Please see page 16. This is the quarterly trend of sales by disease area.

Revenues in the oncology area have remained mostly flat, as the downside due to biosimilars has mostly been absorbed by growth in sales of new products.

In the specialty area, sales of Hemlibra and new products are growing steadily. Sales of Ronapreve have fluctuated depending on government deliveries.

Overseas revenue was lower in Q3, which, as already discussed, is due to Actemra shipping delays.

This concludes the section on quarterly trends.

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P/L Jan - Sep(vs. Forecast)

(Billions of JPY)	Actual 2022	Forecast 2022		2021
	Jan - Sep	Jan - Dec	Progress	Progress*
Revenues	729.5	1,150.0	63.4%	67.8%
Sales	644.7	1,031.5	62.5%	67.1%
Domestic	387.6	646.3	60.0%	69.9%
Overseas	257.1	385.2	66.7%	62.0%
Royalties and other operating income	84.9	118.5	71.6%	70.5%
Royalty and profit-sharing income	80.7	114.0	70.8%	72.3%
Other operating income	4.2	4.5	93.3%	34.7%
Cost of sales	- 262.4	- 460.0	57.0%	67.3%
(cost to sales ratio)	40.7%	44.6%	-	-
Operating expenses	- 168.1	- 250.0	67.2%	70.0%
M&D and G&A	- 67.1	- 100.5	66.8%	66.6%
Research and development	- 101.0	- 149.5	67.6%	72.5%
Operating profit	299.0	440.0	68.0%	67.0%
(operating margin)	41.0%	38.3%	-	-
Net income	213.0	312.5	68.2%	67.3%
EPS (JPY)	129.48	190.00	68.1%	67.3%

Domestic Sales

Overall progress nearly in line with forecast
Ronapreve supply to the government expected in the fourth quarter

Overseas sales

Export of Actemra was delayed due to manufacturing timing

Royalty and profit-sharing income

Progress steady in view of forecast

Other operating income

Progress nearly in line with forecast

Cost of Sales

Cost to sales ratio nearly in line with Jan to Sep forecast

Operating expenses

Overall progress slightly lower than forecast

Operating profit

Progress nearly in line with forecast

* Jan - Sep progress versus Jan - Dec

17

Next, on page 17, is progress against the forecast.

The progress rate to the full-year forecast as of the end of Q3 is generally in line with our expectation for domestic sales, other operating expenses, and cost of sales.

First, the progress rate of domestic sales and cost of sales is a little lower than last year. Of the forecast Ronapreve sales, about 70%, or just under JPY140 billion, will be recorded in Q4. This is the reason why the progress rate of domestic sales and cost of sales appears low.

In the overseas segment, progress has been low due to Actemra shipment delays. We expect that this will also carry forward to affect the timing of Q4 shipments.

As for royalty and profit-sharing income, sales of Roche's Hemlibra have been growing steadily and are progressing well against our expectations.

Lastly, operating profit is generally in line with our forecast, as the effects of the Actemra shipment delays were offset by favorable royalty income and unrecognized expenses.

Now, on the next page, we will look at the contents in dimensions, such as the balance of the forecast.

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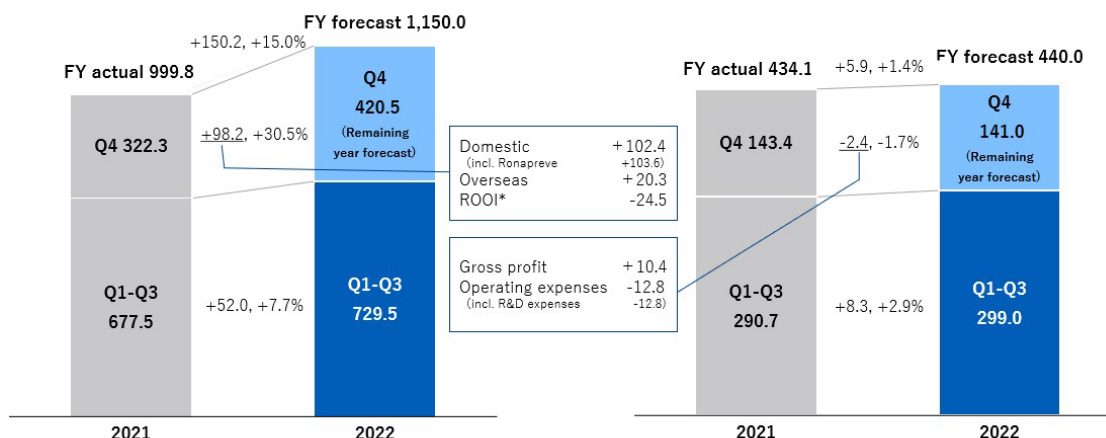
Jan-Sep Actual and Remaining Year Forecast (Year on Year)

(billions of JPY)

<Revenues>

<Operating profit>

* ROOI: Royalties and other operating income



18

See page 18.

This slide shows revenue on the left half, and operating profit on the right half, for the previous and current fiscal years, respectively.

The figures for Q4 of the current fiscal year are written as the projected balance for the full year minus the actual results through to Q3. Projecting the Q4 results based on the remainder from the full-year forecast, we forecast a 30.5% increase in revenue in Q4, while operating profit is forecast to decrease by 1.7%.

The results up to Q3 showed an increase in revenue and profit, but when we look at the remainder for Q4, there is a discontinuity between the increase in revenue and the decrease in profit. This can be explained with the figures in the boxes by the charts.

First, in terms of revenue, domestic sales are forecast to increase YoY by JPY102.4 billion because of the government delivery of Ronapreve in this Q4. Overseas sales are forecast to remain strong, increasing JPY20.3 billion. The ROOI is anticipated to fall by JPY24.5 billion due to the loss of royalty 2 income from Hemlibra.

As a result, forecast revenue in Q4, net of various factors, is plus JPY98.2 billion, a YoY increase of 30.5% due to the Ronapreve effect.

On the other hand, if you look at the operating profit balloon, gross profit will increase by only JPY10.4 billion.

Ronapreve, a factor in the increase in revenues explained earlier, is a sublicense product with a high cost of sales ratio. The gross profit margin and ROOI of minus JPY24.5 billion, which is a factor that lowers profits, will net JPY98.2 billion increase in revenues, but only JPY10.4 billion increase in gross profit.

There is a JPY12.8 billion increase there, which is an increase in expenses. This is because there is a budget for research and development expenses, which has been lowered by a huge amount, so if we net it out, the operating income has decreased by JPY2.4 billion.

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As a result, there is a distortion or discontinuity in this forecast balance base of increased revenues and decreased profits.

That is an analysis from the perspective of the forecast balance, but looking at the most recent forecast, there are changes in the forecast balance. These have occurred due to delays in Actemra shipments, which also affects Q4, and downside factors such as the upward shift in Ronapreve's cost of sales due to the weak yen. The downside is that the yen's depreciation will push up the cost of Ronapreve.

However, we hope to achieve results as planned at the beginning of the term by absorbing the downside through the positive effect of yen depreciation on the earnings portion of unhedged revenue, favorable ROOI, and cost control.

FY2022 Q3 Consolidated Financial Overview (Core)



Sales Jan - Sep(vs. Forecast)

(Billions of JPY)	Actual	Forecast		2021
	2022 Jan - Sep	2022 Jan - Dec	Progress	
Sales	644.7	1,031.5	62.5%	67.1%
Domestic	387.6	646.3	60.0%	69.9%
Oncology	186.5	260.5	71.6%	73.1%
Avastin	50.9	69.4	73.3%	73.9%
Tecentriq	43.9	62.0	70.8%	74.1%
Perjeta	23.5	33.7	69.7%	73.9%
Alecensa	20.9	28.7	72.8%	72.6%
Polivy	9.1	16.2	56.2%	51.5%
Kadcyla	13.6	16.0	85.0%	71.3%
Herceptin	5.4	8.3	65.1%	76.5%
Gazyva	3.1	5.4	57.4%	71.1%
Rituxan	3.3	4.1	80.5%	70.6%
Foundation Medicine	5.3	9.1	58.2%	68.6%
Other	7.7	7.5	102.7%	75.9%
Specialty	201.0	385.8	52.1%	66.7%
Ronapreve	60.8	199.0	30.6%	55.3%
Hemlibra	35.2	51.8	68.0%	70.4%
Actemra	31.2	41.9	74.5%	73.8%
Enspryng	11.5	16.7	68.9%	63.9%
Edirol	8.5	10.8	78.7%	78.5%
Mircera	8.1	10.2	79.4%	74.3%
Evrysdi	8.0	8.8	90.9%	17.4%
CellCept	5.8	7.4	78.4%	73.8%
Bonviva	5.3	7.0	75.7%	74.4%
Oxarol	4.1	5.1	80.4%	74.2%
Vabysmo	3.2	4.6	69.6%	-
Other	19.2	22.5	85.3%	67.8%
Overseas	257.1	385.2	66.7%	62.0%
Hemlibra	135.0	186.0	72.6%	54.0%
Actemra	80.2	144.4	55.5%	61.8%
Alecensa	27.0	34.1	79.2%	76.4%
Enspryng	2.0	4.6	43.5%	80.0%
Neutrogen	6.7	8.8	76.1%	74.7%
Edirol	0.0	0.1	0.0%	-
Other	6.2	7.4	83.8%	74.2%

↑ exceed forecast
↓ below forecast

* Jan - Sep progress versus Jan - Dec

19

Next, on page 19, we see the sales forecast ratio as a percentage of total sales.

We have explained that the total domestic revenue is generally as expected, and overall overseas revenue has been showing a little bit slow progress. However, looking at individual products, progress has been mixed. We have placed blue upward arrows next to items that are progressing better than expected and gray downward arrows for those with less progress. The other products are generally as expected.

The progress toward full-year forecast of the products marked with upward arrows is generally over 80%. Many of the products with downward arrows have not attained progress to the full-year forecast of 70%. Of these, two products, both in the specialty area, deserve special mention. The first is Ronapreve. As mentioned earlier, a government delivery is planned for Q4, so progress to the full-year forecast is only 30.6% at present.

Vabysmo is at 69.6% progress to the full-year forecast, which does not seem particularly good when you look at it alone. However, since it was launched in May, it has penetrated the market at a very rapid pace, exceeding our expectations. I think it will be able to exceed our initial forecast.

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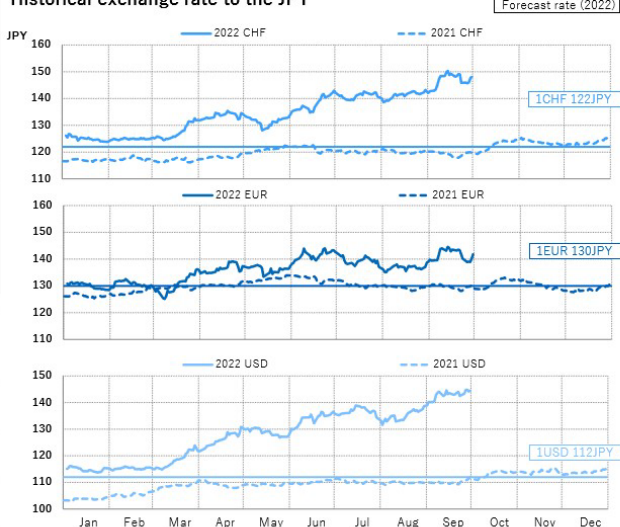


Impact from Foreign Exchange Jan - Sep

(billions of JPY)	vs. 2021 Actual	vs. 2022 Assumption
Revenues		
Sales	+20.6	+5.1
Royalties and other operating income	+13.8	+2.4
	+6.8	+2.7
Cost of sales	-7.6	-0.6
Operating expenses	-3.3	-2.1
Operating profit	+9.7	+2.4

Market average exchange rate(JPY)	2021 Actual	2022 Assumption	2022 Actual
1CHF	119.03	122.00	134.54
1EUR	129.77	130.00	136.10
1USD	108.45	112.00	128.01

Historical exchange rate to the JPY



20

Page 20 is on exchange rate fluctuations.

Compared to the previous year, since the yen was hedged against last year's depreciation, revenue increased by JPY20.6 billion and costs, including costs and expenses, increased by JPY10.9 billion. This resulted in a net increase in operating profit of JPY9.7 billion.

Next, in terms of the forecast, because transactions that are not hedged and to which we have exposure inevitably appear in Q3, the revenue variance is favorable by JPY5.1 billion and the cost variance is unfavorable by JPY2.7 billion in total. This results in a net favorable variance of JPY2.4 billion at the operating profit level.

As you can see, the weak yen is beneficial until Q3, but in Q4, it is a hindrance. Since the Ronapreve government delivery is scheduled in Q4, sales and cost of sales are expected to be recorded only after Q4. The purchase portion is affected by the yen's depreciation due to the lack of currency hedging, resulting in an unfavorable variance in the cost of sales recorded in Q4.

For the full year, the effect on operating profit is expected to be unfavorable, that is, negative, based on the assumed exchange rates in this table.

This concludes the explanation of profit and loss.

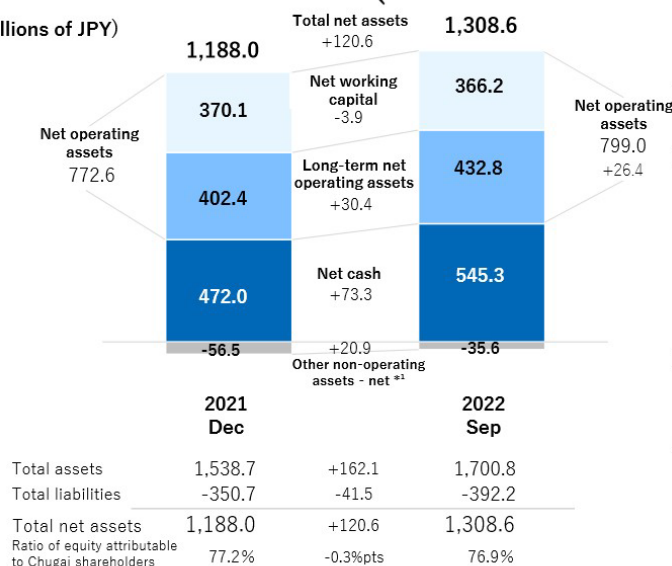
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Financial Position (vs. 2021 Year End)

(Billions of JPY)



Decrease in net working capital

Decrease mainly in trade accounts receivable

Increase in long-term net operating assets

Increase in property, plant and equipment due mainly to the following investments

- Chugai Life Science Park Yokohama
- New manufacturing building for APIs^{*2} (FJ2) at Fujieda Plant
- Biopharmaceutical APIs manufacturing building (UK4) at Ukima Branch

Increase in net cash

(See next slide)

Increase in other non-operating assets - net

Decrease mainly in current income tax liabilities

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

21

Page 21 covers the balance sheet.

If you look at the second line from the bottom on the left, as of the end of September, total net assets were JPY1.3086 trillion, an increase of JPY120.6 billion from the end of the previous period.

Above that, in the top row, liabilities increased by JPY41.5 billion, but assets increased by more than that, JPY162.1 billion.

Net cash increased by JPY73.3 billion to a balance of JPY545.3 billion, and a breakdown of the change in net cash is shown on the next page.

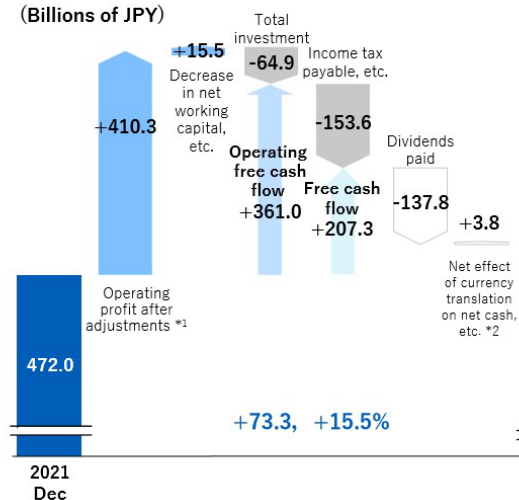
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Net Cash (vs. 2021 Year End)

(Billions of JPY)



Operating profit after adjustment *1	+410.3
Operating profit *1	+383.8
Depreciation, amortization and impairment *1	+22.6
Decrease in net working capital, etc.	+15.5
Total investment	-64.9
Property, plant and equipment	-50.7
Payment for lease liabilities	-5.7
Intangible assets	-8.6
Operating free cash flow	+361.0
Income tax payable, etc.	-153.6
Income tax payable	-151.1
Free cash flow	+207.3
Dividends paid	-137.8
Net effect of currency transaction on net cash, etc. *2	+3.8

*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)

22

Please see page 22.

Cash flow in from operating activities, the second item from the left here is adjusted operating income, which was JPY410.3 billion. There is no core or full basis for cash flow, so you can start with full basis here.

Thus, this included a cash-in donation from Alexion for the settlement. At the rate at the time the settlement was concluded, JPY91.9 billion was recorded, but due to the depreciation of the yen, the amount received in foreign currency was converted to yen, which alone gave a swing of JPY4.4 billion.

From this, we add JPY15.5 billion in working capital, a decrease in net working capital, and subtract JPY64.9 billion in payments for new research and manufacturing facilities, and we have a positive operating free cash flow of JPY361 billion.

The total of JPY153.6 billion in taxes and year-end dividends, plus interim dividends, will result in a net cash outflow of JPY137.8 billion. This gives a net cash increase of JPY73.3 billion, leaving a net cash balance of JPY545.3 billion at the end of September.

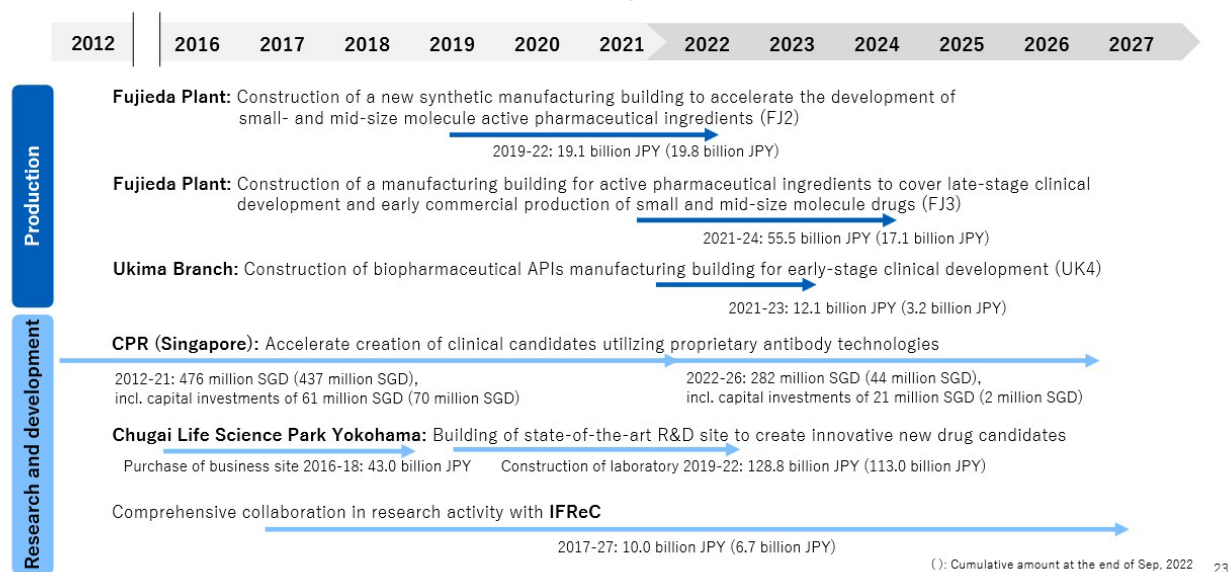
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Current Status / Plan for Major Investments



This is the last of my slides, page 23, and it covers the status of major investments.

No new projects have been added, just an update of the actual amount. FJ2 in Fujieda was completed on August 30, and Chugai Life Science Park Yokohama was successfully completed last week on October 15. Construction of FJ3 and UK4 in Ukima is well underway.

This concludes my presentation.

Sasai: Now, Mr. Yamaguchi will discuss the overview of development pipeline.

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Overview of Development Pipeline

Q3 Topics



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

As of October 24, 2022

Launched	Mitchga*	Itching associated with atopic dermatitis (only when existing treatment is insufficiently effective) (JP)	August 2022
Approved	Edirol Polivy	Edirol tablet (Additional dosage form) Previously untreated DLBCL	August 2022 August 2022
Filed	SKY59/crovalimab Actemra RG6264** FoundationOne Liquid CDx cancer genomic profile	PNH (China) (priority review designation) Systemic sclerosis with interstitial lung disease (EU) HER2-positive breast and colorectal cancer Expanded use of the results in the detection of genetic alterations "copy number alterations" in 324 genes related to cancer and the information of "bTMB scores" as a comprehensive genomic profiling	Q3 2022 August 2022 September 2022 October 2022
New to pipeline	SA237/Enspryng SA237/Enspryng RG7828/mosunetuzumab RG6396/pralsetinib DONQ52 RG6330/KRAS G12C inhibitor RG6433/SHP2 inhibitor	MOGAD AIE r/r aNHL (in combination with Polivy) Solid tumors Celiac disease Solid tumors Solid tumors	P3(August 2022) P3(September 2022) P3(October 2022) P2(October 2022) P1(September 2022) P1(September 2022) P1(September 2022)
Medical conference	DONQ52	Non-clinical study results including MOA and results of clinical research : ICDS2022	October 2022
Others	Introduction of PRIME technology NXT007	A license agreement for Noile-Immune's PRIME CAR-T technology Out-licensing agreement with Roche	August 2022 August 2022
Development discontinued	RG7446/Tecentriq	RCC (adjuvant) (IMmotion010 study)	

* Out-licensed to Maruho in Japan ** PER/HER fixed-dose subcutaneous combination

25

Tetsuya Yamaguchi: My name is Yamaguchi.

Please proceed to slide 25. This covers themes in Q3.

We have already announced the launch, approval, and filing, so I will skip those, but I would like to talk about the pipeline.

First, Enspryng, an in-house product, has entered global Phase III studies for MOGAD, an anti-myelin oligodendrocyte glycoprotein antibody-related disease, and AIE, an autoimmune encephalitis.

In addition, as mentioned earlier, Phase I trial has begun for DONQ52, an in-house project, for celiac disease.

We have in-licensed RG6330, a KRAS G12C inhibitor, and RG6433, a SHP2 inhibitor, from Roche and started Phase I trials in Japan. These will be explained in more detail later.

In other areas, we signed a license agreement in August for PRIME technology, a CAR-T therapy owned by Noile-Immune and will aim to make CAR-T cell therapy available for patients with solid tumors by utilizing PRIME technology and Chugai's drug discovery technology.

In August, Roche signed a licensing agreement for NXT007, the next generation product of Hemlibra, which was introduced earlier. We will continue to collaborate with Roche to strengthen our hemophilia franchise.

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DONQ52 (Celiac Disease)

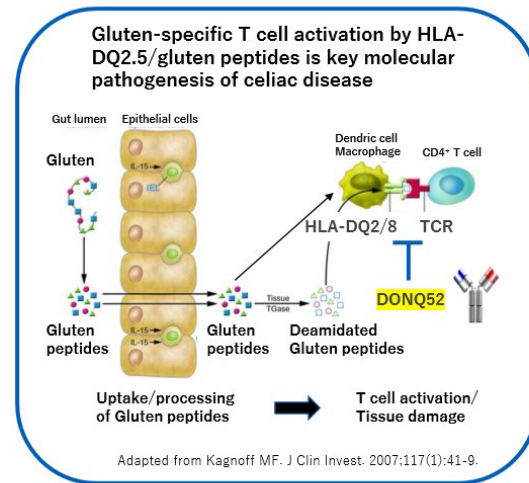
Anti-HLA-DQ2.5/gluten peptides bispecific antibody for celiac disease. P1 study initiated.

Celiac disease (CeD): Autoimmune disease caused by gluten. Abnormal immune reaction to gluten damages small intestine.

- ~1% of global population is affected by CeD.
- >90% of patients have HLA-DQ2.5 allele.
- Gluten Free Diet (GFD) is the only treatment and there are no available medicines.

DONQ52: Bispecific antibody against complex of HLA-DQ2.5/gluten peptides.

- DONQ52 directly inhibits gluten dependent T cell activation by neutralizing interaction of T cell receptor (TCR) and complex of HLA-DQ2.5/gluten peptides.
- DONQ52 covers >25 gluten derived peptides including all immunodominant gluten peptides for CeD.
- Gluten-specific blockade enables long-acting (subcutaneous injection) and high safety profile.



26

Please proceed to slide 26. This covers DONQ52.

Celiac disease is an autoimmune disease caused by gluten, in which an abnormal immune reaction to gluten damages small intestine.

About 1% of the world's population is affected by celiac disease. In Japan, it is a rare disease, with less than 1,000 patients diagnosed. More than 90% of patients have the HLA-DQ2.5 allele. Currently, there is no available medicines, and a gluten-free diet is the only treatment available.

DONQ52 is our originated bispecific antibody that binds a complex of HLA-DQ2.5 and gluten peptides. It specifically binds to the complex of HLA-DQ2.5 and gluten peptides and inhibits T cell activation.

Since it works for a long time in the blood, it can be administered subcutaneously in small doses and is also expected to have a good safety profile.

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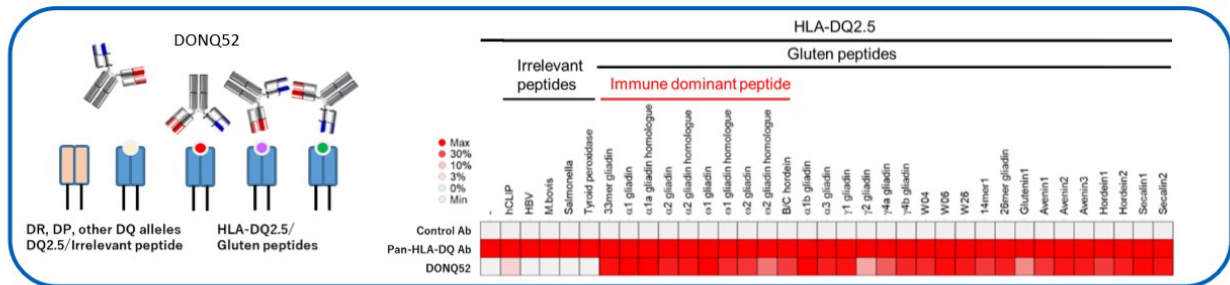
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DONQ52 : Preclinical Study Results

DONQ52 binds to more than 25 types of gluten peptides that cause celiac disease

Binding property of DONQ52

- Specific binding to complex of HLA-DQ2.5/gluten peptides.
- No binding to HLA molecule itself or complex of HLA-DQ2.5/irrelevant peptides.
- Bispecific technology enables binding to more than 25 gluten peptides, including all dominant peptides responsible for celiac disease



Source: International Celiac Disease Symposium 2022

27

Please proceed to slide 27. We are pleased to present the results of our non-clinical studies on the unique binding properties of DONQ52.

The lower right graph shows the complex of HLA-DQ2.5 and various peptides on the horizontal axis, and the red concentration in the cell indicates the binding strength of the antibody.

The second row from the bottom shows antibodies against pan-HLA-DQ, which bind to complexes other than gluten peptides and do not show gluten specificity.

On the other hand, the bottom line is DONQ52, which binds specifically only to the HLA complex of more than 25 gluten peptides, including the dominant peptide that is the main cause of celiac disease.

There have been cases in which gluten-free diets have not completely eliminated gluten, and intestinal problems persist. Phase I study has been initiated in the US for these patients.

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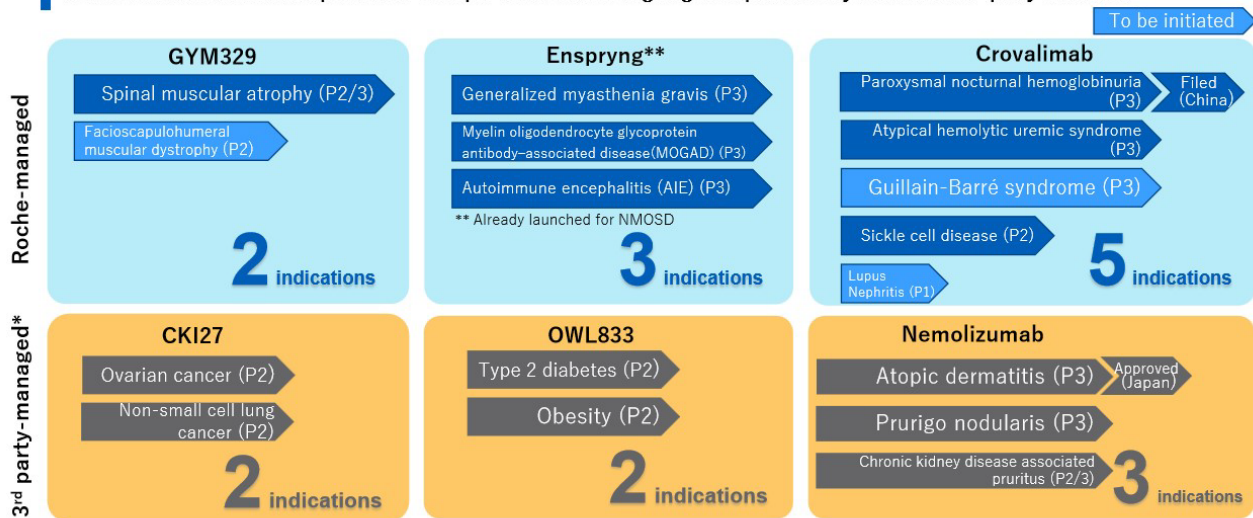
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Overview of Development Pipeline

Accelerate Multiple Simultaneous Development to Maximize the Value of In-house Developed Late-stage Products



Global simultaneous developments of multiple diseases are ongoing for 6 products by Roche and 3rd party licensees



* CKI27: Developed by Verastem, OWL833: Developed by Eli Lilly, Nemolizumab: Developed by Galderma (overseas) and Maruho (Japan)

28

Please proceed to slide 28.

As you can see, we are collaborating with Roche and the third-party licensees in the lower row to simultaneously develop our late-stage in-house development items for multiple diseases.

In the middle of the upper row, we can see Enspryng. It is currently marketed for the indication of NMOSD. We have selected three autoimmune diseases with high unmet medical need in which IL-6 has been confirmed to be involved and have started Phase III trials.

On the right side, we are conducting clinical trials for crovalimab in five diseases where complement is involved and where there is a high unmet medical need. We have selected these diseases in consideration of the therapeutic area strategy and business potential.

Currently, we are developing six in-house products for a total of 17 diseases. We will continue to aggressively expand the number of indications in order to increase the scale of our in-house developed products.

Starting with the next slide, I will discuss MOGAD and AIE, for which new Phase III trials for Enspryng have been initiated.

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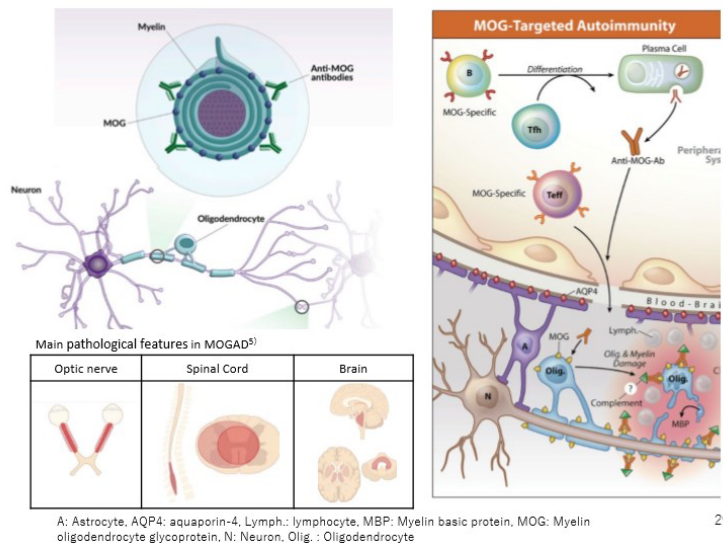
Enspryng: Myelin Oligodendrocyte Glycoprotein Antibody-associated Disease (MOGAD)

Blockade of IL-6 signalling may lead to reduced pathogenic autoantibody production and anti-inflammatory effects.
Global Phase 3 study initiated.

- MOGAD is a demyelinating disorder in which a pathogenic autoantibody “anti-MOG antibody” binds to MOG, which is expressed on the surface of myelin sheath in CNS. Symptoms include optic neuritis, myelitis, and encephalitis.¹⁾
- Currently, there are no approved therapies for MOGAD, and repeated recurrence are reported in some cases on available therapies. High UMN remains for efficacy and/or safety.^{1,2,3)}
- The number of patients in Japan is estimated to be 2,000. The first epidemiological survey has been conducted since 2021.⁴⁾

- 1) Ichiro N : Brain and Nerve. 69(11):1331-1336,2017
- 2) Ichiro N : Neurotherapeutics 36(3):220-224,2019
- 3) Zamvil SS, et al. Neurol Neuroimmunol Neuroinflamm. 2(1):e62, 2015
- 4) Specified non-profit corporation MS CABIN
<https://www.ms-cabin.org/archives/13551>
- 5) Bruba GD, et al. RadioGraphics 2018; 38:169-193

UMN: unmet medical need



29

Slide 29 will cover anti-MOG antibody-associated disease, or MOGAD.

MOGAD is a demyelinating disorder in which a pathogenic autoantibody “anti-MOG antibody” binds to MOG, which is expressed on the surface of myelin sheath in CNS. The main symptoms include optic neuritis, myelitis, and encephalitis.

There are no approved drugs for MOGAD. With current therapies, recurrence can occur multiple times, so there is a high unmet medical need.

In Japan, the first nationwide epidemiological survey has been conducted since last year, and the number of patients is estimated to be around 2,000.

Although there are no clinical data using Enspryng, an increase in IL-6 in cerebrospinal fluid and blood has been reported in MOGAD, and we expect a decrease in MOG antibody production and anti-inflammatory effects through IL-6 inhibition. In collaboration with Roche, we have started a Phase III placebo-controlled comparative study, METEOROID.

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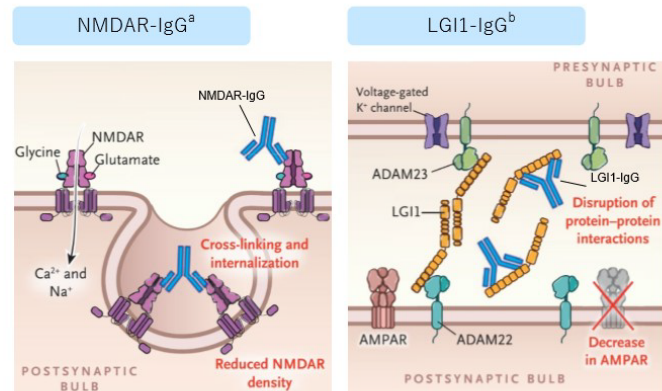
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Enspryng: Autoimmune Encephalitis (AIE)

Blockade of IL-6 signalling may lead to a decrease in the production of pathogenic autoantibodies and normalization of BBB.⁵⁾
Global Phase 3 study initiated.

- Autoimmune encephalitis is a pathological condition presenting with various psychiatric and neurological symptoms due to autoimmune responses to various antigens.^{1,2)} Typical examples are anti-NMDA receptor encephalitis and anti-LGI1 antibody encephalitis.³⁾
- In addition to consciousness disturbance and memory disorder, convulsion-like seizure may be observed as clinical symptoms.³⁾
- There are no approved therapies for AIE. Since current therapies do not show sufficient efficacy and safety, UMN remains high.^{1,2,3)}
- In Japan, estimated number of AIE patient is approximately 1,000 -2,000.⁴⁾

1) Satoshi Yoneda: Journal of the Japanese Society of Internal Medicine 102 (8): 2060 -2064, 2013
2) Takashi Inuzuka, Masaru Kuriyama, Takashi Kanda: Brain and Nerve 68 (9): 999 -999, 2016
3) Yukitoshi Takahashi: Clinical Neurology 52 (11): 836 -839, 2012
4) Mariko Oishi, et al.: The 60th Annual Meeting of the Japanese Society of Neurology PJ-051, 2019
5) Takeshita Y, et al. Neurol Neuroimmunol Neuroinflamm. 2021 Oct 19;8(6):e1076
a IgG1 is the predominant antibody subclass in anti-NMDAR encephalitis.
b IgG4 is the predominant antibody subclass in anti-LGI1 encephalitis.



BBB: blood-brain barrier, LGI1: leucine-rich glioma-inactivated protein 1, NMDAR: N-methyl-D-aspartate receptor

30

Next is page 30.

Autoimmune encephalitis, or AIE, is a disease that causes various psychiatric and neurological symptoms such as impaired consciousness, memory impairment, and seizure-like attacks. The disease is caused by an autoimmune response at the synaptic junction of nerve cells. Typical examples are anti-NMDA receptor encephalitis and anti-LGI1 antibody encephalitis.

There are no approved drugs for AIE, and a high unmet medical need remains in the area of treatment.

In Japan, the number of patients is estimated at 1,000 to 2,000.

Although there are no clinical data using Enspryng, an increase in IL-6 has been reported in cerebrospinal fluid in AIE. Blockade of IL-6 has the potential to reduce the production of pathogenic autoantibodies and normalize the blood-brain barrier.

We have just started a Phase III placebo-controlled comparative trial, CIELO, in collaboration with Roche.

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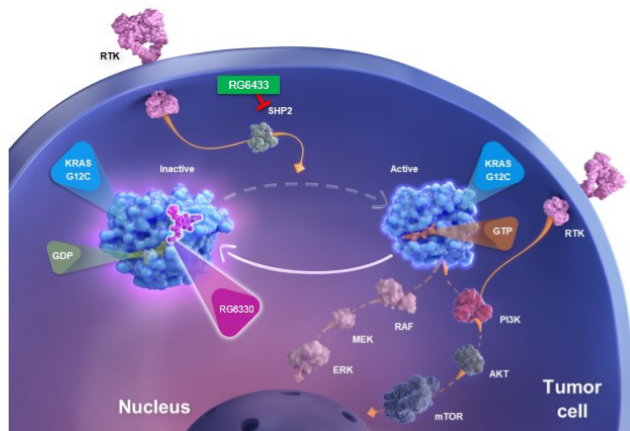
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RG6330(KRAS G12C inhibitor)/ RG6433(SHP2 inhibitor)

The combination of RG6330 with RG6433 will be expected synergistic anti-tumor activity.
Local Phase 1 study initiated.



【RG6330 (KRAS G12C inhibitor)】

- GTP-bound KRAS activates multiple downstream signalling pathways involved in cell proliferation, migration, and survival, including MAPK and PI3K pathways. KRAS G12C is in constantly active state, and increases downstream oncogenic signalling, resulting in uncontrollable cancer cell growth and tumor formation.
- RG6330 is designed as an orally available small molecule, and preclinical models showed potent and selective inhibition of the KRAS G12C protein.

【RG6433 (SHP2 inhibitor)】

- Non-receptor protein tyrosine phosphatase SHP2 (PTPN11) plays an important role in the regulation of RAS/MAPK signal transduction, which is downstream of growth factor receptor activation.¹
- RG6433 is a potent, selective, and orally bioavailable small-molecule SHP2 inhibitor that stabilizes SHP2 in a closed, auto-inhibited conformation.¹

1. Bret Williams et al. AACR 2022 31

Next, slide 31. Here I will talk about a KRAS G12C inhibitor and SHP2 inhibitor introduced from Roche.

The KRAS gene is the oldest identified oncogene mutation, with this mutation being found at a high frequency in tumors. It has been considered impossible to target for nearly 40 years, until the recent introduction of new drugs. Among the KRAS mutations, RG6330 is a potent and selective inhibitor of the G12C mutation and was discovered by Genentech.

RG6433, on the other hand, is an inhibitor of SHP2, which plays an important role in regulating cancer cell signaling. It was discovered by Relay Therapeutics and in-licensed by Genentech.

A Phase I study of the combination of the two drugs has been initiated in Japan.

LUNA18, which entered clinical trial last year, is a pan-RAS inhibitor and targets a wide range of cancer types in which RAS is involved.

With the introduction of RG6330 and RG6433, the RAS franchise will now have multiple drugs, including LUNA18, and will consider optimal combination strategies in the future.

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2022: Key R&D Milestones

	Product	Indication/Study name	Progress
Projects to be approved	Actemra	COVID-19 pneumonia (Japan)	✓
	Mitchga	Atopic dermatitis (Japan)	✓
	Hemlibra	Acquired hemophilia A (Japan)	✓
	Herceptin/Perjeta	HER2 positive colorectal cancer	✓
	Vabysmo	Neovascular age-related macular degeneration (nAMD)	✓
	Vabysmo	Diabetic macular edema (DME)	✓
	Tecentriq	Non-small cell lung cancer (NSCLC) [adjuvant]	✓
	Polivy	<u>Previously untreated diffuse large B-cell lymphoma (DLBCL)</u>	✓
P3/Pivotal readouts	Alecensa	ALINA Study: NSCLC [adjuvant]	2023
	crovalimab	COMMODORE 3 study (China): PNH	✓
	nemolizumab	OLYMPIA 2 study: Prurigo nodularis	✓
	gantenerumab	GRADUATE 1/2 study: Alzheimer's disease	
	Vabysmo	<u>BALATON/COMINO study: RVO</u>	
	Tecentriq	<u>IMpower030 study: NSCLC [neoadjuvant]</u>	2023
	Tecentriq	IMmotion010 study: RCC [adjuvant]	✗
	Tecentriq	IMvove010 study: HNC [adjuvant]	Continuous assessment
	Tecentriq + Avastin	<u>IMbrave050 study: HCC [adjuvant]</u>	2023
	Tecentriq + tiragolumab	SKYSCRAPER-01 study: NSCLC [1st line]	Continuous assessment
	Tecentriq + tiragolumab	SKYSCRAPER-02 study: SCLC	✗

Letters in orange : in-house projects (development in global) Letters in blue : in-licensed from Roche (development and distribution in Japan)
 *Underlined are new progress since July 21, 2022

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Please proceed to slide 32. The progress of key R&D milestones this year, especially from Q2 results, are underlined.

As for Phase III readouts, the readout for Tecentriq's IMpower030 and IMbrave050 trials have been postponed to 2023.

Meanwhile, two Phase III readouts for Vabysmo are planned in Q4.

For gantenerumab, as you know, we are planning two Phase III readouts in November.

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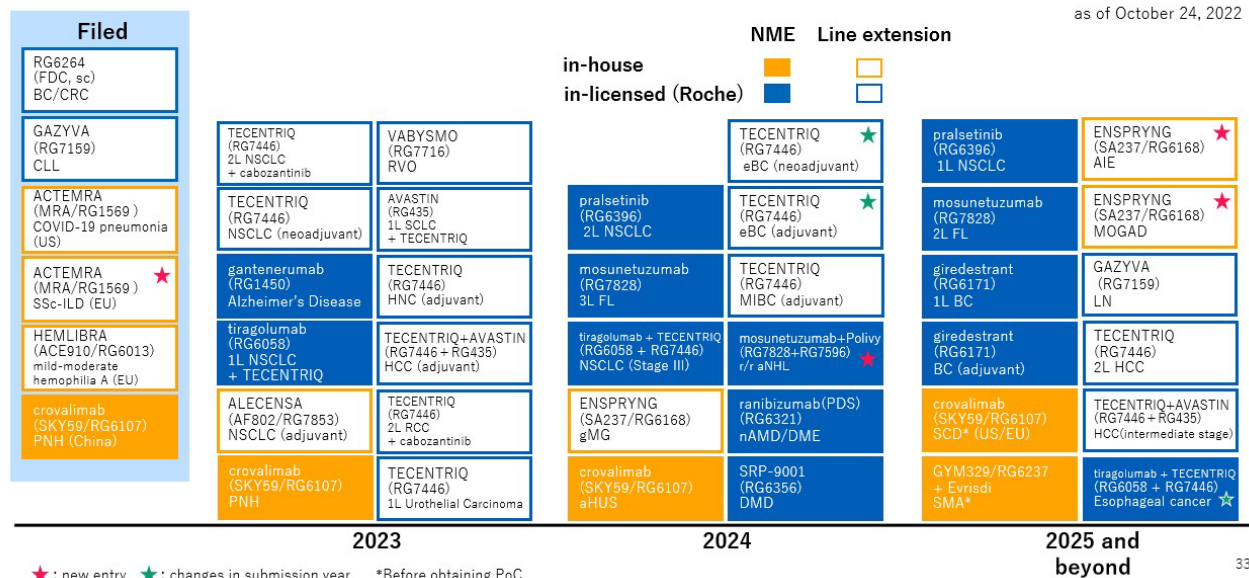
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Projected Submissions (Post PoC NMEs and Products)



as of October 24, 2022



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Starting on slide 33 is a list of upcoming submissions and the status of the development pipeline. We hope you will refer to this information as appropriate.

This concludes my presentation.

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Question & Answer

Sasai [M]: Okay, we will now move on to the Q&A session.

Please be advised that Mr. Hidaka, Executive Vice President, Head of Marketing and Sales Division, is also present for the Q&A session.

We apologize for the inconvenience, but in order to encourage as many people as possible to ask questions, we would appreciate your cooperation in limiting the number of questions to two per person. Please note that the audio of your questions will be posted on our website at a later date, along with the presentation.

We will now take your questions. When it is your turn to ask a question, I will call your name.

I would like to start with your first question. First of all, Mr. Yamaguchi of Citigroup Global Markets, please go ahead.

Hidemaru Yamaguchi [Q]: Thank you very much. Yamaguchi from Citi. I have two questions.

This is my first question. In the Q4 projections that you mentioned in the Q3 results presentation, you mentioned the delay in the Actemra export. Specifically in terms of sales, it appears from the figures that there will be a jump of about JPY15 billion or so.

Regarding your plan to stick with the current full-year forecast, and aim to cover the difference with royalties and cost-cutting, could you say more specifically where you will absorb the reduction from Actemra?

Itagaki [A]: Thank you. This is Itagaki.

First, regarding the Actemra export figure that will shift from Q3 to Q4. As you said, the reduction in Q3 was about JPY15 billion, or half the Q3 forecast figure. We expect that the same amount of the shipment will be delayed from Actemra Q4 results, and the overseas sales forecast may not be met.

The Ronapreve CoGs will be higher than the forecast due to weak yen in the unhedged part of the Ronapreve stocking. This is another minus element that needs to be absorbed. Fortunately, domestic sales is strong. As explained earlier, ROOI is also strong.

Expenses in Q3 were a little slow, and we will continue to control expenses that do not reach the budgeted amount. We expect that the downside and upside will be almost in balance, so we will aim to achieve the full-year results we forecast at the beginning of the fiscal year.

Hidemaru Yamaguchi [Q]: Thank you very much.

This is my second question. You mentioned that Vabysmo is doing well, and I believe it is attracting new patients, but I would like to know what positive factors are at play here.

Hidaka [A]: I am Hidaka, Head of Marketing and Sales Division. Thank you for your question.

I believe that as you indicated, we have made a good start with Vabysmo. Take-up by medical facilities has been good, and as well as patients switching from other therapies, we have also had some treatment-naïve patients. Doctors have been more enthusiastic about the treatment than we had expected. This is because it is a new mechanism of action, and a 16-week dosing interval is possible.

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Hidemaru Yamaguchi [M]: Thank you.

Sasai [M]: Thank you very much.

Next, Mr. Wakao, JPMorgan Securities, please go ahead.

Wakao [Q]: Wakao from JPMorgan. I also have two questions.

The first is about the outlook for the next fiscal year, which was not discussed today. In Q3, there were issues such as the delays in Actemra shipments. On the other hand, royalties seemed to be strong, and my understanding is that the performance of Hemlibra was good. Looking at the next fiscal year, it seems the fact that Hemlibra is doing rather well is an upside to the royalty outlook.

Regarding the outlook for the next fiscal year, you said that there will be no significant cliff as of Q2, but at this point, if royalties are progressing well for the next fiscal year, I was wondering if they will be rather stronger than in Q2. What is your outlook for the next fiscal year?

Itagaki [A]: Mr. Wakao, the last time we announced our financial results was in July, and I mentioned that there were some downside items in the next fiscal year. I think there were four of them, and I referred to them as so-called cliffs. I mentioned that we could avoid big cliffs by absorbing the downsides by our five upsides.

Three months have passed since then, and during this period, new downside risks to next fiscal year's forecast have emerged. First of all, under the assumption that Hemlibra sales will continue to rise from next year onward, as you mentioned, there is talk that inventory reduction might be possible by inventory adjustment of Hemlibra by Roche.

Just to confirm, global demand and market penetration of Hemlibra has been favorable, as has been the case recently, and there is talk of adjusting inventory levels, not of changing the outlook for global sales in the next fiscal year and beyond.

However, this is still very initial information, and we are not sure what the impact on our exports will be. It is the size of the inventory adjustment, the timing, and these things that change our exports. We are in the process of formulating next year's amounts on this point, so we will closely examine the impact.

The new information that I would like to share with you today is that we are seeing some cases of temporary effects on export sales.

Wakao [Q]: Understood. The nuance was that there would not be a significant decrease in profit, but since we are now scrutinizing the situation again, is it my understanding that you cannot comment now on whether this would result in a larger decrease in profit than in the past, or what the level of profit would be?

Itagaki [A]: Yes, that's right. The inventory adjustment is also a bit of an emerging situation, so I can't say for sure. I wouldn't like to talk about a cliff in this context, because it is not possible to identify the level of effect at present.

Wakao [Q]: Thank you very much.

You were able to license out NXT007 to Roche. What is the outlook for the future, and when can we expect the next stage up, and is the next study pivotal?

In addition, could you please let me know if the data from Phase I/II will be presented at a conference or other presentation in the near future? That is all.

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Tetsuya Yamaguchi [A]: My name is Yamaguchi.

Your question is about NXT007, when the next stage up is, or whether or not the next study will be pivotal, or when Phase I data will be available. I regret to inform you that we have no information that we are able to disclose. Sorry about that.

Wakao [Q]: Understood. However, the fact that Roche has introduced it suggests that they are confident that they will be able to compete with recent advances like gene therapy and Mim8?

Tetsuya Yamaguchi [A]: Indeed. Roche conducted due diligence on NXT007, and as a result of this due diligence, we believe that Roche has found sufficient potential in this product.

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

Sasai [M]: Thank you very much.

Please continue, Mr. Kohtani from Nomura Securities.

Kohtani [Q]: I am Kohtani from Nomura Securities.

Firstly, you have explained about Enspryng in today's session. During the Q2 briefing, I wondered if by any chance Enspryng might have a new mechanism. I have asked if there might be a mechanism to repair breakdown of the blood-brain barrier, and this slide shows this in great detail. Now that you have started testing in this area of autoimmune encephalitis, I wonder if you will actively examine this area. Will you continue to pursue trials in this area to see if it can be used for other diseases that require repair of the blood-brain barrier?

Also, is this only for the NMDA receptor and one other receptor, which I don't know at the moment. Or, with further demonstration of the mechanism, this could be used in other types of encephalitis, and could benefit a large number of patients. How about this first point?

Tetsuya Yamaguchi [A]: Thank you for your question, Mr. Kohtani.

It is difficult to say whether this is a repair of the brain-blood barrier, or a disruption of the barrier caused by the various immune responses that occur during the progression of this disease.

We are currently examining what is actually happening with this IL-6 blockade in various clinical trials, and I hope you will understand that I have mentioned this possibility a little more strongly this time.

Therefore, while this possibility will naturally be considered in the future expansion of indications, the current policy of screening mainly for IL-6-related diseases has not changed significantly.

In addition, we are planning to conduct clinical trials on autoantibodies in this type of population, and we will share the scope of final indication with the authorities based on the results of the trials.

Thank you.

Kohtani [Q]: I understand.

The second question is that dialysis patients on nemolizumab. A Phase II/III trial on itching was started by Galderma, I believe. It was removed from the pipeline at the end of 2019 because your company temporarily suspended development. I think it is probably that trial, but a paper was published after that saying that the

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Phase II trial did not show a statistically significant difference in itchiness versus placebo. Perhaps the reason is that this placebo improved symptoms quite substantially.

This time, this Phase II/III trial has been started, and there are many changes in the primary endpoints, inclusion criteria, and many other things, but your company used VAS in Phase II, but I was wondering why NRS was used. Also, why was this Phase II/III trial started? I thought that the dialysis pruritus was not going well, and therefore, I was wondering if you could tell me how you view the probability of success resulting from changing the key endpoints. Thank you.

Tetsuya Yamaguchi [A]: Thank you. I will take this question.

As you mentioned, in the Phase II study conducted by our company, our impression at that time was that the results of dialysis pruritus were not quite positive or negative.

On the other hand, at the time we were considering out-licensing nemolizumab overseas. Our first step was to focus on skin diseases, especially atopic dermatitis, so we did not consider further possibilities for pruritus dialysis at that time.

I understand that Galderma is now conducting the trial with a slightly narrower target patient population in order to investigate the drug again, based on the results of the Phase II trial at that time.

Beyond that, I would like to refrain from mentioning it, as it is Galderma's decision.

Kohtani [M]: I understand. Thank you very much.

Sasai [M]: Thank you very much.

Next, Mr. Muraoka from Morgan Stanley MUFG Securities.

Muraoka [Q]: Hello. Morgan Stanley, Muraoka. Thank you very much.

First, regarding the risk of Roche's inventory adjustment of Hemlibra as explained by Mr. Itagaki earlier, it is a risk. Global sales of Hemlibra are growing very steadily. In addition, in the next fiscal year, the effect of the yen's depreciation will be about 20% positive in YoY. Should I be mentally prepared for a degree of risk great enough that even these can't fully absorb it? Or is there no way that the degree of risk is that high? Please let me know.

Thank you.

Itagaki [A]: We still have no idea what is going to happen with the Hemlibra story, the amount of impact or timing. Of course, sales of Hemlibra have been increasing in volume. In terms of export revenue, the weak yen obviously has a positive effect. We will continue to closely examine what knock-on effects there will be.

Muraoka [Q]: Are you saying that you can't rule out the risk of a large negative factor?

Itagaki [A]: We don't know at this time.

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

Second question. I would like to ask about OWL, the oral GLP-1. I think the Phase II results for both diabetes and obesity were supposed to be available around the end of the year or at the beginning of the next year, but I was wondering if you could be more specific about the timing. Also, could you tell us whether this would eventually have to wait for Lilly's press release or the conference for the announcement, or if you could

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disclose this in some other way. If it is a conference or something, I think it will be next year's ADA, which is in May or June. Would we have to wait until then? Thank you.

Tetsuya Yamaguchi [A]: I will take this question.

Regarding OWL833, I had explained that the data acquisition would take place roughly around this time, based on Eli Lilly's official announcement. Since we have licensed out the clinical development rights to Lilly, we are not in a position to actively disclose information.

As you know, Eli Lilly could choose to present the results at a conference, issue a press release, or make an announcement when they move to the next phase. All of these options are at Lilly's discretion, so we are unable to make any specific comment about them.

However, I understand that Eli Lilly has stated that it has high expectations for OWL833 for both diabetes and obesity through its IR disclosures, and we are looking forward to their announcement.

Muraoka [Q]: I understand. Lilly mentions it in meetings and such, so are you saying the best thing to do is to keep checking with them?

Tetsuya Yamaguchi [A]: Yes, indeed.

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

Sasai [M]: Thank you very much.

Next, Mr. Osakabe of Nikkan Yakugyo.

Osakabe [Q]: I am Osakabe from the Nikkan Yakugyo. In the pipeline this time, there was mention of the discontinuation of the development of RG7446. Could you tell us a bit more about the background and reasoning behind this decision?

Tetsuya Yamaguchi [A]: Thank you.

RG7446, which is a renal cell carcinoma adjuvant of Tecentriq, was discontinued due to negative trial results.

Osakabe [M]: I understand. Thank you very much.

Sasai [M]: Thank you very much.

Next, Mr. Sakai from Credit Suisse Securities.

Sakai [Q]: This is Sakai from Credit Suisse. Two simple questions.

First, I would like to ask about Actemra's outlook for the future. On the Roche side, they have already begun to factor in the decrease in coronavirus sales. In fact, the guidance mentions a decrease in sales, but in the case of your company, there is a gap in terms of exports. Although I understand that there is a time gap, I am under the impression that Actemra sales on the Roche side will not have an impact on your company's exports until Q2 of next year. Is my understanding correct?

Also, in the conference call, Roche mentioned that Actemra's biosimilar will have almost no impact in FY2023. Is it correct to say that this has already been confirmed with your company? This is the first question.

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Itagaki [A]: Sales of Actemra by Roche are down, as with the Omicron variant, coronavirus-related demand is quite low.

There is some anticipation in the timing of our exports, but demand relating to coronavirus will fall both in this year and in next year. At some level, we have been meeting the reduction in inventory that occurred in the previous year, and we are exporting to recover the inventory this year. If during the next fiscal year, inventory levels return to a baseline, then by that logic we could expect exports to be lower next year than this year.

Whether that is in Q2 or not, it is difficult to say, as the timing of shipments is also a factor. However, based on that assumption, I think that shipments will be down in the next fiscal year.

As for the impact of biosimilars, Roche publicly announced that they did not anticipate an impact in 2023, and we will ship according to their orders, so we are not anticipating an impact in this area for the next fiscal year.

Sakai [Q]: Thank you.

My second question is about gantenerumab. In what form will your company announce it? I know that your company often translates Roche's announcement as is, but I wonder whether you will disclose in that way or whether you will disclose Roche's announcement itself, as I think it will attract a lot of attention.

Tetsuya Yamaguchi [A]: Thank you for your question.

CHUGAI is also participating in the gantenerumab trials, and once the results are obtained, we will release the results in some form or another in a joint effort.

Detailed data will be presented at the medical conference or other forum, but as you say, it will attract a lot of attention, so I think we would like to do something.

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

Sasai [M]: Thank you very much.

Next, BofA Securities, Mamegano.

Mamegano [Q]: My name is Mamegano from BofA Securities. I would like to ask two questions regarding the development pipeline.

The first is about DONQ52. I think that there is a market expectation since more than 90% of patients with celiac disease have this allele, but what are your thoughts on the severity of the disease that is actually being targeted? What can you tell us about this?

Tetsuya Yamaguchi [A]: Thank you for your question.

We will be better placed to discuss the target, the severity of the disease, after further investigating the efficacy of the compound. For the time being, we will target patients with non-responsive celiac disease, which is not easily controlled on a gluten-free diet.

I have heard that around 20% to 30% of people with celiac disease cannot be easily controlled on a gluten-free diet.

Mamegano [Q]: Thank you.

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One more point, Novartis has just announced that their drug has shown superiority in a comparative study in PNH, against an anti-complement drug not from your company. I am a little concerned about the impact on the future development strategy of crovalimab and other areas, but I would like to know what your company thinks about this data. Thank you.

Tetsuya Yamaguchi [A]: Thank you for your question.

I can't comment in detail on the data from Novartis, as it is another company's data, but their drug has a completely different mode of action. Basically, this has not been positioned as a competitor to our C5 inhibitor antibody.

Since the C5 blockade is a fairly well-established treatment for PNH, a very serious disease, we have anticipated competition among this mode of action.

Mamegano [M]: Thank you.

Sasai [M]: Thank you very much.

Now, due to time constraints, this will be the last question.

Lastly, Ms. Sogi of Sanford C. Bernstein, please.

Sogi [Q]: I have two questions.

One is regarding Actemra. In the US, a German company has submitted an application to the FDA for a biosimilar of Actemra. Do you have any plans to respond to this, for example with legal action?

Itagaki [A]: Itagaki here. Thank you very much.

I believe the German company you are referring to is Fresenius Kabi. Their application to the FDA was received on August 1 of this year and is under review. I believe the same is true for the EMA.

On the other hand, I think Fresenius Kabi had filed legal documents against us regarding Actemra's patents, but we have reached a settlement with them, and they have withdrawn those objections. Of course, our company was able to reach a settlement because there was a content worthy of agreement for us.

At this time, Roche and Chugai do not anticipate any impact on their immediate sales in any of their respective countries or regions. As we are planning to announce our financial results on February 2, 2023 and we will disclose the specific figures of forecast for the next fiscal year at that time. That is the situation.

Sogi [Q]: I understand. Thank you very much.

Another question I would like to ask is about the status of HER2-positive breast cancer. I understand that the sales of Perjeta are slow, but does this mean that the Perjeta's market is becoming saturated?

Also, I believe that Kadcyra's sales continue to grow, but I believe that this product may actually be impacted by DAIICHI SANKYO's ENHERTU. I would like to know your current thoughts on these two points.

Hidaka [A]: Thank you for your question. I will take your question.

As for Perjeta, it has been on a bit of a back-and-forth with Kadcyra, so I think there is a bit of a negative impact in that relationship.

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With regard to the impact of ENHERTU on Kadcyła, since DAIICHI SANKYO is about to receive approval for its application, I believe that it will definitely be affected in some way in the future. However, I am not sure of the detailed prospects. We will be better placed to consider this next year.

Sogi [M]: Thank you very much.

Sasai [M]: Thank you very much.

This is the end of the Q3 financial results briefing. As always, if you have any additional 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]

Document Notes

- 1.
2. *Speaker speech is classified based on whether it [Q] asks a question to the Company, [A] provides an answer from the Company, or [M] neither asks nor answers a question.*
3. *This document has been translated by SCRIPTS Asia.*

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