



TOP INNOVATOR  
**TOPi 2030**

# Conference on FY2022.12 2Q Financial Results

## CHUGAI PHARMACEUTICAL CO., LTD.

21 July 2022



# 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. Chugai’s recognition of non-recurring items may differ from that of Roche due to the difference in the scale of operations, the scope of business and other factors. 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.

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**

Director, Executive Vice President & CFO

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**Tetsuya Yamaguchi**

Executive Vice President, Head of Project & Lifecycle Management Unit

# FY2022 Q2 Overview

**Dr. Osamu Okuda**

President & CEO

# Financial Overview

- Significant increases in revenues and profits as expected due to the contribution of RON, in addition to strong sales of new products and exports to Roche, etc.
- The impact of yen depreciation\* is expected on some second-half year costs denominated in foreign currencies, but the company will continue aiming to achieve its initial forecast

Core (billions of JPY)	2021 Jan -Jun actual	2022 Jan -Jun actual	Growth		2022 Jan - Dec forecast	Progress (%)
<b>Revenues</b>	<b>390.2</b>	<b>504.3</b>	<b>+114.1</b>	<b>+29.2%</b>	<b>1150.0</b>	<b>43.9%</b>
Domestic sales	203.4	273.8	+70.4	+34.6%	646.3	42.4%
Overseas sales	100.7	179.0	+78.3	+77.8%	385.2	46.5%
ROOI	86.1	51.4	-34.7	-40.3%	118.5	43.4%
<b>Operating profit</b>	<b>165.8</b>	<b>201.4</b>	<b>+35.6</b>	<b>+21.5%</b>	<b>440.0</b>	<b>45.8%</b>
Operating margin	42.5%	39.9%	-2.6pts		38.3%	-
<b>Net income</b>	<b>121.7</b>	<b>144.7</b>	<b>+23.0</b>	<b>+18.9%</b>	<b>312.5</b>	<b>46.3%</b>
<b>EPS (yen)</b>	<b>73.99</b>	<b>87.97</b>	<b>+13.98</b>	<b>+18.9%</b>	<b>190.00</b>	<b>46.3%</b>

- Despite the impact of the NHI drug price revision and other factors, domestic sales grew as expected due to contributions from new products. RON was not delivered to the government in April-June as initially expected.
- Overseas sales increased significantly mainly due to HEM and ACT exports to Roche as initially expected.
- Significant decrease in ROOI associated with initial shipping inventory of HEM
- Russia/Ukraine situation had no negative impact on performance and limited impact on development activities

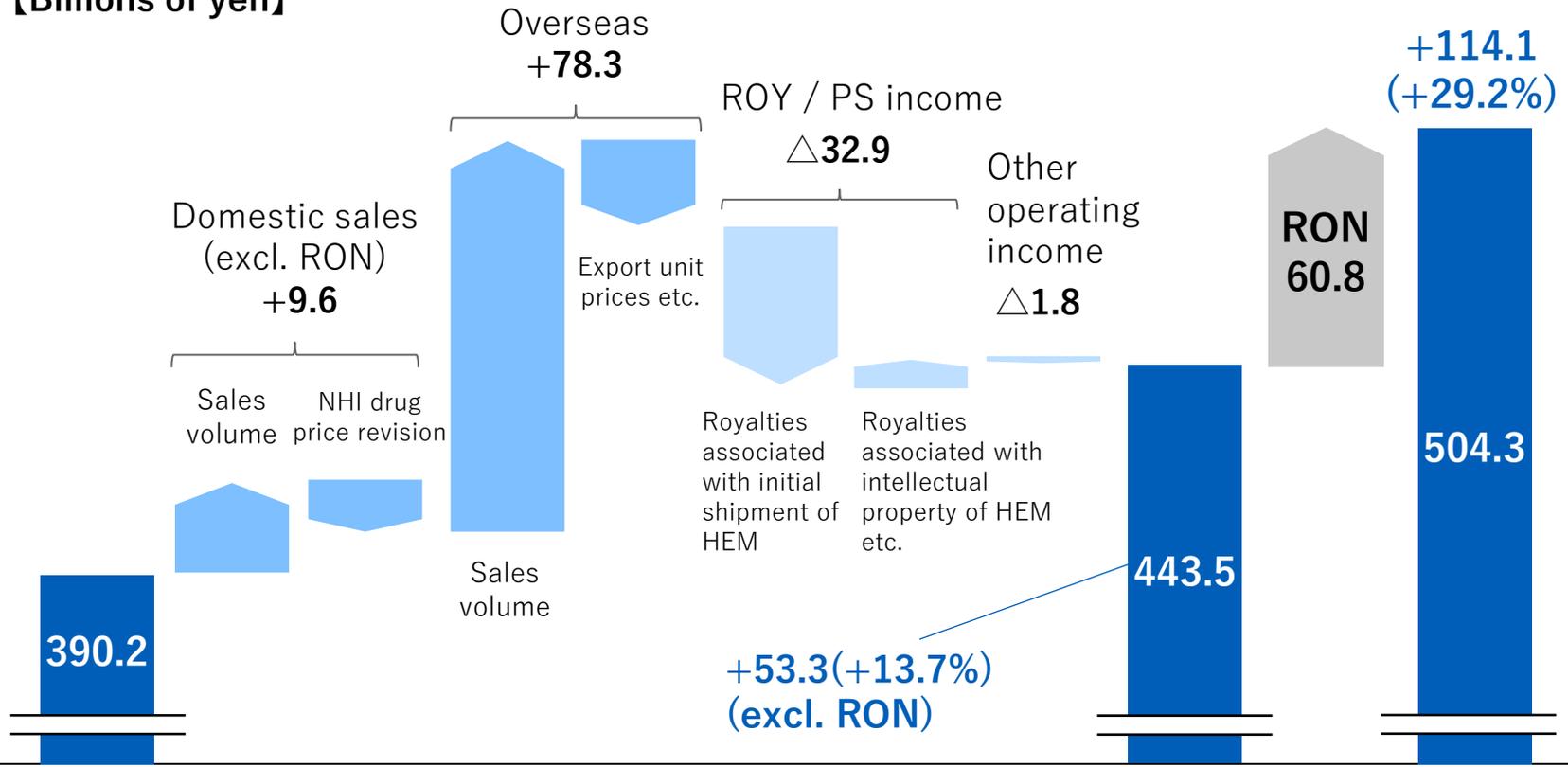
ROOI: Royalty and other operating income RON: Ronapreve HEM: Hemlibra ACT: Actemra

\*Supply of RON to the Japanese government (denominated in Swiss francs) in the second half of the year is not hedged against exchange rates at the beginning of the fiscal year, therefore cost of sales is expected to be higher than the initial assumption due to yen depreciation.

# Topline Overview

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

【Billions of yen】



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

# R&D Overview

■ Progress of the projects with high market potential is expected to contribute to future sales growth

- A full-scale entry into the ophthalmology field by launching Vabysmo in May 2022
- Tecentriq obtained an additional indication for NSCLC adj as the first immunotherapy in Japan
- Nemozumab achieved the primary endpoints in GP3\* study for prurigo nodularis

Letters in blue: Planned this year

## Phase 3 study readout

- ① crovalimab (China/Q1)
- ② tiragolumab (May)
- ③ nemozumab (June)
- ④ Tecentriq
- ⑤ gantenerumab

- ① Paroxysmal nocturnal hemoglobinuria
- ② NSCLC: PFS not met / OS continuous assessment (Numerically improved for both PFS/OS)
- ③ Prurigo nodularis: GP3 primary endpoints achieved
- ④ Two studies for early-stage cancer (NSCLC neo adj, HCC adj)
- ⑤ GRADUATE 1/2 study (Alzheimer's disease)

## Regulatory filing

- ① Actemra (US/April)
- ② crovalimab (China)
- ③ RG6264\*\*

- ① COVID-19 pneumonia (US priority review designation)
- ② Paroxysmal nocturnal hemoglobinuria
- ③ HER2 positive breast cancer

\* Conducted by Galderma  
 \*\* Herceptin + Perjeta (subcutaneous injection)  
 \*\*\* Out-licensed to Maruho in Japan

NSCLC: non-small cell lung cancer  
 HCC: hepatocellular carcinoma  
 GP3: global phase 3 study

(neo) adj: (neo) adjuvant therapy  
 nAMD: age-related macular degeneration associated with subfoveal choroidal neovascularization

## Launch/Additional indication

- ① Vabysmo (Launch/May)
- ② Tecentriq (Additional indication/May)
- ③ Hemlibra (Additional indication/June)
- ④ Edirool (China/Launch/July)
- ⑤ Mitchga (Japan/Launch) \*\*\*
- ⑥ Actemra (US/Additional indication)
- ⑦ Polivy (Additional indication)

- ① nAMD, DME
- ② NSCLC adj
- ③ Acquired hemophilia A
- ④ Postmenopausal osteoporosis
- ⑤ Pruritus associated with atopic dermatitis
- ⑥ COVID-19 pneumonia
- ⑦ DLBCL (1L)

DME: diabetic macular edema  
 DLBCL: diffuse large B-cell lymphoma

# Strategic Policies for 2022 -Main Progress in the First Half-

<p><b>Continuous creation of R&amp;D output</b></p>	<ul style="list-style-type: none"> <li>• Approval/Launch: Actemra (COVID-19 (Japan)), Vabysmo (nAMD/DME), Tecentriq (NSCLC adj), Hemlibra (acquired hemophilia A (Japan)), Ediol (postmenopausal osteoporosis (China)), etc.</li> <li>• Regulatory filing: Actemra (COVID-19 (USA)), Gazyva (chronic lymphocytic leukemia)</li> <li>• Start of clinical study(in-house product): crovalimab (P2 SCD), GYM329 (P2/3 SMA)</li> </ul>
<p><b>Maximize the value of growth drivers</b></p>	<ul style="list-style-type: none"> <li>• Accelerating market penetration of growth drivers in Japan and overseas             <ul style="list-style-type: none"> <li>➢ Hemlibra: Strong performance in Japan, the US, Europe, and the rest of the world. Expected to add non-inhibitor (mild to moderate) indications in Europe</li> <li>➢ Tecentriq: Sales declined due to the market expansion re-pricing in August last year and supply restrictions on the combination drug</li> <li>➢ Enspryng: Approved in a total of 72 countries (as of July 2022). Steady market penetration in Japan and overseas</li> <li>➢ Polivy, Evrysdi: Steady market penetration as new products</li> </ul> </li> <li>• Introducing new products and additional indications to the market             <ul style="list-style-type: none"> <li>➢ Vabysmo: Chugai is fully prepared to meet highly specialized information needs. Solid start after Launch on May 25</li> <li>➢ Tecentriq (NSCLC adj): Reinforcing "patient-centric safety countermeasure activities" by enhancing cooperation of Value Delivery 3 divisions<sup>1</sup></li> </ul> </li> </ul>
<p><b>Strengthen business foundation</b></p>	<ul style="list-style-type: none"> <li>• Received DX Grand Prix 2022 Awards for the first time as a leading company in promoting DX</li> <li>• Established and held a Special Committee at the request of the revised Corporate Governance Code</li> <li>• Continuous selection for major ESG indices (GPIF selected domestic equity ESG index including FTSE Blossom Japan Sector Relative Index)</li> </ul>

Promote and deploy with 3 Key drivers

**DX**

**RED<sup>2</sup> SHIFT**

**Open Innovation**

1: Marketing / Medical Affairs / Safety, 2: Research & Early Development  
 SCD: sickle cell disease, SMA: spinal muscular atrophy

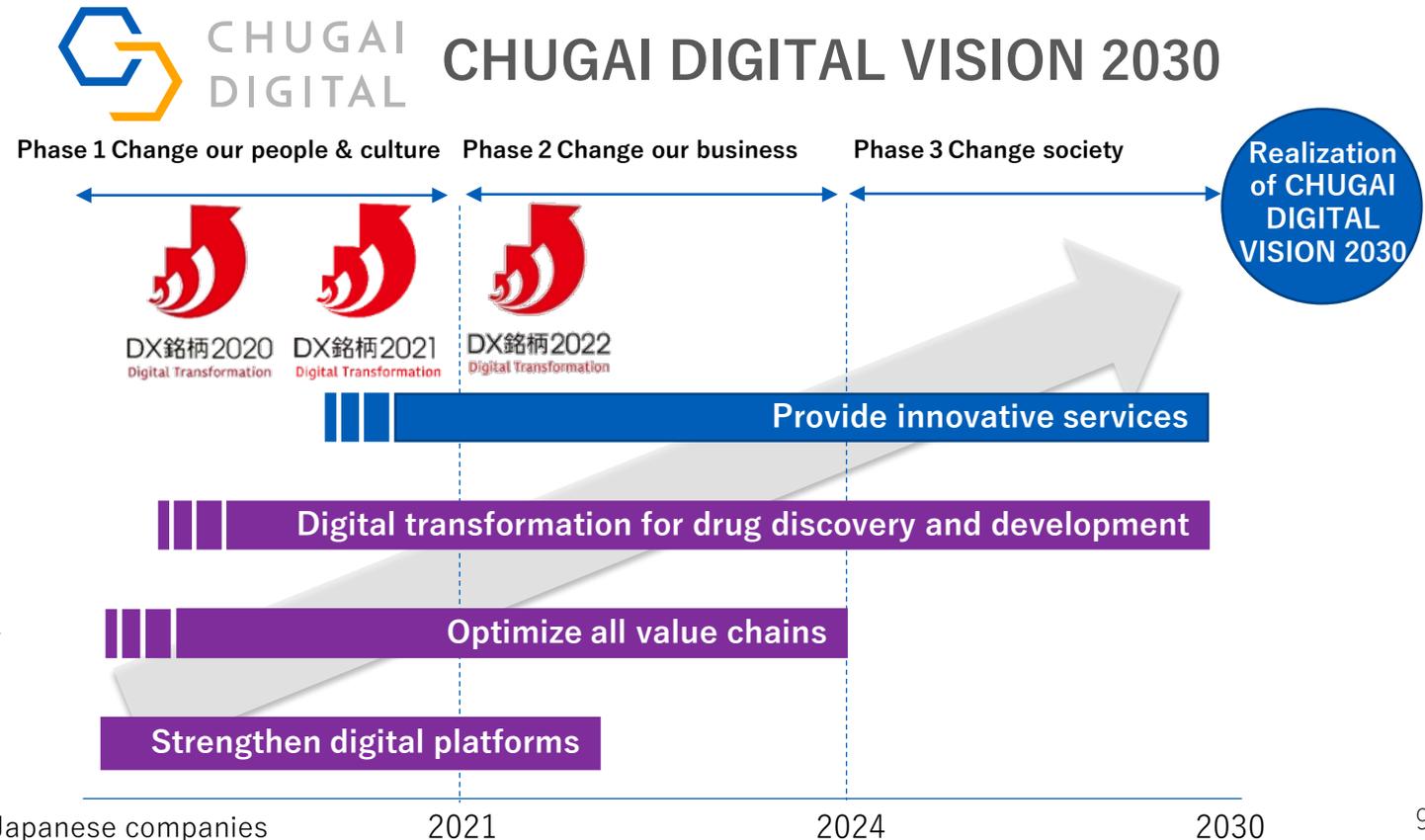
# DX Promotion for the Realization of "TOP I 2030"

- The efforts for promoting DX so far have been highly recognized, and Chugai has been selected as a DX stock\* consecutively and received DX Grand Prix 2022 Awards
- Continue to promote company-wide efforts toward the realization of "CHUGAI DIGITAL VISION 2030"



DXグランプリ2022  
Digital Transformation

Growth strategy "TOP I 2030" is well linked with "CHUGAI DIGITAL VISION 2030," the company's vision for promoting DX, and its achievements in a series of initiatives for drug discovery and manufacturing processes, as well as those for healthcare professionals and patients. These comprehensive efforts were highly recognized.

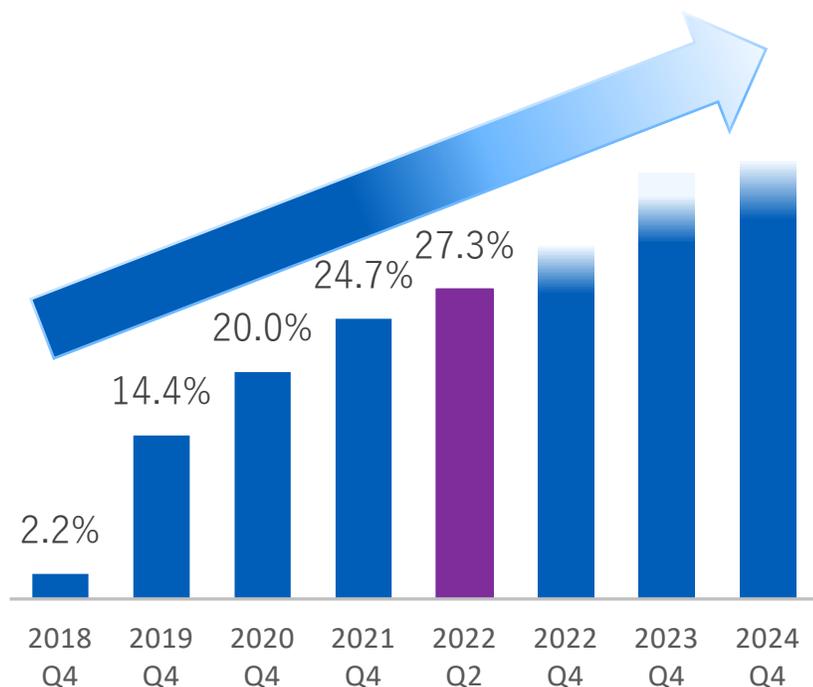


\* The DX Stocks are jointly selected by METI and TSE to accelerate DX of Japanese companies

# Situations on Hemlibra

- The patient share continues to increase steadily and can be further expanded
- Hemlibra may continue to be selected even in the presence of competitors due to the accumulation and penetration of long-term efficacy and safety data, in addition to convenience of administration

Hemlibra: Trends of domestic hemophilia A patient share\*1, \*2



Major competitors in the late development stage\*3

Modality	Company	Developing product	Route of administration / interval	Developing stage
Half-life extended FVIII	Sanofi	BIVV001	IV, QW	P3
Bispecific antibody	Novo Nordisk	Mim8	SC, QW/QM	P3
Gene therapy	Biomarin	Roctavian	IV(one-time)	Filing*4
Gene therapy	Pfizer	SB-525	IV(one-time)	P3
siRNA	Sanofi	Fitusiran	SC, QM	P3
Antibody	Novo Nordisk	Concizumab	SC, Daily	P3
Antibody	Pfizer	Marstacimab	SC, QW	P3

\*3 Based on public information of each company (as of July 21)

\*4 The European Medicines Agency's Drug Evaluation Committee recommends conditional approval (US: preparing for reapplication)

IV: intravenous injection, SC: subcutaneous injection, QW: weekly administration, QM: monthly administration

\*1 Past patient shares are recalculated to reflect the latest survey results

\*2 Charts for Q4 2022 and beyond are growth images

# Partial Revision of the Basic Alliance Agreement with Roche

## ■ Background

- Under the previous Basic Alliance Agreement (BAA), Roche has agreed to cooperate in maintaining Chugai's listing on the first section of the Tokyo Stock Exchange.
- Following the revision of the market classification on the Tokyo Stock Exchange, new listing criteria were established for the Prime Market, which commenced operations on April 4, 2022.
- Chugai and Roche have made relevant revisions in light of the current situation while inheriting the basic spirit of the agreement.

## ■ Revised content

- The main revisions to the BAA are as follows:
  - ✓ Roche will cooperate in maintaining Chugai's listing on the Prime Market<sup>1</sup> of the Tokyo Stock Exchange.
  - ✓ In the event that Chugai issues shares, etc., Roche has the pre-emptive right\* in order to maintain its current and future shareholding ratio in Chugai<sup>2</sup>.

1: Revised from "first section"

2: Revised from "50.1%"

\* Right to acquire the shares at the same price and under the same conditions as a third party

# Summary

- **First half results:** Significant increase in revenues and profits due to strong sales of new products and exports to Roche
- **Full-year results:** Aiming to increase revenues and profits for the sixth consecutive year, although there are concerns about the impact of foreign exchange on profits
- **R&D:** Steady progress of the projects with high market potential is expected to contribute to the future sales growth
- **DX promotion:** Efforts to realize "TOP I 2030" were highly recognized. Expect to continue the company-wide initiatives moving forward
- **HEM:** Expect sustainable growth by maintaining competitive advantage of clinical evidence and high convenience
- **Governance:** Partially revised the Basic Alliance Agreement with Roche

# FY2022 Q2 Consolidated Financial Overview(Core)

**Toshiaki Itagaki**

Director, Executive Vice President & CFO

# IFRS and Core Results Jan – Jun

(Billions of JPY)	IFRS results	Non-core items		Core results
		Intangible assets	Others	
<b>Revenues</b>	<b>596.2</b>		<b>-91.9</b>	<b>504.3</b>
Sales	452.8			452.8
Royalties and other operating income	51.4			51.4
Other revenue	91.9		-91.9	-
Cost of sales	-194.2	+0.6		-193.7
<b>Operating expenses</b>	<b>-115.0</b>	<b>+0.2</b>	<b>+5.6</b>	<b>-109.2</b>
M&D and G&A	-47.3		+3.9	-43.4
Research and development	-67.7	+0.2	+1.8	-65.8
<b>Operating profit</b>	<b>286.9</b>	<b>+0.7</b>	<b>-86.3</b>	<b>201.4</b>
Financial account balance	-0.0			-0.0
Income taxes	-82.8	-0.2	+26.3	-56.7
<b>Net income</b>	<b>204.2</b>	<b>+0.5</b>	<b>-59.9</b>	<b>144.7</b>
<b>EPS (JPY)</b>	<b>124.08</b>			<b>87.97</b>

## Non-Core items

(Billions of JPY)

### Intangible assets

Amortization	+0.6
Impairment	+0.2

### Others

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

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

(Billions of JPY)	2021	2022	Growth	
<b>Revenues</b>	<b>390.2</b>	<b>504.3</b>	+ 114.1	+ 29.2%
Sales	304.1	452.8	+ 148.7	+ 48.9%
Domestic	203.4	273.8	+ 70.4	+ 34.6%
Overseas	100.7	179.0	+ 78.3	+ 77.8%
Royalties and other operating income	86.1	51.4	- 34.7	- 40.3%
Royalty and profit-sharing income	83.3	50.4	- 32.9	- 39.5%
Other operating income	2.8	1.0	- 1.8	- 64.3%
<b>Cost of sales</b>	<b>-121.9</b>	<b>-193.7</b>	<b>- 71.8</b>	<b>+ 58.9%</b>
(cost to sales ratio)	40.1%	42.8%	+2.7%pts	-
<b>Operating expenses</b>	<b>-102.5</b>	<b>-109.2</b>	<b>- 6.7</b>	<b>+ 6.5%</b>
M&D and G&A *	-42.7	-43.4	- 0.7	+ 1.6%
Research and development	-59.9	-65.8	- 5.9	+ 9.8%
<b>Operating profit</b>	<b>165.8</b>	<b>201.4</b>	<b>+ 35.6</b>	<b>+ 21.5%</b>
(operating margin)	42.5%	39.9%	-2.6%pts	-
Financial account balance	0.6	-0.0	- 0.6	-
Income taxes	-44.7	-56.7	- 12.0	+ 26.8%
<b>Net income</b>	<b>121.7</b>	<b>144.7</b>	<b>+ 23.0</b>	<b>+ 18.9%</b>
<b>EPS (JPY)</b>	<b>73.99</b>	<b>87.97</b>	<b>+13.98</b>	<b>+ 18.9%</b>

## Domestic sales

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

## Overseas sales

Significant increase in sales of Hemlibra and Actemra

## Royalty and profit-sharing income

Significant decrease in royalty income for initial shipping inventory of Hemlibra

## Other operating income

Decrease in one-time income

## Cost of sales

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

## Operating expenses

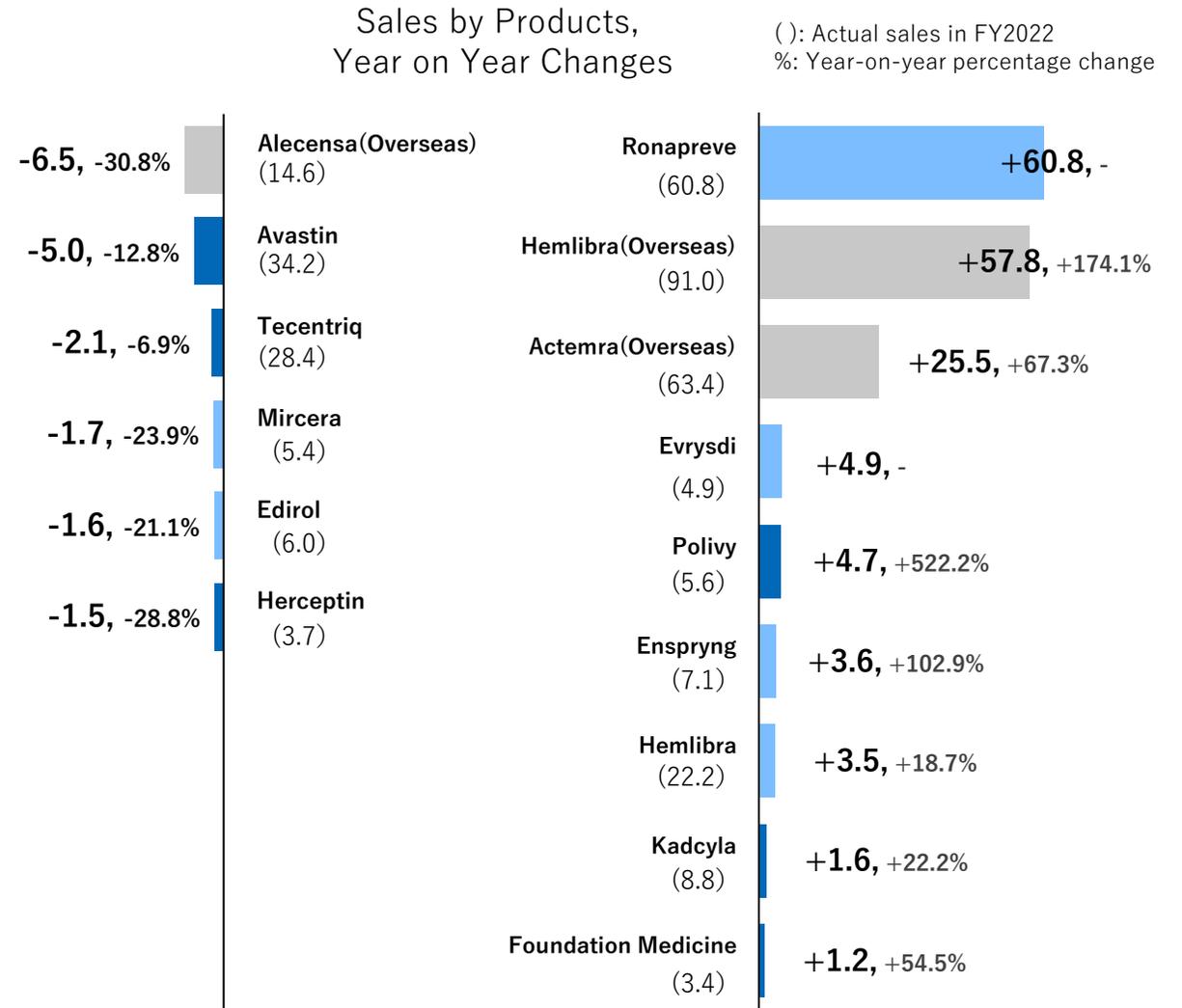
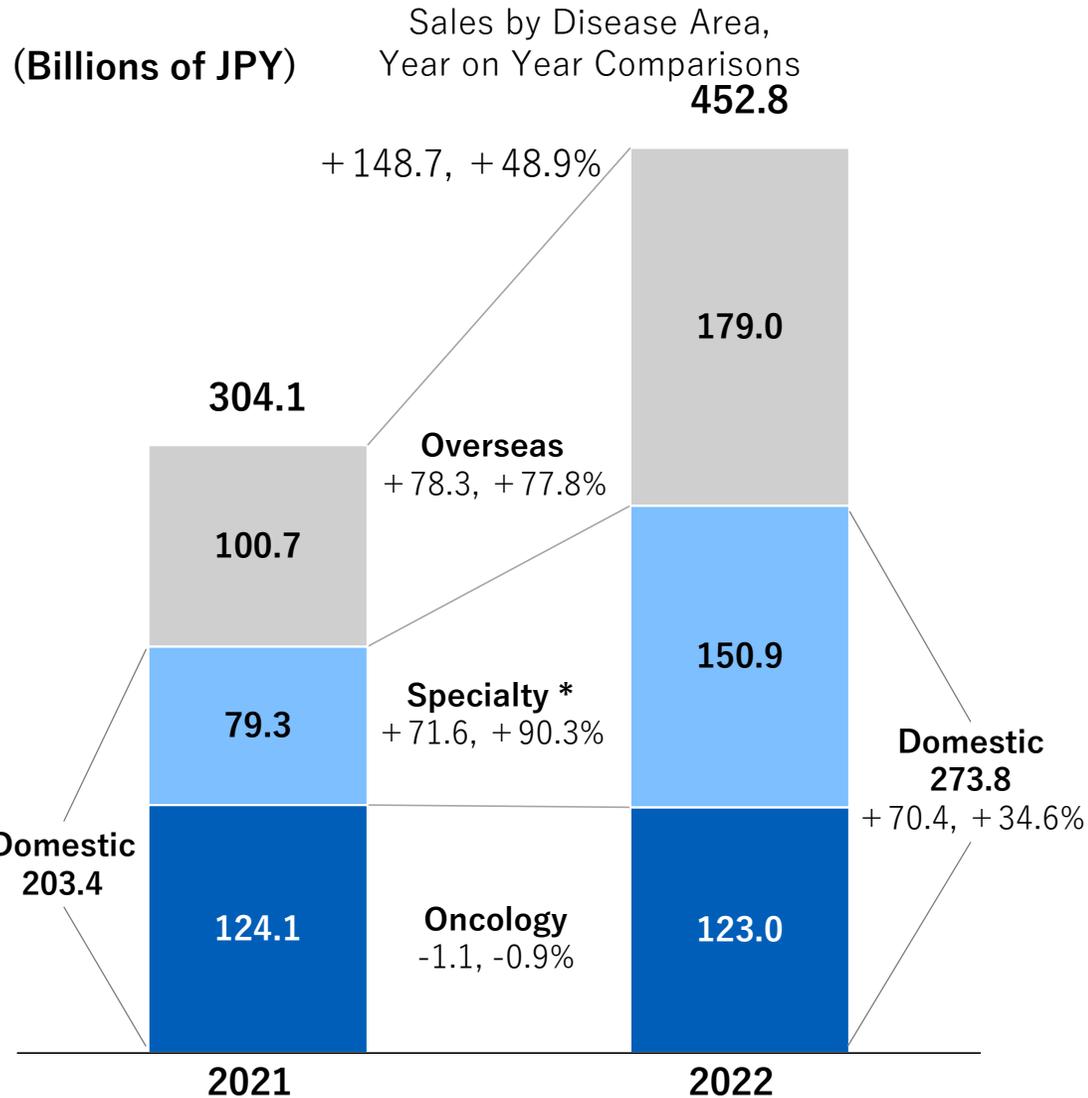
Increase due to impact of yen depreciation on costs denominated in foreign currencies and progress of development projects, etc.

## Operating profit

Growth mainly due to increase in sales

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

# Sales Jan - Jun (Year on Year)



\* Area name changed from "Primary" to "Specialty" from July 2022.

# Export of Actemra to Roche

(Billions of JPY)

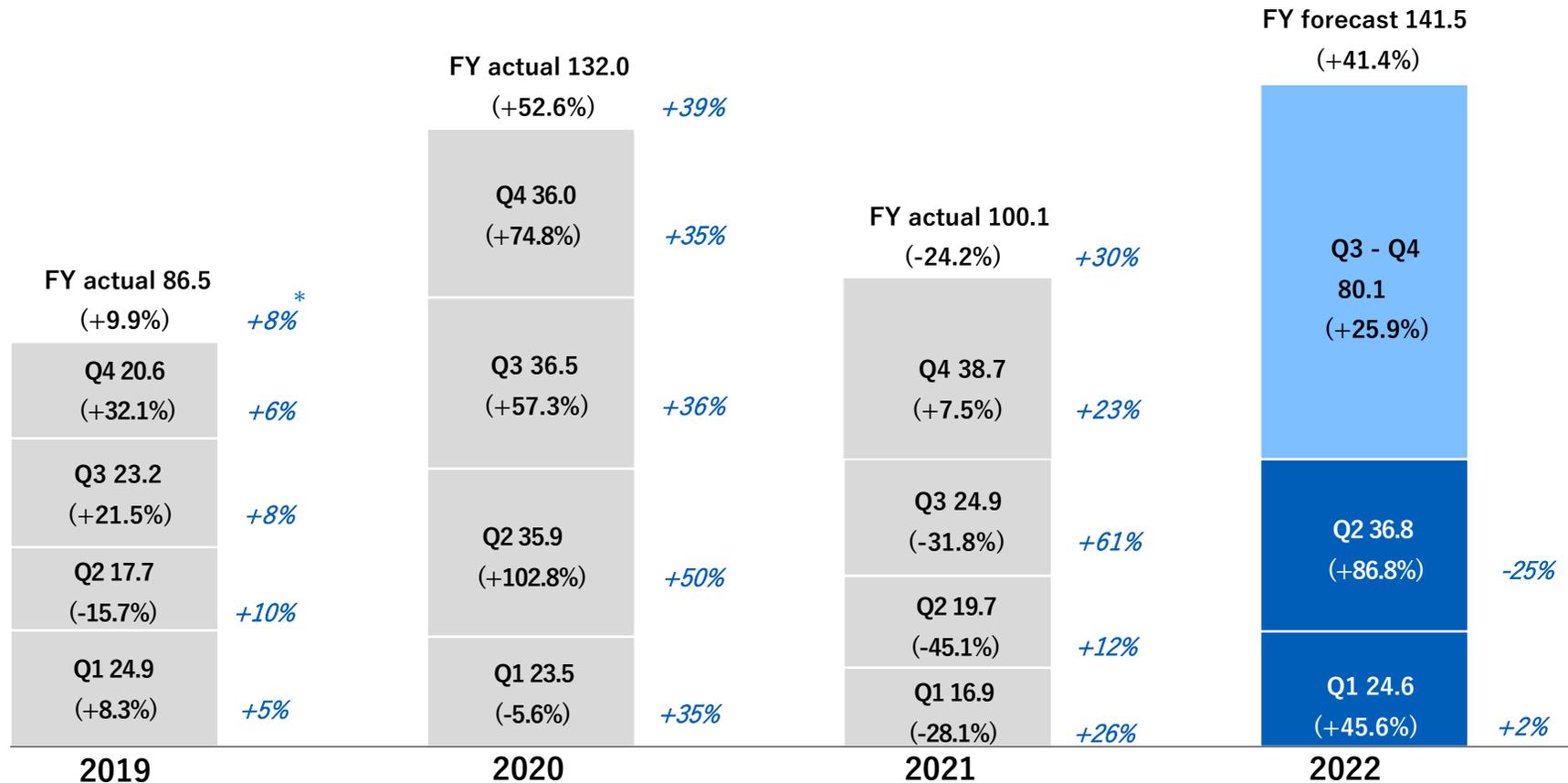


=: year on year growth

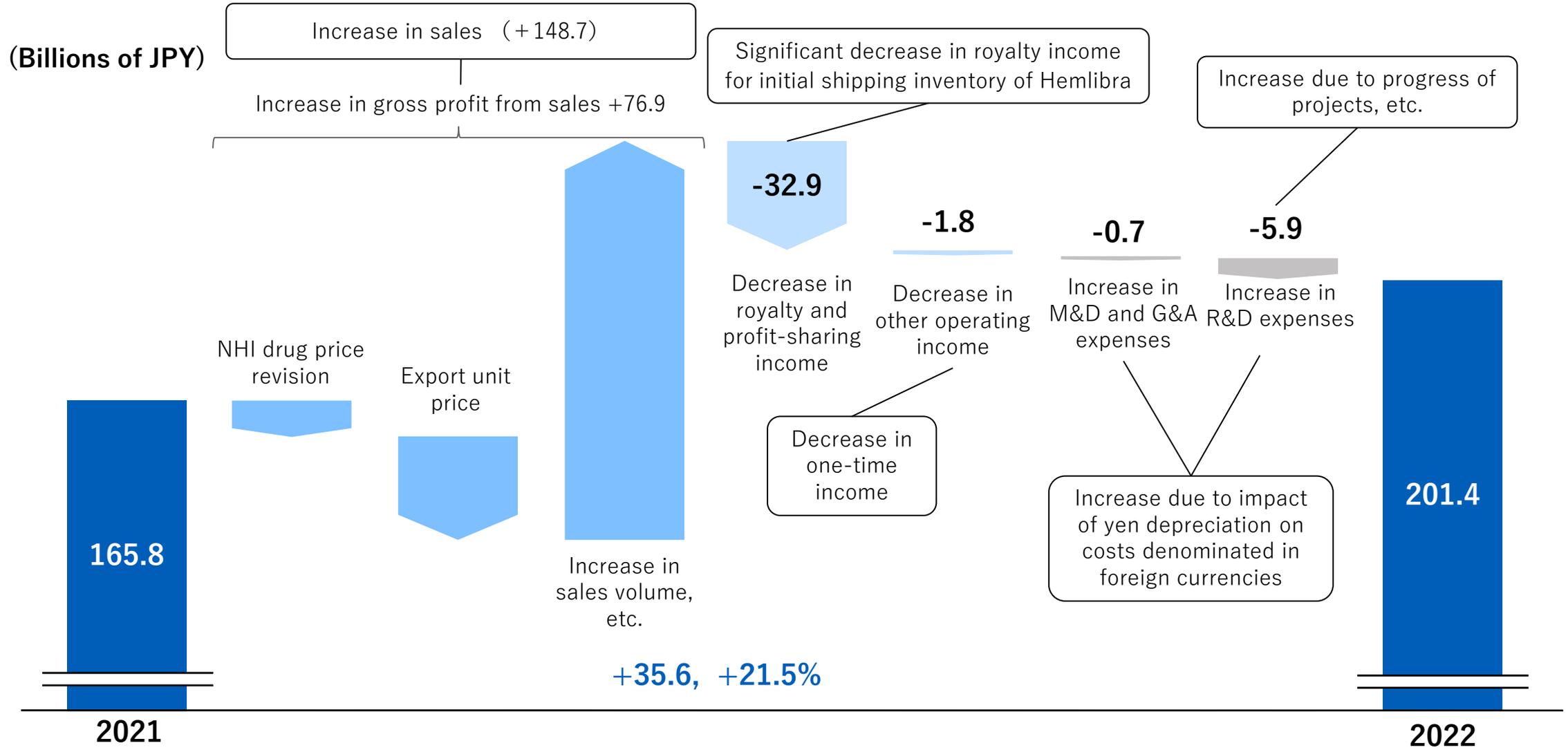
black: Chugai sales to Roche

blue\*: Roche sales excluding Japan (for reference)

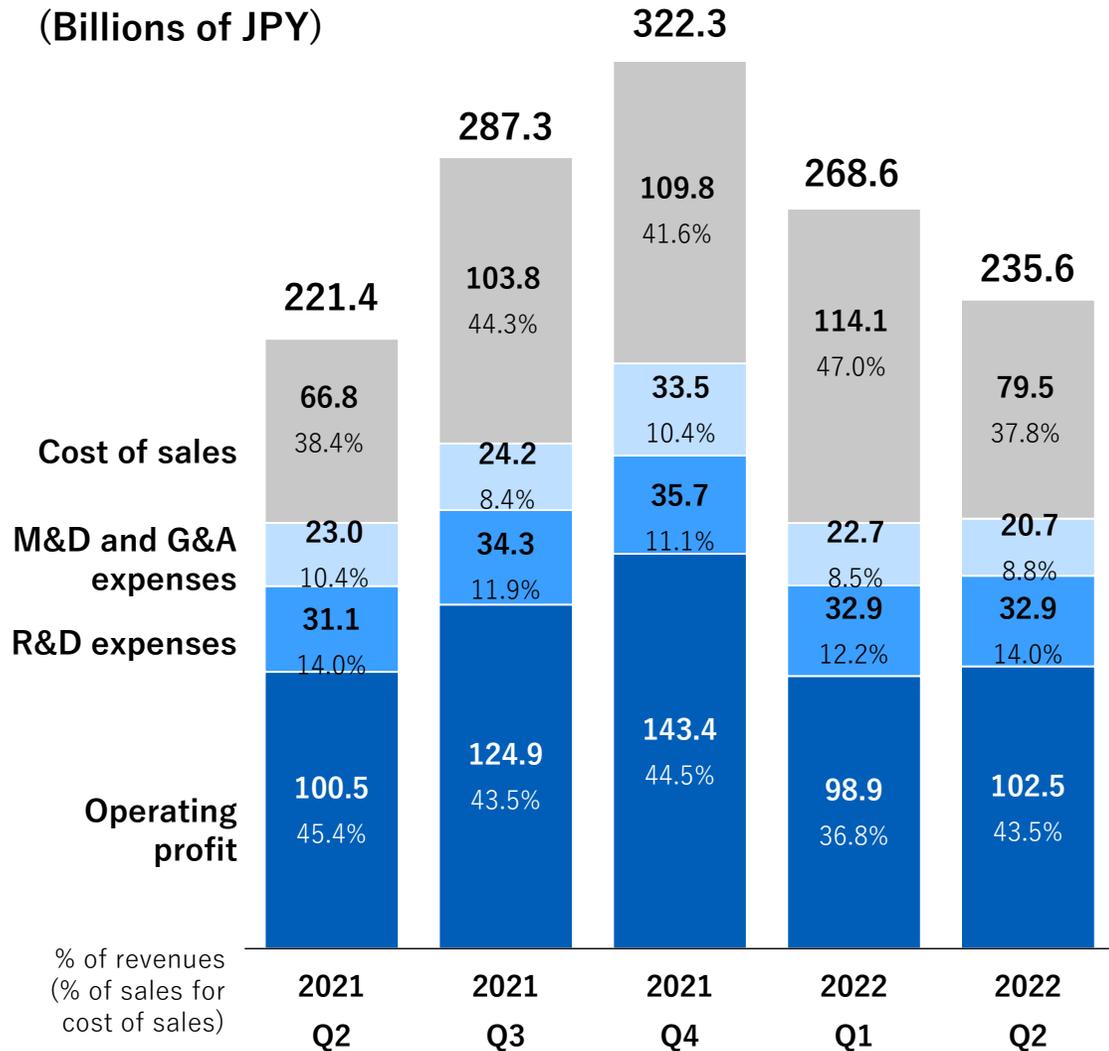
\*Growth rates in blue are calculated with the effects of exchange rate fluctuations eliminated.



# Operating Profit Jan - Jun (Year on Year)



# Structure of Costs and Profit by Quarter



## vs. Year on Year (2021 Q2)

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

M&D and G&A expenses: decrease due to gain on sales of property, plant and equipment, etc.

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

Operating profit: increase of +2.0 (+2.0%)

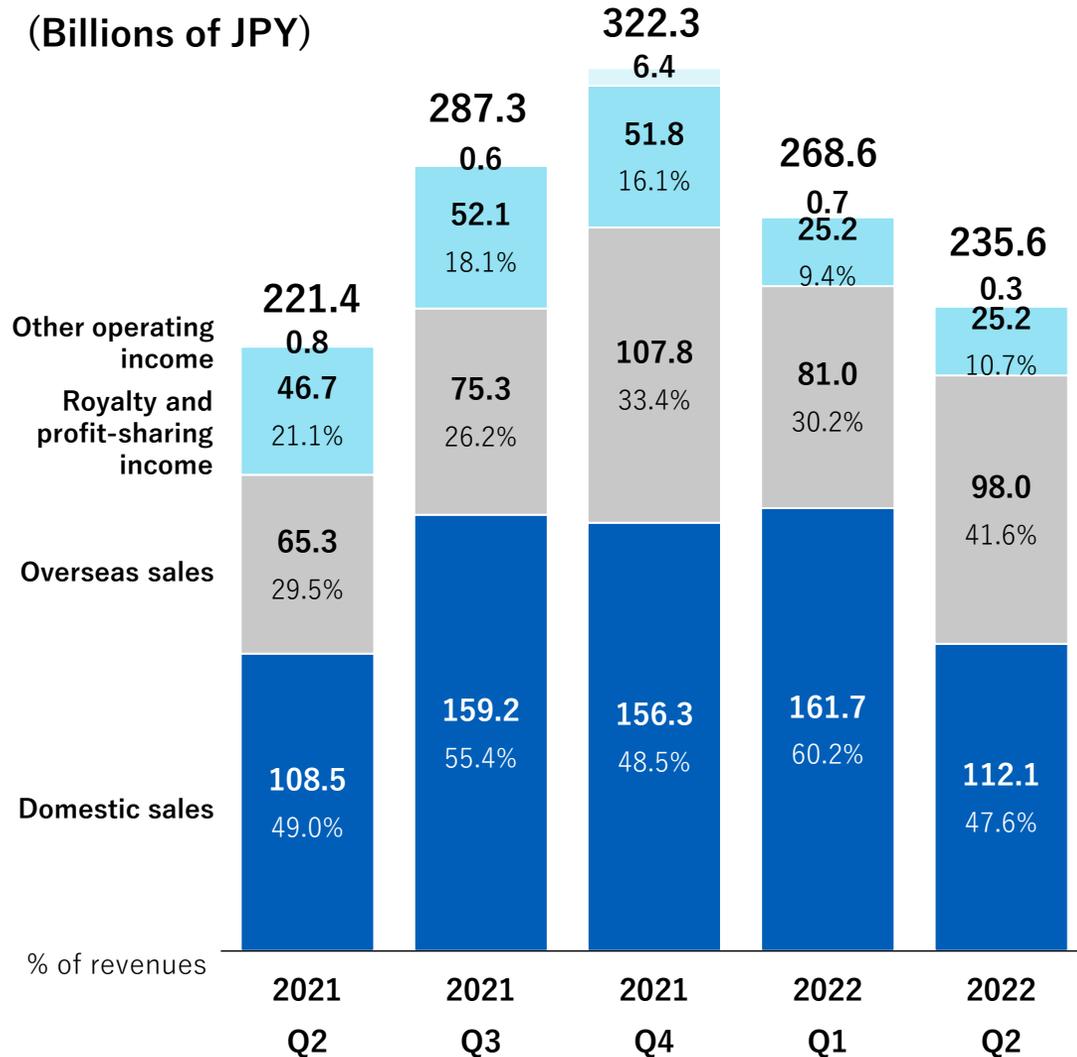
## vs. Previous Quarter (2022 Q1)

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

M&D and G&A expenses: decrease due to gain on sales of property, plant and equipment, etc.

Operating profit: increase of +3.6 (+3.6%)

# Structure of Revenues by Quarter



## vs. Year on Year (2021 Q2)

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

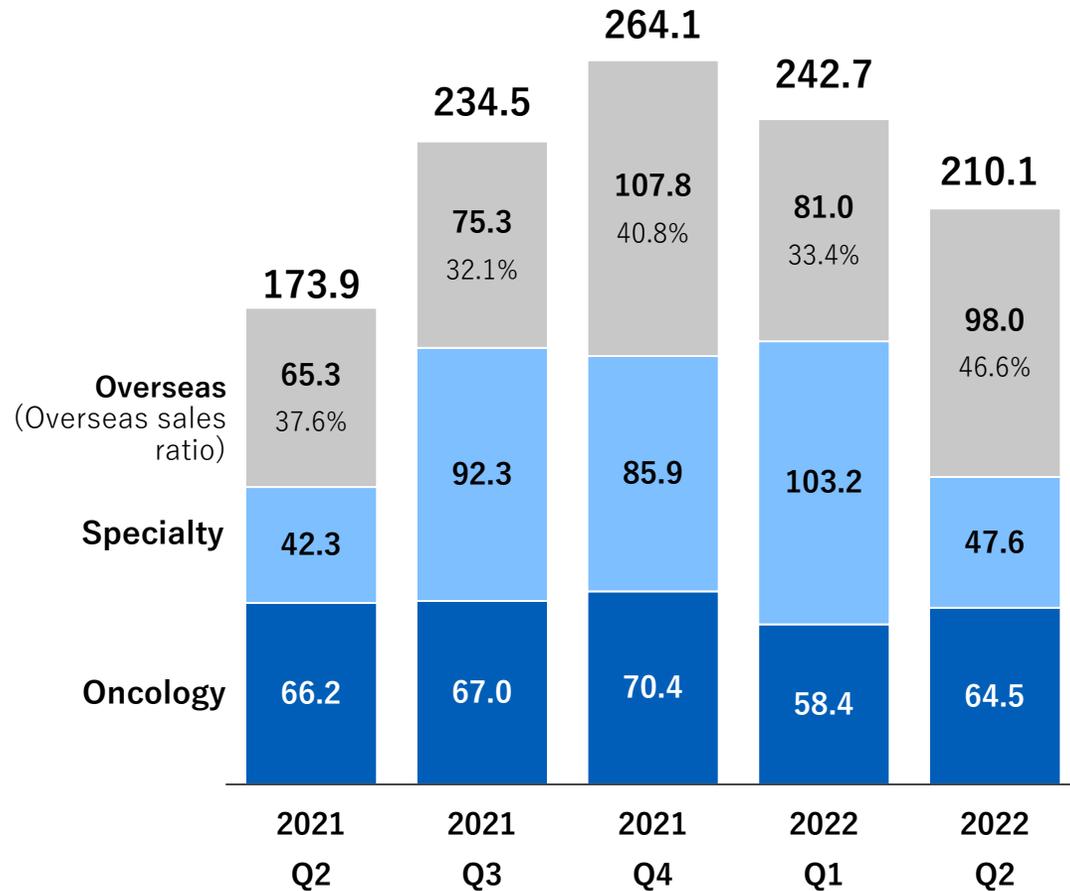
## vs. Previous Quarter (2022 Q1)

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

Overseas sales: significant increase in sales of Actemra

# Structure of Sales by Quarter

(Billions of JPY)



## vs. Year on Year (2021 Q2)

<b>Oncology</b>	Polivy:	+2.0	Kadcyla:	+0.8
	Avastin:	-2.7	Tecentriq:	-1.4
<b>Specialty</b>	Evrysdi:	+2.8	Hemlibra:	+2.2
	Enspryng:	+1.7	Edirol:	-2.0
<b>Overseas</b>	Hemlibra:	+21.6	Actemra:	+17.2

## vs. Previous Quarter (2022 Q1)

<b>Oncology</b>	Tecentriq:	+1.6	Avastin:	+1.2
	Alecensa:	+1.1		
<b>Specialty</b>	Ronapreve:	-60.8	Hemlibra:	+2.1
	Vabysmo:	+0.9		
<b>Overseas</b>	Actemra:	+12.0	Alecensa:	+4.2
	Hemlibra:	+1.6		

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

(Billions of JPY)	Actual	Forecast		2021
	2022 Jan - Jun	2022 Jan - Dec	Progress	Progress*
<b>Revenues</b>	<b>504.3</b>	<b>1,150.0</b>	<b>43.9%</b>	<b>39.0%</b>
Sales	452.8	1,031.5	43.9%	37.9%
Domestic	273.8	646.3	42.4%	39.2%
Overseas	179.0	385.2	46.5%	35.5%
Royalties and other operating income	51.4	118.5	43.4%	43.7%
Royalty and profit-sharing income	50.4	114.0	44.2%	44.5%
Other operating income	1.0	4.5	22.2%	28.6%
<b>Cost of sales</b>	<b>- 193.7</b>	<b>- 460.0</b>	<b>42.1%</b>	<b>36.3%</b>
(cost to sales ratio)	42.8%	44.6%	-	-
<b>Operating expenses</b>	<b>- 109.2</b>	<b>- 250.0</b>	<b>43.7%</b>	<b>44.5%</b>
M&D and G&A	- 43.4	- 100.5	43.2%	42.5%
Research and development	- 65.8	- 149.5	44.0%	46.1%
<b>Operating profit</b>	<b>201.4</b>	<b>440.0</b>	<b>45.8%</b>	<b>38.2%</b>
(operating margin)	39.9%	38.3%	-	-
<b>Net income</b>	<b>144.7</b>	<b>312.5</b>	<b>46.3%</b>	<b>39.1%</b>
<b>EPS (JPY)</b>	<b>87.97</b>	190.00	46.3%	39.1%

## Domestic Sales

Overall progress nearly in line with forecast  
(2021 progress: low level as Ronapreve supply to the government scheduled for H2)

## Overseas sales

Progress nearly in line with forecast  
(2021 progress: low level as full-scale export of Hemlibra to Roche at ordinary supply prices started from middle of second quarter)

## Royalty and profit-sharing income

Progress nearly in line with forecast

## Other operating income

Progress nearly in line with forecast

## Cost of Sales

Cost to sales ratio nearly in line with H1 forecast

## Operating expenses

Progress nearly in line with forecast

## Operating profit

Progress nearly in line with forecast

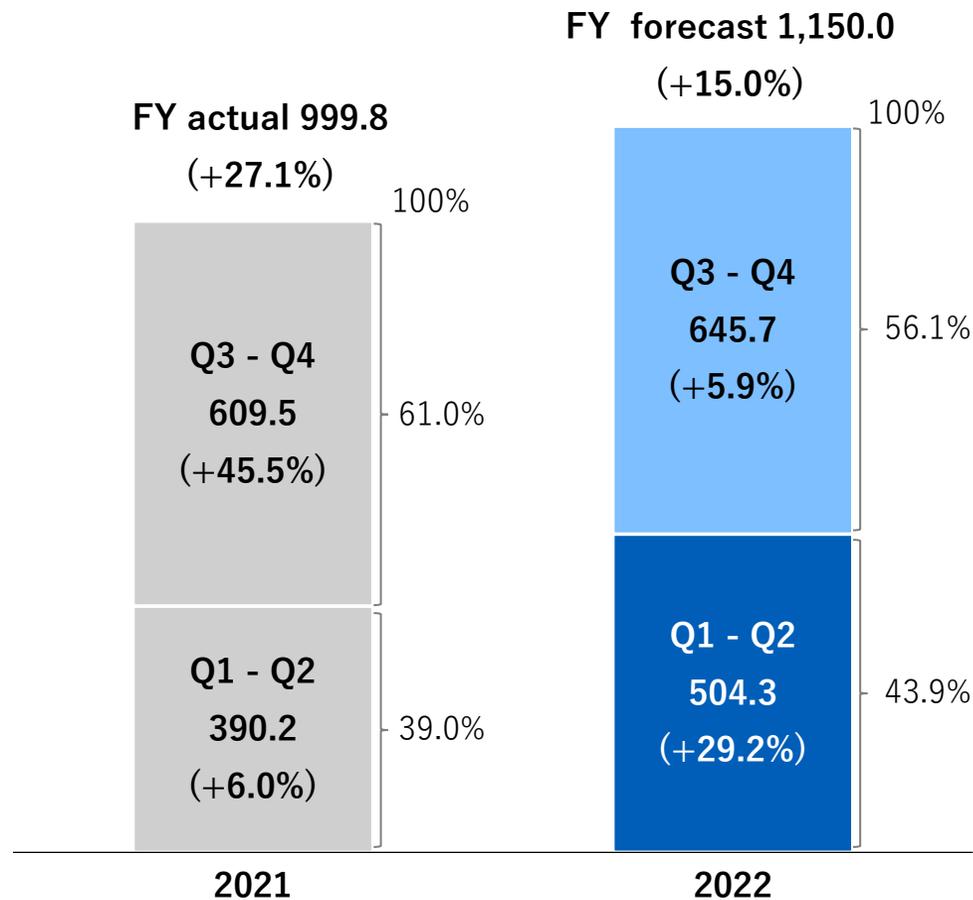
\* Jan – Jun progress versus Jan – Dec

# H1 Actual and Remaining Year Forecast (Year on Year)

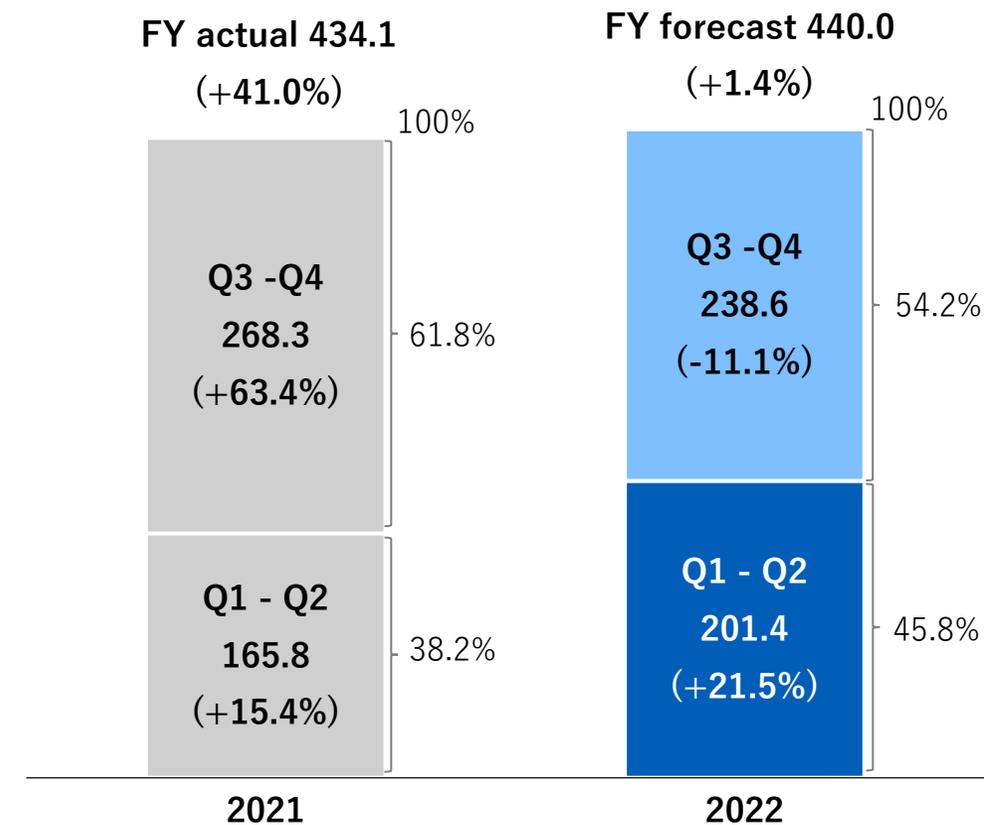
(billions of JPY)

( ):Year-on-year percentage change

## <Revenues>



## <Operating profit>



# Sales Jan - Jun (vs. Forecast)

(Billions of JPY)	Actual	Forecast		2021
	2022 Jan - Jun	2022 Jan - Dec	Progress	Progress *
<b>Sales</b>	<b>452.8</b>	<b>1,031.5</b>	<b>43.9%</b>	<b>37.9%</b>
<b>Domestic</b>	<b>273.8</b>	<b>646.3</b>	<b>42.4%</b>	<b>39.2%</b>
<b>Oncology</b>	<b>123.0</b>	<b>260.5</b>	<b>47.2%</b>	<b>47.5%</b>
Avastin	34.2	69.4	49.3%	48.5%
Tecentriq	28.4	62.0	45.8%	49.0%
Perjeta	15.6	33.7	46.3%	48.8%
Alecensa	13.7	28.7	47.7%	47.3%
Polivy	5.6	16.2	34.6%	13.2%
Kadcyla	8.8	16.0	55.0%	45.9%
Herceptin	3.7	8.3	44.6%	53.1%
Gazyva	2.1	5.4	38.9%	46.7%
Rituxan	2.2	4.1	53.7%	47.1%
Foundation Medicine	3.4	9.1	37.4%	43.1%
Other	5.2	7.5	69.3%	49.1%

(Billions of JPY)	Actual	Forecast		2021
	2022 Jan - Jun	2022 Jan - Dec	Progress	Progress *
<b>Specialty</b>	<b>150.9</b>	<b>385.8</b>	<b>39.1%</b>	<b>30.8%</b>
Ronapreve	60.8	199.0	30.6%	0.0%
Hemlibra	22.2	51.8	42.9%	45.0%
Actemra	20.6	41.9	49.2%	47.0%
Enspryng	7.1	16.7	42.5%	36.1%
Edirol	6.0	10.8	55.6%	34.1%
Mircera	5.4	10.2	52.9%	49.3%
Evrysdi	4.9	8.8	55.7%	0.0%
CellCept	3.8	7.4	51.4%	48.8%
Bonviva	3.6	7.0	51.4%	50.0%
Oxarol	2.8	5.1	54.9%	48.4%
Vabysmo	0.9	4.6	19.6%	-
Other	12.8	22.5	56.9%	46.6%
<b>Overseas</b>	<b>179.0</b>	<b>385.2</b>	<b>46.5%</b>	<b>35.5%</b>
Hemlibra	91.0	186.0	48.9%	29.1%
Actemra	63.4	144.4	43.9%	36.9%
Alecensa	14.6	34.1	42.8%	42.1%
Enspryng	1.7	4.6	37.0%	60.0%
Neutrogen	4.6	8.8	52.3%	52.7%
Other	3.7	7.4	50.0%	48.4%

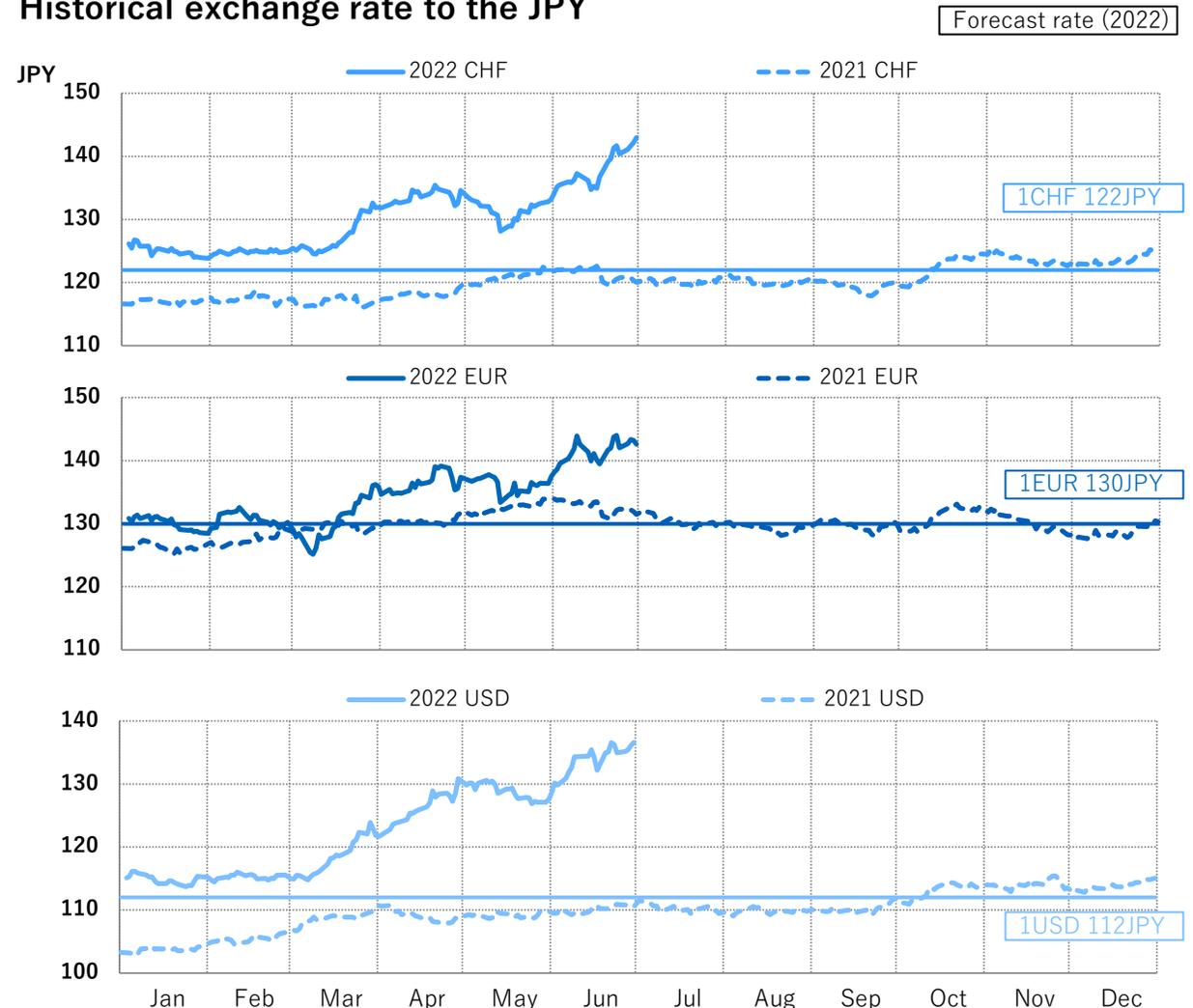
\* Jan - Jun progress versus Jan - Dec

# Impact from Foreign Exchange Jan - Jun

(billions of JPY)	vs. 2021 Actual	vs. 2022 Assumption
<b>Revenues</b>		
Sales	+13.3	+2.2
Royalties and other operating income	+9.5	+0.9
	+3.8	+1.3
<b>Cost of sales</b>	-5.8	-0.1
<b>Operating expenses</b>	-1.8	-0.9
<b>Operating profit</b>	+5.7	+1.2

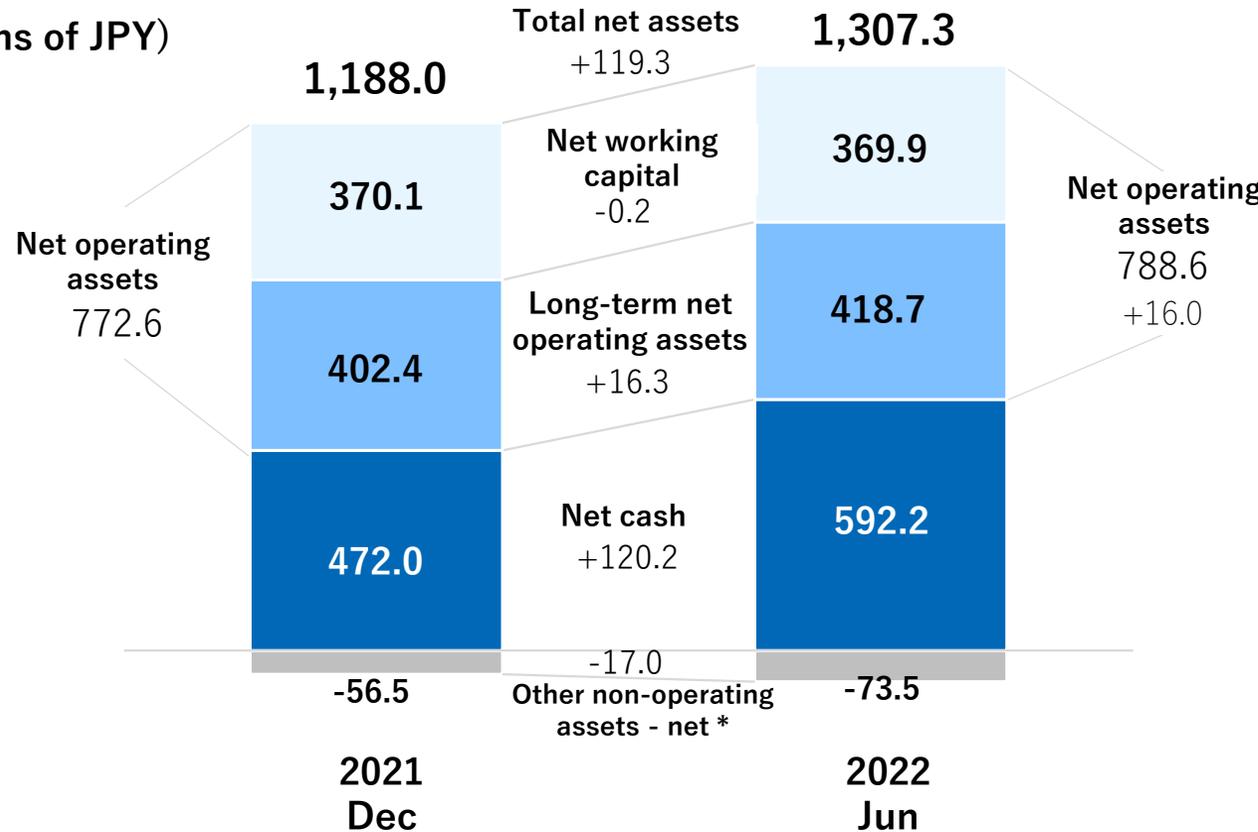
Market average exchange rate(JPY)	2021 Actual	2022 Assumption	2022 Actual
1CHF	118.60	122.00	130.15
1EUR	129.76	130.00	134.35
1USD	107.63	112.00	122.87

Historical exchange rate to the JPY



# Financial Position (vs. 2021 Year End)

(Billions of JPY)



## Decrease in net working capital

Same level as the end of Dec 2021, mainly due to decrease in accounts receivable offset by payment for API manufacturing building (FJ3) at Fujieda plant

## Increase in long-term net operating assets

Increase in property, plant and equipment due mainly to the following investments  
 - Chugai Life Science Park Yokohama  
 - Biopharmaceutical API manufacturing building(UK4) at Ukima Branch

## Increase in net cash

(See next slide)

## Decrease in other non-operating assets – net

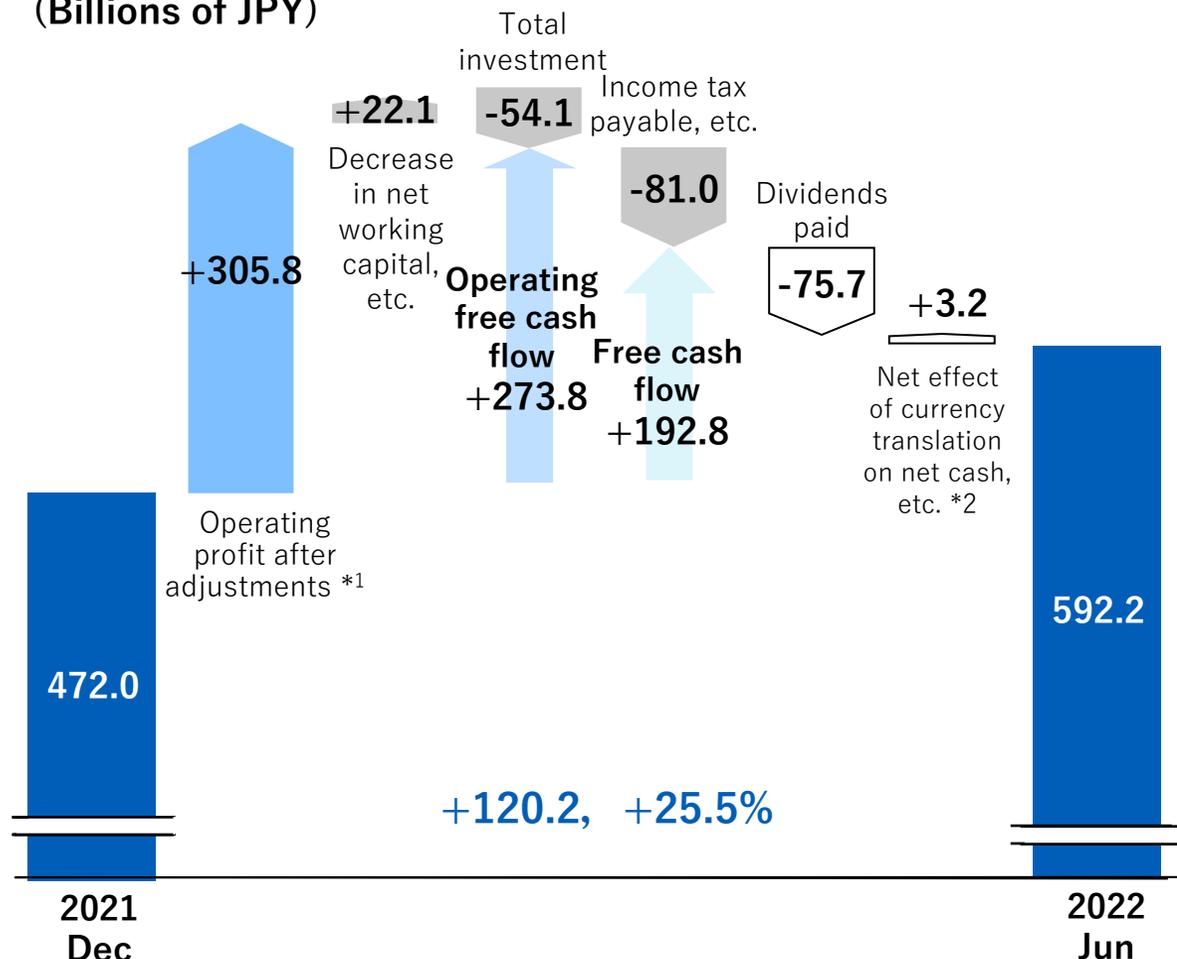
Increase mainly in foreign exchange contracts liabilities, etc.

Total assets	1,538.7	+86.9	1,625.6
Total liabilities	-350.7	+32.4	-318.3
<b>Total net assets</b>	<b>1,188.0</b>	<b>+119.3</b>	<b>1,307.3</b>
Ratio of equity attributable to Chugai shareholders	77.2%	+3.2%pts	80.4%

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

# Net Cash (vs. 2021 Year End)

(Billions of JPY)



<b>Operating profit after adjustment *1</b>	<b>+305.8</b>
Operating profit *1	+286.9
Depreciation, amortization and impairment *1	+14.7
<b>decrease in net working capital, etc.</b>	<b>+22.1</b>
<b>Total investment</b>	<b>-54.1</b>
Property, plant and equipment	-43.6
Payment for lease liabilities	-3.7
Intangible assets	-6.7
<b>Operating free cash flow</b>	<b>+273.8</b>
<b>Income tax payable, etc.</b>	<b>-81.0</b>
Income tax payable	-86.2
<b>Free cash flow</b>	<b>+192.8</b>
<b>Dividends paid</b>	<b>-75.7</b>
<b>Net effect of currency transaction on net cash, etc. *2</b>	<b>+3.2</b>

\*1 Including Non-Core (IFRS results)

\*2 Net effect of currency translation on net cash, etc. = Transaction in own equity instruments + Purchase of non-controlling interests + Net effect of currency translation on net cash(\*3)

\*3 Results from using different types of exchange rates when consolidating overseas subsidiaries in financial statements, i.e. net cash using end of period exchange rate and free cash flows using average exchange rate. (Chugai defines this term based on International Accounting Standard (IAS) 7 and IAS 21)

# Current Status / Plan for Major Investments



Production

**Fujieda Plant:** Construction of a new synthetic manufacturing building to accelerate the development of small- and mid-size molecule active pharmaceutical ingredients (FJ2)



2019-22: 19.1 billion JPY (16.8 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 (FJ3)



2021-24: 55.5 billion JPY (16.4 billion JPY)

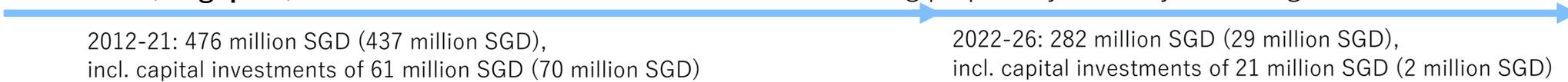
**Ukima Branch:** Construction of biopharmaceutical API manufacturing building for early-stage clinical development (UK4)



2021-23: 12.1 billion JPY (3.2 billion JPY)

Research and development

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



2012-21: 476 million SGD (437 million SGD),  
incl. capital investments of 61 million SGD (70 million SGD)

2022-26: 282 million SGD (29 million SGD),  
incl. capital investments of 21 million SGD (2 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 (109.6 billion JPY)

Comprehensive collaboration in research activity with **IFReC**



2017-27: 10.0 billion JPY (6.3 billion JPY)

# Overview of Development Pipeline

**Tetsuya Yamaguchi**

Executive Vice President, Head of Project & Lifecycle Management Unit

# Q2 Topics (1/2)



As of July 21, 2022

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

<b>Launched</b>	<b>Vabysmo</b>	Age-related macular degeneration associated with subfoveal choroidal neovascularization and diabetic macular edema	May 2022
	<b>Edirol</b>	Postmenopausal osteoporosis (China)	July 2022
<b>Approved</b>	<b>Tecentriq</b>	PD-L1-positive NSCLC (adjuvant)	May 2022
	<b>FoundationOne® CDx Cancer Genomic Profile</b>	<ul style="list-style-type: none"> <li>• dacomitinib hydrate: NSCLC (Activated <i>EGFR</i> alterations)</li> <li>• brigatinib: NSCLC (<i>ALK</i> fusion genes)</li> <li>• encorafenib, binimetinib: Malignant melanoma (<i>BRAF</i>V600E and V600K alterations)</li> </ul>	June 2022
	<b>Hemlibra</b>	Acquired hemophilia A	June 2022
	<b>Avastin</b>	Additional dosage and administration in ovarian cancer: every 2 weeks (public knowledge-based application)	June 2022
	<b>Neutrogen</b>	Relapse or refractory acute myeloid leukemia in combination with other anticancer agents (public knowledge-based application)	June 2022
	<b>Rituxan</b>	Prevention of recurrence of NMOSD (including neuromyelitis optica)	June 2022
<b>Readout in pivotal study</b>	<b>RG6058/tiragolumab</b>	NSCLC P3 (SKYSCRAPER-01) PFS: did not meet / OS: continuously evaluate	May 2022
	<b>RG7446/Tecentriq</b>	Renal cell carcinoma (adjuvant) P3 (IMmotion010) DFS: did not meet	June 2022
	<b>CIM331 / nemolizumab</b>	Prurigo nodularis P3 (OLYMPIA 2 conducted by Galderma) Primary endpoints were met	June 2022

NSCLC: non-small cell lung cancer; NMOSD: neuromyelitis optica spectrum disorder

PFS: Progression-free Survival; OS: Overall Survival; DFS: Disease-free Survival

# Q2 Topics (2/2)



As of July 21, 2022

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

<b>Medical conference</b>	<b>Evrysdi</b>	FIREFISH study, three-year data presented at European Paediatric Neurology Society Congress	April 2022
	<b>OWL833 (LY3502970)</b>	P1 study, PK data in healthy volunteers presented at American Diabetes Association*	June 2022
	<b>Hemlibra</b>	HAVEN 6 study, data in mild-moderate hemophilia A without inhibitors presented at ISTH	July 2022
	<b>Hemlibra</b>	AGEHA study, data in acquired hemophilia A presented at ISTH	July 2022
	<b>Vabysmo</b>	TENAYA & LUCERNE studies, two-year data in nAMD presented at ASRS	July 2022
	<b>Perjeta</b>	APHINITY study in combination with Herceptin, eight-year data in HER2 positive early BC at ESMO Virtual Plenary	July 2022
<b>New to pipeline</b>	<b>RG7159/Gazyva</b>	Lupus nephritis	domestic P3 (June 2022)
	<b>GYM329 (RG6237)</b>	Spinal Muscular Atrophy (MANATEE study) in combination with Evrysdi	P2/3 (June 2022)
	<b>RG6396/pralsetinib</b>	NSCLC (2nd line)	domestic P2 (June 2022)
<b>Development discontinued</b>	<b>RG6058/tiragolumab</b>	SCLC (1st Line), SKYSCRAPER-02 study in combination with Tecentriq	
	<b>RG7446/Tecentriq</b>	Ovarian cancer (1st Line), IMagyn050 study in combination with Avastin	
	<b>RG7880/efmarodocokin alfa</b>	Inflammatory bowel disease	

NSCLC: non-small cell lung cancer; BC: breast cancer; nAMD: neovascular age-related macular degeneration; ISTH: International Society on Thrombosis and Haemostasis; ASRS: American Society of Retina Specialists Annual Scientific Meeting; ESMO: European Society for Medical Oncology

\* Conducted by Eli Lilly, the overseas licensee

# Nemolizumab

Galderma announced the phase III OLYMPIA 2 trial met all primary endpoints in patients with PN

- Prurigo nodularis (PN) is a chronic skin disorder with hard dome-like or wart-like nodules and intense pruritus
- No treatments for PN is approved despite negatively affecting QOL
- Nemolizumab is a Chugai originated first in class antibody designed to inhibit IL-31 signal which is involved in PN pathology

## < Data from OLYMPIA 2 trial\* >

- **Meet two primary endpoints by nemolizumab monotherapy\*\*. Safety profile was consistent with the phase II trial.**
  - Skin lesions (IGA score): 38% of nemolizumab group reached clearance or almost-clearance of skin lesions, compared to 11% of placebo group. (p<0.0001)
  - Itch (PP-NRS score): 56% of nemolizumab group achieved an at least four-point reduction, compared to 21% of placebo group. (p<0.0001)
- **Data confirm early onset of action on itch, skin lesions and sleep disturbance as the trial also met all key secondary endpoints.**
- **Favorable results of OLYMPIA 2 reproduce the data of the P2 study, granted breakthrough therapy designation by the US FDA in December 2019**

\* OLYMPIA 2 is a randomized, double-blind, placebo-controlled phase III clinical trial, to assess the efficacy and safety of nemolizumab monotherapy compared with placebo in patients at least 18 years of age with prurigo nodularis after a 16-week treatment period. 274 patients with moderate-to-severe prurigo nodularis joined the trial. A second phase III trial investigating the efficacy of nemolizumab in patients with prurigo nodularis, named OLYMPIA 1, is ongoing. The OLYMPIA 1 trial has a similar design to OLYMPIA 2.

\*\* without background topical corticosteroids or topical calcineurin inhibitors

IGA: Investigator's Global Assessment, PP-NRS: Peak Pruritus Numerical Rating Scale

# GYM329: Global P2/3 study (MANATEE)

Study in combination with Evrysdi in pediatric patients with Spinal Muscular Atrophy (SMA)

- Evrysdi increases and sustains the production of the survival motor neuron (SMN) protein which is critical for maintaining healthy motor neurons and movement.
- GYM329 inhibits latent myostatin which suppresses muscle growth and is expected to control progression of loss in muscle strength in neuromuscular disease
- Combination therapy of these drugs is expected to further improve motor movement and clinical outcome in SMA

## Overview of MANATEE

### Indication: SMA

ambulant (able to walk independently) children with SMA aged 2 to 10 years

### < part 1 > : dose ascending study

Enrolment: approximately 36 participants  
Purpose: select the optimal dose of part 2\*<sup>1</sup>, safety and PK/PD  
Time frame: double-blind for 24 weeks followed by open-label for 72 weeks  
Treatment: GYM329+Evrysdi or Placebo+Evrysdi

### < part 2 > : pivotal study

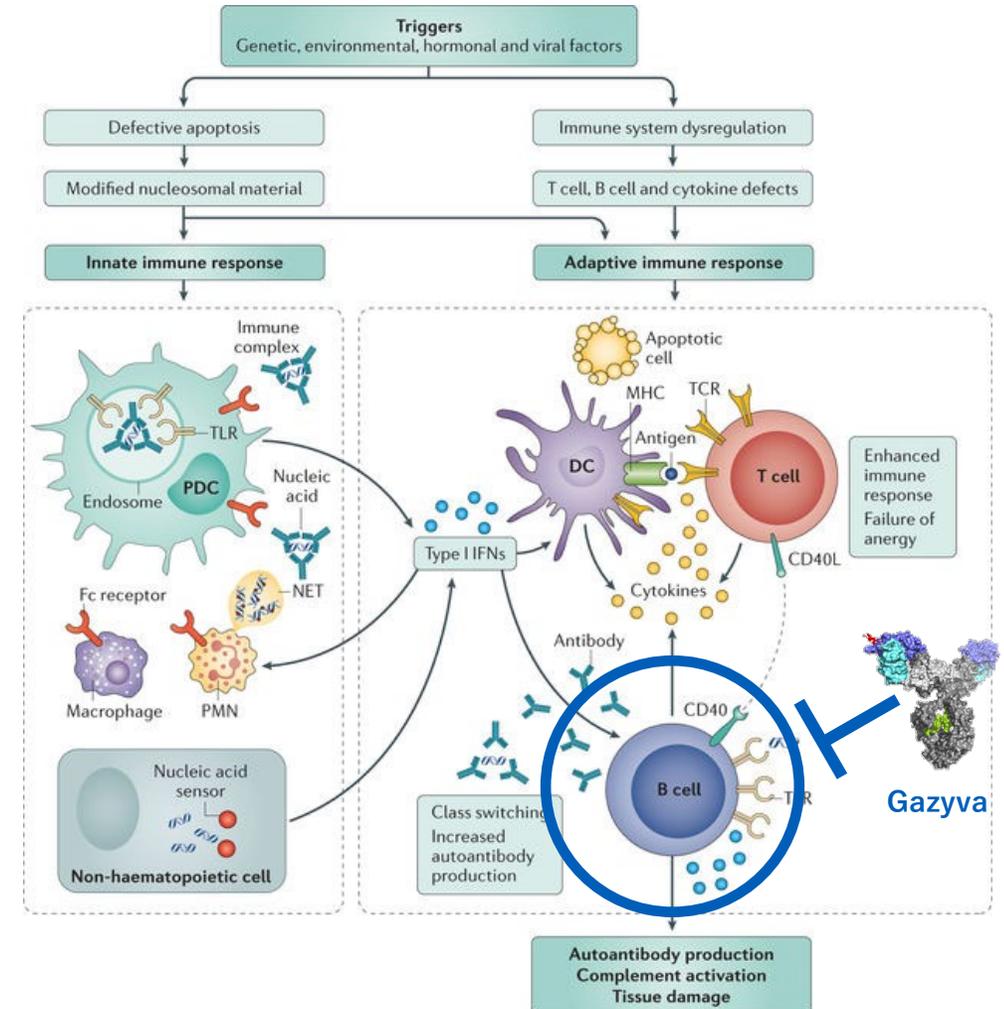
Enrolment: approximately 144 participants  
Purpose: evaluate efficacy of GYM329 in combination with Evrysdi ※  
Time frame: double-blind for 72 weeks  
Treatment: GYM329+Evrysdi or Placebo+Evrysdi  
※Primary endpoint is change from baseline in RHS\*<sup>2</sup> total score

\*<sup>1</sup> administration of GYM329: Q4W, SC \*<sup>2</sup> RHS: Revised Hammersmith Scale (Scale for evaluation of motor function in children with SMA)

# Gazyva (Obinutuzumab) for Lupus Nephritis

Gazyva provides enhanced B cell depletion which could bring benefit to LN patients, local Phase 3 initiated

- **Lupus Nephritis (LN):** An autoimmune disease, frequent complication in people who have systemic lupus erythematosus which leads to impaired kidney function or kidney failure caused by activation of self-reactive T cells and B cells and tissue deposition of immune complexes formed by autoantibodies produced by B cells
- **Humanized anti-CD20 monoclonal antibody** that binds to the CD20 antigen, engineered to induce greater ADCC and direct cell death\*<sup>1</sup>
- **Positive results of Phase 2 study in Lupus nephritis confirmed** \*<sup>2</sup>

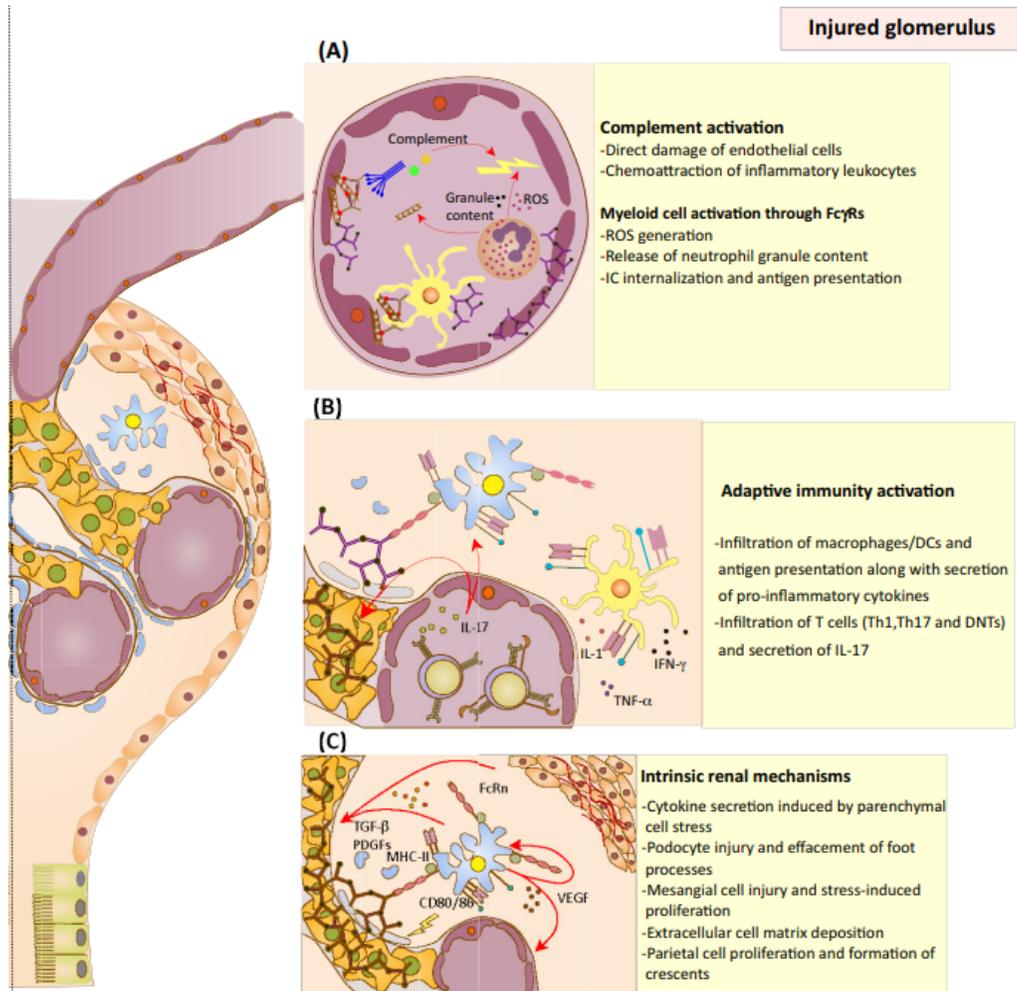


\*<sup>1</sup> launched for CD20-positive follicular lymphoma in August 2018 in Japan

\*<sup>2</sup> Ann Rheum Dis 2022;81:100-107

# Crovalimab for Lupus Nephritis (LN)

Inhibiting terminal complement pathway could prevent cell damage in glomerulus and inflammation: P1 study to be initiated



■ Recycling antibody created by Chugai, targeting complement C5 and inhibits cleavage of C5 into C5a and C5b

■ Expected to prevent cell damage in glomerulus and inflammation by inhibiting terminal complement pathway. Phase 1 study of crovalimab in LN is to be initiated

□ Complement activation following immune complex deposition in glomerulus is reported to be associated with pathophysiology of LN

- C5a causes migration of macrophage and neutrophils to glomerulus and subsequent activation
- MAC (Membrane-attack complex) attacks endothelial cells

■ Synergy with Gazyva in renal disease area (lupus nephritis) is expected

# Tiragolumab: Development Status

Exploring the role of new cancer immunotherapy in ongoing multiple global P3 studies in combination with Tecentriq

- 1L SCLC (SKYSCRAPER-02): did not meet its co-primary endpoint of PFS. OS is unlikely to reach statistical significance
- 1L NSCLC (SKYSCRAPER-01): did not meet its co-primary endpoint of PFS. OS will be assessed continuously. A numerical improvement was observed in both primary endpoints
- No new safety signals were identified in both studies in combination therapy with tiragolumab and Tecentriq
- Other global P3 studies for NSCLC (stage III) and esophageal cancer are ongoing

## < Global P3 study participating from Japan >

\* A numerical improvement was observed in both PFS and OS.

Study	Indication	Design	Primary endpoint	Filing
SKYSCRAPER-01 <a href="#">(NCT04294810)</a>	1L NSCLC (PD-L1-high)	Tecentriq ± tiragolumab	PFS*: did not meet OS*: continuous assessment	2023
SKYSCRAPER-02 <a href="#">(NCT04256421)</a>	1L SCLC	Tecentriq + chemo ± tiragolumab	PFS: did not meet OS: unlikely to meet	Development discontinued
SKYSCRAPER-03 <a href="#">(NCT04513925)</a>	NSCLC (stage III)	Tecentriq + tiragolumab vs. durvalumab	PFS	2024
SKYSCRAPER-07 <a href="#">(NCT04543617)</a>	esophageal cancer	Tecentriq ± tiragolumab vs. placebo	PFS/OS	2024

# 2022: Key R&D Milestones



	Product	Indication/Study name	Progress
Projects to be approved	<b>Actemra</b>	COVID-19 pneumonia (Japan)	✓
	<b>Mitchga</b>	Atopic dermatitis (Japan)	✓
	<b>Hemlibra</b>	<u>Acquired hemophilia A (Japan)</u>	✓
	<b>Herceptin/Perjeta</b>	HER2 positive colorectal cancer	✓
	<b>Vabysmo</b>	Neovascular age-related macular degeneration (nAMD)	✓
	<b>Vabysmo</b>	Diabetic macular edema (DME)	✓
	<b>Tecentriq</b>	<u>Non-small cell lung cancer (NSCLC) [adjuvant]</u>	✓
P3/Pivotal readouts	<b>Polivy</b>	Previously untreated diffuse large B-cell lymphoma (DLBCL)	
	<b>Alecensa</b>	ALINA Study: NSCLC [adjuvant]	2023
	<b>crovalimab</b>	<u>COMMODORE 3 study (China): PNH</u>	✓
	<b>nemolizumab</b>	<u>OLYMPIA 2 study: Prurigo nodularis</u>	✓
	<b>gantenerumab</b>	GRADUATE 1/2 study: Alzheimer's disease	
	<b>Tecentriq</b>	IMpower030 study: NSCLC [neoadjuvant]	
	<b>Tecentriq</b>	<u>IMmotion010 study: RCC [adjuvant]</u>	✗
	<b>Tecentriq</b>	<u>IMvoke010 study: HNC [adjuvant]</u>	Continuous assessment
	<b>Tecentriq + Avastin</b>	IMbrave050 study: HCC [adjuvant]	
<b>Tecentriq + tiragolumab</b>	<u>SKYSCRAPER-01 study: NSCLC [1st line]</u>	Continuous assessment	
<b>Tecentriq + tiragolumab</b>	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 April 25, 2022

PNH: Paroxysmal nocturnal hemoglobinuria; RCC: renal cell carcinoma; HNC: head and neck carcinoma; HCC: hepatocellular carcinoma; NSCLC: non-small cell lung cancer; SCLC: small cell lung cancer

# Projected Submissions (Post PoC NMEs and Products)

NME Line extension



in-house  
in-licensed (Roche)

**Filed**

GAZYVA (RG7159) CLL
POLIVY (RG7596) 1L DLBCL
ACTEMRA (MRA/RG1569) COVID-19 pneumonia (US)
HEMLIBRA (ACE910/RG6013) mild-moderate hemophilia A (EU)
RG6264 (FDC, sc) Breast Cancer

TECENTRIQ (RG7446) NSCLC (neoadjuvant)	VABYSMO (RG7716) RVO
gantenerumab (RG1450) Alzheimer's Disease	AVASTIN (RG435) 1L SCLC + TECENTRIQ
tiragolumab (RG6058) 1L NSCLC + TECENTRIQ	TECENTRIQ (RG7446) HNC (adjuvant) ★
ipatasertib (RG7440) 1L Prostate Cancer	TECENTRIQ+AVASTIN (RG7446 + RG435) HCC (adjuvant)
ALECENSA (AF802/RG7853) NSCLC (adjuvant)	TECENTRIQ (RG7446) 2L RCC + cabozantinib
crovalimab (SKY59/RG6107) PNH (China: to be filed in 2022)	TECENTRIQ (RG7446) 1L Urothelial Carcinoma
	TECENTRIQ (RG7446) 2L NSCLC + cabozantinib

aHUS: atypical hemolytic uremic syndrome  
BC: Breast cancer  
eBC: early Breast cancer  
CLL: chronic lymphocytic leukemia  
DLBCL: diffuse large B-cell lymphoma  
DMD: duchenne muscular dystrophy  
FDC: fixed-dose combination  
gMG: generalized myasthenia gravis  
HCC: hepatocellular carcinoma  
HNC: head and neck carcinoma  
MIBC: muscle-invasive bladder cancer

nAMD: neovascular age-related macular degeneration  
NSCLC: non-small cell lung cancer  
PDS: Port Delivery System with ranibizumab  
PNH: paroxysmal nocturnal hemoglobinuria  
RCC: renal cell carcinoma  
RVO: retinal vein occlusion  
SCD: Sickle cell disease  
SCLC: small cell lung cancer

mosunetuzumab (RG7828) 3L Follicular lymphoma	pralsetinib (RG6396) ★ 1L NSCLC	as of July 21, 2022
tiragolumab + TECENTRIQ (RG6058 + RG7446) Esophageal Cancer	TECENTRIQ (RG7446) MIBC (adjuvant)	mosunetuzumab (RG7828) 2L Follicular lymphoma
tiragolumab + TECENTRIQ (RG6058 + RG7446) NSCLC (Stage III)	ranibizumab(PDS) (RG6321) nAMD/DME	GAZYVA (RG7159) ★ lupus nephritis
ENSPRYNG (SA237/RG6168) gMG	SRP-9001 (RG6356) DMD	giredestrant (RG6171) 1L BC
crovalimab (SKY59/RG6107) aHUS	pralsetinib (RG6396) ★ 2L NSCLC	giredestrant (RG6171) BC (adjuvant)
		crovalimab (SKY59/RG6107) SCD (US/EU)
		GYM329/RG6237 ★ + Efrisdi SMA
		TECENTRIQ (RG7446) eBC (neoadjuvant)
		TECENTRIQ (RG7446) eBC (adjuvant)

2022

2023

2024

2025 and beyond

★ : new entry   ★ : changes in submission year

# Projects under Development (1/2)



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

As of July 21, 2022

	Phase I	Phase II	Phase III	Filed	
Cancer	<b>LUNA18</b> - solid tumors	<b>RG7421 / cobimetinib</b> - solid tumors	<b>RG6396 / pralsetinib</b> - NSCLC (2L) ★	<b>RG7440 / ipatasertib</b> - prostate cancer (1L)	<b>RG7596 / Polivy</b> - DLBCL
	<b>GC33 / codrituzumab</b> - HCC	<b>RG7802 / cibisatamab</b> - solid tumors		<b>RG7446 / Tecentriq</b> - NSCLC (neoadjuvant) - NSCLC (2L) - urothelial carcinoma (1L) - MIBC (adjuvant) - RCC (adjuvant) - RCC (2L) - early BC (adjuvant) - early BC (neoadjuvant) - HCC (2L) - HNC (adjuvant) - prostate cancer (2L)	<b>RG6264 (Herceptin+Perjeta)</b> - breast cancer (Fixed-dose combination, subcutaneous injection)
	<b>ERY974</b> - solid tumors	<b>RG6026 / glofitamab</b> - hematologic tumors			<b>RG6058 / tiragolumab + RG7446 / Tecentriq</b> - NSCLC (1L) - NSCLC(stage III) - esophageal cancer
	<b>STA551</b> - solid tumors	<b>RG6194 / HER2-TDB</b> - solid tumors			
	<b>SOF10 (RG6440)</b> - solid tumors				
	<b>SPYK04</b> - solid tumors				
	<b>RG7828 / mosunetuzumab</b> - follicular lymphoma (3L)			<b>RG7446 / Tecentriq + RG435 / Avastin</b> - SCLC (adjuvant) - HCC (adjuvant) - HCC (intermediate stage)	<b>RG6171 / giredestrant</b> - BC (1L) - BC (adjuvant)
				<b>RG7828 / mosunetuzumab</b> - follicular lymphoma (2L)	
				<b>RG6396 / pralsetinib</b> - NSCLC (1L)	

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

★: Projects with advances in stages since April 25, 2022

BC: breast cancer

CLL: chronic lymphocytic leukemia

DLBCL: diffuse large B-cell lymphoma

HCC: hepatocellular carcinoma

HNC: head and neck carcinoma

MIBC: muscle-invasive bladder cancer

NSCLC: non-small cell lung cancer

RCC: renal cell carcinoma

SCLC: small cell lung cancer

TDB: T cell-dependent bispecific

# Projects under Development (2/2)



As of July 21, 2022

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

	Phase I	Phase II	Phase III	Filed
<b>Immunology</b>			<b>RG7159 / Gazyva</b> - lupus nephritis ★	<b>MRA (RG1569) / Actemra (US)</b> - COVID-19 pneumonia
<b>Neurology</b>	<b>GYM329 (RG6237)</b> - neuromuscular disease <b>RG7935 / prasinezumab</b> - Parkinson's disease <b>RG6100 / semorinemab</b> - Alzheimer's disease <b>RG6102 (BS-Gante)</b> - Alzheimer's disease	<b>GYM329 (RG6237)</b> + <b>RG7916/ Evrysdi</b> - SMA ★ <b>RG7906 / ralmitaront</b> - schizophrenia	<b>SA237 (RG6168) / Enspryng</b> - generalized myasthenia gravis (gMG)  <b>RG1450 / gantenerumab</b> - Alzheimer's disease  <b>RG6042 / tominersen</b> - Huntington's disease	<b>SRP-9001 (RG6356) / delandistrogene moxeparvovec</b> -DMD *
<b>Hematology</b>	<b>NXT007</b> - hemophilia A (PI/II)	<b>SKY59 (RG6107) / crovalimab</b> - sickle cell disease (SCD)	<b>SKY59 (RG6107) / crovalimab</b> - PNH - Atypical hemolytic uremic syndrome (aHUS)	<b>ACE910 (RG6013) / Hemlibra (EU)</b> - mild/moderate hemophilia A
<b>Ophthalmology</b>	<b>RG6321 / PDS</b> - DME - nAMD		<b>RG7716 / Vabysmo</b> - retinal vein occlusion	
<b>Other</b>	<b>AMY109</b> - endometriosis			

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

★: Projects with advances in stages since April 25, 2022

\* Sarepta manages the global study, including Japan

DMD: Duchenne muscular dystrophy

DME: diabetic macular edema

gMG: generalized myasthenia gravis

nAMD: neovascular age-related macular degeneration

PDS: Port Delivery System with ranibizumab

PNH: paroxysmal nocturnal hemoglobinuria

# Advances in Chugai Originated Projects Licensed Out to the 3<sup>rd</sup> Party

★: changes since April 25, 2022

As of July 21, 2022

Development code	Mode of Action	Licensee	Granted rights to licensee	Indication	Stage	Progress
<b>CKI27</b> (VS-6766)	RAF/MEK inhibitor	Verastem Oncology	exclusive global license for the manufacturing, development and marketing	Ovarian cancer	global: P2	<ul style="list-style-type: none"> <li>US FDA BTB (recurrent LGSOC in combination with defactinib)</li> </ul>
				NSCLC	global: P2	—
					global: P1/2	<ul style="list-style-type: none"> <li>RAMP 203 trial (in combination with KRAS G12C inhibitor sotorasib) initiated</li> <li>RAMP 204 trial (in combination with KRAS G12C inhibitor, adagrasib) to be initiated</li> </ul>
<b>CIM331/</b> <b>nemolizumab</b>	Anti-IL-31 receptor A humanized monoclonal antibody	Global (Galderma) Japan (Maruho)	Galderma exclusive global license for the development and marketing excluding Japan and Taiwan  Maruho rights for development and marketing in the skin disease area for the Japanese market	Atopic dermatitis	global: P3	—
				Prurigo nodularis	Japan: approved	Granted regulatory approval for itch associated with atopic dermatitis
					global: P3	<ul style="list-style-type: none"> <li>US FDA BTB</li> <li>Primary endpoint was met in the one of two P3 studies ★</li> </ul>
					Japan: P2/3	—
CKDaP	global: P2/3	—				
<b>OWL833</b> (LY3502970)	Oral non-peptidic GLP-1 receptor agonist	Eli Lilly and Company	worldwide development and commercialization rights	Type 2 diabetes	global: P2	<ul style="list-style-type: none"> <li>Conduct a 12-week proof of concept study in type 2 diabetes (P1b)</li> <li>✓ Highest dose group of OWL833 shows 4.71 kg weight loss and 1.77% lowering of HbA1c</li> </ul>
				Obesity	global: P2	<ul style="list-style-type: none"> <li>PK data in healthy volunteers were presented in June 2022 ★</li> </ul>

CKDaP: CKD associated pruritus

LGSOC: low-grade serous ovarian

# FoundationOne CDx Cancer Genomic Profile -Companion diagnostic indications-

As of July 21, 2022

Alterations	Cancer type	Relevant drugs
Activated <i>EGFR</i> gene alterations	Non-small cell lung cancer (NSCLC)	afatinib dimaleate, erlotinib hydrochloride, gefitinib, osimertinib mesylate, <u>dacomitinib hydrate</u>
<i>EGFR</i> exon 20 T790M alterations		osimertinib mesylate
<i>ALK</i> fusion genes		alectinib hydrochloride, crizotinib, ceritinib, <u>brigatinib</u>
<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, <u>encorafenib</u> , <u>binimetinib</u>
<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)
Tumor Mutational Burden-High		pembrolizumab (genetical recombination)
<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

\* Underlined are companion diagnostics approved on 2 June 2022  
 Application withdrawn for *BRAF*V600E alteration-positive NSCLC (dabrafenib, trametinib) based on the result of PMDA review.

# FoundationOne Liquid CDx Cancer Genomic Profile

## Companion diagnostic indications

As of July 21, 2022

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

# Public Clinical Trial Information regarding Chugai Originated Products to be initiated

**NOTE:**

No additional data other than public information are disclosed prior to initiation of trials

Development Code	Indication	Phase	CT information
AF802 / Alecensa	NSCLC (stage III) platform study	P3	<a href="#">NCT05170204</a>
SA237 / Enspryng	MOGAD	P3	<a href="#">NCT05271409</a>
	Autoimmune encephalitis	P3	<a href="#">2021-002395-39</a>
SKY59 / crovalimab	Guillain-Barre Syndrome	P3	<a href="#">2021-002968-49</a>
	Lupus nephritis	P1	<a href="#">ISRCTN12809537</a>
DONQ52	Celiac Disease	P1	<a href="#">NCT05425446</a>

NSCLC: Non-small cell lung cancer; MOGAD: Myelin oligodendrocyte glycoprotein antibody-associated disease

# Contacts



## Corporate Communications Dept.

### For Media: Media Relations Group

**Tel :** +81 (0)3-3273-0881

**E-mail :** [pr@chugai-pharm.co.jp](mailto:pr@chugai-pharm.co.jp)

**Person in charge :** Tomoko Shimizu, Shumpei Yokoyama, Mitsuka Saito, Kaho Izumi, Mari Otsuka

### For Investors: Investor Relations Group

**Tel :** +81 (0)3-3273-0554

**E-mail :** [ir@chugai-pharm.co.jp](mailto:ir@chugai-pharm.co.jp)

**Person in charge :** Takayuki Sakurai, Hideki Sato, Tomoyuki Shimamura, Sachiyo Yoshimura, Yayoi Yamada



 Roche Group

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