Conference on FY2023.12 Q1 Financial Results

CHUGAI PHARMACEUTICAL CO., LTD.

27 April 2023

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

01	FY2023 Q1 Overview	**Dr. Osamu Okuda** President & CEO
02	FY2023 Q1 Consolidated Financial Overview (Core)	**Toshiaki Itagaki** Director, Executive Vice President & CFO
03	Overview of Development Pipeline	**Tetsuya Yamaguchi** Executive Vice President, Head of Project & Lifecycle Management Unit

FY2023 Q1 Overview

Dr. Osamu Okuda

President & CEO

Financial Overview

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

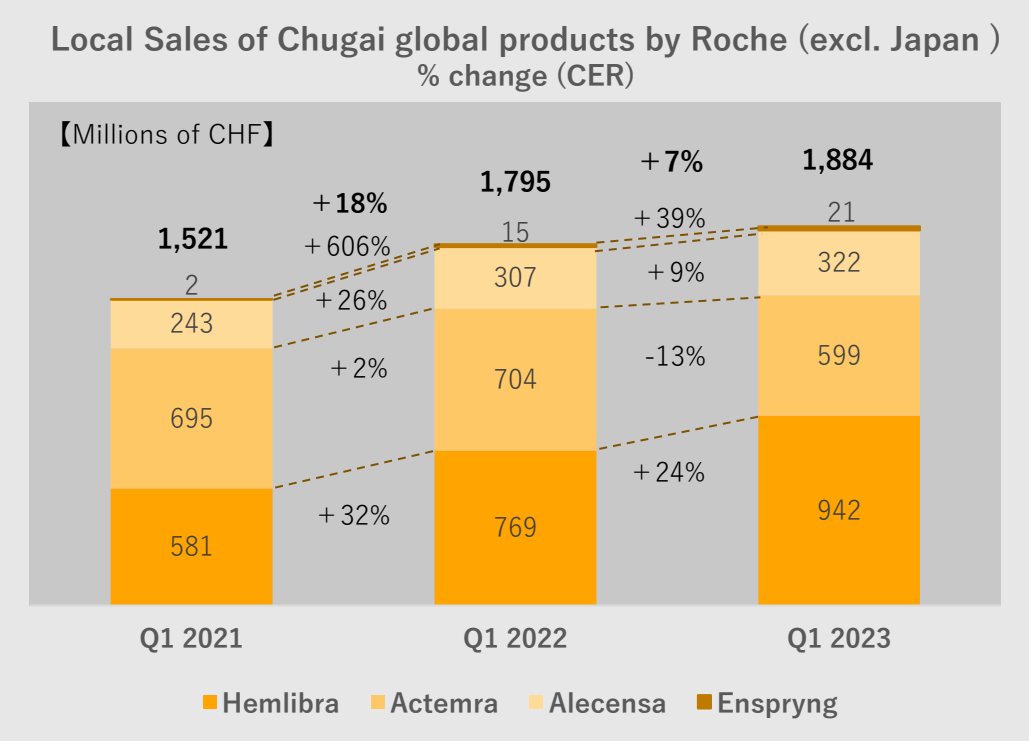
Core (billions of JPY)	2022 Jan -Mar actual*	2023 Jan -Mar actual	Growth		2023 Jan - Dec forecast	Progress (%)
Revenue	**268.4**	**312.2**	**+43.8**	**+16.3%**	**1,070.0**	**29.2%**
Domestic sales	161.7	192.7	+31.0	+19.2%	541.7	35.6%
Overseas sales	81.0	98.8	+17.8	+22.0%	378.3	26.1%
Other revenue	25.7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

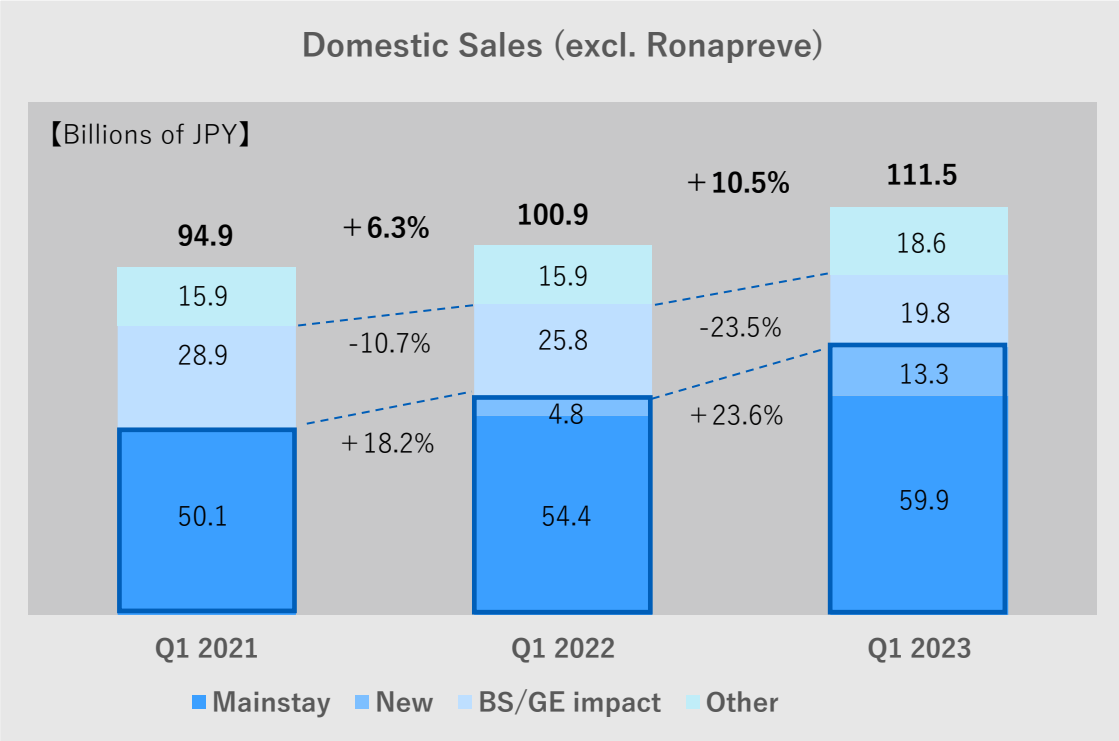
- Domestic sales grew mainly due to the supply of Ronapreve to the government and the good market penetration of new/mainstay products despite the impact of NHI drug price revision and generics. Domestic sales excl. Ronapreve maintained steady growth at 111.5 billion yen (+ 10.5%)
- Overseas sales increased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

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

Progress of Q1 Sales of Chugai Global Products and Domestic Sales

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





Hemlibra: Patient Share in Hemophilia A in Japan

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

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

Updates of In-house Developed Late-stage Products

Crovalimab and nemolizumab sequentially achieved primary endpoints in the pivotal studies

Product	Expected indication	Pivotal Study	Medical conference	Expected file/launch year
crovalimab Initiated by Roche	PNH	COMMODORE2 met primary endpoints and the other P3 study COMMODORE1 supported the favorable benefit-risk profile in February 2023	To be presented at EHA 2023 (June 8-11)	To be filed in H1 2023 (JP/US/EU) * In China, filed in 2022
nemolizumab [overseas] Initiated by Galderma	Atopic dermatitis	Two P3 studies (ARCADIA1/2) met all co-primary endpoints and key secondary endpoints in Q1 2023	To be presented in H2 2023	To be launched in H2 2024 (US)
	Prurigo nodularis	OLYMPIA2 met all primary endpoints and all key secondary endpoints. The other P3 study OLYMPIA1 is on track.	Results of OLYMPIA 2 were presented as a late-breaking presentation at AAD in March 2023	To be launched in H2 2024 (US)
orforglipron (OWL833) Initiated by Eli Lilly and Company	Type 2 diabetes	P3 study scheduled to start in H1 2023	–	–
	Obesity	P3 study scheduled to start in H1 2023	–	–

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

Research Facilities for Drug Discovery and Pharmaceutical Technology

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

Drug Discovery Research		Pharmaceutical Technology Research
 Chugai Life Science Park Yokohama	 Chugai Pharmabody Research (Singapore)	 Ukima Research Laboratories

■ **Progress toward relocation of the research laboratories**

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

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

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

Executive Directors

Dr. Osamu Okuda
Representative Director,
President & CEO

Dr. Hisafumi Yamada
Executive Vice President

Toshiaki Itagaki
Executive Vice
President & CFO

Non-Executive Directors

Dr. Christoph Franz

Teresa A. Graham
(CEO Roche Pharmaceuticals)

Dr. James H. Sabry
(Global Head of
Roche Pharma Partnering)

Independent Outside Directors

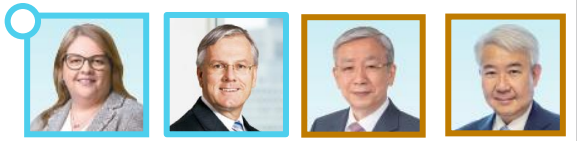
Dr. Mariko Y. Momoi

Dr. Fumio Tateishi

Hideo Teramoto

Appointment Committee

Compensation Committee



Special Committee

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*Outside Audit & Supervisory Board Member: Kenichi Masuda

○○: Chair

Early Retirement Incentive Program

Background

- Increased difficulty in developing new drugs, promotion of measures to curb medical/pharmaceutical expenses in Japan and overseas, expansion of market penetration of generic drugs and biosimilars and other factors, further accelerated the severe business environment
- Change in business activities associated with the advancement of digital technology

Purpose

- Swift response to the drastically changing business environment and our management issues, and implement structural reform toward strategic resource allocation
- Support for employees who retire early and seek new opportunities due to diversified views on work and lifestyles

Outline

➢ Eligible employees	Employees aged 40 or over [Detailed criteria are specified separately]
➢ Application period	From April 3 to April 21, 2023
➢ Retirement date	June 30, 2023
➢ Number of applicants	374 employees
➢ Incentives	(i) Special additional allowance on top of regular retirement allowance (ii) Reemployment support services
➢ Impact on financial performance	Special additional allowance and other expenses related to this program of approximately JPY 10.4 billion will be reported as Non-Core item *Negligible impact on the forecast for FY2023 consolidated core results

FY2023 Q1 Consolidated Financial Overview(Core)

Toshiaki Itagaki

Director, Executive Vice President & CFO

P/L Jan – Mar (Non-core adjustment)

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

Non-core items (Billions of JPY)

Intangible assets

Amortization	+0.5
Impairment	+4.7

Others

Restructuring expenses, etc.	+1.9

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

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

Blue text :renamed categories

0.2 billion JPY

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

0.0 billion JPY

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

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

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

FY2023 Q1 Consolidated Financial Overview (Core)

P/L Jan – Mar (Year on Year)

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

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

Overseas sales
Increase in sales of Alecensa and Actemra

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

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

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

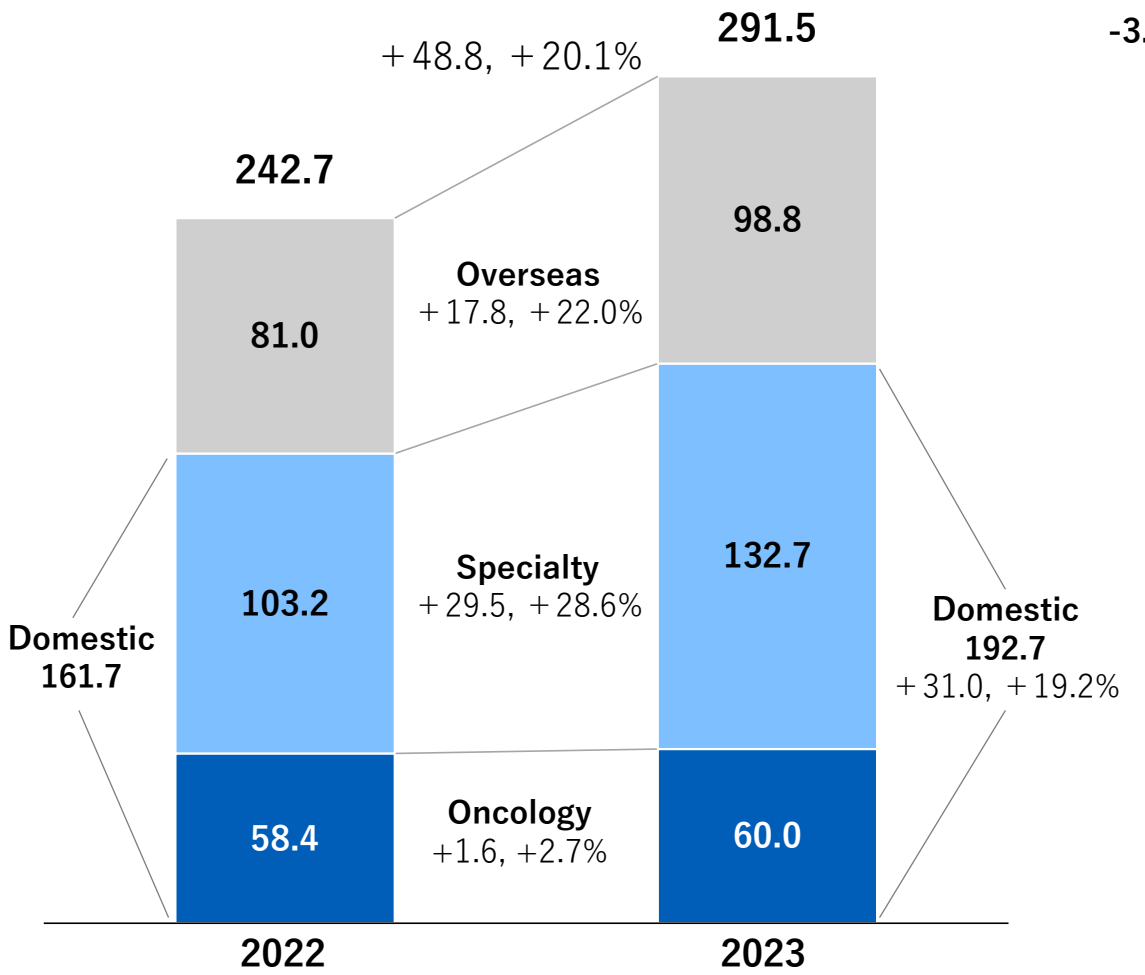
Selling, general and administration
Decrease in various expenses

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

Sales Jan – Mar (Year on Year)

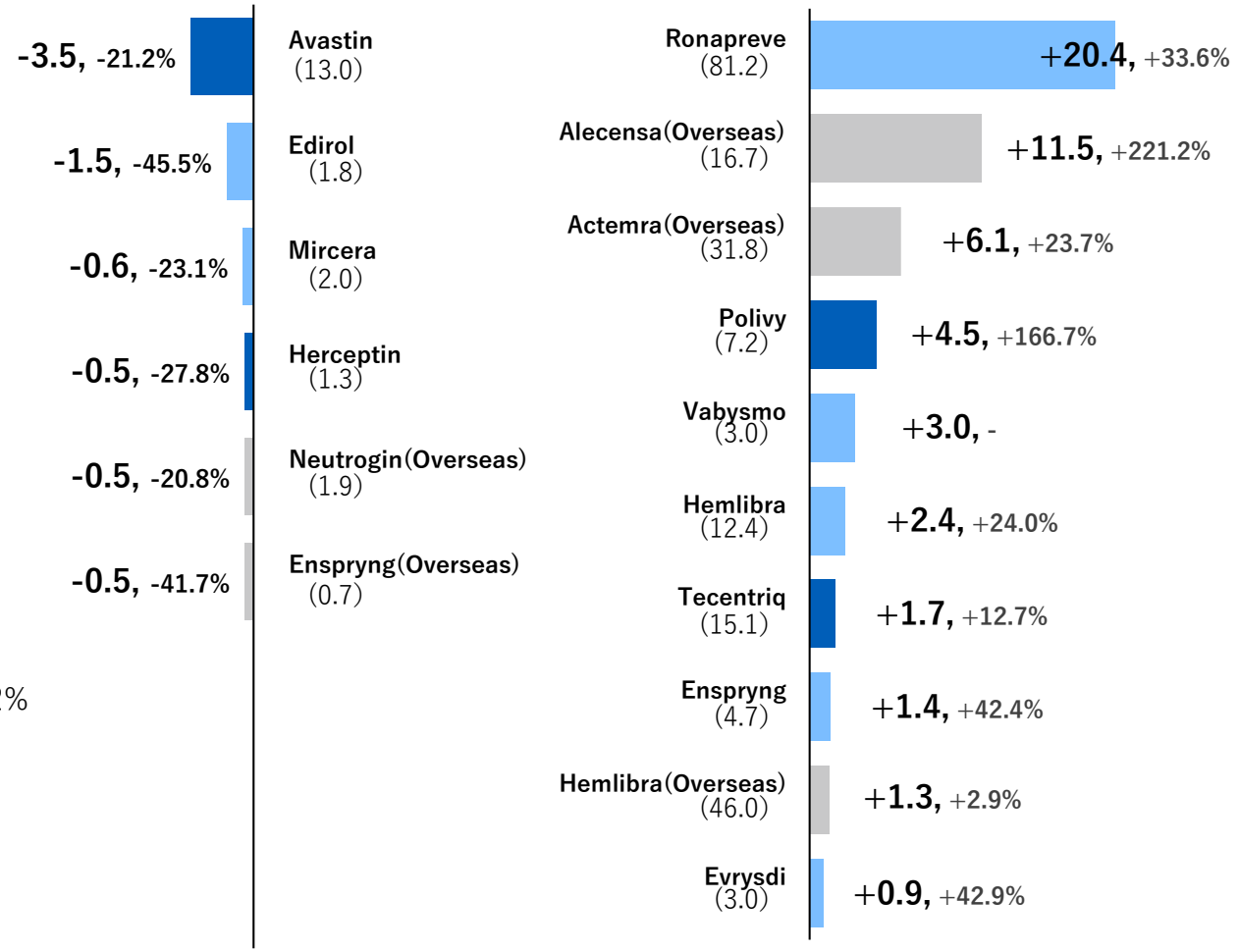
(Billions of JPY)

Sales by Disease Area, Year on Year

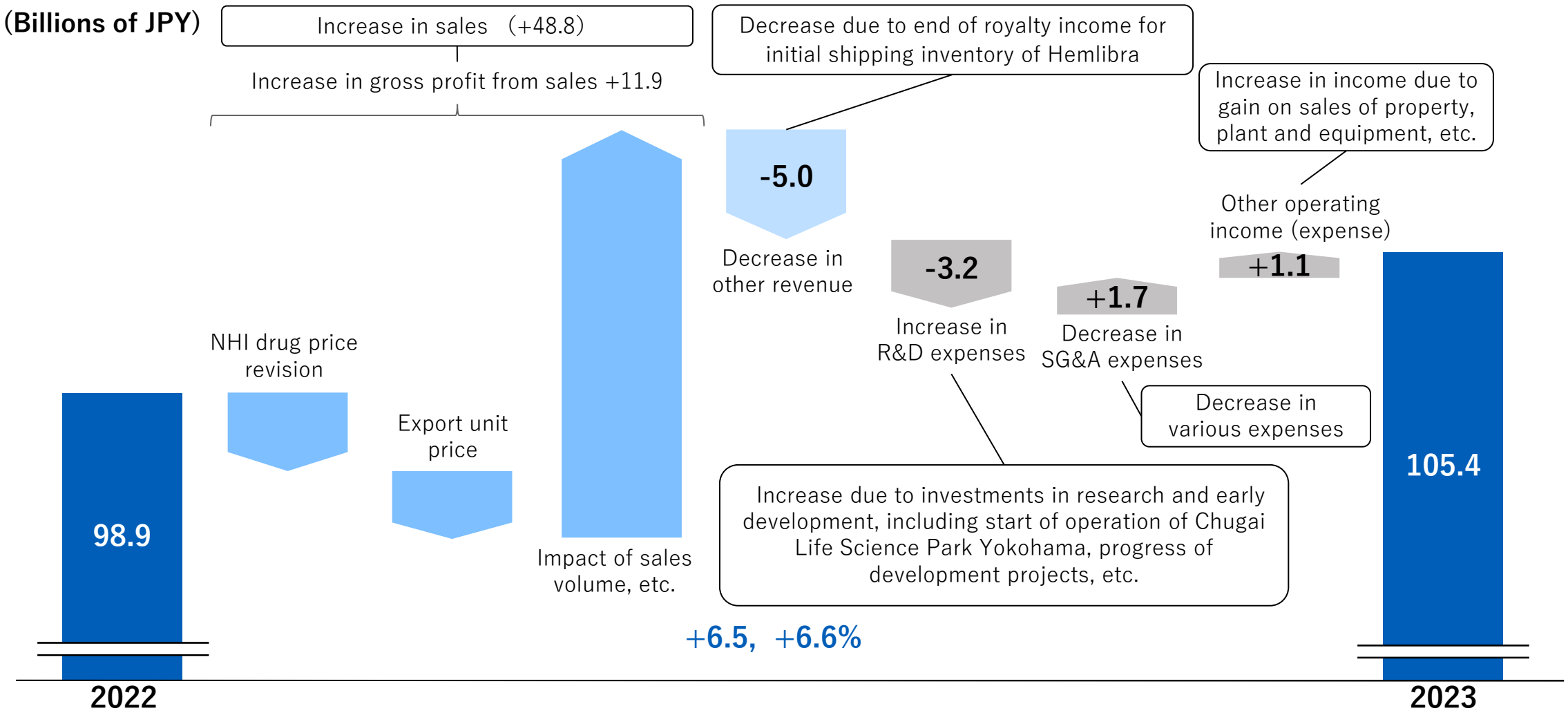


Sales by Product, Year on Year

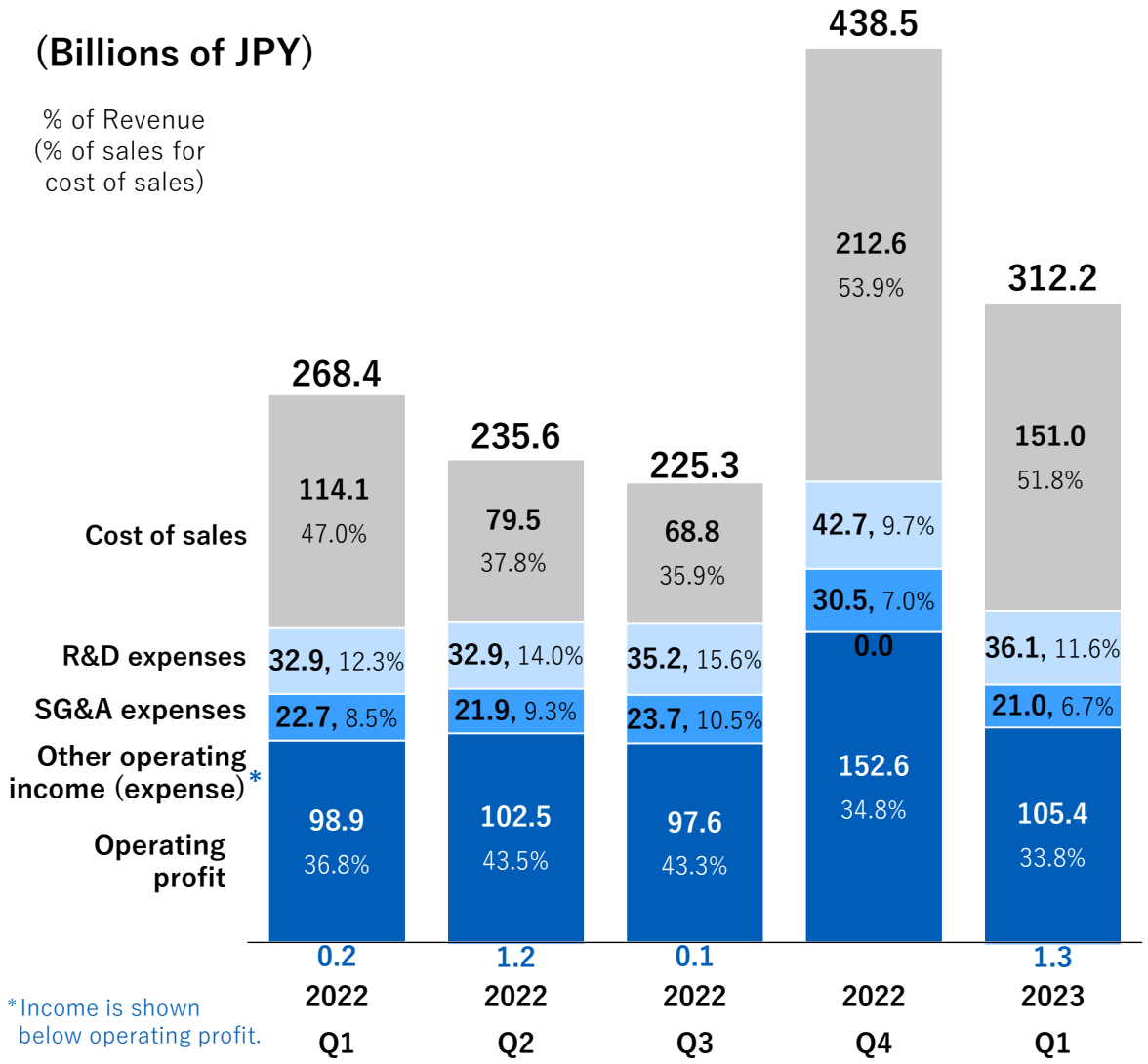
( ): Actual sales in FY2023
%: Year-on-year percentage change



Operating Profit Jan – Mar (Year on Year)



Structure of Costs and Profit by Quarter



Year on Year (2022 Q1)

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

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

SG&A expenses: decrease in various expenses

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

Operating profit: +6.5 billion JPY, +6.6%

Quarter on Quarter (2022 Q4)

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

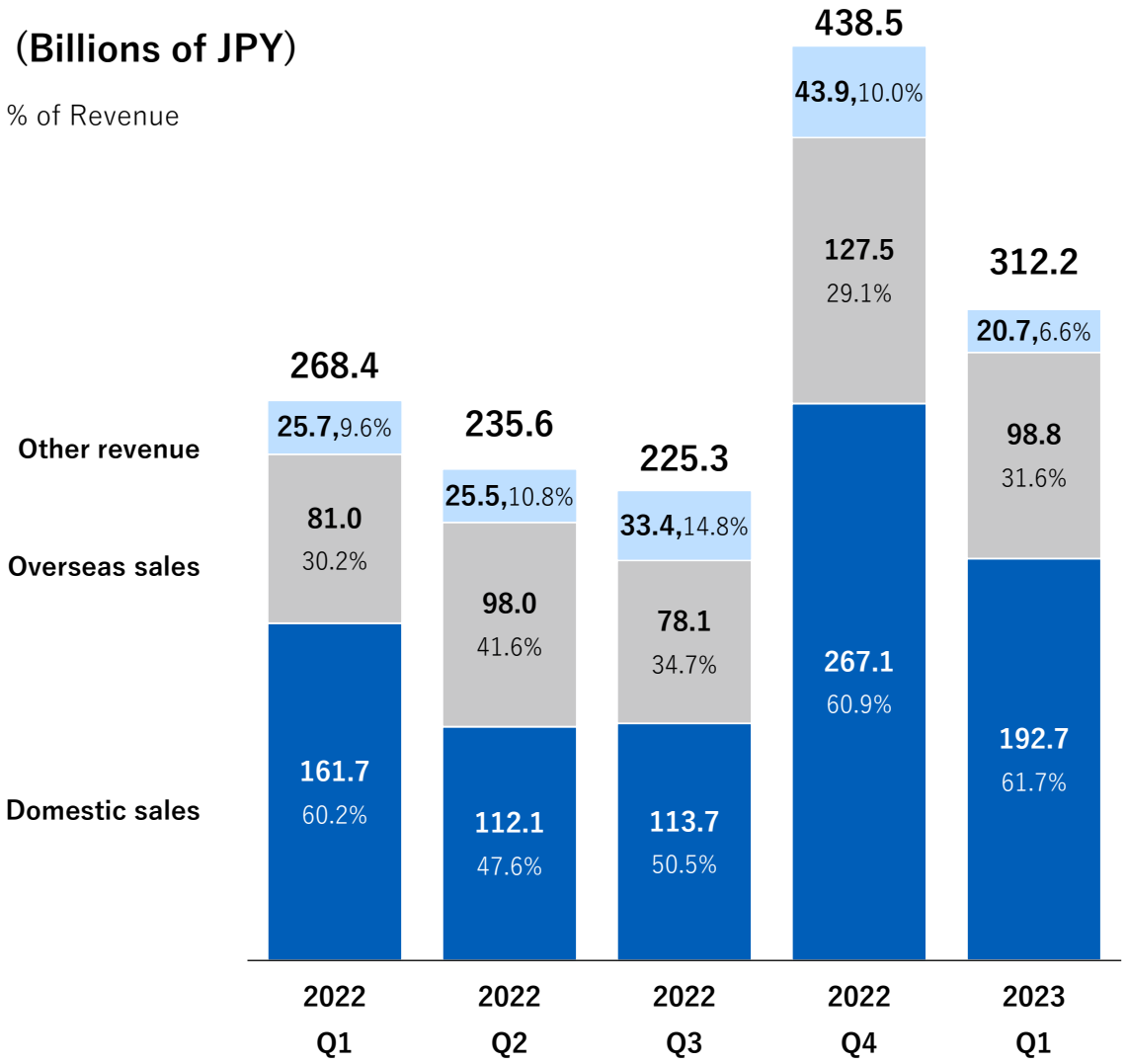
R&D expenses: decrease in line with the trend of previous years

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

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

Operating profit: -47.2 billion JPY, -30.9%

Structure of Revenue by Quarter



Year on Year (2022 Q1)

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

Overseas sales: increase in sales of Alecensa and Actemra

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

Quarter on Quarter (2022 Q4)

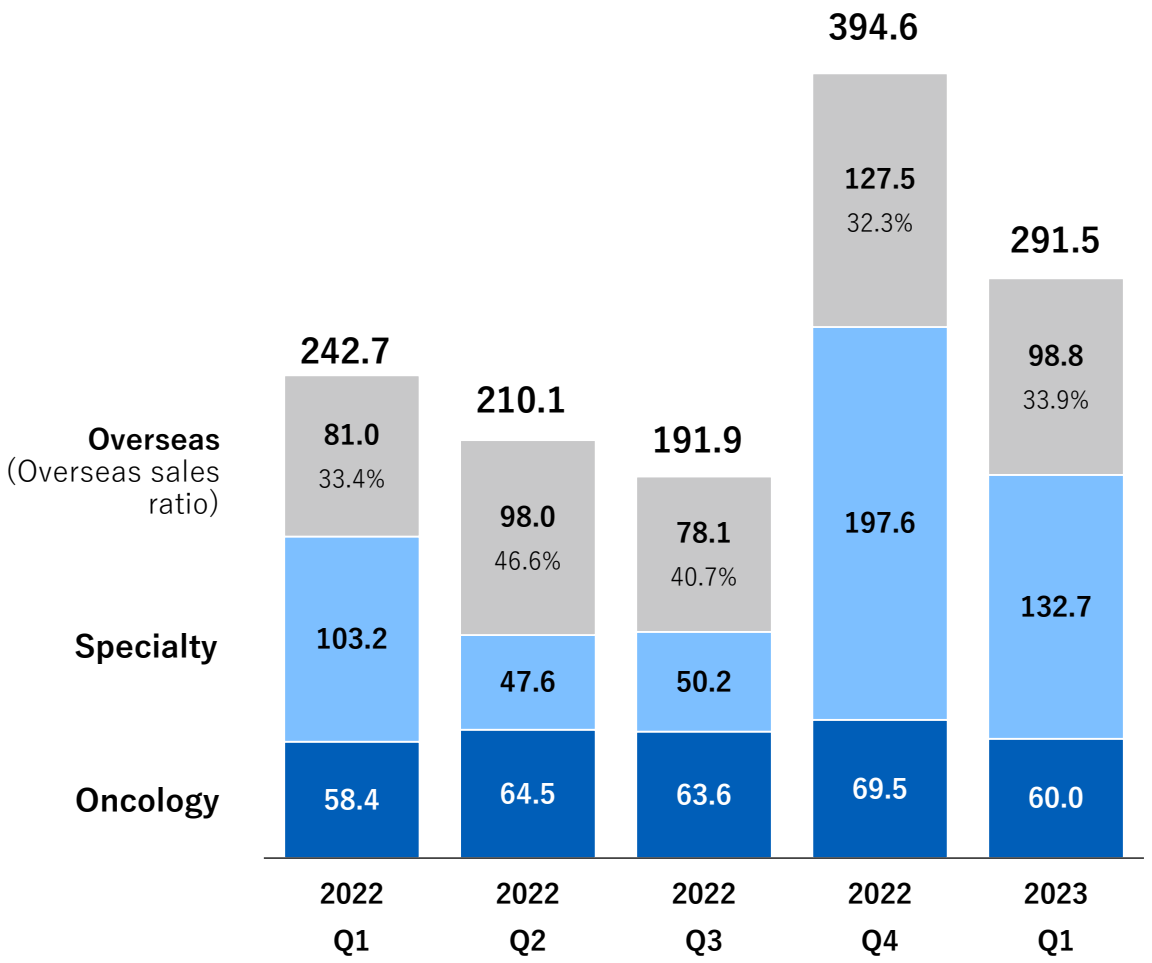
Domestic sales: significant decrease in line with the trend of previous years and sales of Ronapreve

Overseas sales: significant decrease in sales of Actemra and Hemlibra

Other revenue: decrease in income related to Hemlibra and Alecensa

Structure of Sales by Quarter

(Billions of JPY)



Year on Year (2022 Q1)

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

Quarter on Quarter (2022 Q4)

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

P/L Jan – Mar (vs. Forecast)

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

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

Overseas sales
Progress nearly in line with forecast

Other revenue
Progress nearly in line with forecast

Cost of sales
Cost to sales ratio nearly in line with Q1 forecast

Research and development
Progress nearly in line with forecast

Selling, general and administration
Progress nearly in line with forecast

Other operation income (expense)
Progress nearly in line with forecast

* Jan –Mar progress versus Jan – Dec actual

Sales Jan – Mar (vs. Forecast)

(Billions of JPY)	Actual 2023 Jan - Mar	Forecast 2023 Jan - Dec	Forecast Progress	2022 Progress *
Sales	**291.5**	**920.0**	**31.7%**	**23.4%**
Domestic	**192.7**	**541.7**	**35.6%**	**24.7%**
Oncology	**60.0**	**253.3**	**23.7%**	**22.8%**
Tecentriq	15.1	67.7	22.3%	22.0%
Avastin	13.0	48.1	27.0%	24.4%
Polivy	7.2	31.6	22.8%	17.4%
Perjeta	7.5	31.0	24.2%	22.9%
Alecensa	6.6	28.2	23.4%	21.8%
Kadcyla	3.8	14.1	27.0%	22.7%
Herceptin	1.3	4.9	26.5%	25.4%
Gazyva	0.8	4.5	17.8%	25.0%
Rituxan	0.9	3.7	24.3%	22.7%
Foundation Medicine	1.9	8.3	22.9%	22.5%
Other	1.9	11.2	17.0%	25.2%

(Billions of JPY)	Actual 2023 Jan - Mar	Forecast 2023 Jan - Dec	Forecast Progress	2022 Progress *
Specialty	**132.7**	**288.4**	**46.0%**	**25.9%**
Ronapreve	81.2	81.2	100.0%	29.8%
Hemlibra	12.4	53.7	23.1%	20.3%
Actemra	9.9	44.3	22.3%	23.1%
Enspryng	4.7	21.6	21.8%	19.8%
Vabysmo	3.0	17.4	17.2%	0.0%
Evrysdi	3.0	14.1	21.3%	18.3%
Mircera	2.0	7.6	26.3%	24.1%
CellCept	1.6	6.7	23.9%	22.8%
Edirol	1.8	5.2	34.6%	29.5%
Other	13.1	36.7	35.7%	24.6%
Overseas	**98.8**	**378.3**	**26.1%**	**21.1%**
Hemlibra	46.0	185.2	24.8%	23.1%
Actemra	31.8	121.4	26.2%	19.7%
Alecensa	16.7	50.4	33.1%	12.8%
Enspryng	0.7	3.8	18.4%	42.9%
Neutrogin	1.9	7.3	26.0%	27.6%
Edirol	0.0	0.5	0.0%	0.0%
Other	1.8	9.7	18.6%	22.6%

* Jan - Mar progress versus Jan – Dec actual

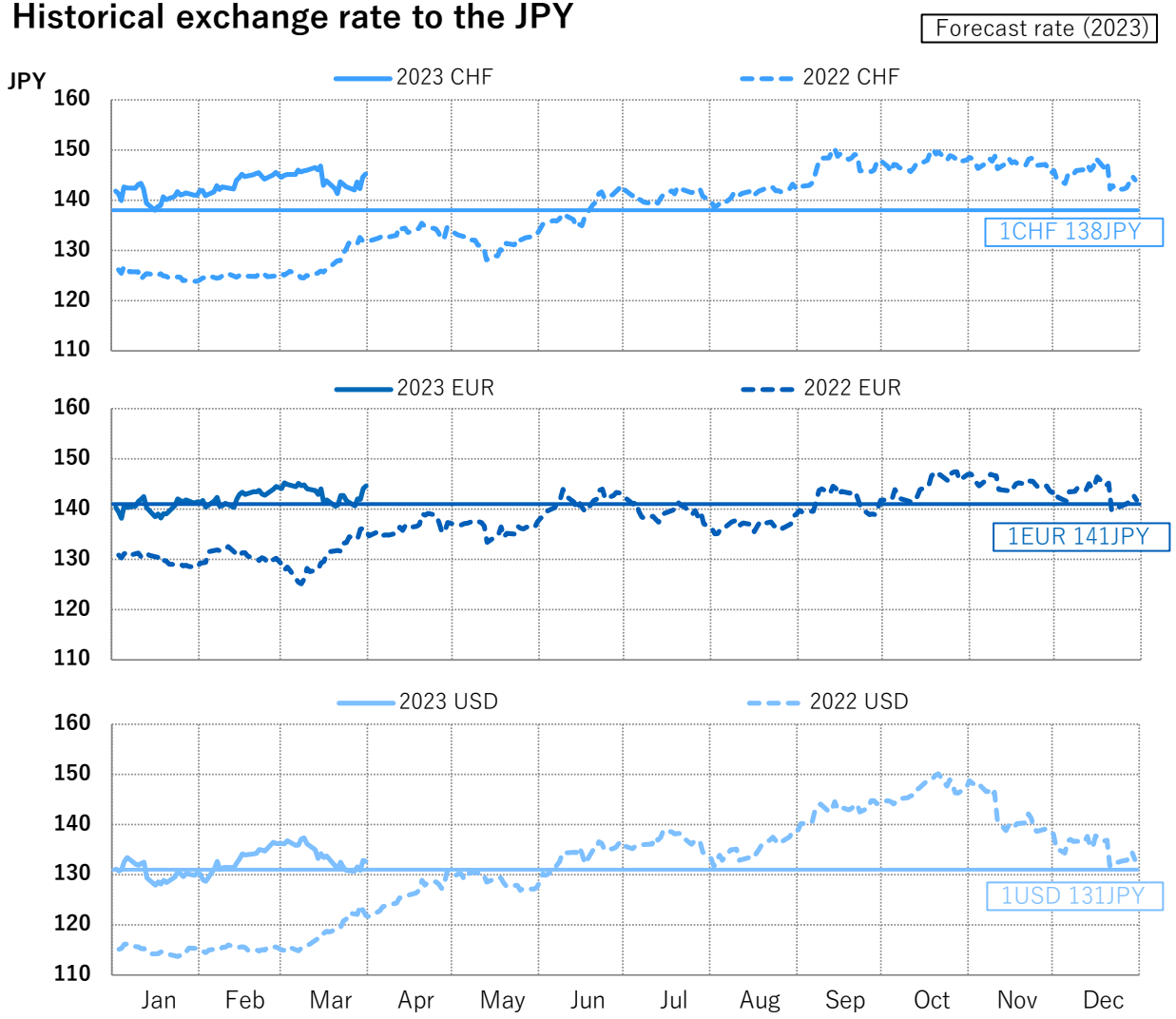
Impact from Foreign Exchange Jan – Mar

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

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

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

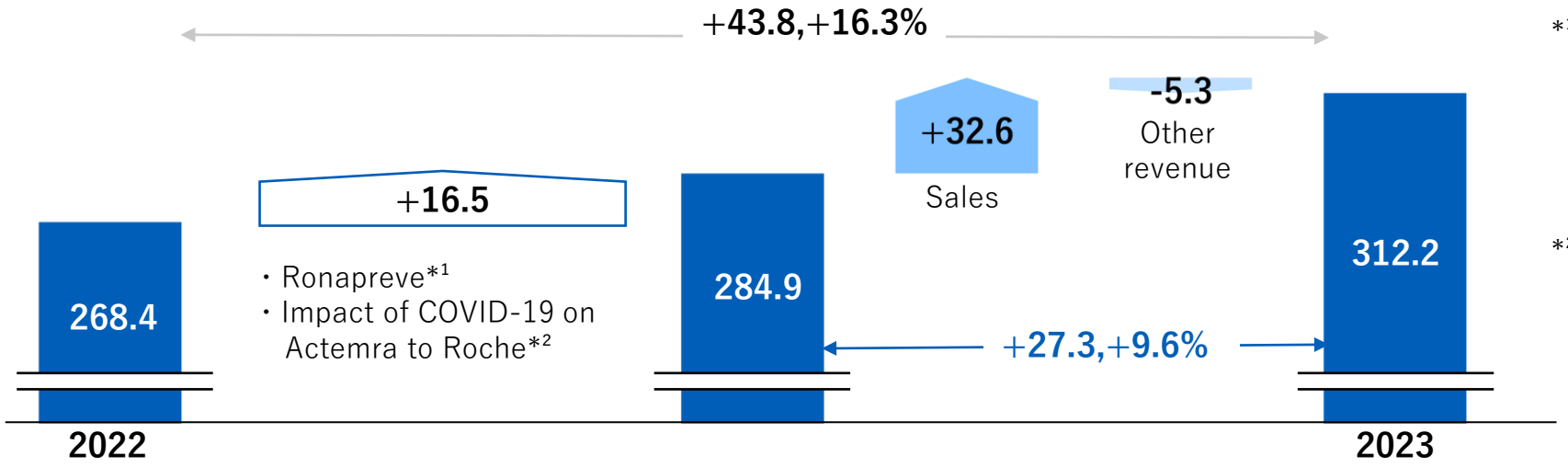
Historical exchange rate to the JPY



P/L Analysis Jan – Mar (Year on Year)

＜Revenue＞

(Billions of JPY)



*1Ronapreve

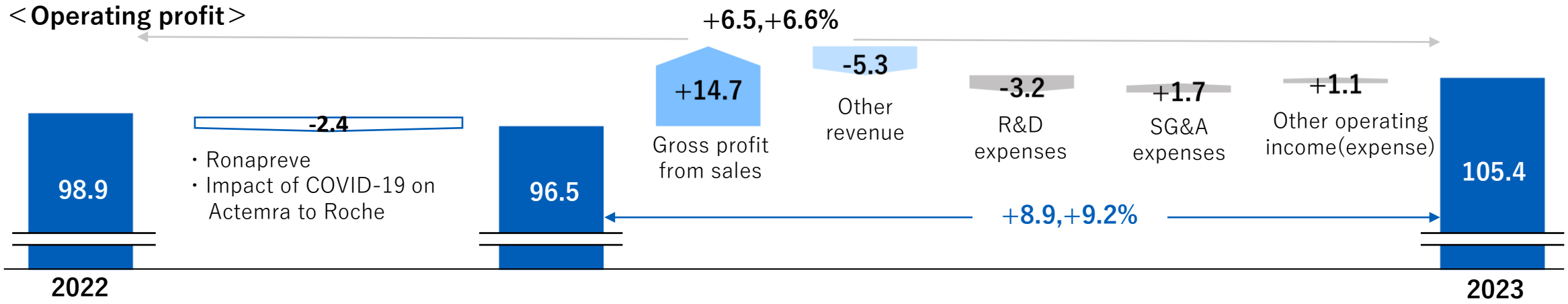
2022 Q1 sales	60.8
2023 Q1 sales	81.2
Year on Year	+20.4

*2Impact of COVID-19 on Actemra to Roche

(Decrease in export of IV products and royalty and profit-sharing income(ROY&PS) considered as impact of COVID-19)

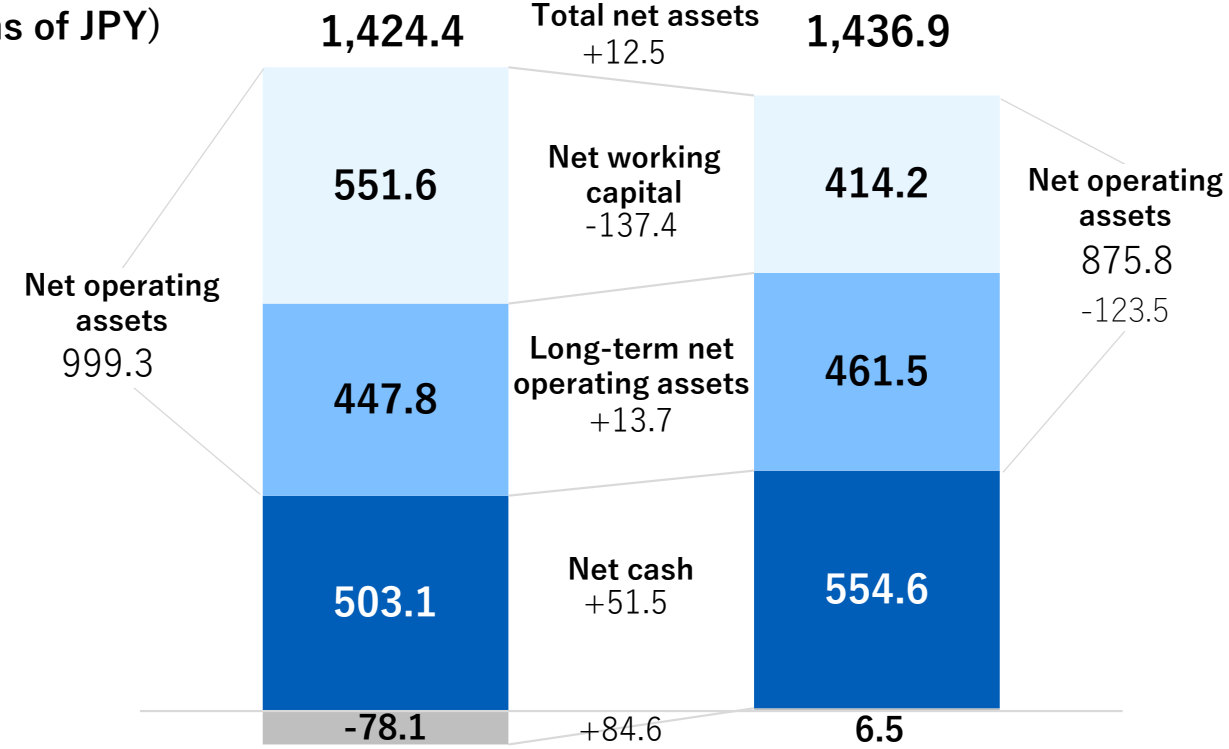
2022 Q1 IV exports・ ROY&PS	12.7
2023 Q1 IV exports・ ROY&PS	8.8
Year on Year	-3.9

＜Operating profit＞



Financial Position (vs. 2022 Year End)

(Billions of JPY)



	2022 Dec	Other non-operating assets - net *1	2023 Mar
Total assets	1,869.8	-97.8	1,772.0
Total liabilities	-445.4	+110.3	-335.1
Total net assets	1,424.4	+12.5	1,436.9
Ratio of equity attributable to Chugai shareholders	76.2%	+4.9%pts	81.1%

Decrease in net working capital

Decrease in trade accounts receivable including Ronapreve

Increase in long-term net operating assets

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

Increase in net cash

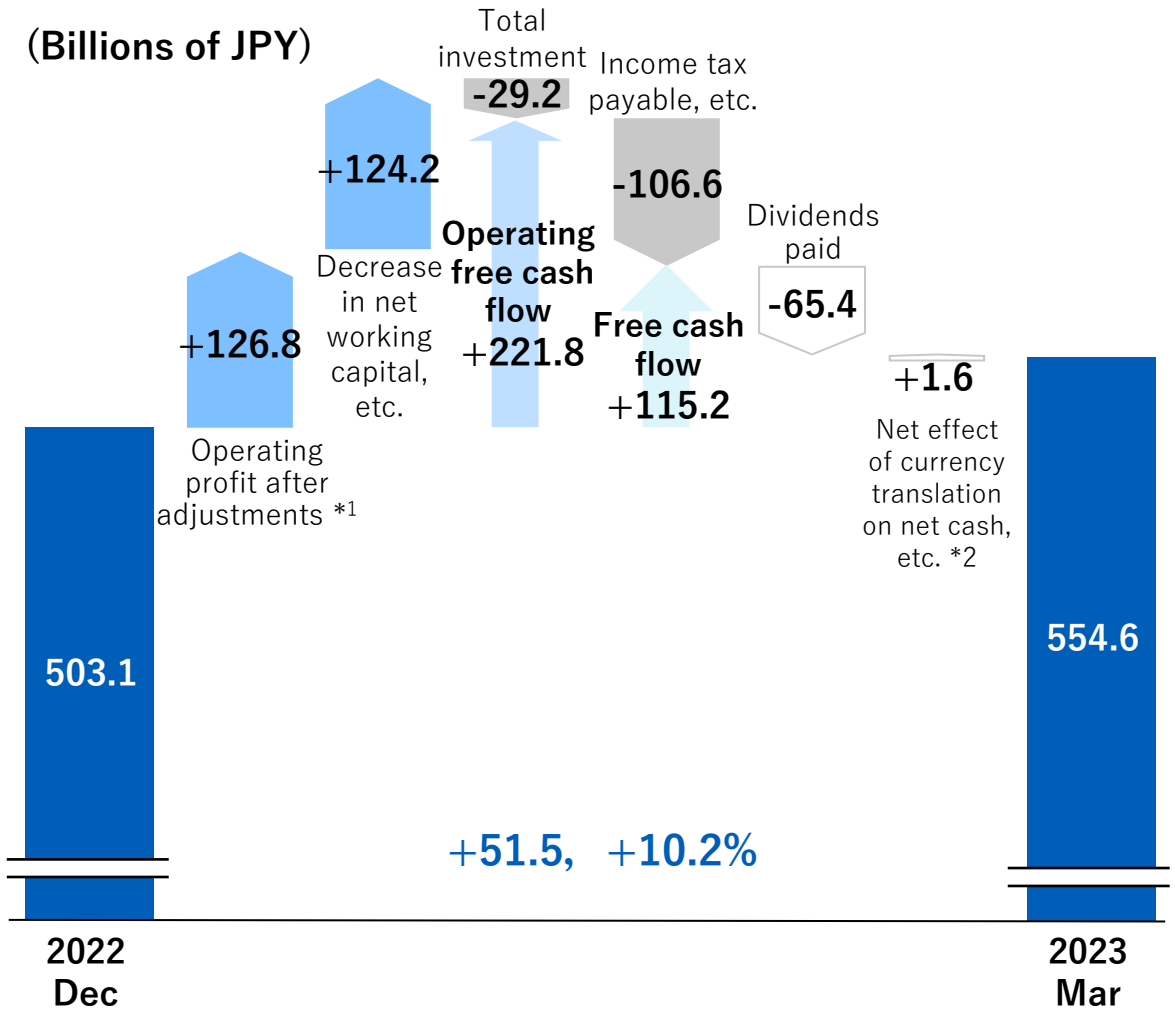
(See next slide)

Increase in other non-operating assets – net

Increase due mainly to a decrease in accrued corporate tax

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

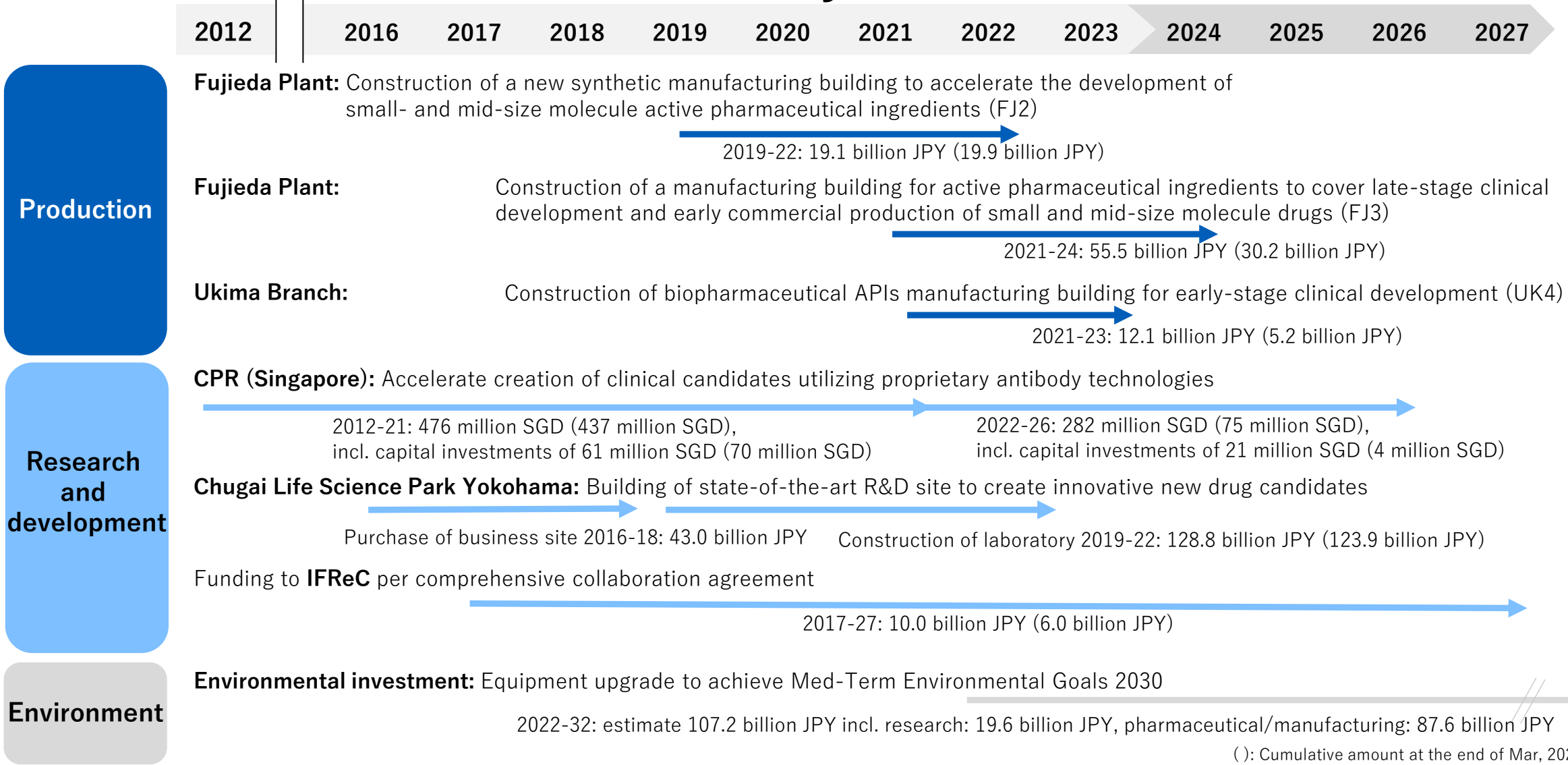
Net Cash (vs. 2022 Year End)



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

*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



( ): Cumulative amount at the end of Mar, 2023

Overview of Development Pipeline

Tetsuya Yamaguchi

Executive Vice President, Head of Project & Lifecycle Management Unit

Overview of Development Pipeline

Q1 Topics (1/2)

As of April 27, 2023

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

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

Overview of Development Pipeline

Q1 Topics (2/2)

As of April 27, 2023

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

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

Overview of Development Pipeline

2023: Key R&D Milestones

Underlined and bolded are new progress since February 2, 2023

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

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

* Readout expected in 2023-2024

Primary Endpoints Met (crovalimab/nemolizumab)

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

crovalimab

COMMODORE 1, COMMODORE 2 (PNH)

COMMODORE 2:
Non-inferiority study with standard therapy in patients with PNH who had not previously been treated with a complement inhibitor met its two primary endpoints. Verified non-inferiority to standard therapy.

[Primary endpoints]
- Transfusion avoidance
- Hemolytic control (LDH level; ongoing RBC destruction)

COMMODORE 1:
P3 study in patients with PNH who switched to crovalimab from an existing complement inhibitor. Efficacy and safety supported the favorable benefit-risk profile of the COMMODORE 2.

- The results of COMMODORE 1/2 will be presented at EHA2023
- Filed in China with COMMODORE 3 results

nemolizumab

ARCADIA 1, ARCADIA 2 (Atopic dermatitis)

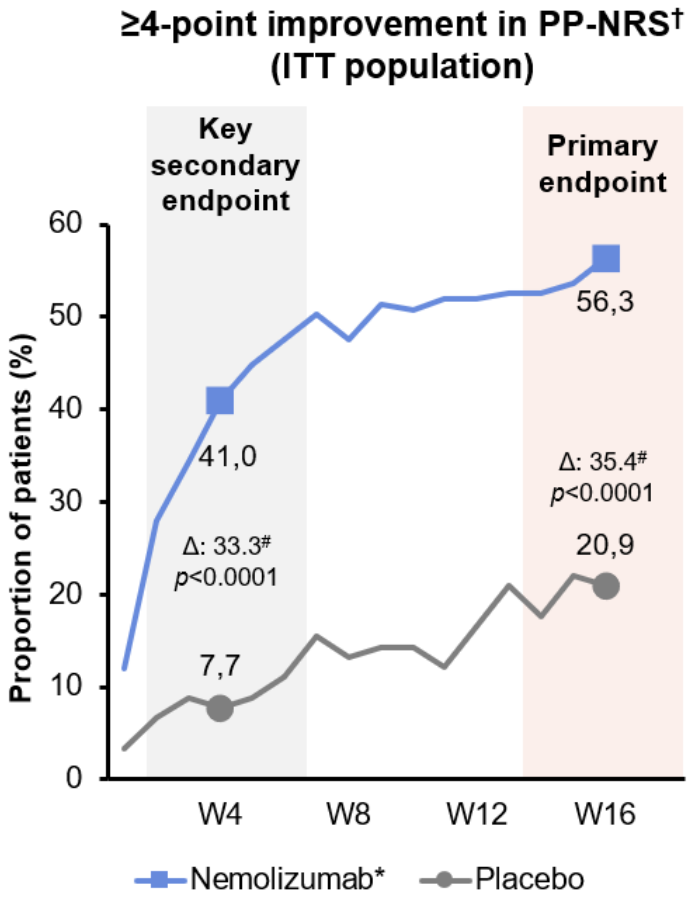
Both ARCADIA 1 and ARCADIA 2 in patients with moderate to severe atopic dermatitis (adolescent to adult) met primary and key secondary endpoints

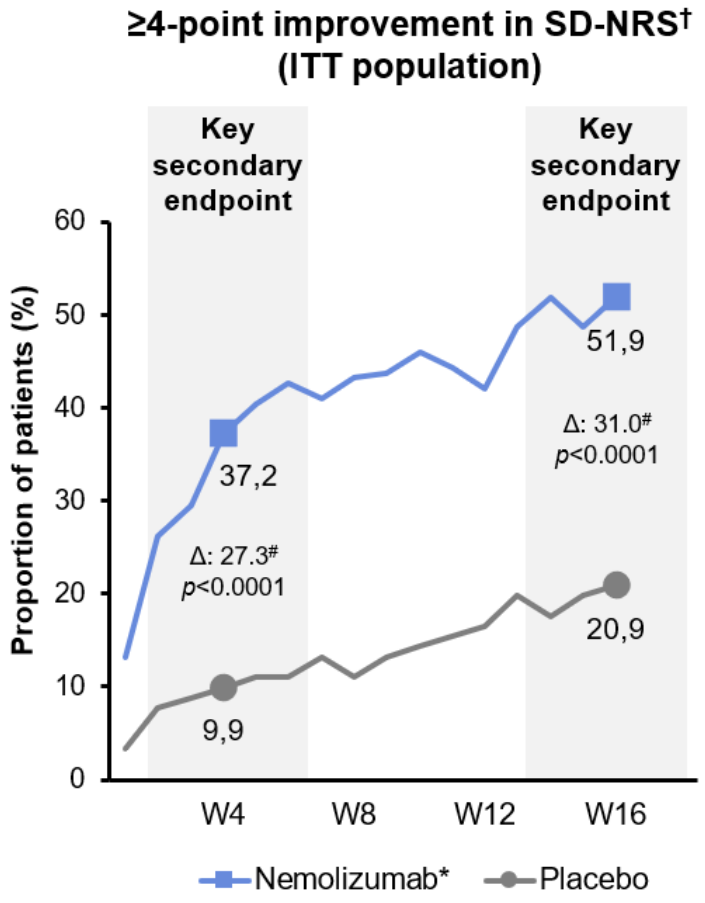
- Nemolizumab in combination with TCS (topical steroid) was evaluated in comparison to placebo, administered subcutaneously every 4 weeks
- Improved skin lesions, itching, sleep disturbances
- Presentation at a conference in late 2023, launch planned in H2 2024 (US)

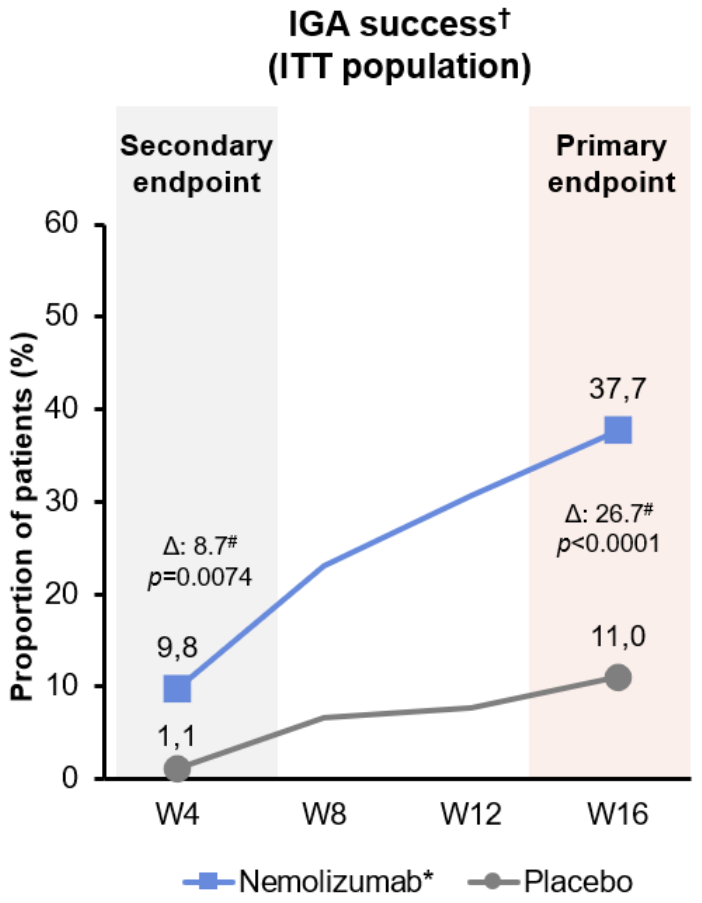
OLYMPIA 1, OLYMPIA 2 (Prurigo Nodularis)

- OLYMPIA 2 study met all primary and all key secondary endpoints. The other P3 study OLYMPIA 1 is on track.
- Details of the OLYMPIA 2 study are on the next slide.
- To be launched in H2 2024 (US)

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







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

Presented at American Academy of Dermatology Annual Meeting (March 17-21)

Overview of Development Pipeline

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

Sales in 2022

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

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

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

Enspryng®
- ✓ Launched in 2020
- ✓ Global Sales 192mCHF*

*Data from Roche financial results

crovalimab related markets in 2028

PNH:
3,090mUSD

No. of Patients
PNH:
12,500

SCD:
3,876mUSD

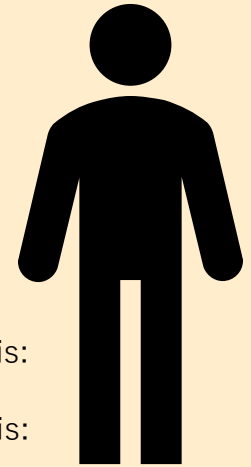
aHUS:1,652mUSD

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

nemolizumab related markets in 2028

Atopic dermatitis:
20,543mUSD

Prurigo nodularis:
No market data



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

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

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

Overview of Development Pipeline

Projected Submissions (Post PoC NMEs and Products)

as of April 27, 2023

Filed

- crovalimab (SKY59/RG6107) PNH (China)
- ACTEMRA (MRA/RG1569) CRS induced by cancer treatment ★
- ACTEMRA (MRA/RG1569) SSc-ILD (EU)
- VABYSMO (RG7716) RVO ★
- RG6264 (FDC, sc) BC/CRC

NME **Line extension**

in-house

in-licensed (Roche)

★ : new entry ★ : changes in submission year *Before obtaining PoC

2023

- TECENTRIQ+AVASTIN (RG7446＋RG435) HCC (adjuvant)
- tiragolumab (RG6058) 1L NSCLC + TECENTRIQ
- ALECENSA (AF802/RG7853) NSCLC (adjuvant)
- crovalimab (SKY59/RG6107) PNH

2024

- SRP-9001 (RG6356) DMD
- mosunetuzumab (RG7828) 3L FL
- tiragolumab + TECENTRIQ (RG6058 + RG7446) 1L NSQ NSCLC ★
- tiragolumab + TECENTRIQ (RG6058 + RG7446) NSCLC (Stage III)
- ENSPRYNG (SA237/RG6168) gMG
- TECENTRIQ (RG7446) HNC (adjuvant)
- TECENTRIQ (RG7446) NSCLC (neoadjuvant)
- AVASTIN (RG435) 1L SCLC + TECENTRIQ
- TECENTRIQ (RG7446) eBC (neoadjuvant)
- TECENTRIQ (RG7446) MIBC (adjuvant)

2025

- giredestrant (RG6171)) 1L~3L BC ★
- tiragolumab + TECENTRIQ (RG6058 + RG7446) EC
- ENSPRYNG (SA237/RG6168) AIE
- crovalimab (SKY59/RG6107) aHUS ★
- Vabysmo (RG7716) Angioid streaks ★
- TECENTRIQ+AVASTIN (RG7446＋RG435) HCC(intermediate stage)
- ranibizumab(PDS) (RG6321) DME ★
- ranibizumab(PDS) (RG6321) nAMD ★
- mosunetuzumab+ POLIVY (RG7828+RG7596) r/r aNHL ★

2026 and beyond

- GYM329/RG6237 FSHD* ★
- ENSPRYNG (SA237/RG6168) MOGAD
- ALECENSA (AF802/RG7853) NSCLC (Stage III)
- GYM329/RG6237 SMA* + EVRYSDI
- crovalimab (SKY59/RG6107) SCD* (US/EU)
- GAZYVA (RG7159) Pediatric nephrotic syndrome ★
- GAZYVA (RG7159) LN
- TECENTRIQ (RG7446) 2L HCC
- giredestrant (RG6171) 1L BC
- giredestrant (RG6171) BC (adjuvant)
- mosunetuzumab (RG7828) 2L FL

Appendix

Overview of Development Pipeline

Projects under Development (1/2)

As of April 27, 2023

	Phase I	Phase II	Phase III	Filed
Cancer	**LUNA18** - solid tumors **GC33 / codrituzumab** - HCC **ERY974** - solid tumors **STA551** - solid tumors **SOF10 (RG6440)** - solid tumors **SPYK04** - solid tumors **ALPS12 (RG6524)** - solid tumors **SAIL66** - CLDN6 positive solid tumors ★ **RG7828 / mosunetuzumab** - FL (3L) **RG7421 / cobimetinib** - solid tumors **RG7802 / cibisatamab** - solid tumors **RG6026 / glofitamab** - hematologic tumors **RG6194 / runimotamab** - solid tumors **RG6330 / KRAS G12C inhibitor** - solid tumors **RG6433 / SHP2 inhibitor** - solid tumors **RG6160 / cevostamab** - r/r MM	**RG6396 / pralsetinib** - NSCLC (2L) - solid tumors	**AF802 (RG7853) / Alecensa** - NSCLC (adjuvant) - NSCLC (stage III)* **RG7446 / Tecentriq** - NSCLC (neoadjuvant) - MIBC (adjuvant) - eBC (adjuvant) - eBC (neoadjuvant) - HCC (2L) - HNC (adjuvant) - PC (2L) **RG7446 / Tecentriq + RG435 / Avastin** - SCLC (1L) - HCC (adjuvant) - HCC (intermediate stage) **RG6058 / tiragolumab + RG7446 / Tecentriq** - NSCLC (1L) - NSCLC (stage III) - NSQ NSCLC (1L) - EC **RG6171 / giredestrant** - BC (adjuvant) - BC (1L) - BC (1L-3L) ★ **RG7828 / mosunetuzumab** - FL (2L) **RG7828 / mosunetuzumab + RG7596 / Polivy** - r/r aNHL **RG6396 / pralsetinib** - NSCLC (1L)	**RG6264 (PER/HER FDC)** - BC/CRC **MRA(RG1569) / Actemra** - CRS induced by cancer treatment ★

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

In principle, completion of first dose is regarded as the start of clinical studies in each phase.　★: Projects with advances in stages since February 2, 2023

* maintenance therapy after chemoradiation

Overview of Development Pipeline

Projects under Development (2/2)

As of April 27, 2023

	Phase I	Phase II	Phase III	Filed
Immunology	**DONQ52** - Celiac disease **RAY121** - Autoimmune disease **SKY59(RG6107) / crovalimab** - LN ★		**RG7159 / Gazyva** - LN - Pediatric nephrotic syndrome ★	**MRA (RG1569) / Actemra (EU)** - SSc-ILD
Neurology	**RG7935 / prasinezumab** - Parkinson's disease **RG6100 / semorinemab** - Alzheimer's disease **RG6102 / trontinemab** - Alzheimer's disease	**GYM329 (RG6237) + RG7916/ Evrysdi** - SMA (PII/III) - FSHD ★ **RG7906 / ralmitaront** - schizophrenia **RG6042 / tominersen** - Huntington's disease	**SA237 (RG6168) / Enspryng** - gMG - MOGAD - AIE **SRP-9001(RG6356) / delandistrogene moxeparvovec** -DMD *	
Hematology	**NXT007 (RG6512)** - hemophilia A (PI/II)	**SKY59 (RG6107) / crovalimab (US/EU)** - SCD	**SKY59 (RG6107) / crovalimab** - PNH - aHUS	**SKY59 (RG6107) / crovalimab (China)** - PNH
Ophthalmology	**RG6321 / PDS** - nAMD (PI/II) - DME (PI/II)		**RG7716 / Vabysmo** - Angioid streaks ★	**RG7716 / Vabysmo** - RVO ★
Other	**AMY109** - endometriosis			

Letters in orange：in-house projects (development in global) **Letters in blue**：in-licensed from Roche (development and distribution in Japan) * Sarepta manages the global study, including Japan

In principle, completion of first dose is regarded as the start of clinical studies in each phase. ★: Projects with advances in stages since February 2, 2023

Overview of Development Pipeline

Advances in Major Chugai Originated Projects Licensed Out to the 3rd Party

★: changes since February 2, 2023　　As of April 27, 2023

Development code	Mode of Action	Licensee	Granted rights to licensee	Indication	Stage	Progress
CKI27 (**VS-6766**) **avutometinib**	RAF/MEK inhibitor	Verastem Oncology	exclusive global license for the manufacturing, development and marketing	Ovarian cancer	global: P2	• US FDA BTD（recurrent LGSOC in combination with defactinib）
				NSCLC	global: P2	—
					global: P1/2	• RAMP 203 trial (in combination with KRAS G12C inhibitor sotorasib）initiated • RAMP 204 trial (in combination with KRAS G12C inhibitor, adagrasib) initiated
CIM331/ nemolizumab	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	• Two P3 studies met primary endpoints ★
					Japan: launched	• Granted regulatory approval for itch associated with atopic dermatitis
				Prurigo nodularis	global: P3	• US FDA BTD • Primary endpoint was met in the one of two P3 studies
					Japan: P2/3	—
				CKDaP	global: P2/3	—
OWL833 (**LY3502970**) **orforglipron**	Oral non-peptidic GLP-1 receptor agonist	Eli Lilly and Company	worldwide development and commercialization rights	T2D	global: P2	• Results of P2 study (26 wks treatment with OWL833) ✓ Dose-dependent reduction in HbA1c up to 2.1% and weight reduction up to 9.6% were observed
				Obesity	global: P2	• Results of P2 study* (36 wks treatment with OWL833) ✓ Weight reduction of approximately 14%-15% was estimated

* preliminary analysis

FoundationOne CDx Cancer Genomic Profile -Companion diagnostic indications-

As of April 27, 2023

Alterations	Cancer type	Relevant drugs
Activated *EGFR* gene alterations	NSCLC	afatinib dimaleate, erlotinib hydrochloride, gefitinib, osimertinib mesylate, dacomitinib hydrate
EGFR exon 20 T790M alterations		osimertinib mesylate
ALK fusion genes		alectinib hydrochloride, crizotinib, ceritinib, brigatinib
ROS1 fusion genes		entrectinib
MET exon 14 skipping alterations		capmatinib hydrochloride hydrate
BRAF V600E and V600K alterations	Malignant melanoma	dabrafenib mesylate, trametinib dimethyl sulfoxide, vemurafenib, encorafenib, binimetinib
ERBB2 copy number alterations (HER2 gene amplification positive)	BC	trastuzumab (genetical recombination)
KRAS/NRAS wild-type	CRC	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)
NTRK1/2/3 fusion gene		entrectinib, larotrectinib sulfate
BRCA1/2 alterations	Ovarian cancer	olaparib
BRCA1/2 alterations	Prostate cancer	olaparib
FGFR2 fusion genes	Biliary tract cancer	pemigatinib

FoundationOne Liquid CDx Cancer Genomic Profile

Companion diagnostic indications

As of April 27, 2023

Alterations	Cancer type	Relevant drugs
Activated *EGFR* gene alterations	Non-small cell lung cancer (NSCLC)	afatinib dimaleate, erlotinib hydrochloride, gefitinib, osimertinib mesylate
EGFR exon 20 T790M alterations		osimertinib mesylate
ALK fusion genes		alectinib hydrochloride, crizotinib, ceritinib
ROS1 fusion genes		entrectinib
MET exon14 skipping alterations		capmatinib hydrochloride hydrate
NTRK1/2/3 fusion gene	Solid tumors	entrectinib
BRCA1/2 alterations	Prostate cancer	olaparib

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

Overview of Development Pipeline

GYM329: Facioscapulohumeral muscular dystrophy (FSHD)

MANOEUVRE: Global Phase II study

GYM 329 is expected to maintain and improve motor function by promoting muscle growth in FSHD

FSHD: A hereditary muscle disease characterized by muscle degeneration and weakness affecting the face, shoulders, and upper arms. Muscle weakness in the lower limbs also occurs with progression.

- The cause is abnormal activation of *DUX4*.
- The disease is a common form of muscular dystrophy, affecting around 1 in 8,000 people.
- Symptom onset can occur from early childhood through late adulthood but typically occurs in the teens or 20s.
- About 20% of those with FSHD cannot walk and require a wheelchair to move.
- There are no approved disease-modifying drugs.

Trends Mol Med. 2021 Feb;27(2):123-137.

Outline of the MANOEUVRE study

Disease: FSHD
Aged 18 – 65, Ambulant

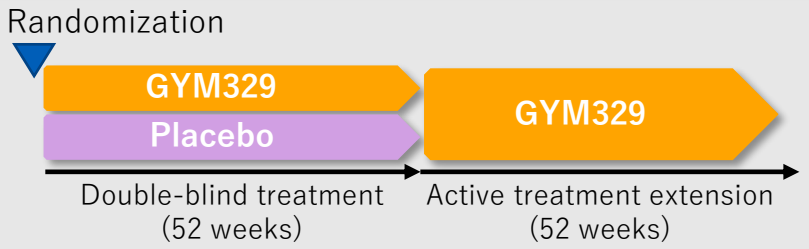
Purpose: Safety, tolerability, efficacy, PK and PD

Estimated enrollment: Up to 48 participants

Duration: Double-blind treatment (52 weeks) followed by active treatment extension (52 weeks)

Treatment: GYM329 or Placebo*

Primary endpoint: Change from baseline in the muscle volume at Week 52, Safety

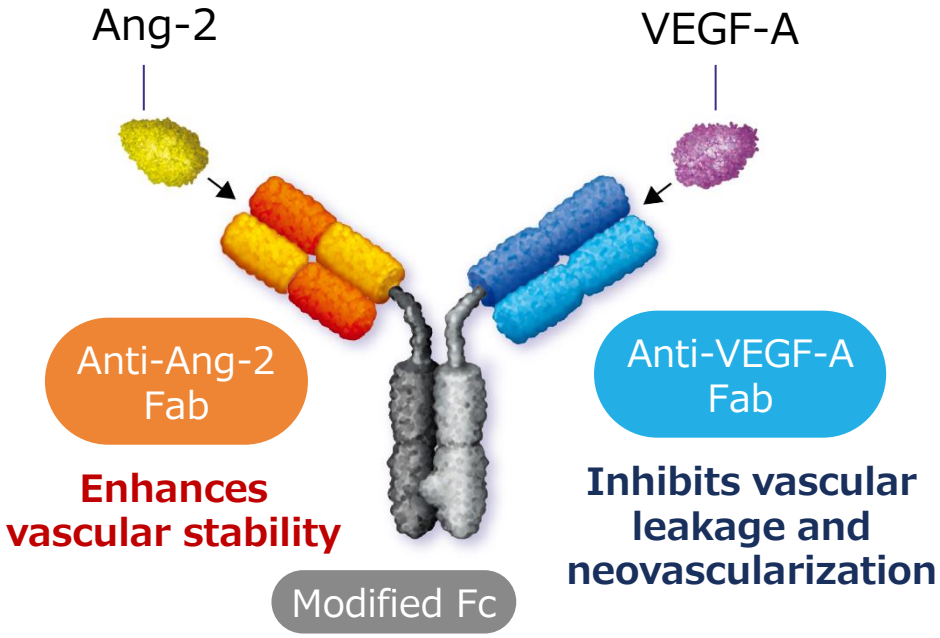


*GYM329/placebo administration: Once every 4 weeks, subcutaneous

VABYSMO: Angioid Streaks

Clinical study for Angioid Streaks was initiated in Japan, and designated as an ODD

- Angioid streaks (AS) are crack-like dehiscence of Bruch's membrane in the retina, which may coexist with systemic diseases, such as pseudoxanthoma elasticum. The choroidal neo-vascularization (CNV) caused by AS in the fovea can result in a deterioration of vision. There is no approved drugs for AS in Japan.
- It is estimated that there are around 350-510 AS patients/year in Japan
- A phase III study of faricimab, which is the first bispecific antibody designed to selectively bind both VEGF-A and Ang-2 for the eye, for the treatment of AS was initiated in Japan.
- Faricimab received orphan drug designation (ODD) for angioid streaks as of Mar 27, 2023.



1. Chatziralli I, et al, Retina. 2019;39:1-11

AS：Angioid streaks, CNV：choroidal neo-vascularization, VEGF-A：Vascular endothelial growth factor-A, Ang-2: Angiopoietin-2, ODD: orphan drug designation

Abbreviations

aHUS	atypical hemolytic uremic syndrome
AIE	autoimmune encephalitis
aNHL	aggressive B-cell non-Hodgkin lymphoma
BC	breast cancer
BS	biosimilar drugs
CRC	colorectal cancer
CRS	cytokine release syndrome
DMD	duchenne muscular dystrophy
DME	diabetic macular edema
eBC	early Breast cancer
EC	esophageal cancer
FDC	fixed-dose combination
FL	follicular lymphoma
FSHD	facioscapulohumeral muscular dystrophy
GE	generic drugs
gMG	generalized myasthenia gravis
HCC	hepatocellular carcinoma
HNC	head and neck carcinoma
LDH	lactate dehydrogenase
LGSOC	low-grade serous ovarian cancer
LN	lupus nephritis
MIBC	muscle-invasive bladder cancer
MM	multiple myeloma
MOA	mode of action
MOGAD	myelin oligodendrocyte glycoprotein antibody–associated disease
nAMD	neovascular age-related macular degeneration
NHI	national health insurance
NSCLC	non-small cell lung cancer
NSQ	non-squamous
PDS	port delivery system with ranibizumab
PNH	paroxysmal nocturnal hemoglobinuria
PS	profit share
r/r	relapsed or refractory
RBC	red blood cell
RCC	renal cell carcinoma
ROY	royalty
RVO	retinal vein occlusion
SCD	sickle cell disease
SCLC	small cell lung cancer
SMA	spinal muscular atrophy
SSc-ILD	systemic sclerosis with interstitial lung disease
T2D	type 2 diabetes

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