



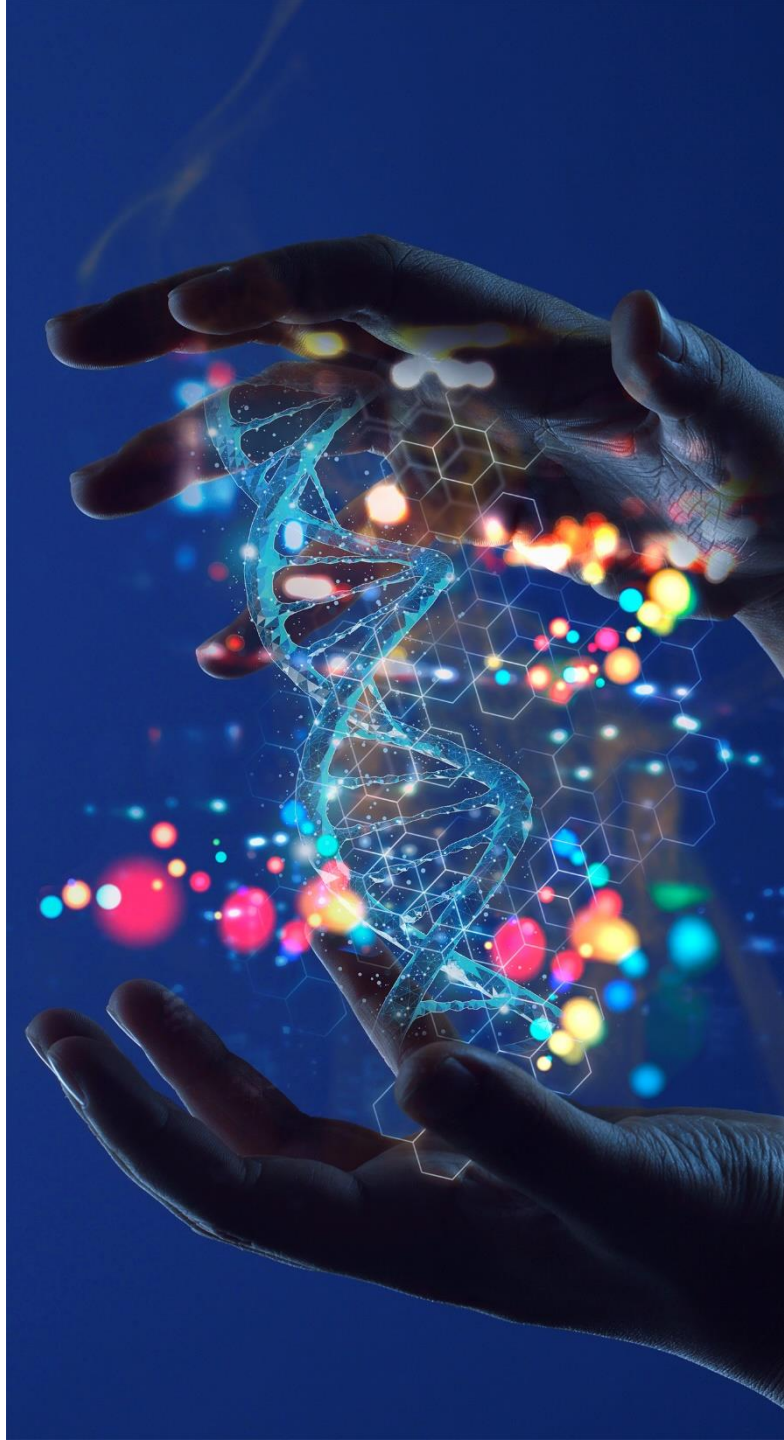
Roche Roche Group

TOP INNOVATOR  
**TOPi** 2030

# Q3 Results (Jan - Sep 2021) Conference Call

## CHUGAI PHARMACEUTICAL CO., LTD.

22 October 2021



# Important Reminder

## Forward-Looking Statements

This presentation may include forward-looking statements pertaining to the business and prospects of Chugai Pharmaceutical Co., Ltd. (the “Company”). These statements reflect the Company’s current analysis of existing information and trends. Actual results may differ from expectations based on risks and uncertainties that may affect the Company’s businesses.

## Core Results

Chugai discloses its results on a Core basis from 2013 in conjunction with its transition to IFRS. Core results are the results after adjusting non-recurring items recognized by Chugai to IFRS results, and are consistent with the Core concept disclosed by Roche. Core results are used by Chugai as an internal performance indicator, for explaining the status of recurring profits both internally and externally, and as the basis for payment-by-results, including return to shareholders.

Note:

- Amounts shown in this report are rounded to the nearest 0.1 billion yen
- Variance and % are calculated based on the amounts shown

# Agenda

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**Dr. Osamu Okuda**

President & CEO

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**Toshiaki Itagaki**

Executive Vice President & CFO

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**Overview of Development Pipeline**

**Tetsuya Yamaguchi**

Senior Vice President, Head of Project &  
Lifecycle Management Unit

# FY2021 Q3 Overview

**Dr. Osamu Okuda**

President & CEO

# Financial Overview

- ✓ YoY increase in revenues and profits in Q3 due to an increase in sales and ROOI
- ✓ Full-year forecast revised upward as outlook for domestic/overseas sales and ROOI exceeded the original forecast
- ✓ Aiming for record highs in the next fiscal year due to growth in mainstay/new products, and an increase in COVID-19-related revenues

Core (billions of JPY)	2020 Jan - Sep actual	2021 Jan - Sep actual	Growth (year on year)		Original Forecast		Revised Forecast	
					Jan - Dec	Progress	Jan - Dec	Vs. 2020 actual
<b>Revenues</b>	<b>576.5</b>	<b>677.5</b>	<b>+101.0</b>	<b>+17.5%</b>	<b>800.0</b>	<b>84.7%</b>	<b>970.0</b>	<b>+23.3%</b>
Domestic sales	303.2	362.6	59.4	+19.6%	393.7	92.1%	513.0	+25.4%
Overseas sales	161.6	176.0	14.4	+8.9%	237.3	74.2%	268.5	+19.8%
ROOI	111.7	138.8	27.1	+24.3%	169.0	82.1%	188.5	+22.7%
<b>Operating profit</b>	<b>231.9</b>	<b>290.7</b>	<b>+55.8</b>	<b>+25.4%</b>	<b>320.0</b>	<b>90.8%</b>	<b>400.0</b>	<b>+29.9%</b>
Operating margin	40.2%	42.9%	+2.7%pts	-	40.0%	-	41.2%	+2.1%pts
<b>Net income</b>	<b>165.6</b>	<b>209.7</b>	<b>+44.1</b>	<b>+26.6%</b>	<b>232.0</b>	<b>90.4%</b>	<b>293.0</b>	<b>+33.5%</b>
<b>EPS (yen)*</b>	<b>100.68</b>	<b>127.45</b>	<b>+26.77</b>	<b>+26.6%</b>	<b>141.00</b>	<b>90.4%</b>	<b>178.00</b>	<b>+33.4%</b>

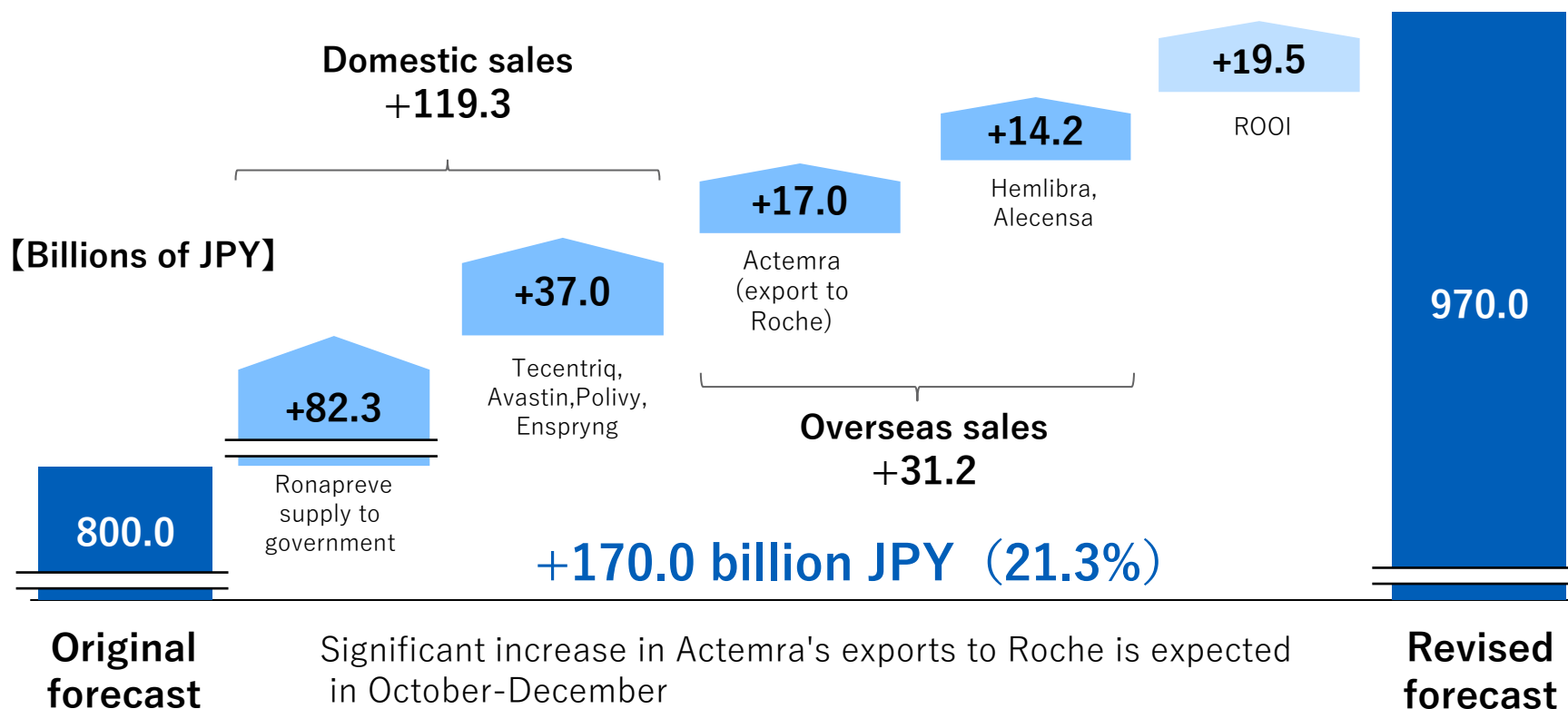
ROOI : Royalties and other operating income

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

- Domestic sales were affected by drug price revisions and generics, but mainstay products and new products were steadily penetrating the market, including the supply of Ronapreve to the government and an additional indication for Tecentrig
- In overseas sales, Actemra's exports to Roche decreased YoY, which was in line with original forecasts. Hemlibra sales increased as expected, while Alecensa sales increased more than expected
- ROOI increased mainly due to an increase in royalty and profit-sharing income based on growth in overseas local sales of Hemlibra
- Revised upward to 170.0 billion yen (+21%) in revenues and 80.0 billion yen (+25%) in operating profit

# Topline Overview

- ✓ Domestic sales of mainstay/new products in addition to the supply of Ronapreve to the government will grow significantly above initial expectations
- ✓ Overseas exports of in-house products to Roche will increase, and ROOI is expected to increase due to an increase in overseas local sales
- ✓ Full-year revenue forecast was revised upward due to the growth in mainstay/new products and an increase in COVID-19 related revenues



- Domestic sales are expected to exceed original forecasts due to mainstay products (Tecentriq and Avastin) and new products (Polivy and Enspryng), in addition to the supply of Ronapreve to the government, despite the impact of drug price revisions and the penetration of generics.
- Overseas sales are expected to exceed original forecasts due to increase in Actemra's COVID-19 related exports to Roche, as well as increase in Hemlibra and Alecensa
- ROOI is expected to increase due to growth in overseas local sales of Actemra and Hemlibra
- As a result of the above, full-year revenues has been revised upward by more than 20% compared to the original forecast

# R&D Overview

## ■ Launch and value enhancement of multiple new products that contribute to business performance

- **Polivy** : Launched in May for relapsed or refractory diffuse large B-cell lymphoma(DLBCL). Polivy/R-CHP combination therapy showed significant improvement as a first-line therapy over standard treatment for untreated DLBCL (P3 POLARIX trial); Scheduled to file this year
- **Evrysdi** : Launched as the first oral drug that can be administered from 2 months of age for SMA (August)
- **FoundationOne Liquid CDx** : Launched a liquid biopsy-based comprehensive genomic profiling (CGP) test for solid tumor (August)

## ■ Progress of development products covering from prophylaxis to severe treatment of COVID-19

Prophylaxis and asymptomatic infection	Ronapreve	Filed for additional indications for prophylaxis and treatment of asymptomatic COVID-19, as well as additional subcutaneous administration (October)
Mild to Moderate	Ronapreve	Approved for the first time in the world (July)
	AT-527	P3 study in progress
Moderate to Severe	Actemra	Scheduled to file this year in Japan

## ■ Progress of in-house early development products that support medium- to long-term growth

- In-house created mid-size molecule development product LUNA18 entered P1 study as a new modality (October)
- Wide range of early-developed products with our unique antibody engineering technology such as switch antibody STA551

# Application for Selection of New Market Segment “Prime Market”

## ■ Results of initial assessment

Chugai received the results of its initial assessment from the Tokyo Stock Exchange on July 9, 2021, and confirmed that the Company complies with the listing criteria for the "Prime Market" in the new market segment.

## ■ Future action

Based on the results, after the resolution by the Board of Directors of the Company, we will proceed with the prescribed procedures related to the application for the selection of the new market segment in accordance with the schedule set by the Tokyo Stock Exchange.



# FY2021 Q3 Consolidated Financial Overview(Core)

**Toshiaki Itagaki**

Executive Vice President & CFO

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

(Billions of JPY)	2020	2021	Growth	
<b>Revenues</b>	<b>576.5</b>	<b>677.5</b>	<b>+ 101.0</b>	<b>+ 17.5%</b>
Sales	464.8	538.7	+ 73.9	+ 15.9%
Domestic	303.2	362.6	+ 59.4	+ 19.6%
Overseas	161.6	176.0	+ 14.4	+ 8.9%
Royalties and other operating income	111.7	138.8	+ 27.1	+ 24.3%
Royalty and profit-sharing income	89.1	135.4	+ 46.3	+ 52.0%
Other operating income	22.6	3.4	- 19.2	- 85.0%
<b>Cost of sales</b>	<b>-200.3</b>	<b>-225.7</b>	<b>- 25.4</b>	<b>+ 12.7%</b>
(cost to sales ratio)	43.1%	41.9%	-1.2%pts	-
<b>Operating expenses</b>	<b>-144.3</b>	<b>-161.1</b>	<b>- 16.8</b>	<b>+ 11.6%</b>
M&D and G&A <sup>*1</sup>	-62.2	-66.9	- 4.7	+ 7.6%
Research and development	-82.2	-94.1	- 11.9	+ 14.5%
<b>Operating profit</b>	<b>231.9</b>	<b>290.7</b>	<b>+ 58.8</b>	<b>+ 25.4%</b>
(operating margin)	40.2%	42.9%	+2.7%pts	-
Financial account balance	-2.2	-1.9	+ 0.3	- 13.6%
Income taxes	-64.1	-79.2	- 15.1	+ 23.6%
<b>Net income</b>	<b>165.6</b>	<b>209.7</b>	<b>+ 44.1</b>	<b>+ 26.6%</b>
EPS (JPY) <sup>*2</sup>	100.68	127.45	+26.77	+ 26.6%

## Domestic sales

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

## Overseas sales

Decrease in sales of Actemra, but increase in sales of Hemlibra and Alecensa

## Royalty and profit-sharing income

Significant increase in income for Hemlibra

## Other operating income

Decrease in one-time income

## Cost of sales

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

## Operating expenses

Increase of M&D and G&A expenses due to recovery in various activities

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

## Operating profit

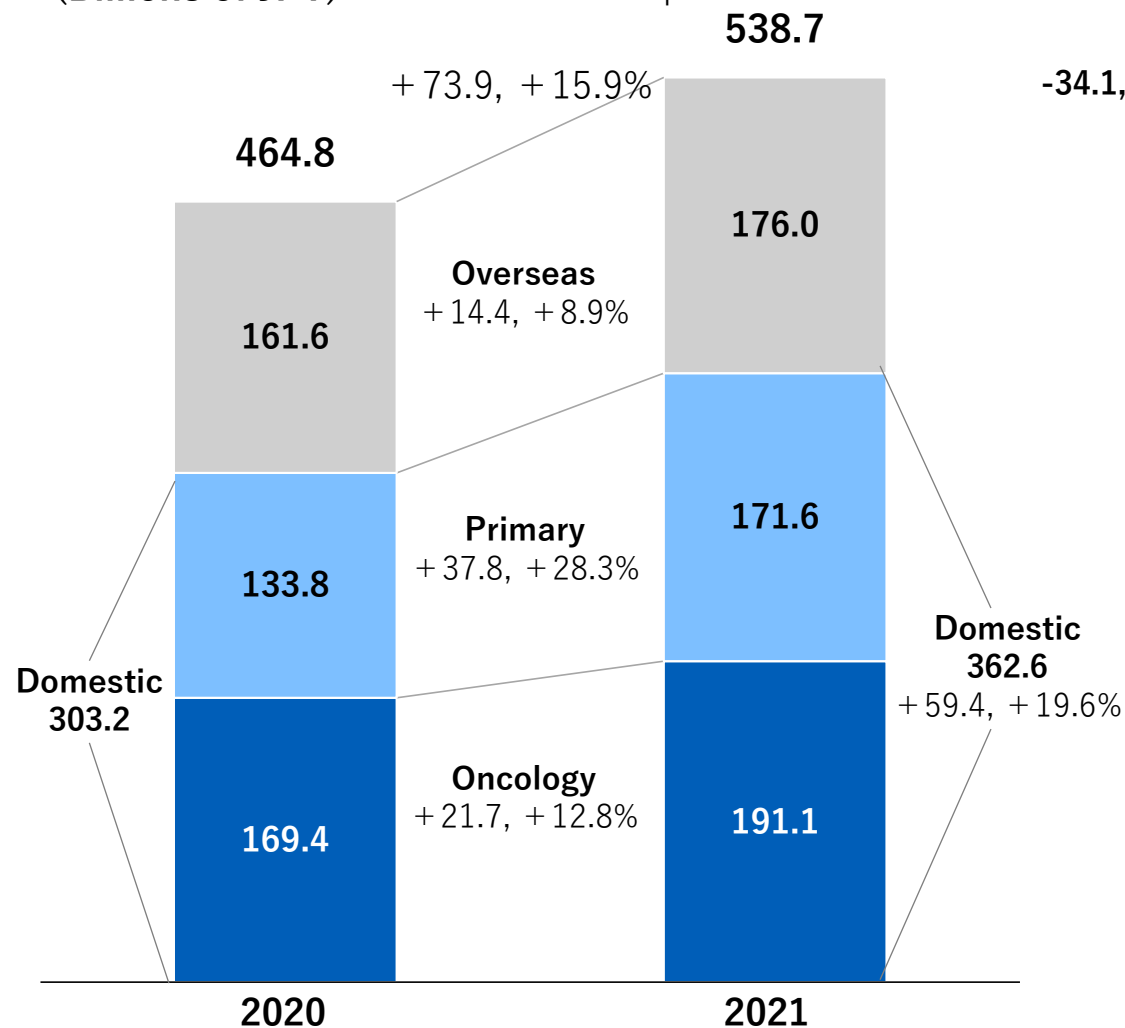
Increased due to higher royalty and profit-sharing income as well as increase in sales

<sup>\*1</sup> M&D: Marketing and distribution, G&A: General and administration

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

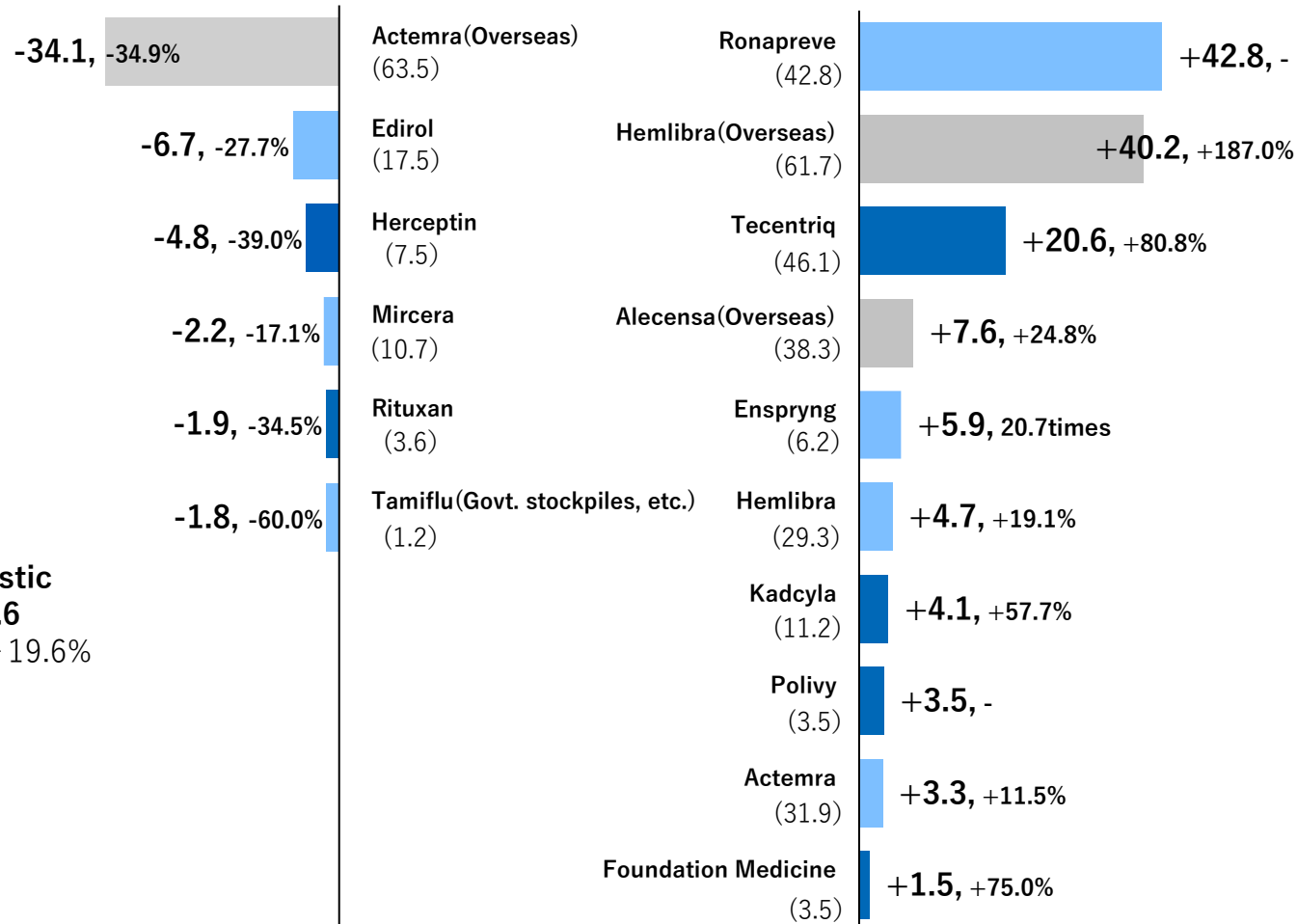
# Sales Jan - Sep (Year on Year)

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



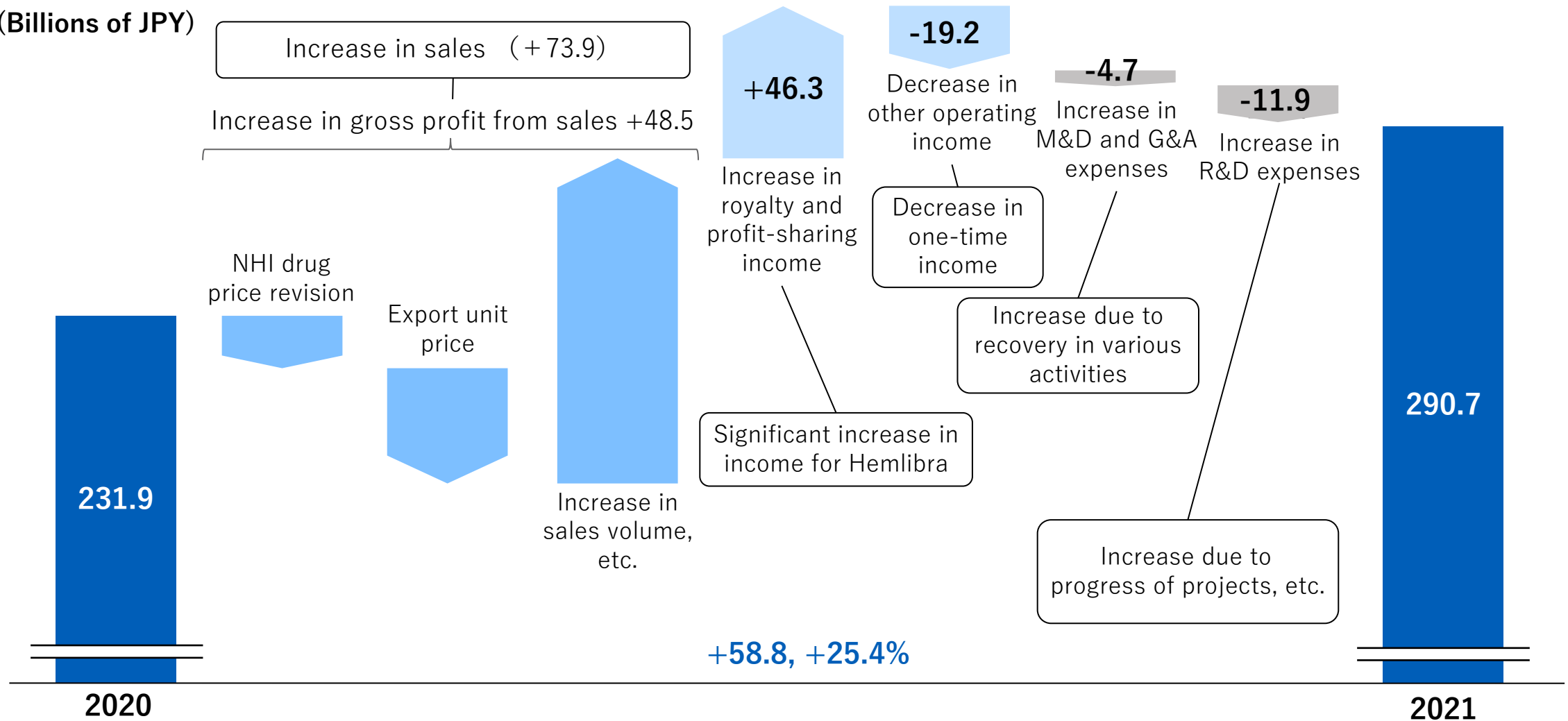
Sales by Products,  
Year on Year Changes

( ): Actual sales in FY2021  
%: Year-on-year percentage change



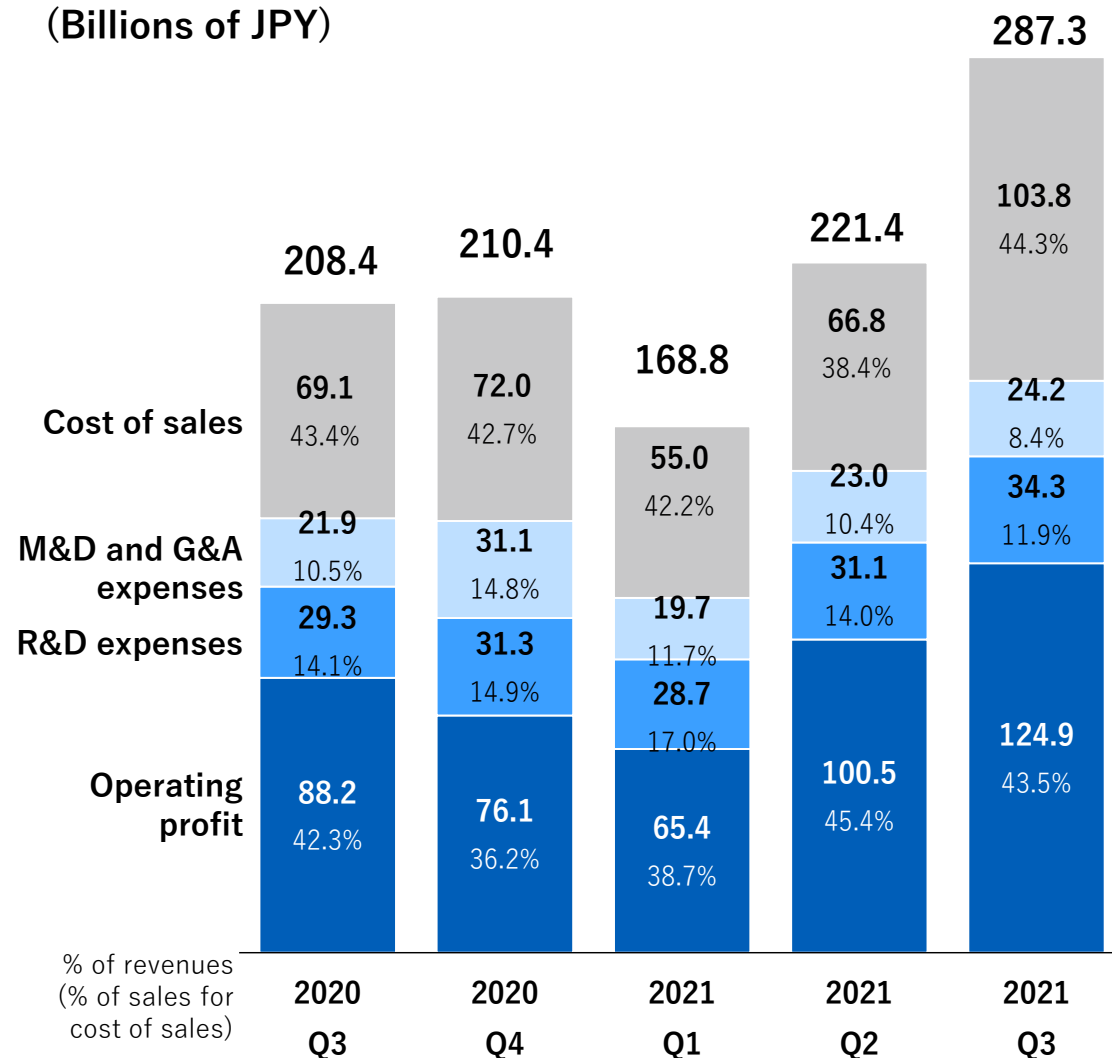
# Operating Profit Jan - Sep (Year on Year)

(Billions of JPY)



# Structure of Costs and Profit by Quarter

(Billions of JPY)



## vs. Year on Year (2020 Q3)

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

M&D and G&A expenses: increase due to recovery in various activities

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

Operating profit: increase of +36.7 (+41.6%)

## vs. Previous Quarter (2021 Q2)

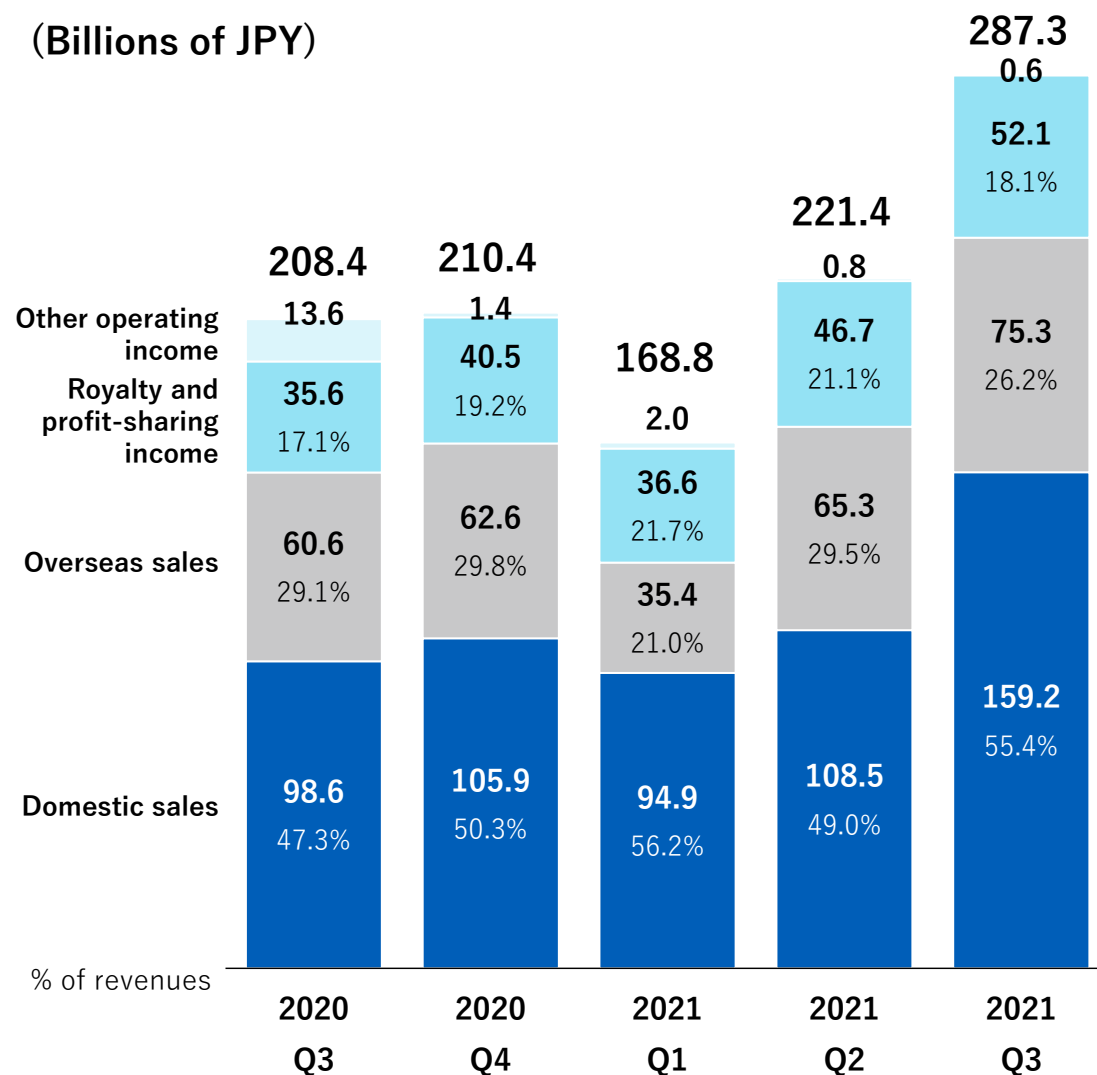
Cost of sales ratio: rise due to a change in product mix, etc.

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

Operating profit: increase of +24.4 (+24.3%)

# Structure of Revenues by Quarter

(Billions of JPY)



## vs. Year on Year (2020 Q3)

Domestic sales: increase due to sales growth of new products and mainstay products despite impact of generic drugs

Overseas sales: decrease in sales of Actemra, but increase in sales of Hemlibra and Alecensa

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

Other operating income: decrease in one-time income

## vs. Previous Quarter (2021 Q2)

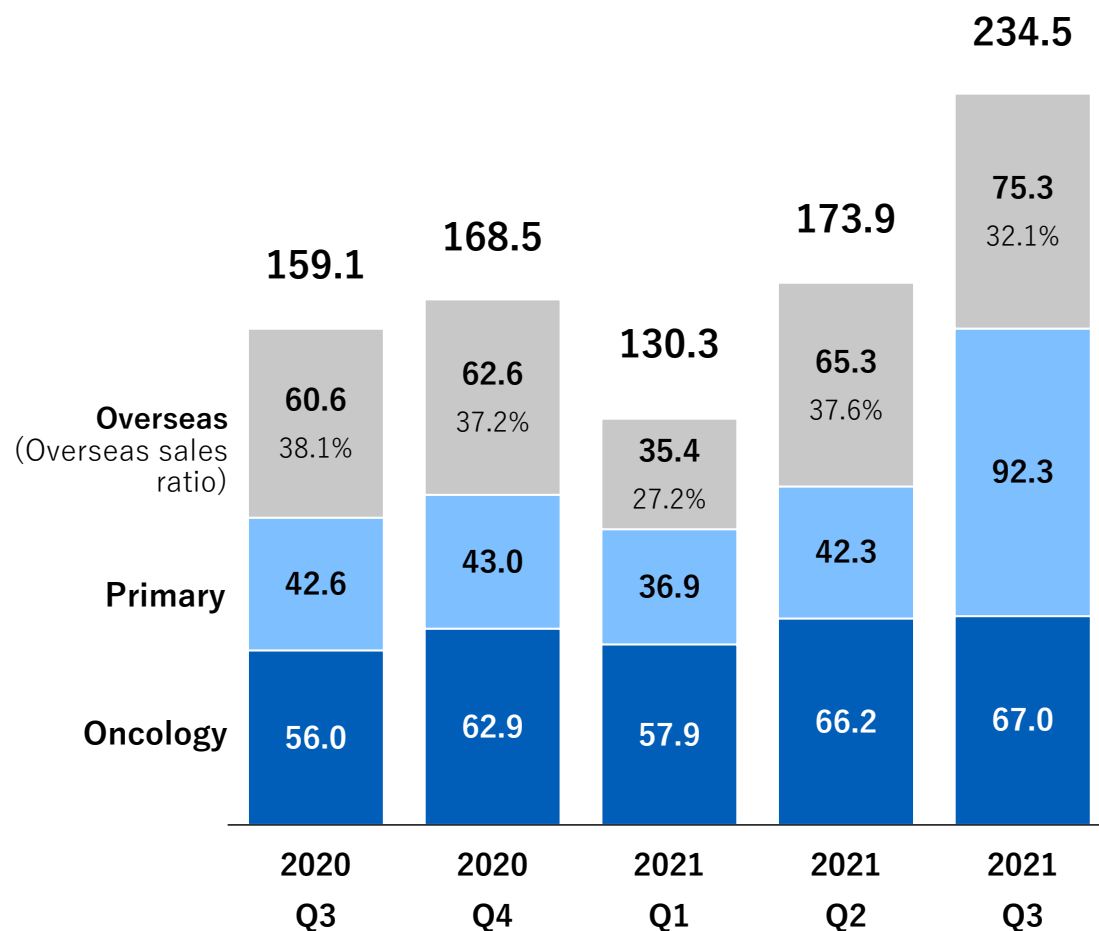
Domestic sales: increase mainly due to sales growth of new products

Overseas sales: increase in sales of Actemra and Hemlibra

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

# Structure of Sales by Quarter

(Billions of JPY)



vs. Year on Year (2020 Q3)

Overseas	Actemra:	-11.4	Hemlibra:	+23.4
	Alecensa:	+3.3		
Oncology	Tecentriq:	+6.6	Polivy:	+2.6
	Kadcyla:	+1.5	Herceptin:	-1.4
Primary	Ronapreve:	+42.8	Edirol:	+4.0
	Enspryng:	+2.3	Hemlibra:	+2.2
	Actemra:	+2.2		

vs. Previous Quarter (2021 Q2)

Overseas	Actemra:	+5.1	Hemlibra:	+3.8
	Alecensa:	+2.2		
Oncology	Polivy:	+1.7	Tecentriq:	-0.9
Primary	Ronapreve:	+42.8	Edirol:	+5.2

# P/L Jan - Dec (Revision of forecast)

(Billions of JPY)	Original Forecast 2021 Jan - Dec	Revised Forecast 2021 Jan - Dec	Revision		Year-on-Year	
<b>Revenues</b>	<b>800.0</b>	<b>970.0</b>	<b>+170.0</b>	<b>+21.3%</b>	<b>+183.1</b>	<b>+23.3%</b>
Sales	631.0	781.5	+150.5	+23.9%	+148.2	+23.4%
Domestic	393.7	513.0	+119.3	+30.3%	+103.9	+25.4%
Overseas	237.3	268.5	+31.2	+13.1%	+44.3	+19.8%
Royalties and other operating income	169.0	188.5	+19.5	+11.5%	+34.9	+22.7%
Royalty and profit-sharing income	163.0	179.5	+16.5	+10.1%	+49.9	+38.5%
Other operating income	6.0	9.0	+3.0	+50.0%	- 15.1	-62.7%
<b>Cost of sales</b>	<b>- 252.5</b>	<b>- 339.0</b>	<b>- 86.5</b>	<b>+34.3%</b>	<b>- 66.7</b>	<b>+24.5%</b>
(cost to sales ratio)	40.0%	43.4%	+3.4%pts	-	+0.4%pts	-
<b>Operating expenses</b>	<b>- 227.5</b>	<b>- 231.0</b>	<b>- 3.5</b>	<b>+1.5%</b>	<b>- 24.3</b>	<b>+11.8%</b>
M&D and G&A	- 96.0	- 99.5	- 3.5	+3.6%	- 6.3	+6.8%
Research and development	- 131.5	- 131.5	0.0	0.0%	- 18.0	+15.9%
<b>Operating profit</b>	<b>320.0</b>	<b>400.0</b>	<b>+80.0</b>	<b>+25.0%</b>	<b>+92.1</b>	<b>+29.9%</b>
(operating margin)	40.0%	41.2%	+1.2%pts	-	+2.1%pts	-
<b>Net income</b>	<b>232.0</b>	<b>293.0</b>	<b>+61.0</b>	<b>+26.3%</b>	<b>+73.6</b>	<b>+33.5%</b>
EPS (JPY) *	141.00	178.00	+37.00	+26.2%	+44.61	+33.4%
Annual Dividend (JPY)	60.00	Undecided	-	-	-	-

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

## Main reason for revision:

### Domestic Sales

Reflects the progress and revised assumptions for each product, including the supply of Ronapreve to the government

### Overseas sales

Exports of Actemra and Hemlibra to Roche will exceed the original forecast

### Royalty and profit-sharing income

Income for Actemra and Hemlibra will exceed the original forecast

### Other operating income

One-time income not included in the original forecast

### Cost of Sales

Cost to sales ratio higher due to a change in product mix from the original forecast, etc.

### Operating expenses

Increase in some expenses including those attributable to foreign exchange effects and increased sales and profits

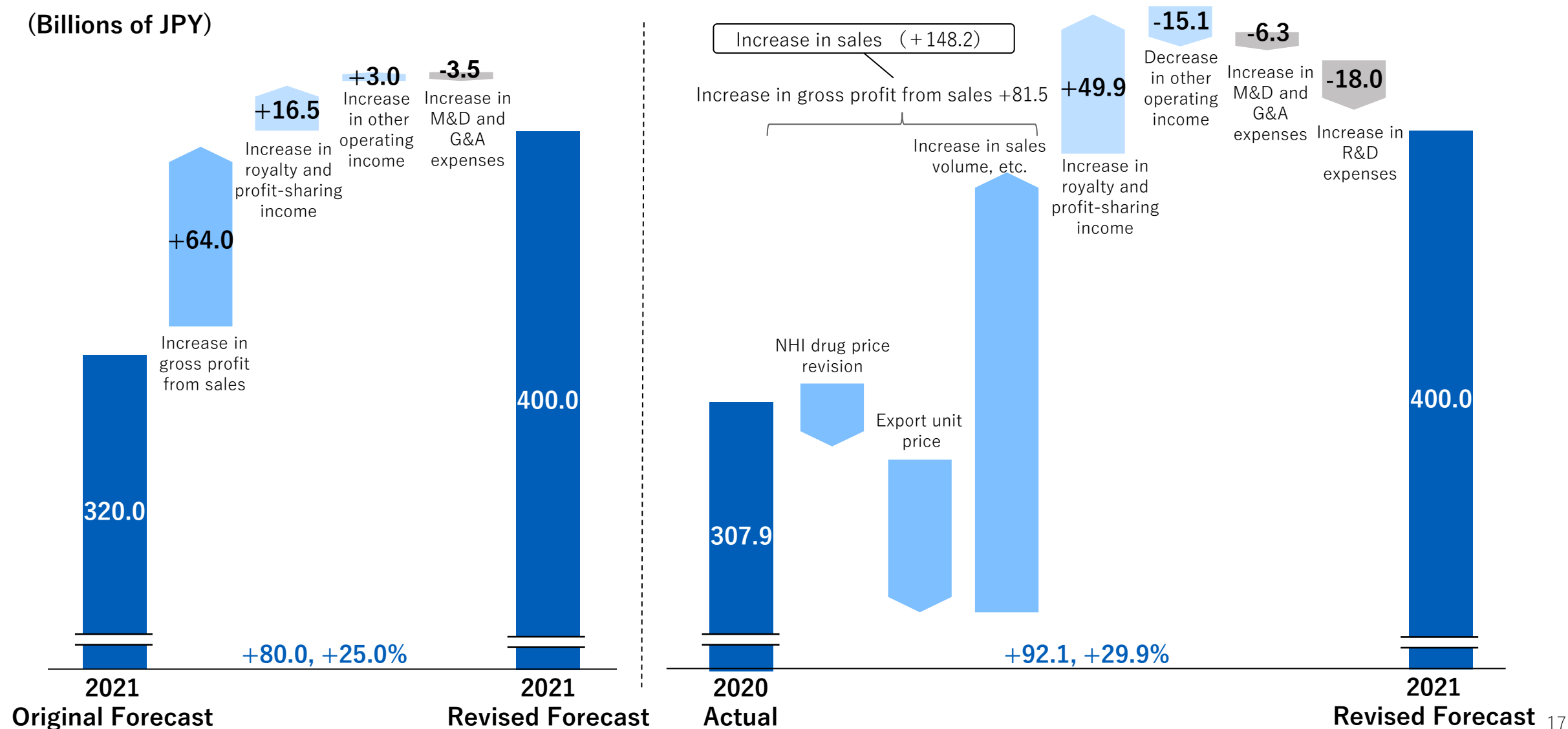
## vs. Year on Year:

Revenues+23.3%, Operating profit+29.9%



# Operating Profit Jan - Sep (Revision of forecast)

(Billions of JPY)



# Sales Jan - Dec (Revision of forecast, 1/2)

(Billions of JPY)	Original Forecast 2021 Jan - Dec	Revised Forecast 2021 Jan - Dec	Revision		Year-on-Year	
<b>Sales</b>	<b>631.0</b>	<b>781.5</b>	<b>+150.5</b>	<b>+23.9%</b>	<b>+148.2</b>	<b>+23.4%</b>
<b>Domestic</b>	<b>393.7</b>	<b>513.0</b>	<b>+119.3</b>	<b>+30.3%</b>	<b>+103.9</b>	<b>+25.4%</b>
<b>Oncology</b>	<b>226.7</b>	<b>256.0</b>	<b>+29.3</b>	<b>+12.9%</b>	<b>+23.7</b>	<b>+10.2%</b>
Avastin	60.5	80.1	+19.6	+32.4%	- 1.4	-1.7%
Tecentriq	49.2	59.8	+10.6	+21.5%	+22.3	+59.5%
Perjeta	31.8	32.0	+0.2	+0.6%	- 1.5	-4.5%
Alecensa	27.0	27.1	+0.1	+0.4%	+1.1	+4.2%
Kadcyla	13.3	14.9	+1.6	+12.0%	+4.7	+46.1%
Herceptin	10.9	9.7	- 1.2	-11.0%	- 6.2	-39.0%
Polivy	3.5	6.1	+2.6	+74.3%	+6.1	-
Rituxan	5.2	4.8	- 0.4	-7.7%	- 2.4	-33.3%
Gazyva	5.7	4.4	- 1.3	-22.8%	- 0.2	-4.3%
Xeloda	2.7	2.6	- 0.1	-3.7%	- 1.0	-27.8%
Rozlytrek	0.9	0.9	0.0	0.0%	+0.5	+125.0%
Foundation Medicine	7.2	5.6	- 1.6	-22.2%	+2.8	+100.0%
Other	8.7	8.1	- 0.6	-6.9%	- 1.0	-11.0%

## Main reason for revision:

### Avastin

Market penetration of hepatocellular carcinoma will exceed the original forecast

Original assumptions updated considering market penetration of biosimilar pharmaceuticals

### Tecentriq

Market penetration of hepatocellular carcinoma will exceed the original forecast

### Polivy

Exceeds the original forecast due to progress in early market penetration

# Sales Jan - Dec (Revision of forecast, 2/2)

(Billions of JPY)	Original Forecast 2021 Jan - Dec	Revised Forecast 2021 Jan - Dec	Revision		Year-on-Year	
<b>Primary</b>	<b>167.0</b>	<b>257.0</b>	<b>+90.0</b>	<b>+53.9%</b>	<b>+80.2</b>	<b>+45.4%</b>
Ronapreve	-	82.3	+82.3	-	+82.3	-
Actemra	38.5	42.5	+4.0	+10.4%	+3.2	+8.1%
Hemlibra	51.7	40.3	- 11.4	-22.1%	+6.2	+18.2%
Edirol	17.3	21.2	+3.9	+22.5%	- 6.6	-23.7%
Mircera	11.7	13.4	+1.7	+14.5%	- 4.1	-23.4%
Enspryng	4.0	9.3	+5.3	+132.5%	+8.0	+615.4%
CellCept	8.3	8.3	0.0	0.0%	- 0.8	-8.8%
Bonviva	8.5	8.1	- 0.4	-4.7%	- 0.8	-9.0%
Oxarol	5.5	6.1	+0.6	+10.9%	- 0.3	-4.7%
Evrysdi	1.0	1.0	0.0	0.0%	+1.0	-
Tamiflu(Ordinary use)	0.8	-0.1	- 0.9	-112.5%	- 0.9	-
Tamiflu(Govt. stockpiles, etc.)	1.2	3.4	+2.2	+183.3%	- 0.3	-8.1%
Other	18.5	21.1	+2.6	+14.1%	- 6.8	-24.4%
<b>Overseas</b>	<b>237.3</b>	<b>268.5</b>	<b>+31.2</b>	<b>+13.1%</b>	<b>+44.3</b>	<b>+19.8%</b>
Actemra	85.3	102.7	+17.4	+20.4%	- 31.7	-23.6%
Hemlibra	89.7	99.0	+9.3	+10.4%	+72.9	+279.3%
Alecensa	44.2	50.4	+6.2	+14.0%	+6.1	+13.8%
Enspryng	3.9	1.2	- 2.7	-69.2%	- 4.4	-78.6%
Neutrogin	8.7	9.2	+0.5	+5.7%	+0.2	+2.2%
Other	5.4	6.1	+0.7	+13.0%	+1.3	+27.1%

## Main reason for revision:

### Ronapreve

Obtained approval in July 2021, supplied under the agreement with the Japanese government

### Hemlibra

Downward revision against ambitious original forecast

### Edirol

Temporary increase in demand due to insufficient supply and shipping adjustments by competitors

### Enspryng

Exceeds original forecast due to successful acquisition of new patients

### Actemra (Overseas)

Exceeds original forecast due to the impact of increased demand of COVID-19, etc.

### Hemlibra (Overseas) / Alecensa (Overseas)

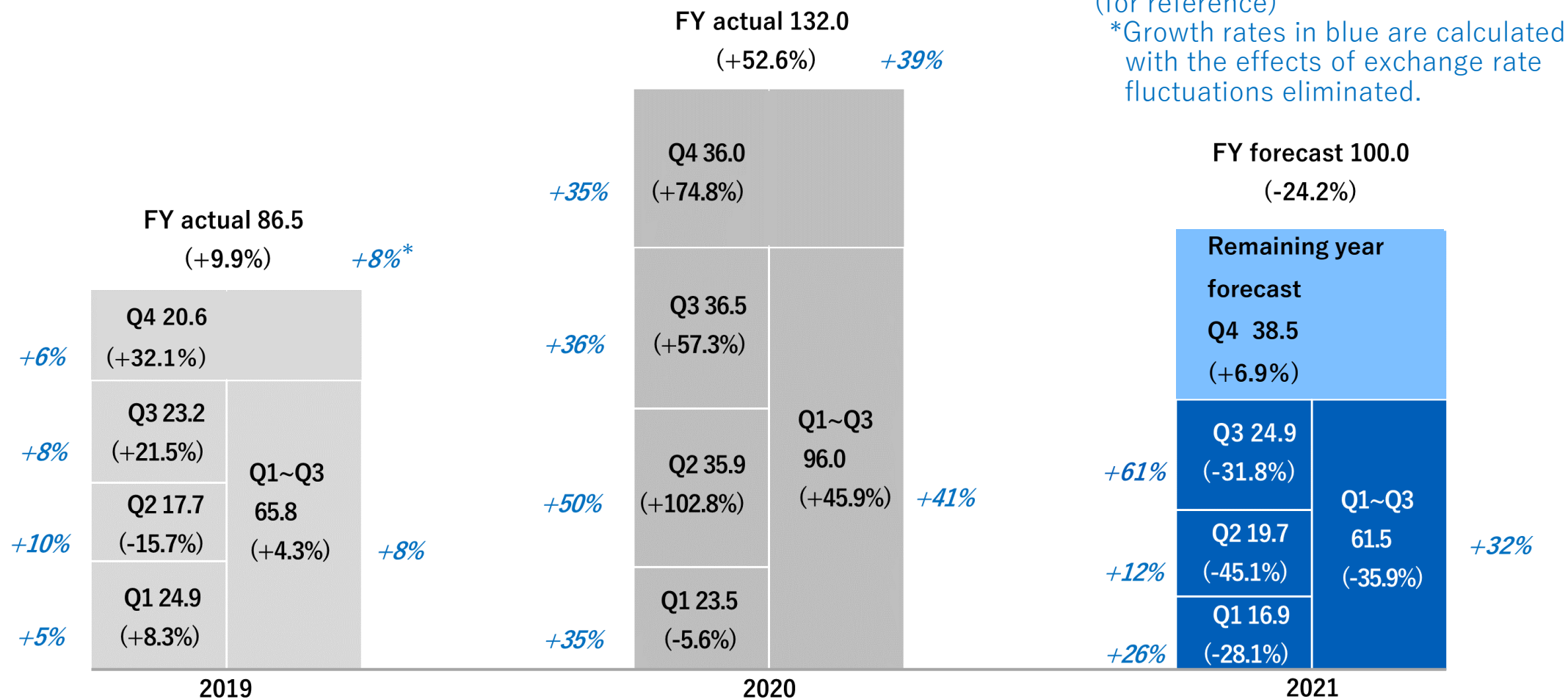
Exceeds original forecast

### Enspryng (Overseas)

Downward revision due to difference in Roche's assumptions of global market penetration, etc.

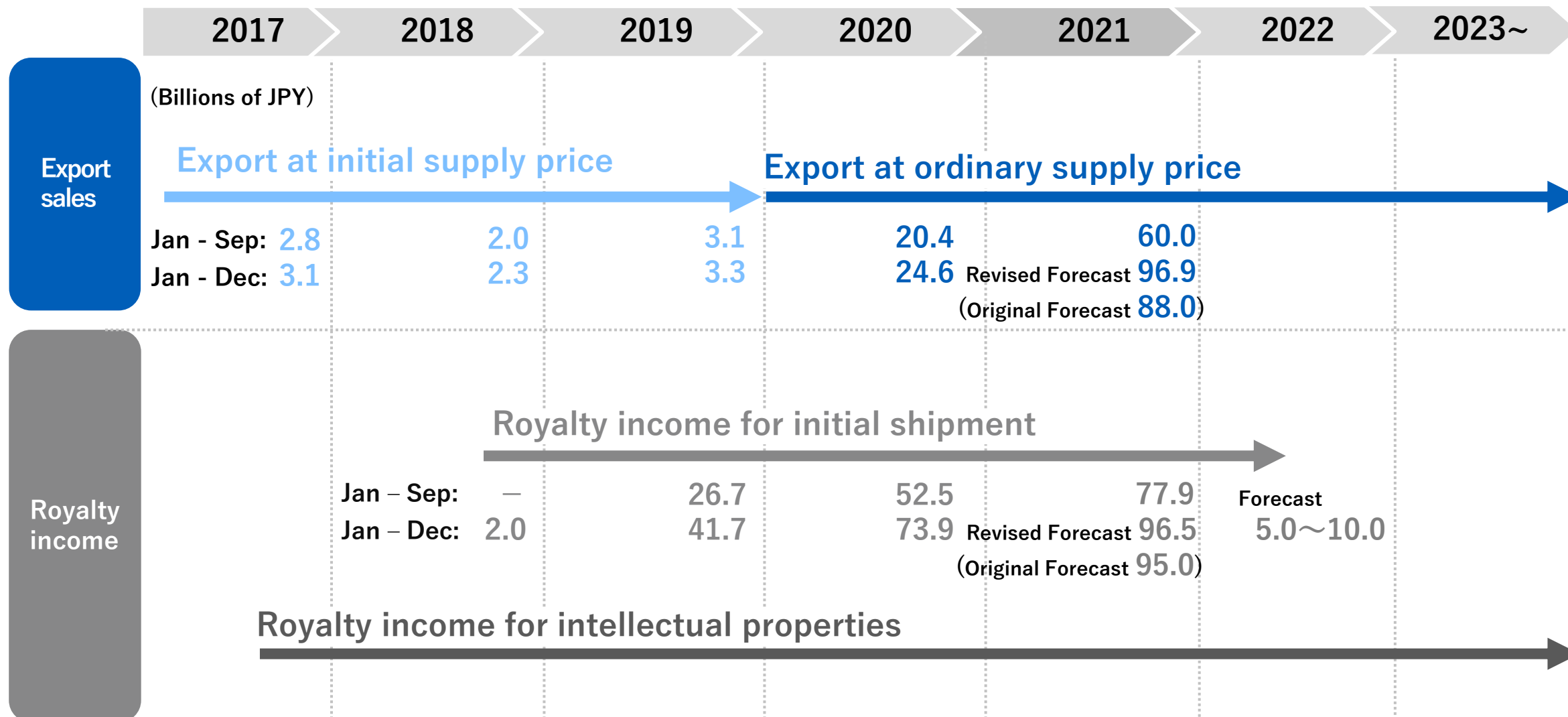
# Export of Actemra to Roche

(Billions of JPY)



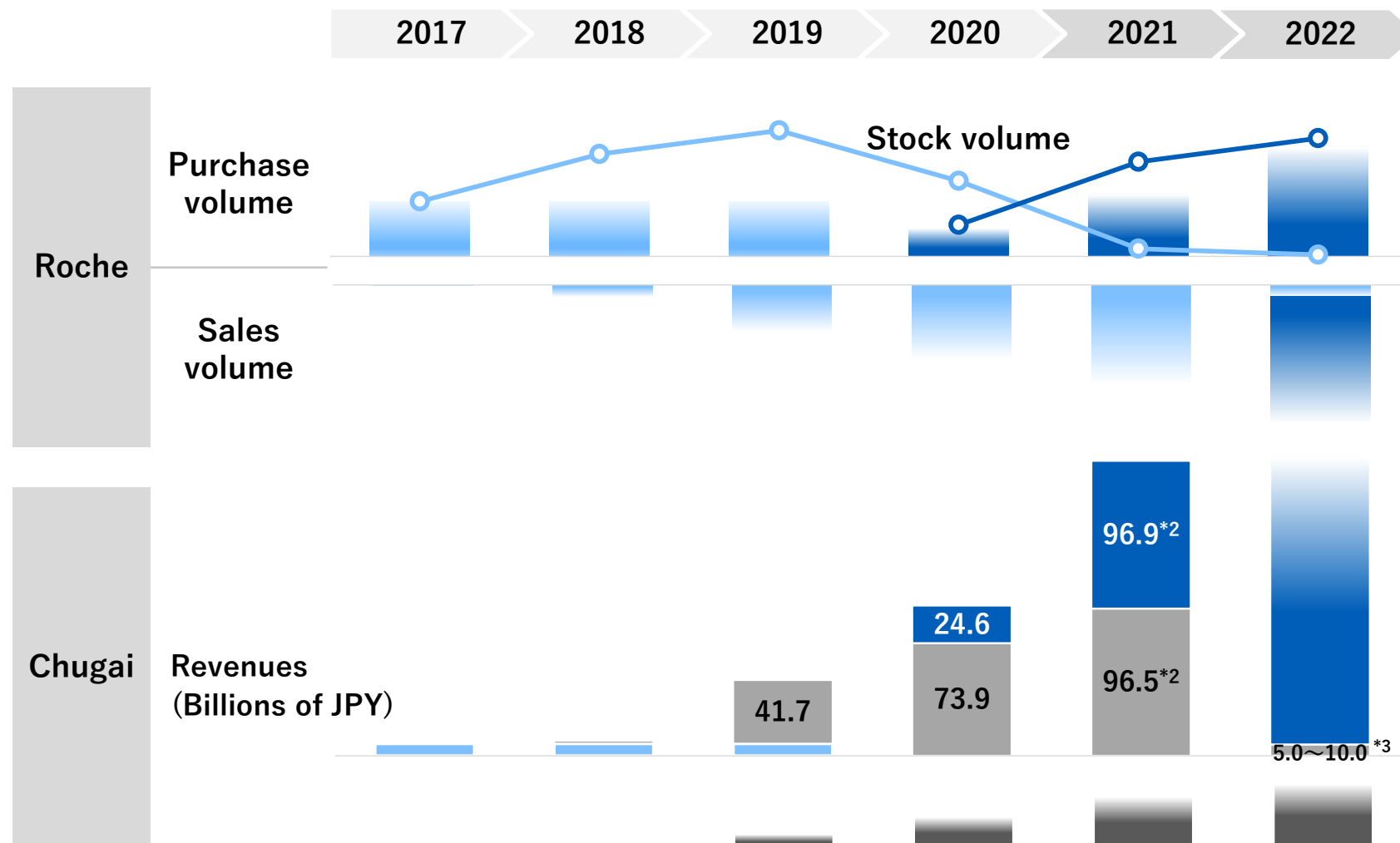
# Outline of Hemlibra Sales to Roche

(Excluding profit-sharing income and expenses in co-promotion countries)



# Outline of Hemlibra Sales to Roche

## Image for Timing of Export Sales and Royalty Income\*1



\*1 This is a conceptual image and may differ from actual amount and volume.

- Ordinary supply
- Initial supply (sales amount is based on first-in first-out method)
- Stock volume of ordinary supply (Year End)
- Stock volume of initial supply (Year End)

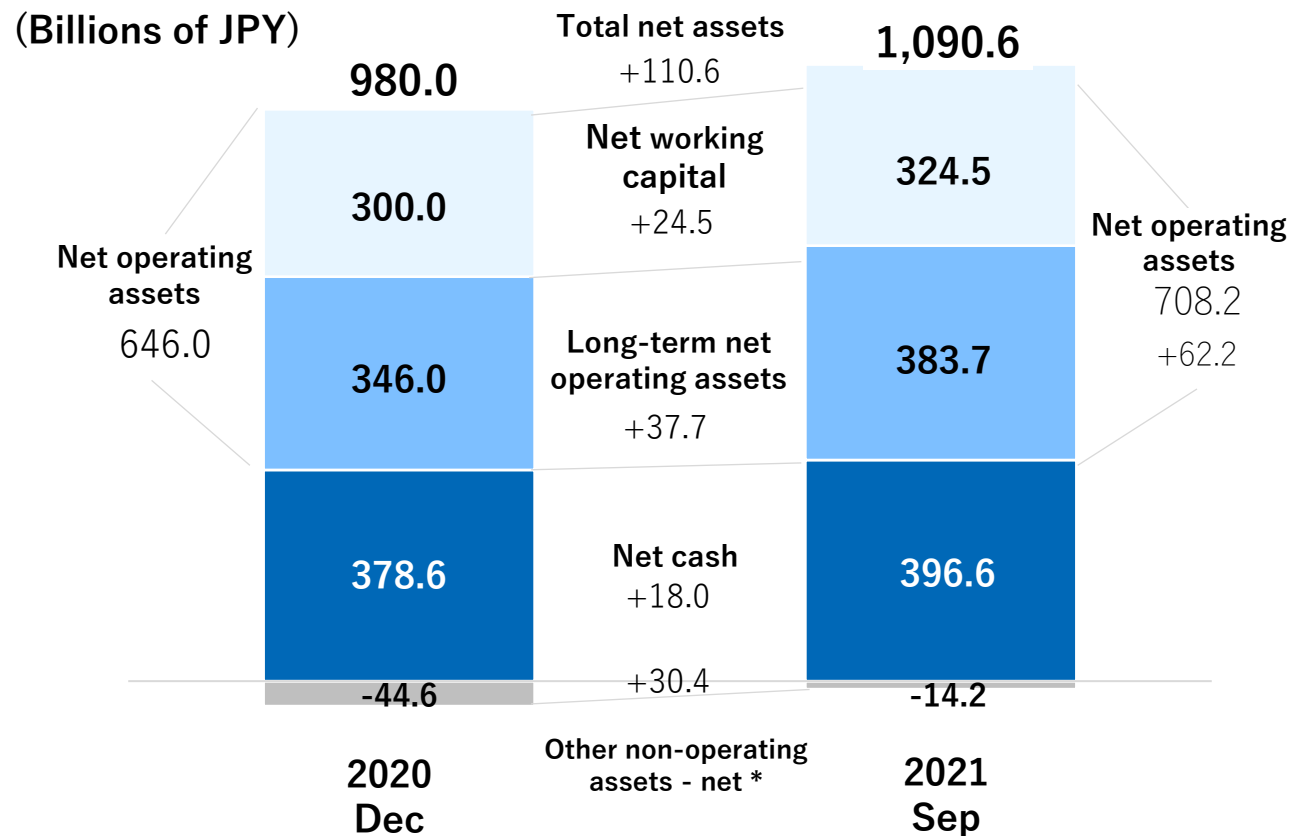
\*2 Revised forecast (Full-Year)

\*3 Forecast

- Export sales at ordinary supply price
- Export sales at initial supply price
- Royalty income for initial shipment
- Royalty income for intellectual properties

# Financial Position (vs. 2020 Year End)

(Billions of JPY)



## Increase in net working capital

Increase mainly in trade accounts receivable

## Increase in long-term net operating assets

Increase mainly in property, plant and equipment

## Increase in net cash

(Please refer to the next slide)

## Increase in other non-operating assets – net

Decrease in current income tax liabilities

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

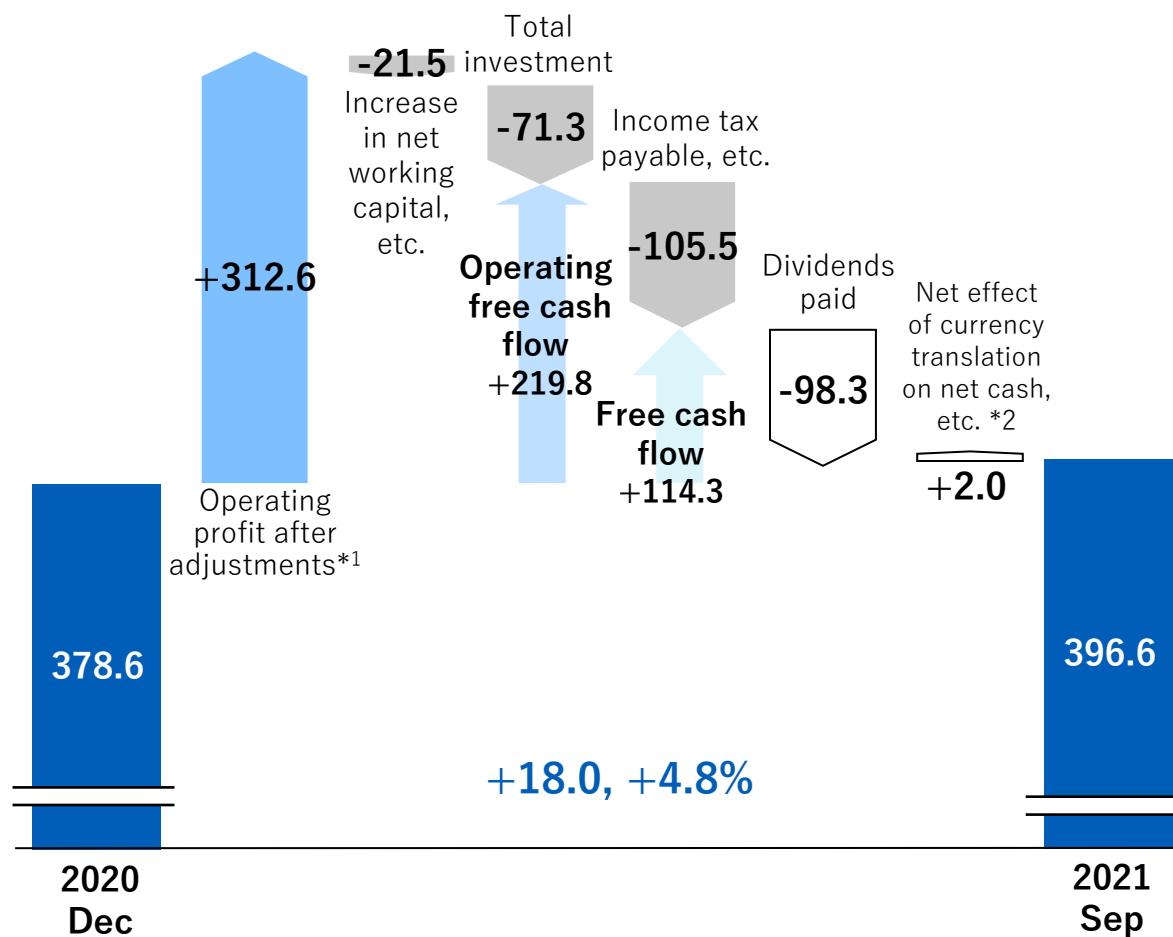
Total assets	1,235.5	+117.9	1,353.4
Total liabilities	-255.5	-7.2	-262.7
Total net assets	980.0	+110.6	1,090.6
Ratio of equity attributable to Chugai shareholders	79.3%	+1.3%pts	80.6%

FX rate to the JPY (end of period)

	2020 Actual	2021 Actual
1CHF	117.10	119.76
1EUR	126.89	129.85
1USD	103.19	111.97

# Net Cash (vs. 2020 Year End)

(Billions of JPY)



Operating profit after adjustment <sup>*1</sup>	+312.6
Operating profit <sup>*1</sup>	+282.8
Depreciation, amortization and impairment <sup>*1</sup>	+26.0
Increase in net working capital, etc.	-21.5
Total investment	-71.3
Property, plant and equipment	-58.1
Payment for lease liabilities	-6.3
Intangible assets	-6.9
<b>Operating free cash flow</b>	<b>+219.8</b>
Income tax payable, etc.	-105.5
Income tax payable	-103.6
<b>Free cash flow</b>	<b>+114.3</b>
Dividends paid	-98.3
Net effect of currency transaction on net cash, etc. <sup>*2</sup>	+2.0

\*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)



# Current Status / Plan for Major Investments

2012 | 2016 2017 2018 2019 2020 2021 2022 2023 2024 2025 2026 2027

## Production

**Fujieda Plant:** Construction of a new synthetic manufacturing building to accelerate the development of small- and mid-size molecule active pharmaceutical ingredients

2019-22: 19.1 billion JPY (16.3 billion JPY)

**Fujieda Plant:** Construction of a manufacturing building for active pharmaceutical ingredients to cover late stage clinical development and early commercial production of small and mid-size molecule drugs

2021-24: 55.5 billion JPY (15.3 billion JPY)

**Ukima Branch:** Construction of antibody API manufacturing building for early stage clinical development

2021-23: 12.1 billion JPY (0.1 billion JPY)

## Research and development

**CPR (Singapore):** Accelerate creation of clinical candidates utilizing proprietary antibody technologies

2012-21: 476 million SGD (420 million SGD), incl. capital investments of 61 million SGD (67 million SGD)      2022-26: 282 million SGD, incl. capital investments of 21 million SGD

**Chugai Life Science Park Yokohama:** Building of state-of-the-art R&D site to create innovative new drug candidates

Purchase of business site 2016-18: 43.0 billion JPY      Construction of laboratory 2019-22: 128.8 billion JPY (86.1 billion JPY)

Comprehensive collaboration in research activity with **IFReC**

2017-27: 10.0 billion JPY (5.4 billion JPY)

# Appendix

# IFRS and Core Results Jan – Sep

(Billions of JPY)	IFRS results	Non-core items		Core results
		Intangible assets	Others	
<b>Revenues</b>	<b>677.5</b>			<b>677.5</b>
Sales	538.7			538.7
Royalties and other operating income	138.8			138.8
Cost of sales	-227.6	+1.9		-225.7
<b>Operating expenses</b>	<b>-167.1</b>	<b>+2.7</b>	<b>+3.3</b>	<b>-161.1</b>
M&D and G&A	-67.6		+0.6	-66.9
Research and development	-99.5	+2.7	+2.7	-94.1
<b>Operating profit</b>	<b>282.8</b>	<b>+4.6</b>	<b>+3.3</b>	<b>290.7</b>
Financial account balance	-1.9			-1.9
Income taxes	-76.8	-1.4	-1.0	-79.2
<b>Net income</b>	<b>204.2</b>	<b>+3.2</b>	<b>+2.3</b>	<b>209.7</b>
EPS (JPY)	124.09			127.45

## Non-Core items

(Billions of JPY)

### **Intangible assets**

Amortization	+1.9
Impairment	+2.7

### **Others**

Restructuring expenses, etc.	+3.3
------------------------------	------

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

(Billions of JPY)	Actual 2021 Jan - Sep	Revised Forecast 2021 Jan - Dec	Progress	2020 Progress *1
<b>Revenues</b>	<b>677.5</b>	<b>970.0</b>	<b>69.8%</b>	<b>73.3%</b>
Sales	538.7	781.5	68.9%	73.4%
Domestic	362.6	513.0	70.7%	74.1%
Overseas	176.0	268.5	65.5%	72.1%
Royalties and other operating income	138.8	188.5	73.6%	72.7%
Royalty and profit-sharing income	135.4	179.5	75.4%	68.8%
Other operating income	3.4	9.0	37.8%	93.8%
<b>Cost of sales</b>	<b>- 225.7</b>	<b>- 339.0</b>	<b>66.6%</b>	<b>73.6%</b>
(cost to sales ratio)	41.9%	43.4%	-	-
<b>Operating expenses</b>	<b>- 161.1</b>	<b>- 231.0</b>	<b>69.7%</b>	<b>69.8%</b>
M&D and G&A	- 66.9	- 99.5	67.2%	66.7%
Research and development	- 94.1	- 131.5	71.6%	72.4%
<b>Operating profit</b>	<b>290.7</b>	<b>400.0</b>	<b>72.7%</b>	<b>75.3%</b>
(operating margin)	42.9%	41.2%	-	-
<b>Net income</b>	<b>209.7</b>	<b>293.0</b>	<b>71.6%</b>	<b>75.5%</b>
EPS (JPY) *2	127.45	178.00	71.6%	75.5%

\*1 Jan – Sep progress versus Jan – Dec

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

# Sales Jan - Sep (vs. Forecast)

(Billions of JPY)	Actual	Revised Forecast		2020
	2021 Jan - Sep	2021 Jan - Dec	Progress	Progress *
<b>Sales</b>	<b>538.7</b>	<b>781.5</b>	<b>68.9%</b>	<b>73.4%</b>
<b>Domestic</b>	<b>362.6</b>	<b>513.0</b>	<b>70.7%</b>	<b>74.1%</b>
<b>Oncology</b>	<b>191.1</b>	<b>256.0</b>	<b>74.6%</b>	<b>72.9%</b>
Avastin	59.8	80.1	74.7%	74.1%
Tecentriq	46.1	59.8	77.1%	68.0%
Perjeta	23.8	32.0	74.4%	74.0%
Alecensa	20.1	27.1	74.2%	71.9%
Kadcyla	11.2	14.9	75.2%	69.6%
Herceptin	7.5	9.7	77.3%	77.4%
Polivy	3.5	6.1	57.4%	-
Rituxan	3.6	4.8	75.0%	76.4%
Gazyva	3.2	4.4	72.7%	69.6%
Xeloda	1.9	2.6	73.1%	77.8%
Rozlytrek	0.6	0.9	66.7%	50.0%
Foundation Medicine	3.5	5.6	62.5%	71.4%
Other	6.3	8.1	77.8%	75.8%

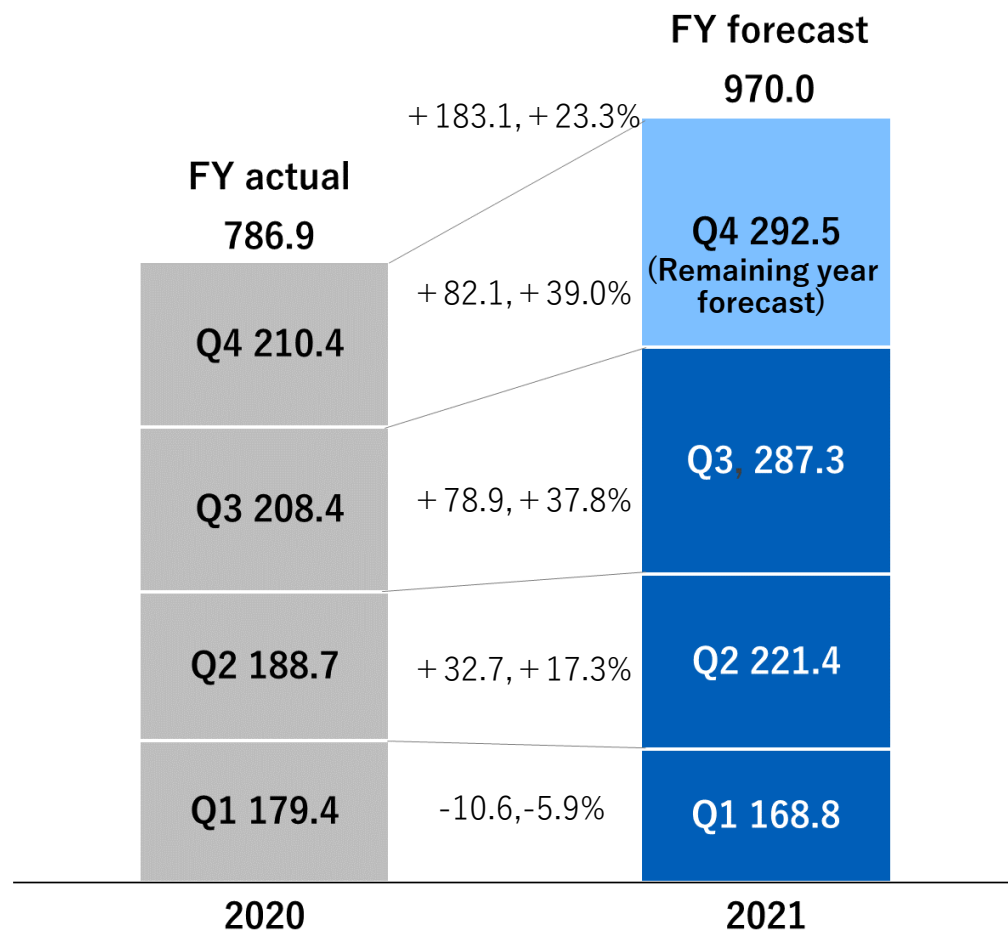
(Billions of JPY)	Actual	Revised Forecast		2020
	2021 Jan - Sep	2021 Jan - Dec	Progress	Progress *
<b>Primary</b>	<b>171.6</b>	<b>257.0</b>	<b>66.8%</b>	<b>75.7%</b>
Ronapreve	42.8	82.3	52.0%	-
Actemra	31.9	42.5	75.1%	72.8%
Hemlibra	29.3	40.3	72.7%	72.1%
Edirol	17.5	21.2	82.5%	87.1%
Mircera	10.7	13.4	79.9%	73.7%
Enspryng	6.2	9.3	66.7%	23.1%
CellCept	6.2	8.3	74.7%	73.6%
Bonviva	6.1	8.1	75.3%	73.0%
Oxarol	4.6	6.1	75.4%	73.4%
Evrysdi	0.4	1.0	40.0%	-
Tamiflu(Ordinary use)	-0.1	-0.1	100.0%	87.5%
Tamiflu(Govt. stockpiles, etc.)	1.2	3.4	35.3%	81.1%
Other	14.9	21.1	70.6%	75.3%
<b>Overseas</b>	<b>176.0</b>	<b>268.5</b>	<b>65.5%</b>	<b>72.1%</b>
Actemra	63.5	102.7	61.8%	72.6%
Hemlibra	61.7	99.0	62.3%	82.4%
Alecensa	38.3	50.4	76.0%	69.3%
Enspryng	1.2	1.2	100.0%	28.6%
Neutrogin	6.8	9.2	73.9%	75.6%
Other	4.6	6.1	75.4%	70.8%

- Jan - Sep progress versus Jan - Dec

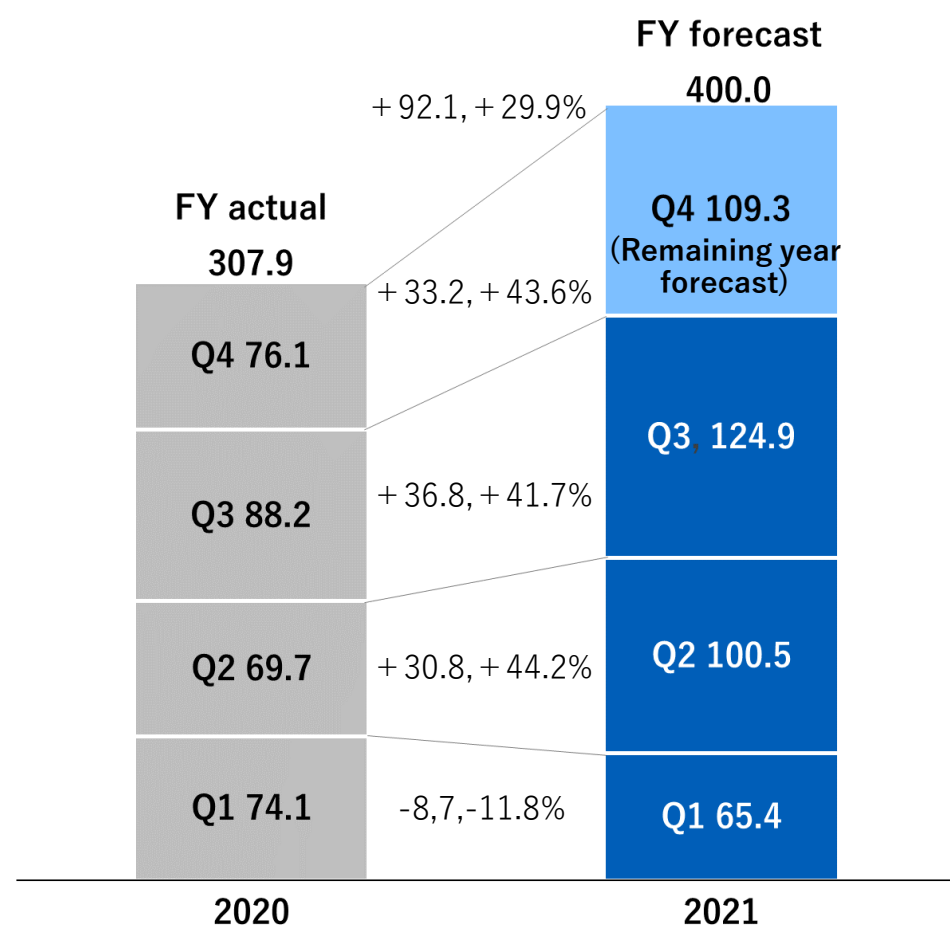
# Q3 Actual and Remaining Year Forecast (Year on Year)

(Billions of JPY)

<Revenues>



<Operating profit>



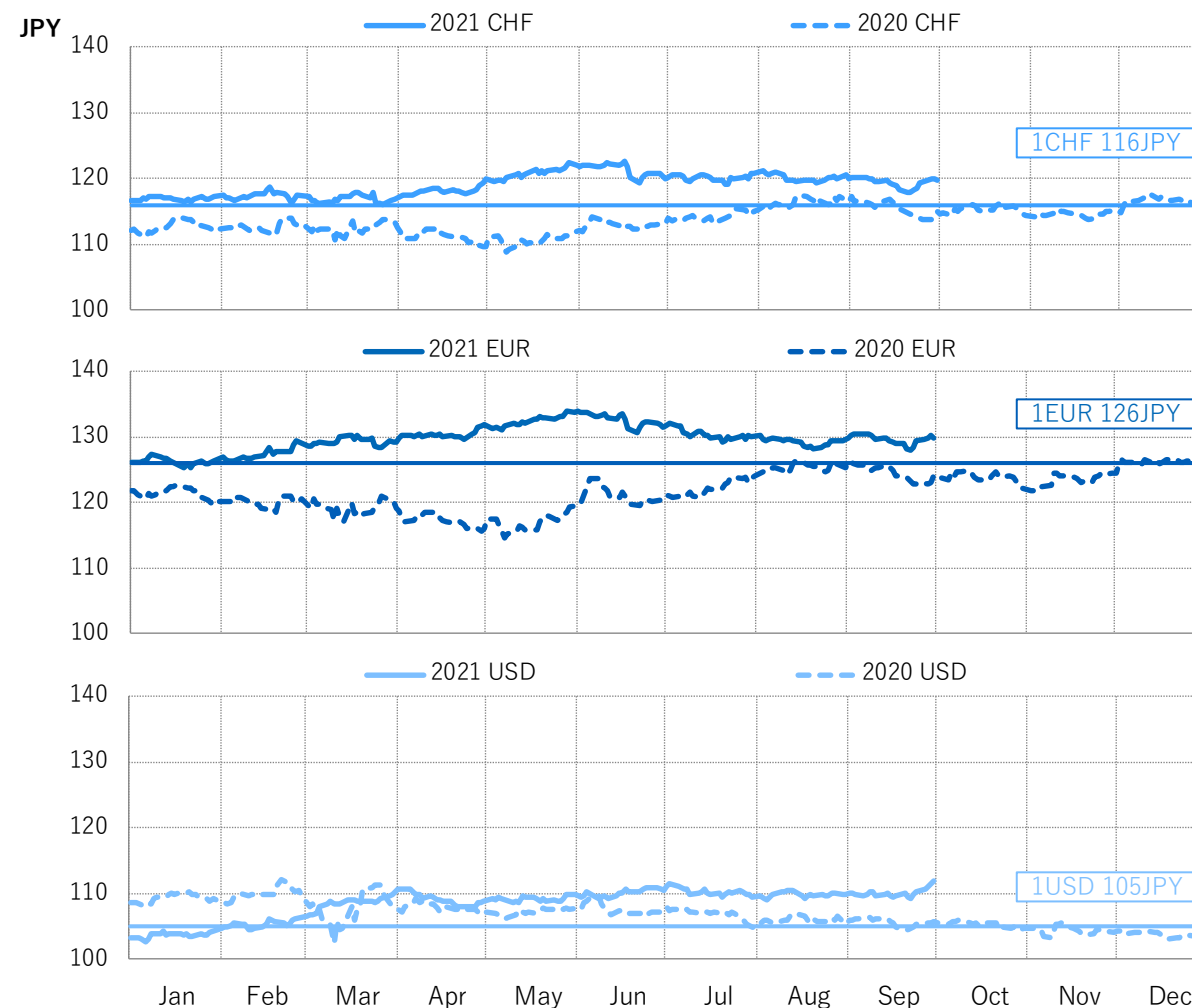
# Impact from Foreign Exchange (vs. Original Forecast)

(billions of JPY)	FX impact 2021 (FX impact vs. Assumption)	
Revenues	Sales	+0.2
	Royalties and other operating income	+1.2
Cost of sales & Operating expenses	Cost of sales	-0.1
	Operating expenses	-1.0
Operating profit	<b>+0.2</b>	

Market average exchange rate(JPY)	2020 Actual	2021 Assumption	2021 Actual
1CHF	113.14	116.00	119.03
1EUR	120.80	126.00	129.77
1USD	107.57	105.00	108.45

Historical exchange rate to the JPY

Assumption rate (2021)



# Outline of Arrangements for Sales, Royalties, and Expenses of Four Products to Roche

P/L account of Chugai	Details of transactions	Actemra	Alecensa	Hemlibra	Enspryng
Sales (Export to Roche)	Export to Roche at the agreed supply price	✓	✓	✓	✓
Royalty and profit-sharing income	Royalty income *1	✓	✓	✓	✓
	Profit Sharing income in co-promotion country *2	✓		✓	
M&D expenses	Cost sharing in co-promotion countries *2	✓		✓	
	Receive promotion service fee from Roche (reimbursement of expenses) *3		✓		

\*1 For Hemlibra, there are two kinds of royalty income, for intellectual properties and initial shipment

\*2 Main co-promotion countries are as follows:

- UK, Germany, France (for Actemra)
- UK, Germany, France, China (for Hemlibra)

\*3 Chugai provides promotion service in UK, Germany, France



# Overview of Development Pipeline

**Tetsuya Yamaguchi**

Executive Vice President, Head of Project & Lifecycle Management Unit

# Q3 Topics

As of October 22, 2021

Launch	FoundationOne Liquid CDx	Blood-based CGP test for solid tumors, CDx	August
	Evrysdi	Spinal muscular atrophy (SMA)	August
Approved	Rituxan	Systemic sclerosis	September
Filed	Actemra	COVID-19 pneumonia (EU)	September
	Ronapreve	Prophylaxis and treatment of asymptomatic COVID-19	October
	Ronapreve	Subcutaneous administration	October
Pipeline entry	RG6171 / giredestrant	Breast cancer (adjuvant)	P3 (August)
	Enspryng	Generalized myasthenia gravis (gMG)	P3 (October)
	LUNA18	Solid tumors (RAS inhibitor)	P1 (October)
Topline results	Polivy	Previously untreated diffuse large B-cell lymphoma : Primary endpoint met	P3 (POLARIX)
Medical conference	Enspryng	SAkuraStar/SAkuraSky studies: four-year data	ECTRIMS** (October)
Others	Hemlibra	Acquired Hemophilia A	Orphan drug designation (October)
	nemolizumab	Pruritus for dialysis patients	Out-license of domestic development and marketing rights to Maruho (September)
	OBP-301*	Oncolytic virus therapy	Agreement on termination of exclusive license agreement
	Evrysdi	SMA: FIREFISH study Part 2	Published in NEJM
	Ronapreve	COVID-19: REGN-COV 2067 study	Published in NEJM

# Chugai's Unique Platform for Mid-Size Molecule

**APOLLO** (*Artificial, Peptidic, Orally available, Limitlessly Localizable Omicron\**) molecules

- By modifying compounds from a uniquely constructed unnatural amino acid-containing peptide library, APOLLO platform is possible to create orally administrable drug candidate molecules with high target specificity that have both membrane permeability and metabolic stability.
- ⇒ Able to target intracellular tough targets that have been difficult to approach with small molecules and antibodies  
(Extracellular targets can also be bound)

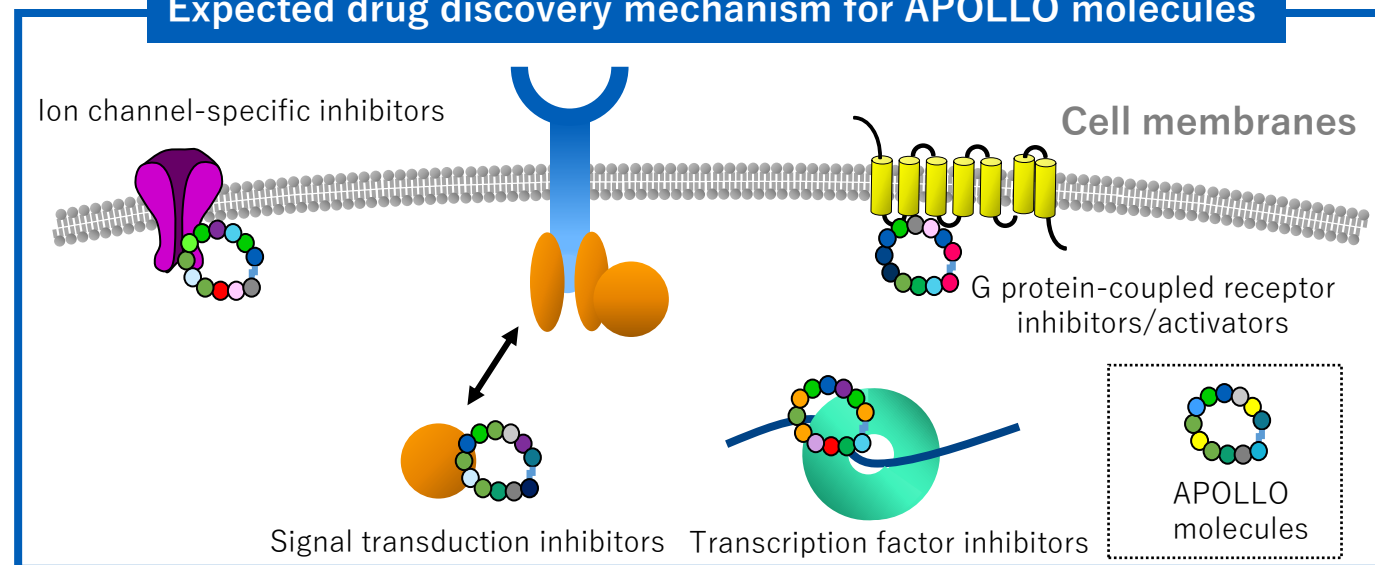
## Comparison of modalities

	Small molecules	APOLLO molecules	Antibody
Molecular weight	-500	500-2000	-150,000-
Administration route	Oral/ Injection	Oral/ Injection	Injection
PPI** inhibition	△	◎	◎
Intracellular targeting	◎	○	△
Target selectivity	△	◎	◎

\*Omicron: Image of Greek letter "O," cyclic peptide

\*\*PPI: Protein-Protein interaction

## Expected drug discovery mechanism for APOLLO molecules



# LUNA18 (RAS Inhibitor)

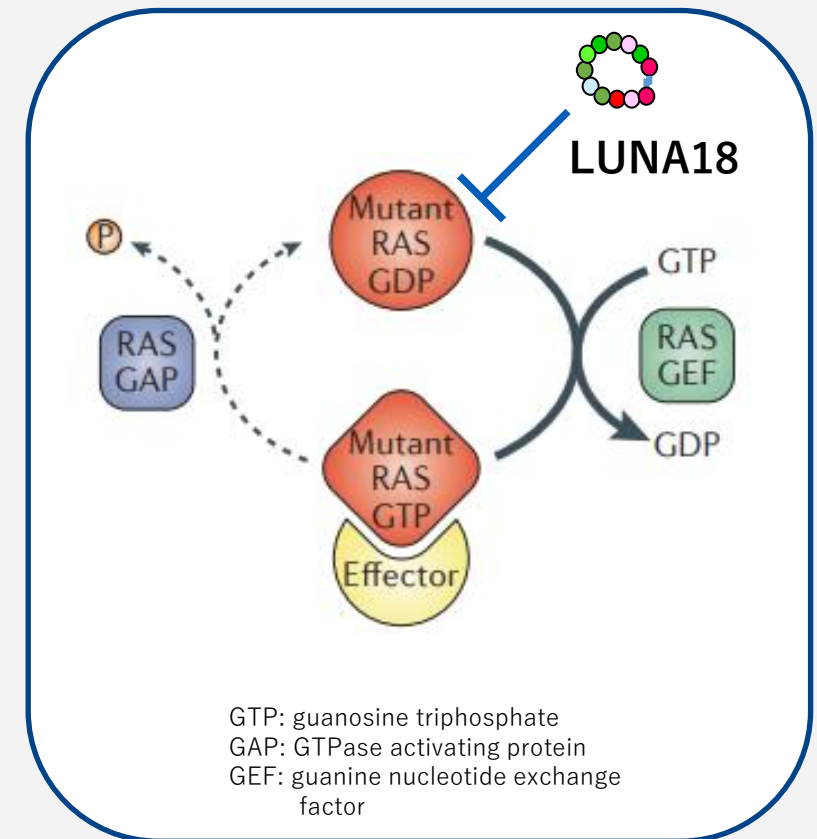
Expected to show anti-tumor effects on segments with a wide range of *RAS* alterations

- **RAS**

- A small molecule GTPase that activates upon binding to GTPs and transduces signals through networks such as RAF/MEK/ERK and PI3K/AKT.
- Plays an important role in cell differentiation, proliferation and survival.
- *Ras* alterations are the most commonly detected oncogenic genetic abnormalities in cancer cells.

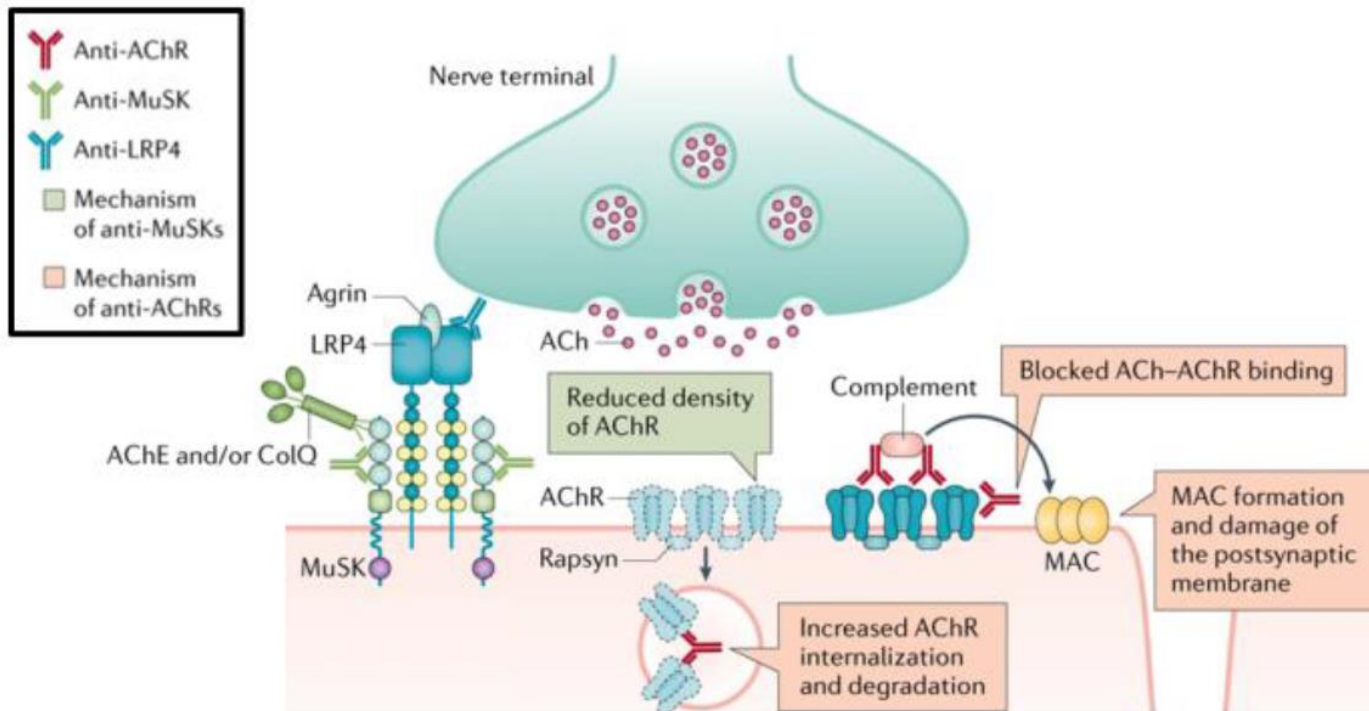
- **LUNA18**

- An orally administrable cyclic peptide molecule created by APOLLO platform.
- Inhibits protein-protein interaction between RAS and GEF to retain RAS in an inactive state.
- Exhibits growth inhibitory activity against tumor cells with various *RAS* alterations (mutations or amplifications) and can be expected to have anti-tumor effects against cancers with *RAS* alterations where there are no therapeutic drugs yet.



# Generalized Myasthenia Gravis (gMG)

## Enspryng: IL-6 blockade may reduce pathogenic autoantibody production



Source: Roche Pharma Day materials (September 14, 2021)

- 1) Myasthenia gravis clinical practice guideline 2014 (supervisor: Japanese Society of Neurology), Nankodo
- 2) Kerty E, Elsaïs A, Argov Z, et al. EFNS/ENS Guidelines for the treatment of ocular myasthenia. European Journal of Neurology 2014;21:687-93.
- 3) Gilhus N, Tzartos S, Evoli A, et al. Myasthenia gravis. Nat Rev Dis Primers 2019;5(30). Available from the Internet: <https://www.nature.com/articles/s41572-019-0079-y>
- 4) Health and Labor Sciences Research Grants Policy Research Project for Intractable Diseases (Policy Research Project for Intractable Diseases) Verification of Diagnostic Criteria, Severity Classification, Guidelines and Patient QOL Based on Evidence of Neuroimmune Diseases Summary / Sharing Research report (2018)

- gMG is an organ-specific autoimmune disease against molecules on the postsynaptic membrane of the neuromuscular junction and is characterized by painless muscle loss with easy fatiguability of skeletal muscle.<sup>1)</sup>
- Transition from initial symptoms such as ptosis and diplopia to systemic type is observed. gMG with cervical limb weakness, dysarthria, dysphagia, breathing disability, etc. accounts for 85% of the total.<sup>1) 2)</sup>
- Although the autoantibody positive rate varies slightly depending on the report, it is reported that 80% of the total are acetylcholine receptor (AChR) antibody positive and about 7% are muscle specific kinase (MuSK) antibody positive.<sup>3)</sup>
- In Japan, the 2018 National Epidemiological Survey estimates that there are 29,210 MG patients, or 23.1 per 100,000.<sup>4)</sup>

# Clinical Status of Therapeutic Drugs in COVID-19 Treatment

Three drugs under development for patients with mild to moderate and severe infections

**Domestic filing for Special Approval for Emergency (October 2021)**

- Prophylaxis and asymptomatic COVID-19
- Additional subcutaneous administration

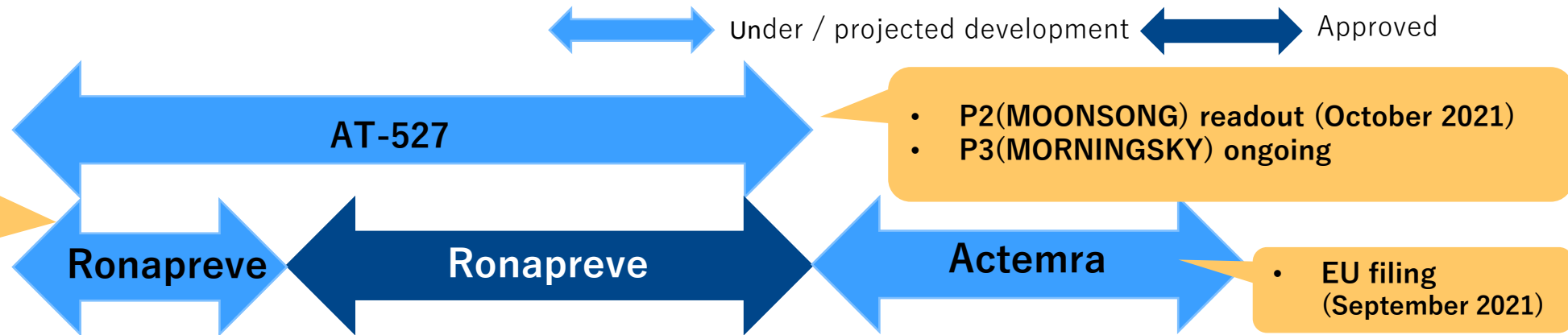
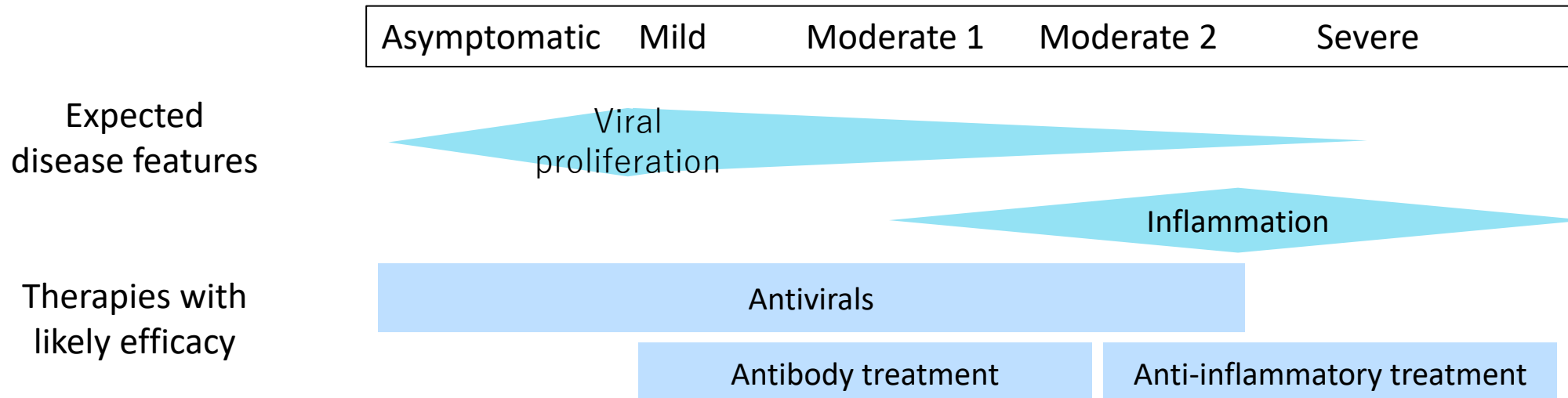


Figure conceptualizing COVID-19 severity and treatment



# Application for Additional Indication of Ronapreve (Antibody Cocktail) Roche Group

## Prophylaxis / Early Treatment and Subcutaneous Administration in Japan

- Submitted a domestic application for Special Approval for Emergency based on the results of the REGN-COV 2069, REGN-COV 20145, and the Japanese P1 study (JV43180) aimed at evaluating safety, tolerability, and pharmacokinetics.
- Submitted a simultaneous application for additional subcutaneous administration

### < REGN-COV 2069 study > : Global P3 study for prophylaxis and asymptomatic COVID-19

- Primary endpoint met
  - ✓ One dose of antibody cocktail (1,200 mg subcutaneous administration) to prevent infections reduced the symptomatic COVID-19 infections by 81% ( $p < 0.0001$ )
- All major secondary points met
  - ✓ When individuals treated with antibody cocktail who still experienced a symptomatic infection, # of weeks with symptoms (mean) in symptomatic individuals was shortened to 1.2 weeks compared to 3.2 weeks with placebo ( $p < 0.0001$ )
  - ✓ In a cohort of recently-infected asymptomatic patients, antibody cocktail reduced the overall risk of progressing to symptomatic COVID-19 by 31% ( $p = 0.0380$ )
- No new safety signals were observed

### < REGN-COV 20145 study > : Global P2 study for dosage and administration determination

- P2 study for low-risk\* outpatient showed significant and comparable viral load reductions across doses ranging from 300 to 2,400 mg.

\* Symptomatic patients with COVID-19 having low-risk in progressing to severe, or asymptomatic patients with COVID-19



# Projected Submissions

(Post PoC NMEs and Products)

in-house in-licensed (Roche)

NME Line extension

Orange box: NME, Blue box: Line extension

as of October 22, 2021

## Filed

RONAPREVE ★  
(RG6413/RG6412)  
COVID-19\*

faricimab  
(RG7716)  
nAMD

TECENTRIQ  
(RG7446)  
NSCLC (adjuvant)

faricimab  
(RG7716)  
Diabetic Macular  
Edema

RCC: renal cell carcinoma  
NSCLC: non-small cell lung cancer  
SCLC: small cell lung cancer  
HNC: head and neck carcinoma  
MIBC: muscle-invasive bladder cancer  
gMG: generalized myasthenia gravis

DLBCL: diffuse large B-cell lymphoma  
FDC: fixed-dose combination  
nAMD: neovascular age-related macular degeneration  
HCC: hepatocellular carcinoma  
PNH: paroxysmal nocturnal hemoglobinuria  
RVO: retinal vein occlusion

ENSPRYNG ★  
(SA237/RG6168)  
gMG

HEMLIBRA ★  
(ACE910/RG6013)  
Acquired hemophilia A

TECENTRIQ  
(RG7446)  
HNC (adjuvant)

AT-527  
(RG6422)  
COVID-19

AVASTIN  
(RG435)  
SCLC

crovalimab  
(SKY59/RG6107)  
PNH

AVASTIN  
(RG435)  
HCC(intermediate stage)

giredestrant ★  
(RG6171)  
Breast Cancer  
(adjuvant)

ACTEMRA  
(MRA/RG1569)  
COVID-19 pneumonia

TECENTRIQ  
(RG7446)  
Ovarian Cancer

tiragolumab  
(RG6058)  
SCLC

AVASTIN  
(RG435)  
HCC (adjuvant)

faricimab  
(RG7716)  
RVO

TECENTRIQ  
(RG7446)  
HCC(intermediate stage)

giredestrant  
(RG6171)  
Breast Cancer

SUVENYL (NRD101)  
Knee Osteoarthritis  
/Shoulder Periarthritis  
(China)

TECENTRIQ  
(RG7446)  
RCC (adjuvant)

RG6264 ★  
(FDC, sc)  
Breast Cancer

TECENTRIQ  
(RG7446)  
HCC (adjuvant)

gantenerumab  
(RG1450)  
Alzheimer's Disease

TECENTRIQ  
(RG7446)  
Early Breast Cancer

tiragolumab  
(RG6058)  
Esophageal Cancer

POLIVY  
(RG7596)  
1L DLBCL

TECENTRIQ  
(RG7446)  
Urothelial Carcinoma

ipatasertib  
(RG7440)  
Prostate Cancer

TECENTRIQ  
(RG7446)  
NSCLC (neoadjuvant)

ALECENSA  
(AF802/RG7853)  
NSCLC (adjuvant)

TECENTRIQ  
(RG7446)  
NSCLC (Stage III)

TECENTRIQ  
(RG7446)  
Esophageal Cancer

2021

2022

2023

2024 and beyond



# P1 Development Status of Chugai Originated Products (Oncology 1)

As of October 22, 2021

Project	GC33	ERY974	AMY109 (CIT)
<b>MoA (Modality)</b>	Anti-Glypican-3 humanized monoclonal antibody	Anti-Glypican-3/CD3 bispecific antibody	Recycling antibody
<b>Target indication</b>	Hepatocellular carcinoma	<ul style="list-style-type: none"> <li>Solid tumors</li> <li>Hepatocellular carcinoma</li> </ul>	Solid tumors
<b>Study start</b>	October 2010	August 2016	March 2020
<b>Status</b>	<ul style="list-style-type: none"> <li>Scheduled to start a P1 study (Investigator Initiated Trial) with GC33 alone in pediatric cancer patients expressing GPC3</li> </ul>	<ul style="list-style-type: none"> <li>A domestic P1 study (single agent) is ongoing with a study design where Actemra is premedicated as a preventive measure against cytokine release syndrome (CRS).</li> <li>A P1b study in patients with hepatocellular carcinoma in combination with Tecentriq and Avastin (premedication with Actemra) is underway in Japan and Taiwan.</li> </ul>	<ul style="list-style-type: none"> <li>A P1 study (combined with Tecentriq) in patients with solid tumors is ongoing.</li> <li>Expected to strengthen tumor immunity and enhance the anti-tumor effect of Tecentriq</li> </ul>

# P1 Development Status of Chugai Originated Products (Oncology 2)

As of October 22, 2021

Project	STA551	SPYK04	SOF10/RG6440
<b>MoA (Modality)</b>	Anti-CD137 agonistic Switch antibody	Small molecule	Anti-latent TGF- $\beta$ 1 monoclonal antibody
<b>Target indication</b>	Solid tumors	Solid tumors	Solid tumors
<b>Study start</b>	March 2020	September 2020	June 2021 (Out-licensed to Roche)
<b>Status</b>	<ul style="list-style-type: none"> <li>A P1 study is ongoing with STA551 alone and in combination with Tecentriq.</li> </ul>	<ul style="list-style-type: none"> <li>A P1 study is ongoing in Japan and the United States for solid tumors. Recruiting patients from EU and Asian countries are considered going forward.</li> <li>In the expanded cohort part, the anti-tumor effect is preliminarily examined. The targets include non-small cell lung cancer and ovarian cancer.</li> </ul>	<ul style="list-style-type: none"> <li>A P1 study in combination with Tecentriq for solid tumors is ongoing. Lung cancer, stomach cancer, pancreatic cancer, etc. are considered as planned indications.</li> <li>Expected to show anti-tumor effect in the segment where cancer immunotherapy is difficult to respond.</li> </ul>

MoA: mode of action

# P1 Development Status of Chugai Originated Products (Others)

As of October 22, 2021

Project	PCO371	AMY109	GYM329/RG6237	NXT007
<b>MoA (Modality)</b>	PTH1 receptor agonist	Recycling antibody	Anti-latent myostatin sweeping antibody	Anti-coagulation factor IXa/X bispecific antibody
<b>Target indication</b>	Hypoparathyroidism	Endometriosis	Neuromuscular disease	Hemophilia A
<b>Study start</b>	June 2015	February 2018	October 2018 (Out-licensed to Roche)	August 2019
<b>Status</b>	<ul style="list-style-type: none"> <li>A P1b study for hypoparathyroidism was discontinued early due to grade 3 adverse events and the uncertain benefit-risk balance in the target patients at this time.</li> </ul>	<ul style="list-style-type: none"> <li>An antibody with anti-inflammatory action, aiming to contribute by a MoA different from hormone therapy, which is the standard of care.</li> <li>A P1 study was suspended due to the impact of COVID-19, but the recruitment was completed.</li> </ul>	<ul style="list-style-type: none"> <li>A P1 study is ongoing.</li> <li>A study on disuse muscular atrophy is in progress to evaluate the effect of GYM329 in the Netherlands.</li> <li>P2/3 study combination with Evrysdi for patients with spinal muscular atrophy is scheduled to start in Q1 2022. (announced by Roche)</li> </ul>	<ul style="list-style-type: none"> <li>Aiming at achieving healthy adult level hemostatic effect and improvement of PK profile.</li> <li>Although the project was affected by COVID-19, P1 /2 study is ongoing as planned.</li> </ul>

# Projects under Development (1)

As of October 22, 2021

	Phase I		Phase II	Phase III		Filed
Cancer	<b>GC33 / codrituzumab</b> - HCC  <b>ERY974</b> - solid tumors  <b>RG7421 / cobimetinib</b> - solid tumors  <b>RG7802 / cibisatamab</b> - solid tumors  <b>RG7828 / mosunetuzumab</b> - hematologic tumors  <b>AMY109</b> - solid tumors  <b>STA551</b> - solid tumors  <b>SPYK04</b> - solid tumors	<b>RG6026 / glofitamab</b> - hematologic tumors  <b>RG7446 / Tecentriq (Actemra or tiragolumab combo)</b> - pancreatic adenocarcinoma  <b>RG6194 / HER2-TDB</b> - solid tumors  <b>OBP-301*</b> (Tecentriq/Avastin combo) - HCC  <b>SOF10 (RG6440)</b> - solid tumors  <b>RG6396 / pralsetinib</b> - solid tumors  <b>LUNA18</b> - solid tumors ★	<b>OBP-301*</b> - esophageal cancer	<b>AF802 (RG7853) / Alecensa</b> - NSCLC (adjuvant)  <b>RG7596 / Polivy</b> - DLBCL  <b>RG7440 / ipatasertib</b> - prostate cancer  <b>RG6264 (Herceptin+Perjeta)</b> - breast cancer (Fixed-dose combination, subcutaneous injection)  <b>RG6058 / tiragolumab (Tecentriq combo)</b> - SCLC - NSCLC - NSCLC(stage III) - esophageal cancer  <b>RG6171 / giredestrant</b> - breast cancer - breast cancer (adjuvant) ★	<b>RG435 / Avastin (Tecentriq combo)</b> - SCLC - HCC (adjuvant) - HCC (intermediate stage)  <b>RG7446 / Tecentriq</b> - NSCLC (neoadjuvant) - NSCLC(stage III) - urothelial carcinoma - MIBC (adjuvant) - RCC (adjuvant) - RCC - early breast cancer - ovarian cancer - HCC (adjuvant) - HCC (intermediate stage) - HNC (adjuvant) - esophageal cancer	<b>RG7446 / Tecentriq</b> - NSCLC (adjuvant)

In principle, completion of first dose is regarded as the start of clinical studies in each phase.

★: Projects with advances in stages since July 26, 2021

Letters in orange: in-house projects

Letters in blue: in-licensed (Roche)

\*in-licensed (Oncolys BioPharma Inc.)

DLBCL: diffuse large B-cell lymphoma

HCC: hepatocellular carcinoma

SCLC: small cell lung cancer

RCC: renal cell carcinoma

NSCLC: non-small cell lung cancer

HNC: head and neck carcinoma

MIBC: muscle-invasive bladder cancer

TDB: T cell-dependent bispecific

# Projects under Development (2)

As of October 22, 2021

	Phase I	Phase II	Phase III	Filed
Bone & Joint			<b>NRD101 / Suvenyl (China)</b> - knee osteoarthritis /shoulder peri arthritis	
Autoimmune	<b>RG7880 (IL-22 fusion protein)</b> - inflammatory bowel disease			
Neurology	<b>RG7935 / prasinezumab</b> - Parkinson's disease <b>GYM329 (RG6237)</b> - neuromuscular disease <b>RG6100 / semorinemab</b> - Alzheimer's disease <b>RG6102 (BS-Gante)</b> - Alzheimer's disease	<b>RG7906 / ralmitaront</b> - schizophrenia	<b>RG1450 / gantenerumab</b> - Alzheimer's disease <b>RG6042 / tominersen</b> - Huntington's disease <b>SA237 (RG6168) / Enspryng</b> - generalized myasthenia gravis gMG ★	
Others	<b>PCO371</b> - hypoparathyroidism <b>AMY109</b> - endometriosis <b>NXT007</b> - hemophilia A (PI/II) <b>RG7992 (anti-FGFR1/KLB)</b> - non-alcoholic steatohepatitis		<b>RG7716 / faricimab</b> - retinal vein occlusion <b>MRA (RG1569) / Actemra (JPN)</b> - COVID-19 pneumonia <b>ACE910 (RG6013) / Hemlibra (JPN)</b> - Acquired hemophilia A <b>SKY59 (RG6107) / crovalimab</b> - PNH <b>RG6422 (AT-527)</b> - COVID-19	<b>RG7716 / faricimab</b> - DME - nAMD  <b>RG6413+RG6412 / Ronapreve</b> - COVID-19* ★

Letters in orange: in-house projects

Letters in blue: in-licensed (Roche)

In principle, completion of first dose is regarded as the start of clinical studies in each phase.

★: Projects with advances in stages since July 26, 2021

PNH: paroxysmal nocturnal hemoglobinuria

nAMD: neovascular age-related macular degeneration

DME: diabetic macular edema

\*prophylaxis of COVID-19 and treatment of asymptomatic COVID-19

# FoundationOne CDx Cancer Genomic Profile

## Companion diagnostic indications

As of October 22, 2021

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

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

# FoundationOne Liquid CDx Cancer Genomic Profile

## Companion diagnostic indications

As of October 22, 2021

Alterations	Cancer type	Relevant drugs
Activated <i>EGFR</i> gene alterations	Non-small cell lung cancer (NSCLC)	afatinib dimaleate, erlotinib hydrochloride, gefitinib, osimertinib mesylate
<i>EGFR</i> exon 20 T790M alterations		osimertinib mesylate
<i>ALK</i> fusion genes		alectinib hydrochloride, crizotinib, ceritinib
<i>ROS1</i> fusion genes		entrectinib
<i>NTRK1/2/3</i> fusion gene	Solid tumors	entrectinib
<i>BRCA1/2</i> alterations	Prostate cancer	olaparib

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# INNOVATION BEYOND IMAGINATION