



 Roche Group

TOP INNOVATOR
TOPi 2030

Q2 Results (Jan - Jun 2021) Conference Call

CHUGAI PHARMACEUTICAL CO., LTD.

26 July 2021



Important Reminder

Forward-Looking Statements

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

Core Results

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

Note:

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

Agenda

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FY2021 Q2 Overview

Dr. Osamu Okuda

President & CEO

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FY2021 Q2 Consolidated Financial Overview (Core)

Toshiaki Itagaki

Executive Vice President & CFO

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Overview of Development Pipeline

Tetsuya Yamaguchi

Senior Vice President, Head of Project &
Lifecycle Management Unit

FY2021 Q2 Overview

Dr. Osamu Okuda

President & CEO

Financial Overview

- YoY increase in revenues and profits in the first half due to an increase in ROOI along with the growth in overseas local sales
- Government purchase of Ronapreve and expected increase in Actemra exports are upside factors to the initial forecast
- Expected to increase revenues and profits YoY for the fifth consecutive year due to the first half results exceeding the initial forecast and the upside factors from the second half onward

Core (billions of JPY)	2020 Jan -Jun actual	2021 Jan -Jun actual	Growth		2021 Jan - Dec forecast	Progress (%)
Revenues	368.1	390.2	+22.1	+6.0%	800.0	48.8%
Domestic sales	204.6	203.4	-1.2	-0.6%	393.7	51.7%
Overseas sales	101.0	100.7	-0.3	-0.3%	237.3	42.4%
ROOI	62.5	86.1	+23.6	+37.8%	169.0	50.9%
Operating profit	143.7	165.8	+22.1	+15.4%	320.0	51.8%
Operating margin	39.0%	42.5%	+3.5%pts		40.0%	-
Net income	104.5	121.7	+17.2	+16.5%	232.0	52.5%
EPS (yen)*	63.51	73.99	+10.48	+16.5%	141.00	52.5%

ROOI: Royalties and other operating income

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

- ✓ No major negative impact on financial performance due to COVID-19
- ✓ Revenues / Operating profit / Net income exceeded expectations due to progress of domestic sales, driven by market penetration of additional indications for mainstay products, and ROOI, driven by Actemra-related income
- ✓ Ronapreve has received Special Approval for Emergency, and is expected to be purchased by the government during this year. (Upside factor from the initial forecast)
- ✓ The COVID-19-related portion included in the full-year forecast for Actemra export is limited. Expected to increase exports to Roche in the second half. (Upside factor from the initial forecast)

Topline Overview

- Domestic mainstay products and ROOI exceeded initial expectations, contributing to strong progress in the first half
- Revenues are expected to exceed full-year forecast due to unexpected upside factors

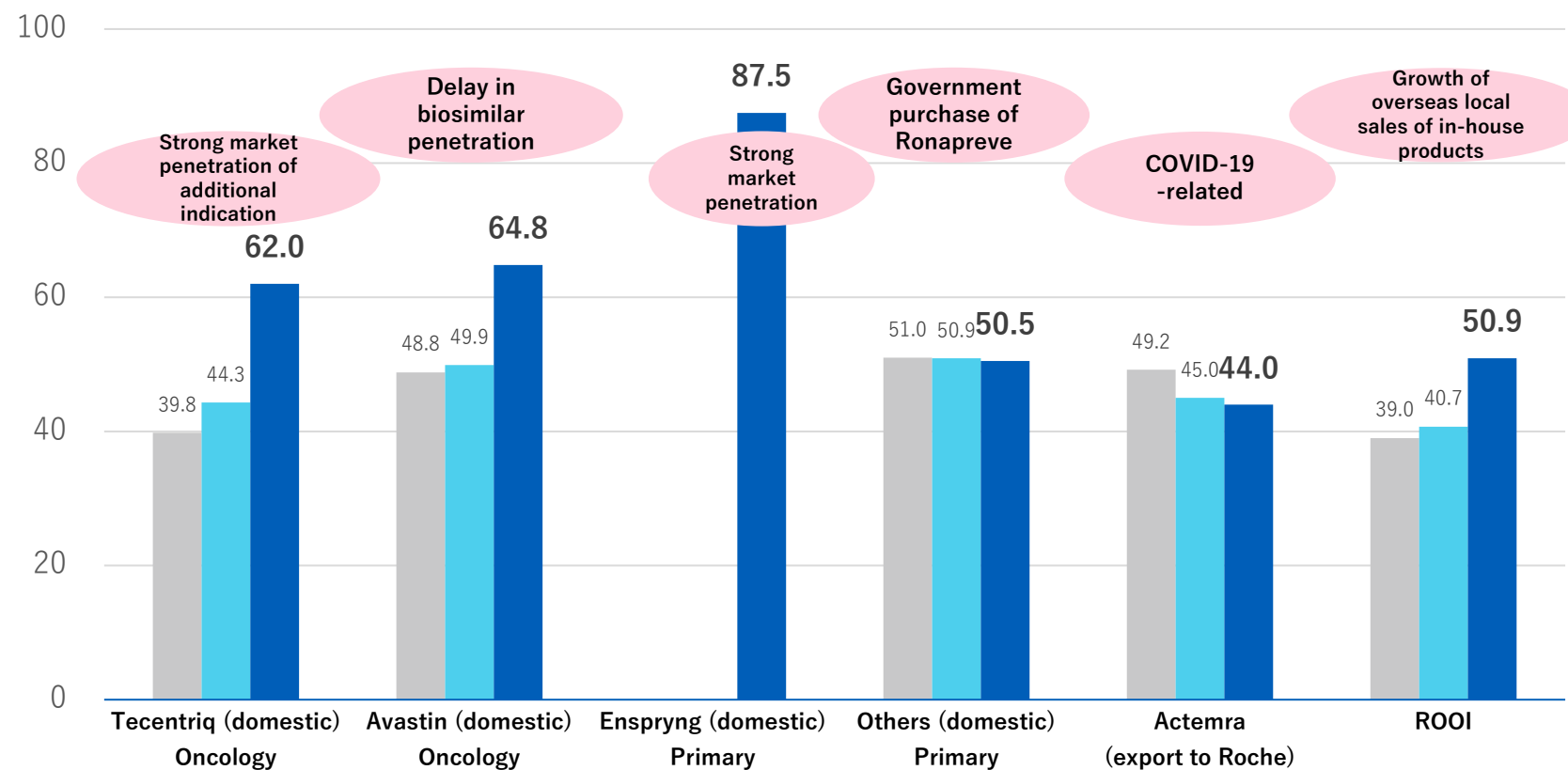
【First half progress (%)】

■ 2019

■ 2020

■ 2021

Upside factor



- ✓ Domestic mainstay products have progressed more than expected due to the expansion of indications last year, and the delay in penetration of biosimilars. Ronapreve received Special Approval for Emergency on July 19 and is expected to increase sales due to government purchase.
- ✓ The progress of overseas exports in the first half fluctuated depending on the timing. Since the initial forecast includes only a limited amount of COVID-19-related items, we anticipate an upside in the second half of the year.
- ✓ ROOI has progressed above expectation due to the growth of Actemra's overseas local sales. Expected to increase further in the second half.

R&D Overview

- In addition to the steady market penetration of mainstay products / new products, sales related to COVID-19 are expected to significantly exceed the initial forecast
- Filing of applications for development products with high market potential will contribute to sales growth in the next fiscal year and onward

Growth of main/new products

- (1) Tecentriq
- (2) Kadcyra
- (3) Enspryng
- (4) Actemra export

- (1)(2) Higher than expected progress due to expansion of indications last year
- (3) Steady domestic market penetration and approval in Europe
- (4) Upside due to COVID-19

Launch of new products

- (1) Polivy (May)
- (2) Ronapreve (July)
- (3) F1L CDx¹
- (4) Evrysdi

- (1) relapsed or refractory DLBCL²
- (2) COVID-19: Government purchase is an upside factor
- (3) Comprehensive genomic profiling for solid tumors using blood samples
- (4) Spinal Muscular Atrophy

Filing

- (1) Faricimab (June)
- (2) Tecentriq (July)
- (3) Actemra
- (4) Polivy
- (5) HER/PER Fixed-dose combination

- (1) Chugai's first product in ophthalmology³
- (2) Non-small cell lung cancer (adjuvant)
- (3) COVID-19
- (4) DLBCL (1st line)
- (5) HER2-positive Breast cancer

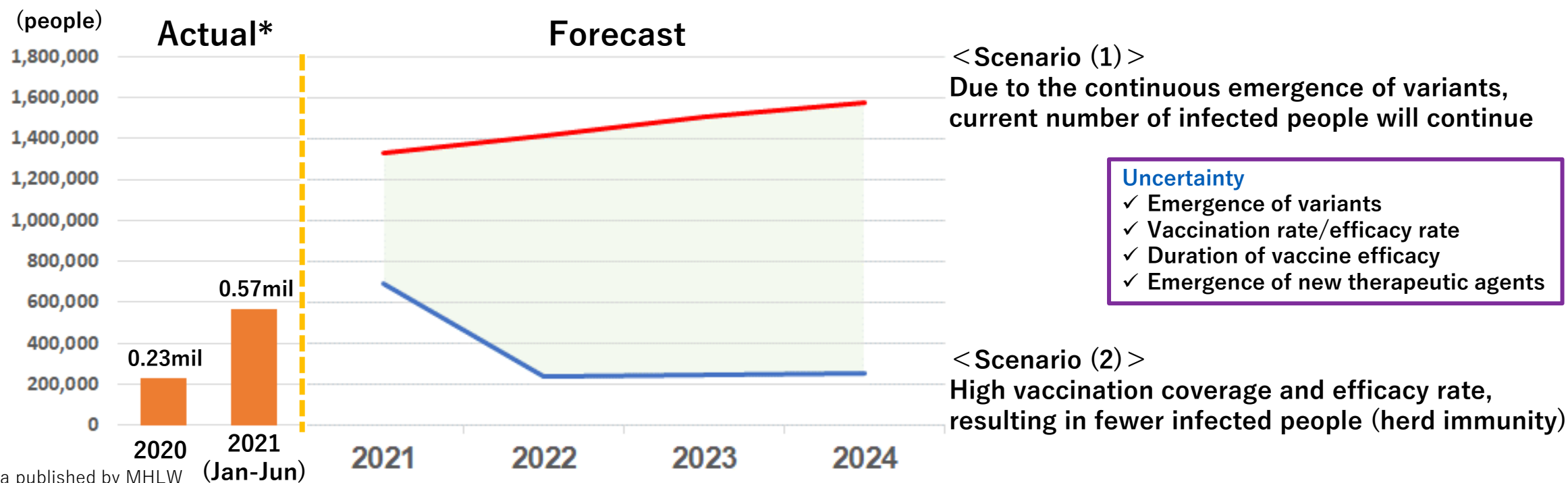
1 FoundationOne Liquid CDx Cancer Genomic Profile

2 DLBCL: diffuse large B-cell lymphoma

3 Filed for diabetic macular edema (DME) and neovascular age-related macular degeneration (nAMD)

Environmental Scenarios for COVID-19

- Repeated outbreaks of infection due to the continuous emergence of variants
- No. of infected people is projected to range from 0.2 - 1.6 million depending on the degree of uncertainty



*: Data published by MHLW

	Pharm needs	Characteristics
Ronapreve	++	First drug developed in Japan specifically for COVID-19. Expectations are high for the drug to treat mild to moderate COVID-19, and it will contribute to reducing the risk of shortage of hospital beds by preventing severe progression of the disease
Actemra	++	Help improve the prognosis of patients with severe COVID-19
AT-527	+++	Convenience of oral administration enables early treatment and contributes to improving social anxiety by preventing mild patients from becoming severe

Progress on 2021 Strategic Policies

Maximizing value of growth drivers

- Hemlibra: Domestic market penetration lower than expected due to COVID-19 etc, but sales remained steady
- Tecentriq: Sales expansion was mainly driven by HCC
- Enspryng: Exceeding expected market penetration due to increased awareness of IL-6 in NMOSD
- Polivy: Steady start with progress in administration to patients who have already been treated

Continuous creation of R&D output

- Filed: faricimab (DME, nAMD), Tecentriq (NSCLC adjuvant)
- Approved: FoundationOne Liquid CDx Cancer Genomic Profile, Evrysdi, Enspryng (EU), Ronapreve
- New to pipeline: ERY974 (HCC), SOF10 (solid tumor)

Acceleration of DX

- Acceleration of AI-based antibody drug discovery supporting technology (MALEXA)
- Initiatives to realize digital plants: High value-added production functions, improved operational efficiency
- Building the foundation for a customer interface platform
- Continued to be selected as a DX brand 2021

Strengthen business foundation

- Acquire and strengthen highly specialized human resources and establish new work styles that enhance productivity and realize work-life synergies
- Continued to be included in major ESG indices (FTSE4Good, MSCI ESG Leaders, etc.)

Investment to “Launch Global in-house Products Every Year”

- Establish stable supply capacity for APIs, such as mid-size molecule drugs, covering all through early clinical development to market launch
- Revised total investment and schedule for completion of building and start of full operation for the Core research center

API Manufacturing Building for Small/Mid-size Molecule Drugs (FJ3) <Fujieda, Shizuoka pref.>

[Purpose] Address the manufacturing functions of small and mid-size molecule drugs, covering Active Pharmaceutical Ingredients (APIs) for late-stage clinical trials and early production after launch

[Total investment] 55.5 billion yen

(Completion of building: Oct 2024; Start of full operation: Mar 2025)

[Environmental aspects] Consideration for reducing environmental loads, such as energy-saving design that suppresses CO₂ emissions as much as possible and recycling of solvents used

[Safety aspects] Earthquake countermeasures by adopting seismic isolation structure and designing the facility to prepare for fires and other incidents



Chugai Life Science Park Yokohama <Yokohama, Kanagawa pref.>

[Purpose] Establish a core research center to create innovative new drugs of the highest quality globally (consolidation of current research laboratories)

[Total Investment] 128.8 billion yen

(Completion of construction: **Oct 2022**; Start of full operation: **Apr 2023**)

[Environmental aspects] Design in harmony with the local community and incorporate environmental considerations such as energy-saving measures and CO₂ reduction

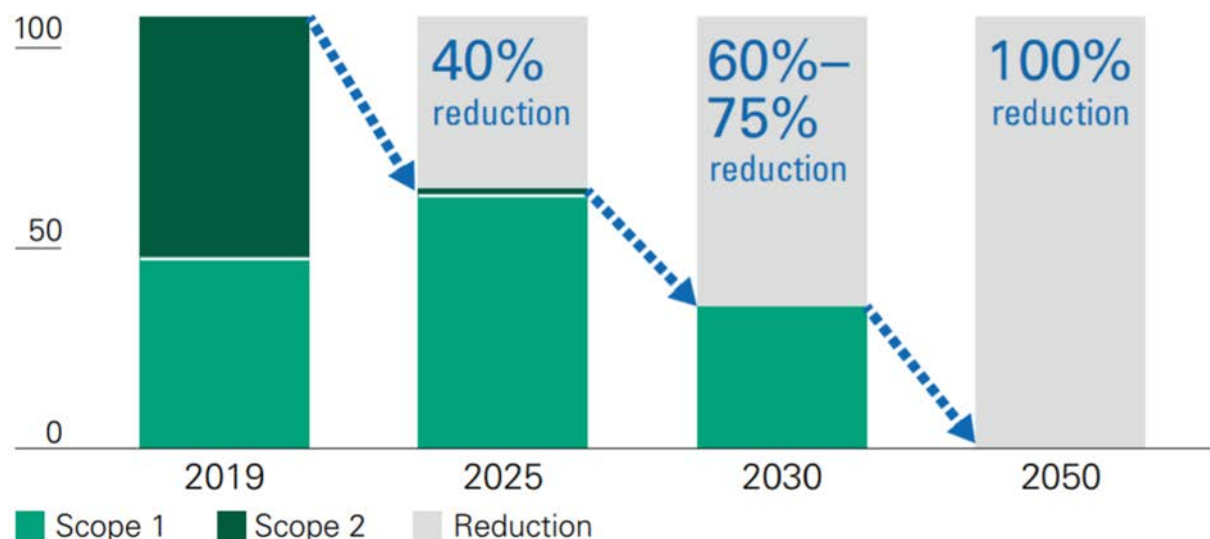


Long-term Plan to Reduce CO₂ Emissions

- Set milestones in 2025, aiming for 100% sustainable electricity usage
- Considering the reduction of direct CO₂ emissions toward 2030

Reductions in CO₂ Emissions

(1,000 t-CO₂)



Scope 1: Direct emissions

Scope 2: Indirect emissions from the generation of purchased energy

2025
40%
reduction

Opening a new research facility at Chugai Life Science Park Yokohama and relocating research laboratories, reducing and making more efficient use of energy, and switching to sustainable electric power sources (reduce Scope 2 emissions to zero)

2030
60~75%
reduction

As direct CO₂ emissions from fuel consumption (Scope 1) also need to be reduced, we are studying options in this area as well, including conversion, rationalization, and redesign of our existing facilities.

2050
100%
reduction

Although we do not have a concrete path to high goals, we will promote initiatives that are not an extension of the past, including the introduction of new sustainable energy in the future.

Summary

- YoY increase in revenues and profits in the first half due to an increase in ROOI along with the growth of overseas local sales
- Expected to increase revenues and profits YoY for the fifth consecutive year due to the high progress of the first half results and upside factors related to COVID-19
- Contributing to sales growth from the next fiscal year onward by continuously filing for approval and launching new products and expanding indications
- The 2021 Strategic Policies are progressing steadily and TOP I 2030 started well
- Started capital investment to establish a stable API supply capacity for small and mid-size molecule drugs
- Aiming for 40% reduction in 2025, toward zero CO₂ emissions in 2050

FY2021 Q2 Consolidated Financial Overview (Core)

Toshiaki Itagaki

Executive Vice President & CFO

P/L Jan - Jun (Year on Year)

(Billions of JPY)	2020	2021	Growth	
Revenues	368.1	390.2	+ 22.1	+ 6.0%
Sales	305.7	304.1	- 1.6	- 0.5%
Domestic	204.6	203.4	- 1.2	- 0.6%
Overseas	101.0	100.7	- 0.3	- 0.3%
Royalties and other operating income	62.5	86.1	+ 23.6	+ 37.8%
Royalty and profit-sharing income	53.5	83.3	+ 29.8	+ 55.7%
Other operating income	9.0	2.8	- 6.2	- 68.9%
Cost of sales	-131.2	-121.9	+ 9.3	- 7.1%
(cost to sales ratio)	42.9%	40.1%	-2.8%pts	-
Operating expenses	-93.2	-102.5	- 9.3	+ 10.0%
M&D and G&A * ¹	-40.2	-42.7	- 2.5	+ 6.2%
Research and development	-52.9	-59.9	- 7.0	+ 13.2%
Operating profit	143.7	165.8	+ 22.1	+ 15.4%
(operating margin)	39.0%	42.5%	+3.5%pts	-
Financial account balance	-1.1	0.6	+ 1.7	-
Income taxes	-38.2	-44.7	- 6.5	+ 17.0%
Net income	104.5	121.7	+ 17.2	+ 16.5%
EPS (JPY) * ²	63.51	73.99	+10.48	+ 16.5%

Domestic sales

Same level as previous year as the negative impact of NHI drug price revision and generic drugs launch was offset by growth in sales volume

Overseas sales

Same level as previous year due to offsetting increases / decreases in export products

Royalty and profit-sharing income

Significant increase in income for Hemlibra

Other operating income

Decrease in one-time income

Cost of sales

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

Operating expenses

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

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

Operating profit

Increase due to higher royalty and profit-sharing income

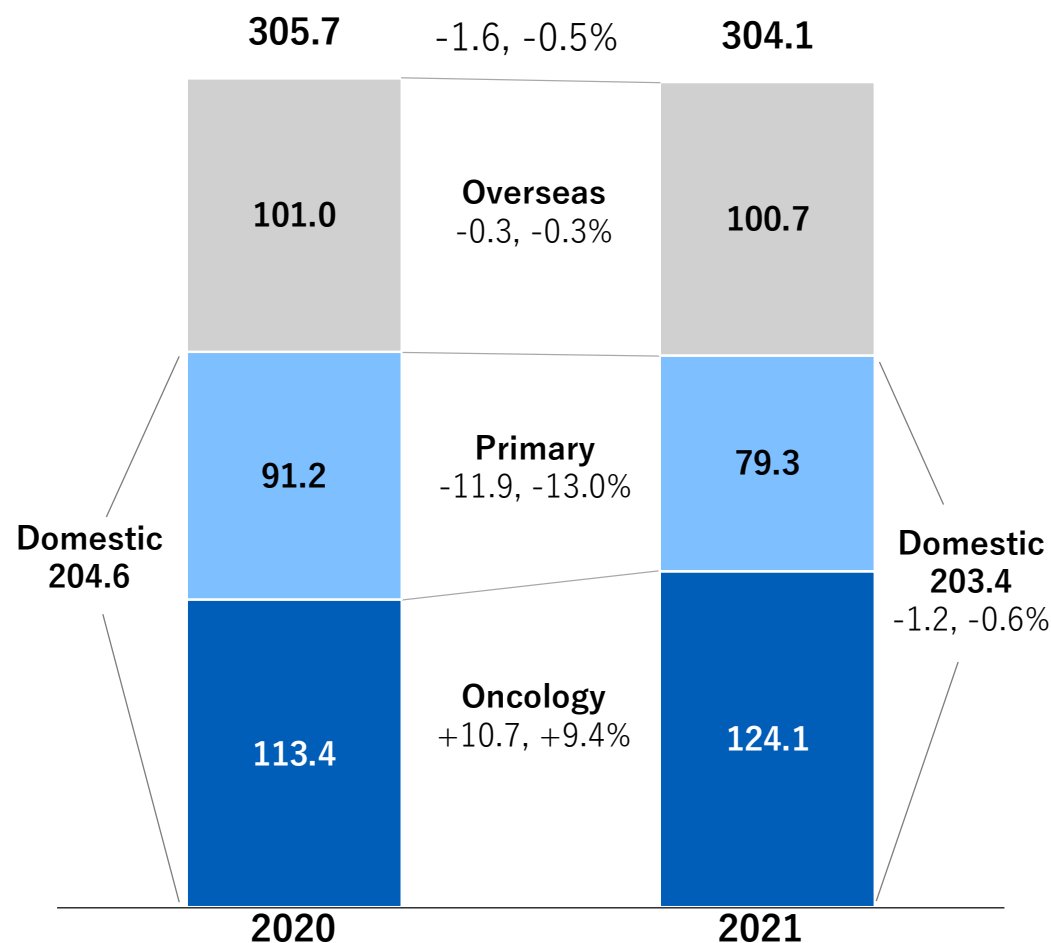
*¹ M&D: Marketing and distribution, G&A: General and administration

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

Sales Jan - Jun (Year on Year)

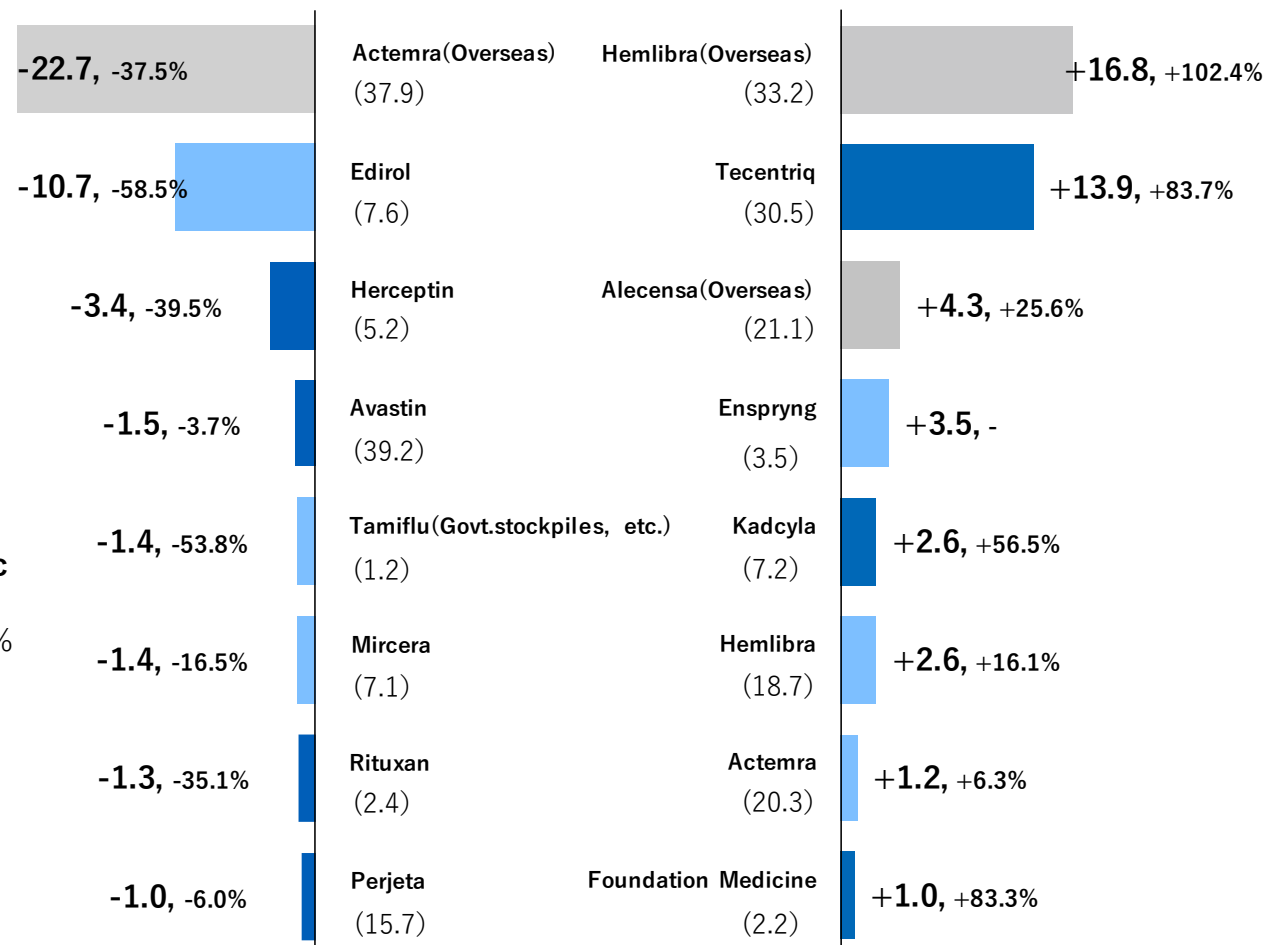
Sales by Disease Area,
Year on Year Comparisons

(Billions of JPY)



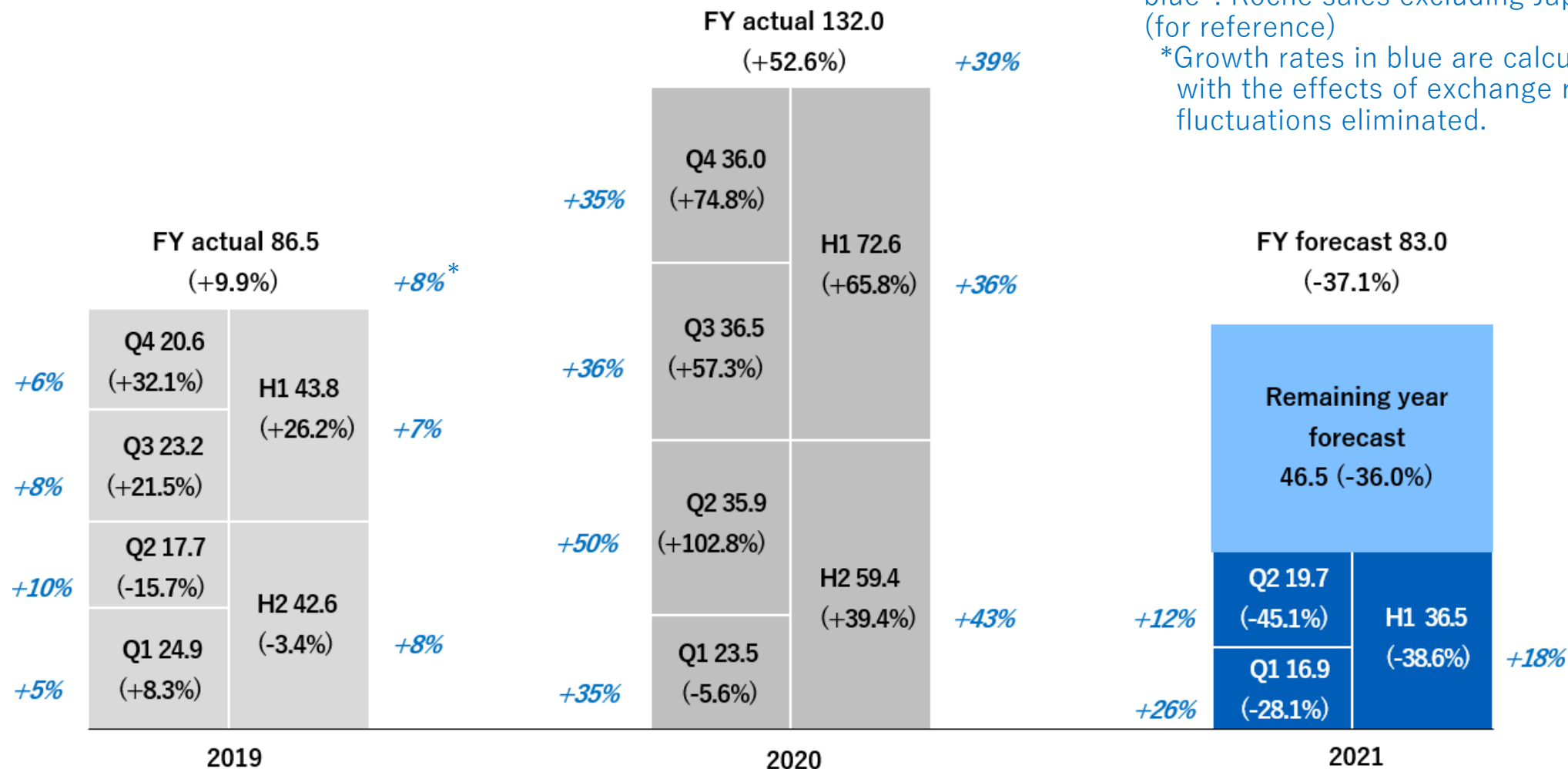
Sales by Products,
Year on Year Changes

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



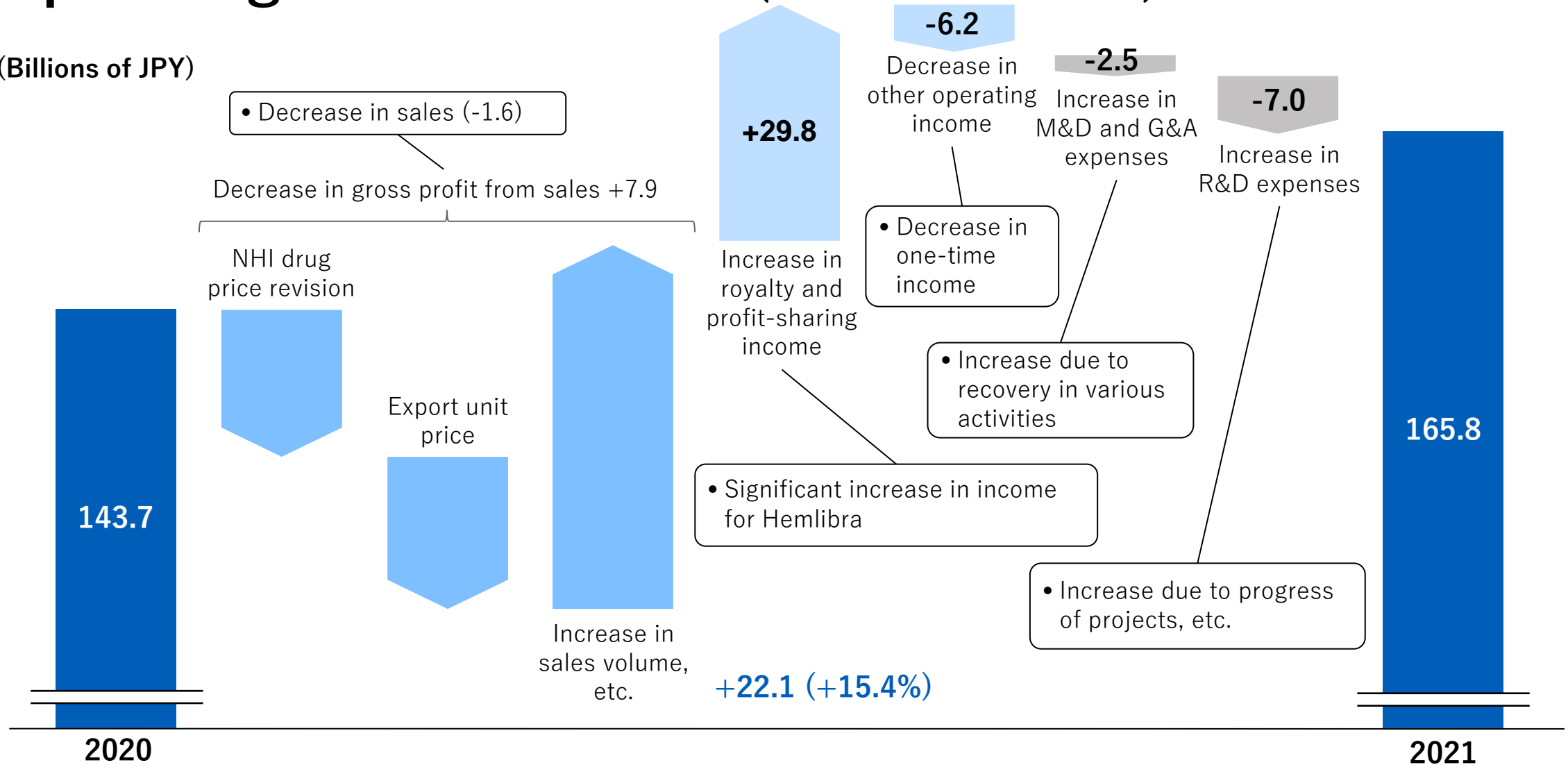
Export of Actemra to Roche

(Billions of JPY)

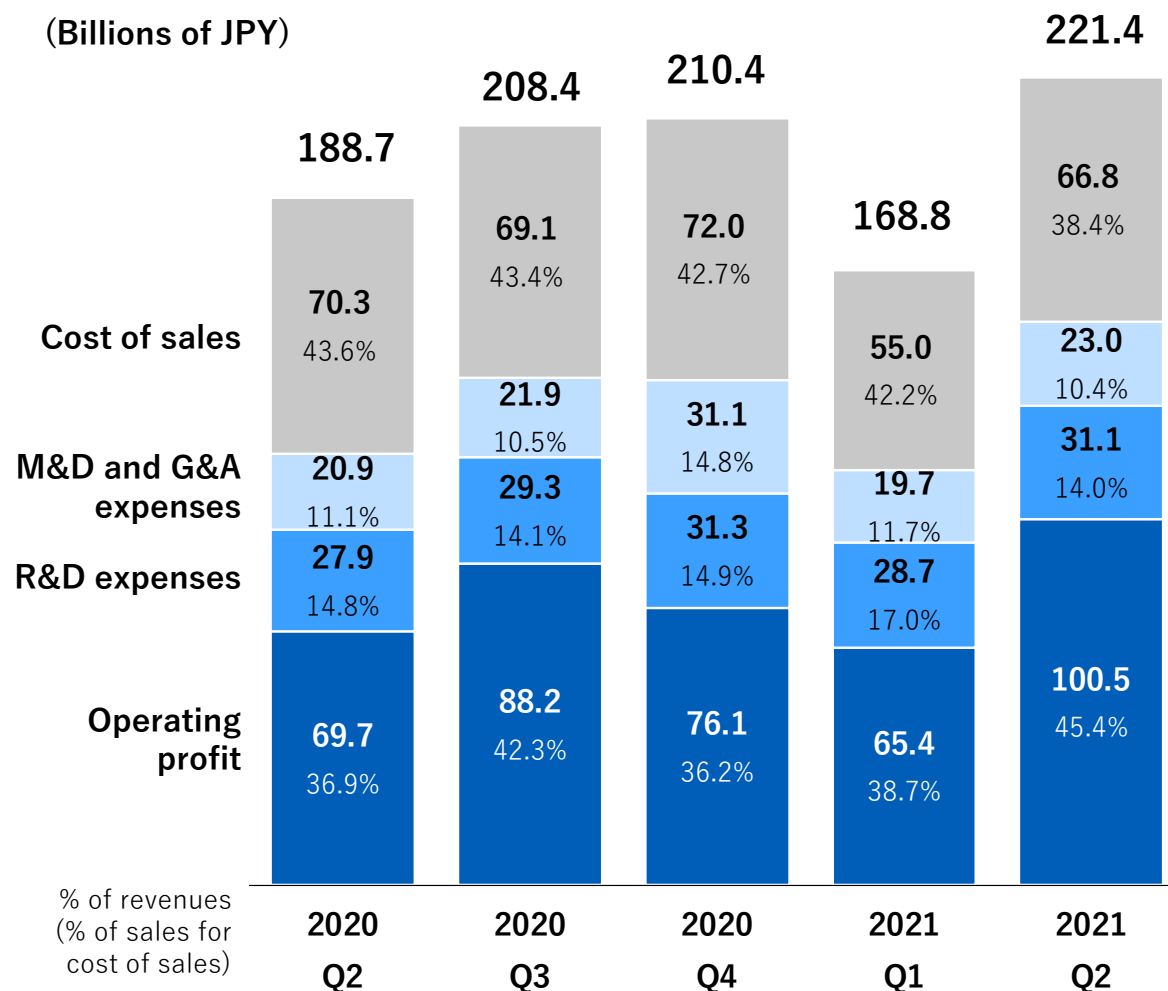


Operating Profit Jan - Jun (Year on Year)

(Billions of JPY)



Structure of Costs and Profit by Quarter



vs. Year on Year (2020 Q2)

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

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

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

Operating profit: increase of +30.8 (+44.2%)

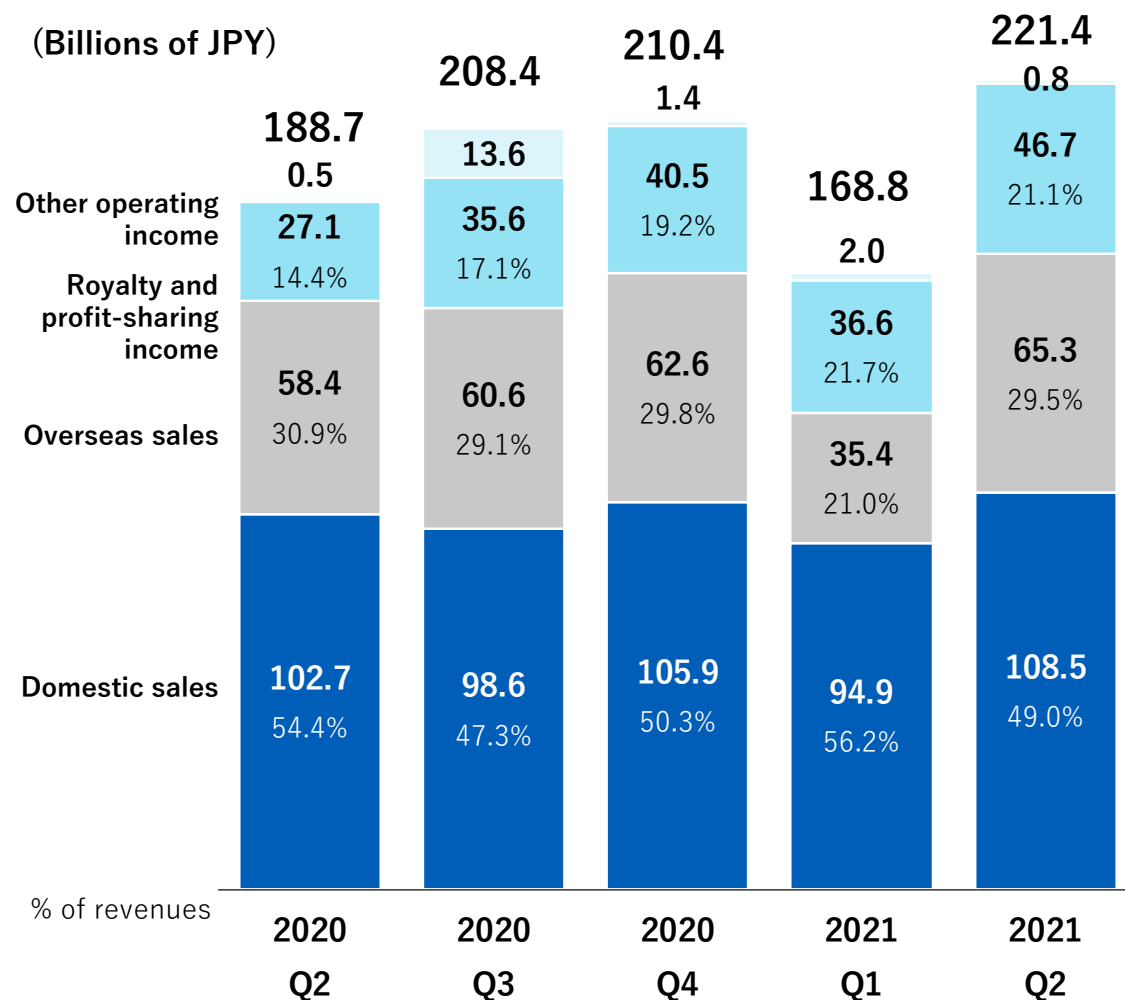
vs. Previous Quarter (2021 Q1)

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

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

Operating profit: increase of +35.1 (+53.7%)

Structure of Revenues by Quarter



vs. Year on Year (2020 Q2)

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

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

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

vs. Previous Quarter (2021 Q1)

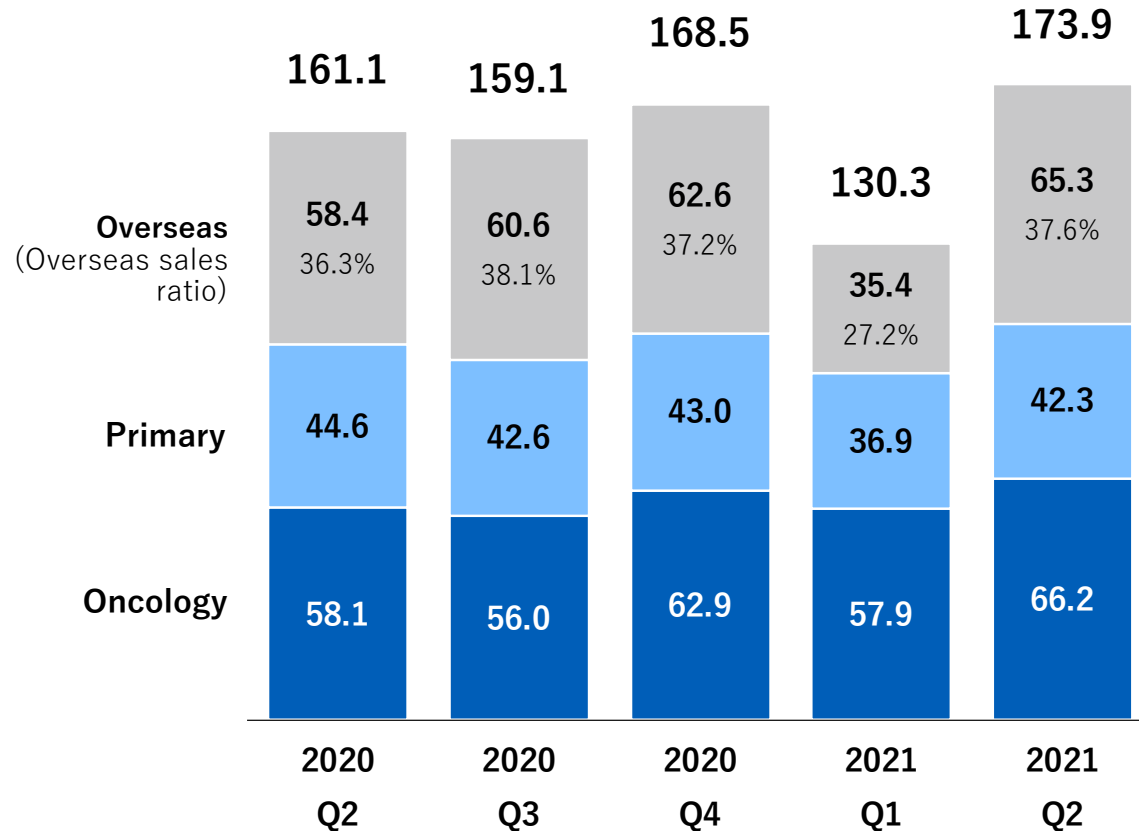
Domestic sales: increase mainly due to sales growth of new products and mainstay products, in addition to the trend of previous years

Overseas sales: increase in sales of Hemlibra

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

Structure of Sales by Quarter

(Billions of JPY)



vs. Year on Year (2020 Q2)

Overseas	Actemra: -16.0	Hemlibra: +16.8
	Alecensa: +4.3	
Oncology	Tecentriq: +7.6	Kadcyla: +1.5
	Herceptin: -1.5	
Primary	Edirol: -4.8	Enspryng: +2.2
	Hemlibra: +1.7	Actemra: +1.3

vs. Previous Quarter (2021 Q1)

Overseas	Hemlibra: +16.2	Alecensa: +9.0
	Actemra: +3.1	
Oncology	Tecentriq: +2.3	Avastin: +1.6
	Alecensa: +1.1	
Primary	Actemra: +1.8	Edirol: +1.8
	Hemlibra: +1.1	Enspryng: +0.8
	Tamiflu (Govt. stockpiles, etc.): -1.2	

P/L Jan - Jun (vs. Forecast)

(Billions of JPY)	Actual 2021 Jan - Jun	Forecast 2021 Jan - Dec	Progress	2020 Progress *1
Revenues	390.2	800.0	48.8%	46.8%
Sales	304.1	631.0	48.2%	48.3%
Domestic	203.4	393.7	51.7%	50.0%
Overseas	100.7	237.3	42.4%	45.0%
Royalties and other operating income	86.1	169.0	50.9%	40.7%
Royalty and profit-sharing income	83.3	163.0	51.1%	41.3%
Other operating income	2.8	6.0	46.7%	37.3%
Cost of sales	- 121.9	- 252.5	48.3%	48.2%
(cost to sales ratio)	40.1%	40.0%	-	-
Operating expenses	- 102.5	- 227.5	45.1%	45.1%
M&D and G&A	- 42.7	- 96.0	44.5%	43.1%
Research and development	- 59.9	- 131.5	45.6%	46.6%
Operating profit	165.8	320.0	51.8%	46.7%
(operating margin)	42.5%	40.0%	-	-
Net income	121.7	232.0	52.5%	47.6%
EPS (JPY) *2	73.99	141.00	52.5%	47.6%

Domestic Sales

Progress steady in view of overall forecast

Overseas sales

Progress nearly in line with forecast

Royalty and profit-sharing income

Progress steady in view of forecast due mainly to income for Actemra

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 steady in view of forecast

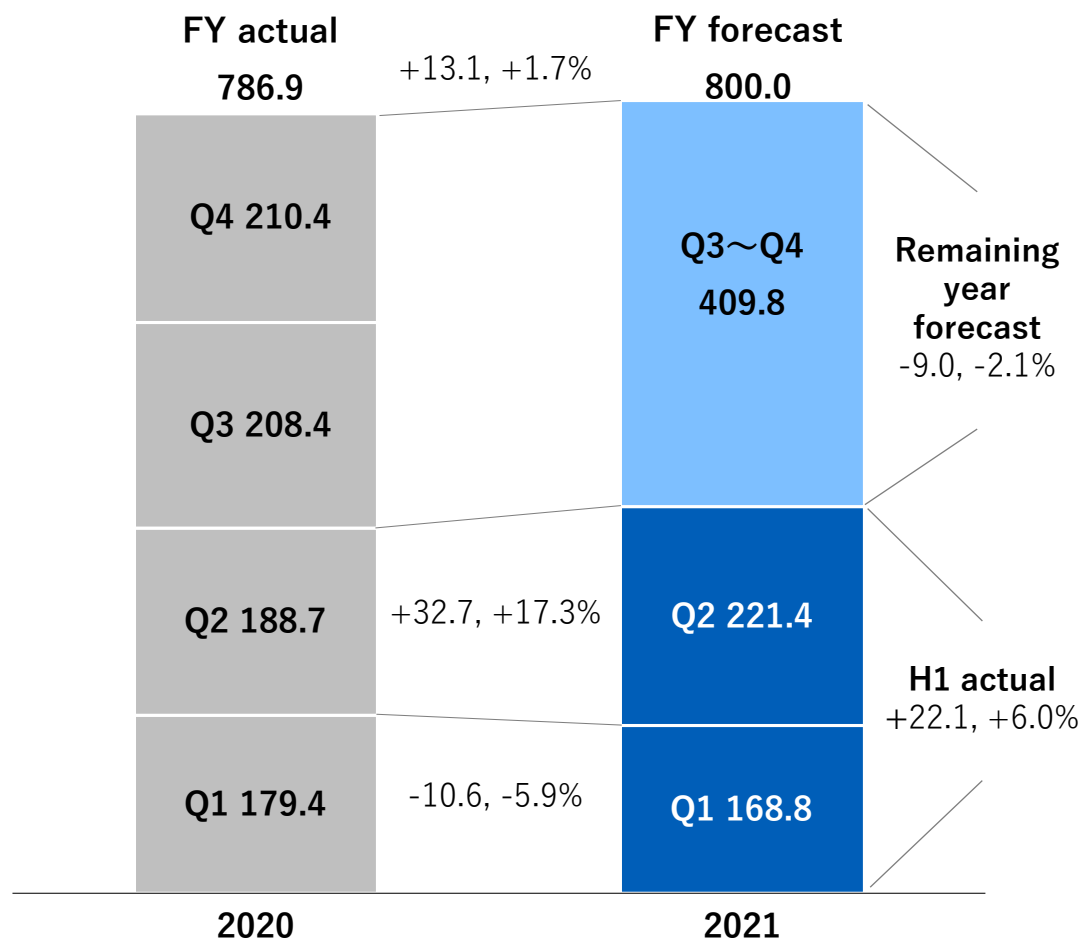
*1 Jan – Jun progress versus Jan – Dec

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

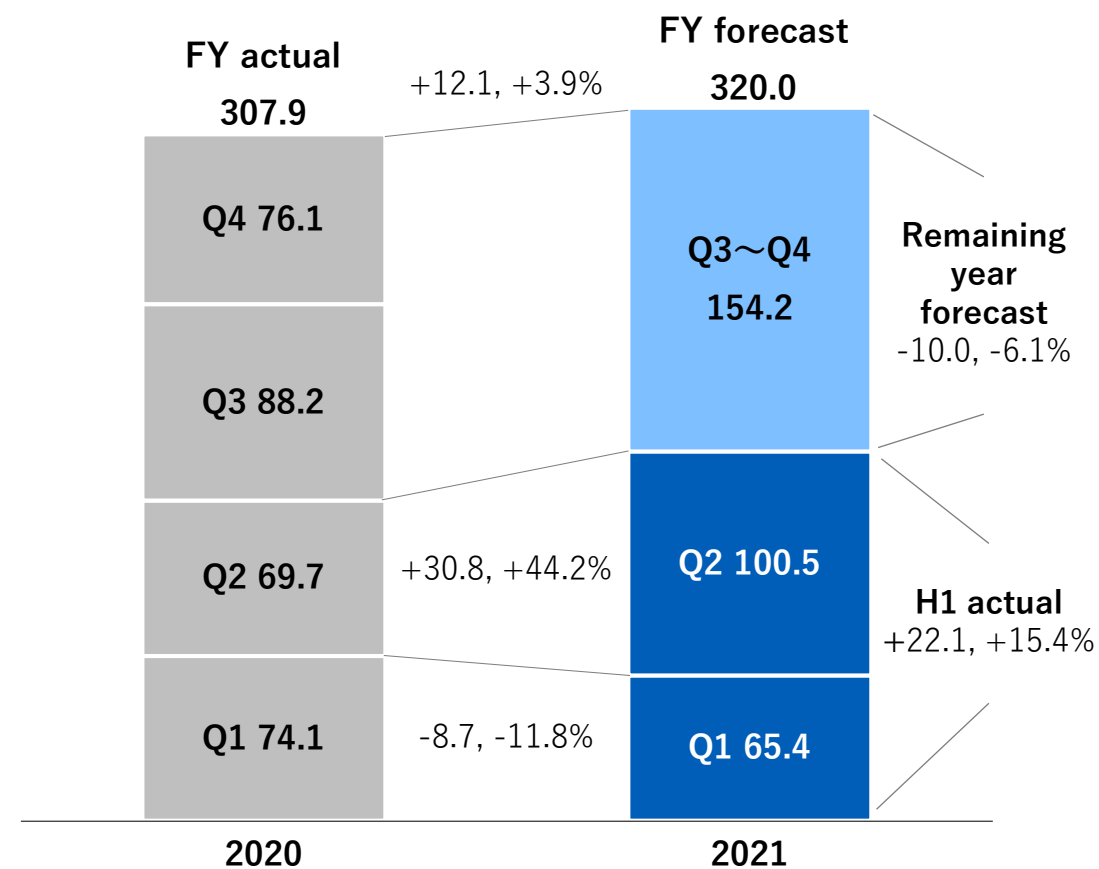
H1 Actual and Remaining Year Forecast (Year on Year)

(billions of JPY)

<Revenues>



<Operating profit>



Sales Jan - Jun (vs. Forecast)

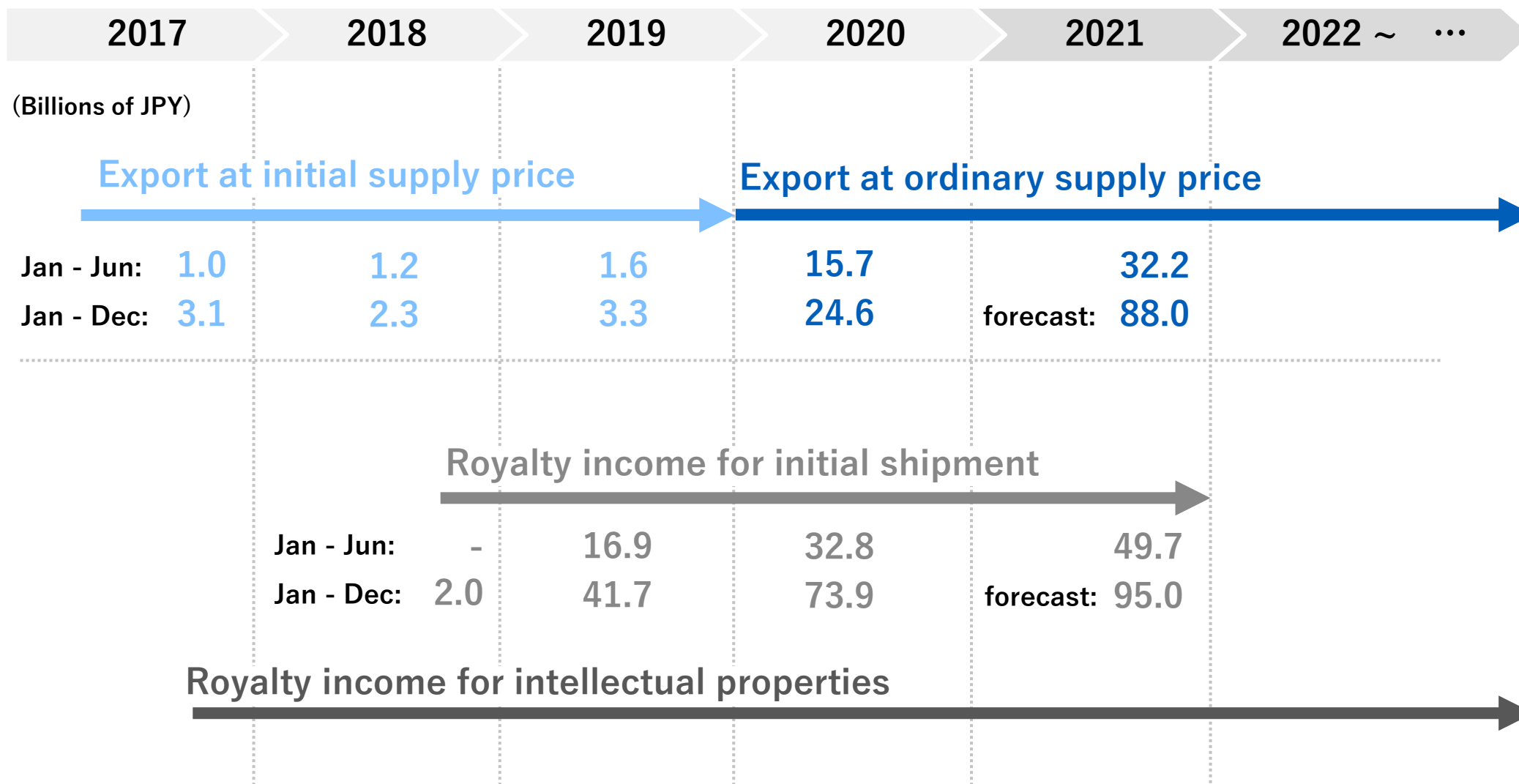
(Billions of JPY)	Actual	Forecast		2020
	2021 Jan - Jun	2021 Jan - Dec	Progress	Progress *
Sales	304.1	631.0	48.2%	48.3%
Domestic	203.4	393.7	51.7%	50.0%
Oncology	124.1	226.7	54.7%	48.8%
Avastin	39.2	60.5	64.8%	49.9%
Tecentriq	30.5	49.2	62.0%	44.3%
Perjeta	15.7	31.8	49.4%	49.9%
Alecensa	13.1	27.0	48.5%	47.3%
Kadcyla	7.2	13.3	54.1%	45.1%
Herceptin	5.2	10.9	47.7%	54.1%
Gazyva	2.1	5.7	36.8%	45.7%
Rituxan	2.4	5.2	46.2%	51.4%
Polivy	0.9	3.5	25.7%	-
Xeloda	1.3	2.7	48.1%	55.6%
Rozlytrek	0.4	0.9	44.4%	25.0%
Foundation Medicine	2.2	7.2	30.6%	42.9%
Other	4.1	8.7	47.1%	53.8%

(Billions of JPY)	Actual	Forecast		2020
	2021 Jan - Jun	2021 Jan - Dec	Progress	Progress *
Primary	79.3	167.0	47.5%	51.6%
Hemlibra	18.7	51.7	36.2%	47.2%
Actemra	20.3	38.5	52.7%	48.6%
Edirol	7.6	17.3	43.9%	65.8%
Mircera	7.1	11.7	60.7%	48.6%
Bonviva	4.1	8.5	48.2%	47.2%
CellCept	4.1	8.3	49.4%	49.5%
Oxarol	3.0	5.5	54.5%	48.4%
Enspryng	3.5	4.0	87.5%	0.0%
Tamiflu(Ordinary use)	-0.1	0.8	-12.5%	87.5%
Tamiflu(Govt. stockpiles, etc.)	1.2	1.2	100.0%	70.3%
Other	9.9	19.6	50.5%	50.9%
Overseas	100.7	237.3	42.4%	45.0%
Hemlibra	33.2	89.7	37.0%	62.8%
Actemra	37.9	85.3	44.4%	45.1%
Alecensa	21.1	44.2	47.7%	37.9%
Enspryng	0.9	3.9	23.1%	7.1%
Neutrogin	4.8	8.7	55.2%	50.0%
Other	3.0	5.4	55.6%	45.8%

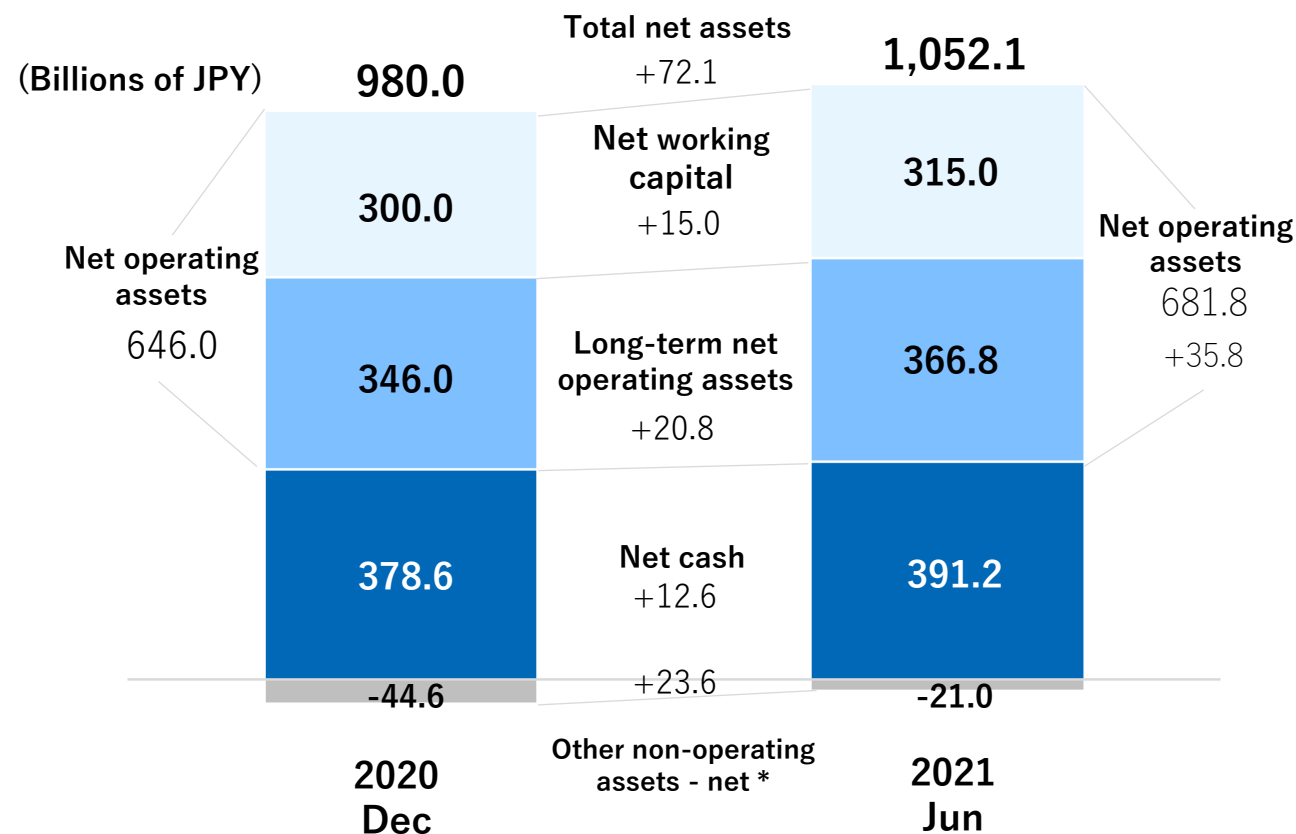
* Jan - Jun progress versus Jan - Dec

Outline of Hemlibra Sales to Roche

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



Financial Position (vs. 2020 Year End)



Increase in net working capital

Increase mainly in inventories

Increase in long-term net operating assets

Increase mainly in property, plant and equipment

Increase in net cash

(Please refer to the next slide)

Increase in other non-operating assets – net

Decrease in current income tax liabilities

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

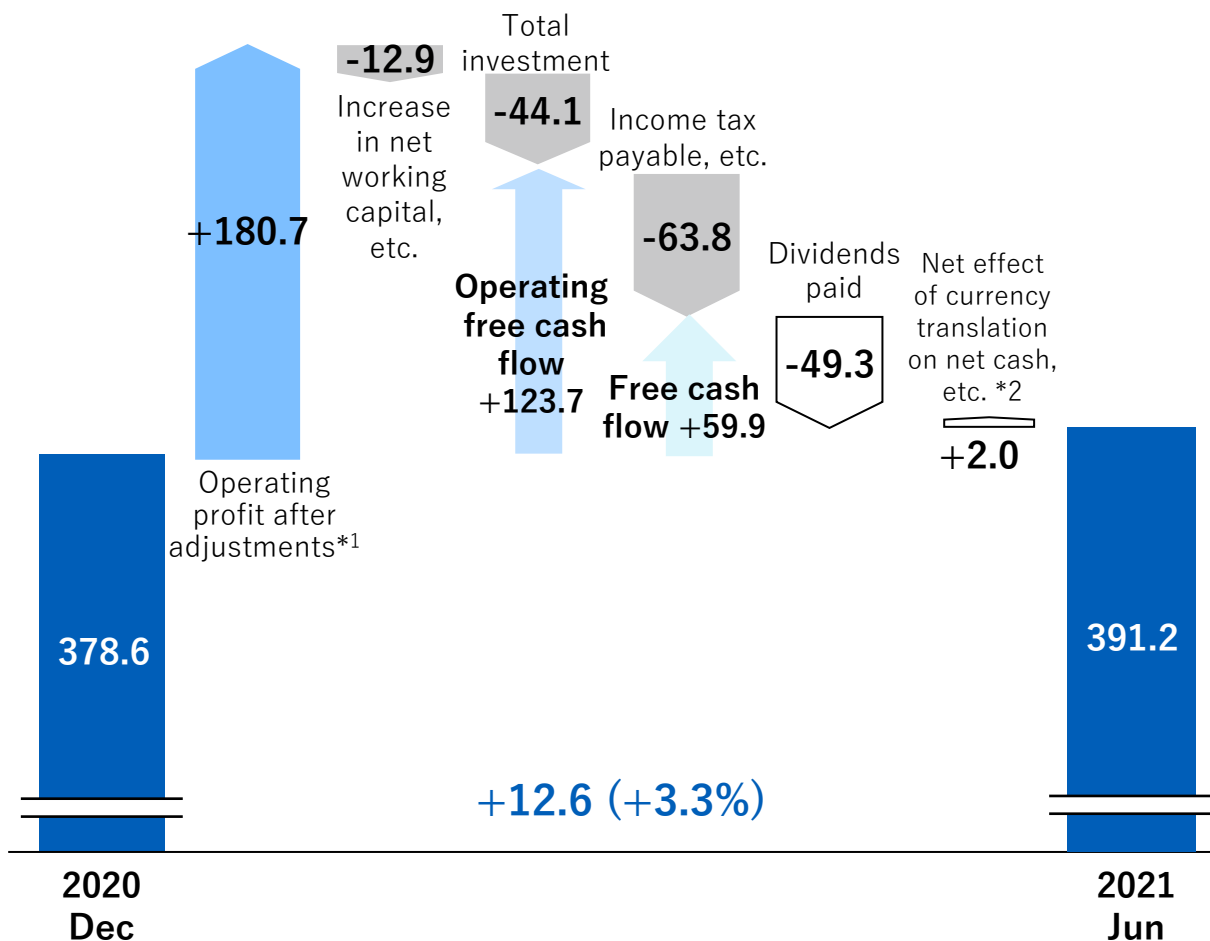
Total assets	1,235.5	+40.3	1,275.8
Total liabilities	-255.5	+31.8	-223.7
Total net assets	980.0	+72.1	1,052.1
Ratio of equity attributable to Chugai shareholders	79.3%	+3.2%pts	82.5%

FX rate to the JPY (end of period)

	2020 Actual	2021 Actual
1CHF	117.10	120.02
1EUR	126.89	131.48
1USD	103.19	110.52

Net Cash (vs. 2020 Year End)

(Billions of JPY)



Operating profit after adjustment *1	+180.7
Operating profit *1	+160.7
Depreciation, amortization and impairment *1	+17.3
Decrease in net working capital, etc.	-12.9
Total investment	-44.1
Property, plant and equipment	-35.4
Payment for lease liabilities	-4.3
Intangible assets	-4.4
Operating free cash flow	+123.7
Income tax payable, etc.	-63.8
Income tax payable	-64.3
Free cash flow	+59.9
Dividends paid	-49.3
End of FY 2020	-49.3
Net effect of currency translation on net cash, etc. *2	+2.0

*1 Including Non-Core (IFRS results)

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

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

Current Status / Plan for Major Investments



Production

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

2019-22: 19.1 billion JPY (13.0 billion JPY)

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

2021-24: 55.5 billion JPY (0.4 billion JPY)

Research and development

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

2012-21: 476 million SGD (390 million SGD), incl. capital investments of 61 million SGD (67 million SGD)

2022-26: 282 million SGD, incl. capital investments of 21 million SGD

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

Purchase of business site 2016-18: 43.0 billion JPY

Construction of laboratory 2019-22: 128.8 billion JPY (85.7 billion JPY)

Ukima Research Laboratories: Construction of a new synthetic research building for strengthening the process

development function of small- and middle-molecule active pharmaceutical ingredients

2018-20: 4.5 billion JPY (4.3 billion JPY)

Comprehensive collaboration in research activity with **IFReC**

2017-27: 10.0 billion JPY (5.1 billion JPY)

Appendix

IFRS and Core Results Jan - Jun

(Billions of JPY)	IFRS results	Non-core items		Core results
		Intangible assets	Others	
Revenues	390.2			390.2
Sales	304.1			304.1
Royalties and other operating income	86.1			86.1
Cost of sales	-123.4	+1.5		-121.9
Operating expenses	-106.2	+1.6	+2.0	-102.5
M&D and G&A	-42.9		+0.2	-42.7
Research and development	-63.3	+1.6	+1.9	-59.9
Operating profit	160.7	+3.1	+2.0	165.8
Financial account balance	0.6			0.6
Income taxes	-43.1	-0.9	-0.6	-44.7
Net income	118.1	+2.2	+1.4	121.7
EPS (JPY)	71.81			73.99

Non-Core items

(Billions of JPY)

Intangible assets

Amortization	+1.5
Impairment	+1.6

Others

Restructuring expenses, etc.	+2.0
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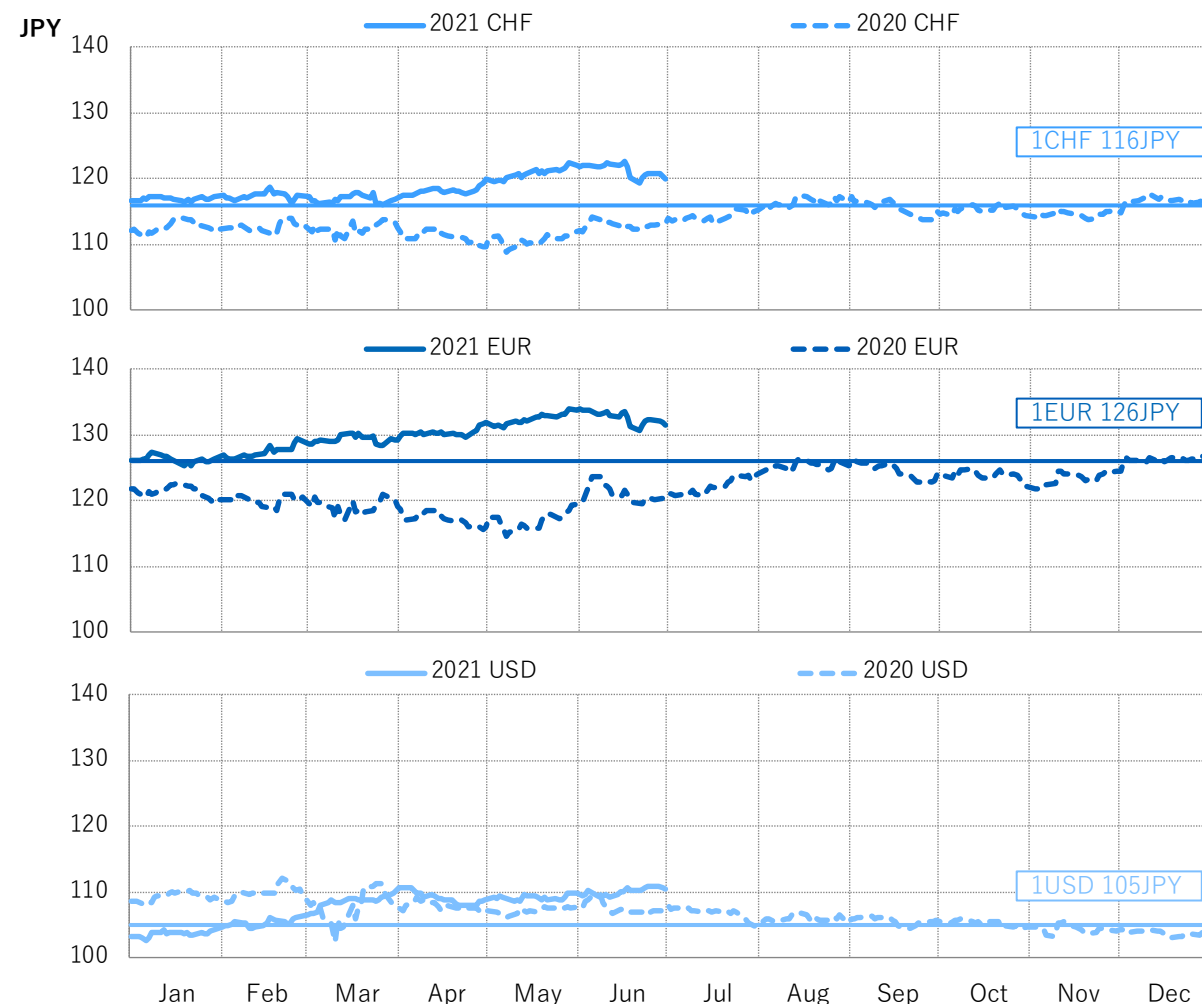
Impact from Foreign Exchange (vs. Forecast)

(billions of JPY)	FX impact 2021 (FX impact vs. Assumption)	
Revenues	Sales	+0.1
	Royalties and other operating income	+0.7
Cost of sales & Operating expenses	Cost of sales	-0.0
	Operating expenses	-0.7
Operating profit	+0.1	

Market average exchange rate(JPY)	2020 Actual	2021 Assumption	2021 Actual
1CHF	112.07	116.00	118.60
1EUR	119.27	126.00	129.76
1USD	108.28	105.00	107.63

Historical exchange rate to the JPY

Assumption rate (2021)



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

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

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

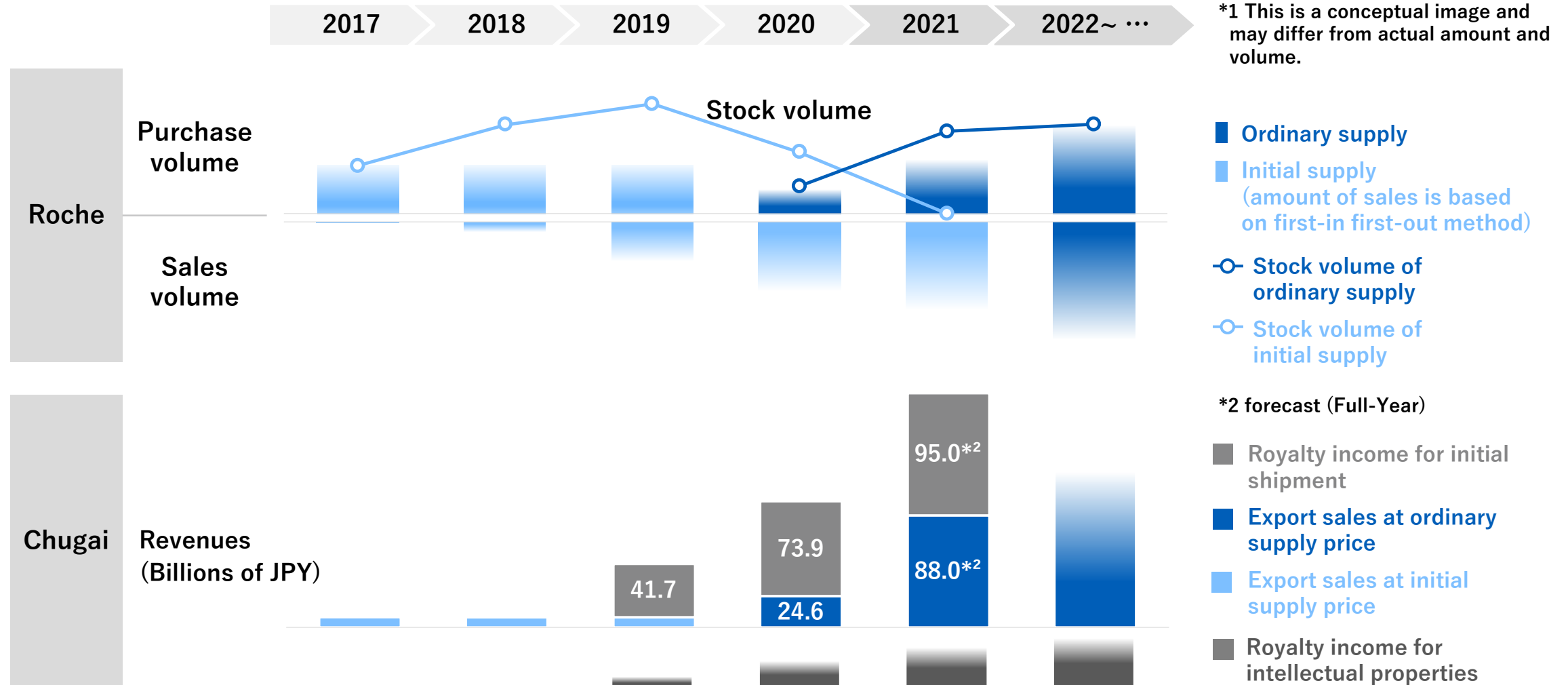
*2 Main co-promotion countries are as follows:

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

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

Outline of Hemlibra Sales to Roche

Image for Timing of Export Sales and Royalty Income*1



Overview of Development Pipeline

Tetsuya Yamaguchi

Senior Vice President, Head of Project & Lifecycle Management Unit

Q2 Topics (1)



As of July 26, 2021

launch	Polivy	r/ r DLBCL	May
	Ronapreve (Antibody Cocktail)	COVID-19	July
approved	Enspryng	NMOSD (EU)	June
	Evrysdi	SMA	June
	Cellcept	GVHD in hematopoietic stem-cell transplantation	June
	FoundationOne Liquid CDx ¹	olaparib: prostate cancer (<i>BRCA1/2</i> alterations)	May
	FoundationOne CDx ²	nivolumab: MSI-High colorectal cancer	June
filed		pembrolizumab: MSI-High tumors	June
	Faricimab	DME/nAMD	June
	Tecentriq	NSCLC [adjuvant]	July
	Herceptin	HER 2 positive salivary gland cancer	April
	Perjeta / Herceptin	HER 2 positive colorectal cancer	April
	FoundationOne CDx ²	pembrolizumab: TMB-High tumors	May

Letters in orange: in-house projects

Letters in blue: in-licensed (Roche)

r/r: relapsed/refractory, DLBCL: diffuse large B-cell lymphoma, NMOSD: neuromyelitis optica spectrum disorder, SMA: spinal muscular atrophy, GVHD: graft-versus-host disease, MSI: microsatellite instability, DME: diabetic macular edema, nAMD: neovascular age-related macular degeneration, NSCLC: non-small cell lung cancer, TMB: tumor mutational burden

1: FoundationOne Liquid CDx Cancer Genomic Profile

2: FoundationOne CDx Cancer Genomic Profile

Q2 Topics (2)



As of July 26, 2021

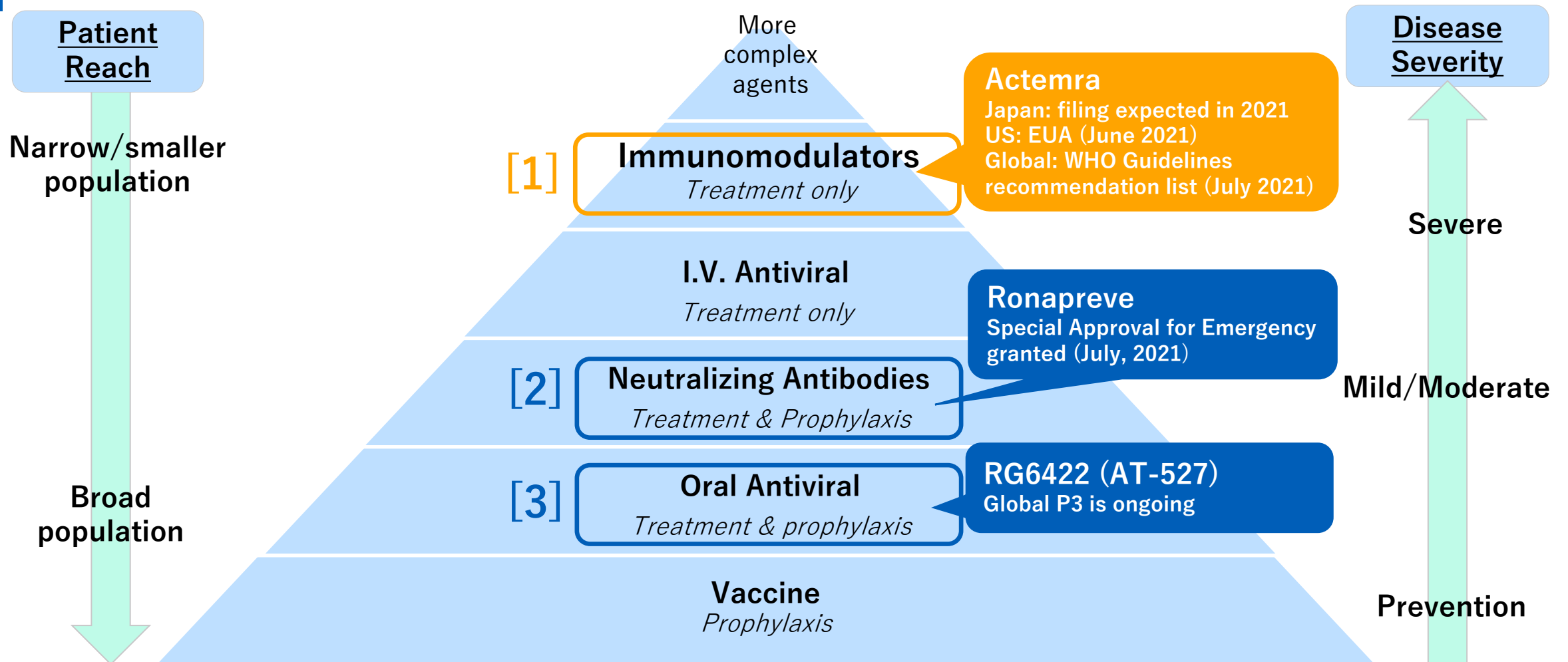
Initiation of study	Tecentriq	Muscle-invasive bladder cancer [adjuvant] (ctDNA positive)	P3 study (IMvigor011)(May)
		HCC [2nd line] (in combination with TKI)	P3 study (IMbrave251)(April)
	RG6422 (AT-527)	COVID-19	P3 study (April)
	ERY974	HCC (in combination with Tecentriq + Avastin)	P1 study (June)
	SOF10 (RG6440)	Solid tumors	P1 study (June)
	RG7992	Non-alcoholic steatohepatitis	P1 study (June)
	RG6102 (Brain Shuttle Gantenerumab)	Alzheimer's disease	P1 study (July)
	RG6396 (pralsetinib)	Solid tumors	P1 study (July)
BTD	VS-6766 (CKI27)	Recurrent low-grade serous ovarian cancer*	May
License-out	EOS789	Option and license agreement (Alebund Pharmaceuticals)	July
Removed from pipeline	ipatasertib	Breast cancer	P3 study (IPATunity150)
Medical conference	Tecentriq	IMpower010 interim analysis	American Society of Clinical Oncology (June)
Others	Actemra	COVID-19 (US EUA/WHO Guidelines recommendation list)	June/July
	License agreement	Alaglio (photodynamic diagnostic agent)	Terminate agreement (SBI Pharm)
	Joint research	Antibody-drug against COVID-19	Ended joint research (A*STAR)

Letters in orange: in-house projects
Letters in blue: in-licensed (Roche)

ctDNA: circulating tumor DNA, HCC: hepatocellular carcinoma, TKI: tyrosine kinase inhibitor, EUA: emergency use authorization
* In combination with FAK inhibitor.

Overview of COVID-19 Treatment Pathway

Clinical trials have been conducted in Japan for 3 products; Actemra, Ronapreve and AT-527



RONAPREVE: Antibody Cocktail

- The world's first regulatory approved treatment granted under Special Approval for Emergency as the first treatment for mild to moderate COVID-19 in Japan
- P3 study in mild to moderate I COVID-19 showed Ronapreve decreased hospitalization or death, and symptom duration
- Retain activity against emerging variants identified so far

severity	oxygen saturation	clinical condition
mild	96% or above	no pneumonia
moderate I	below 96% 93% or above	pneumonia dyspnea
moderate II	below 93%	oxygen therapy
severe		ECMO at the ICU setting

Medical guidance for COVID-19 Version 5.1 (MHLW)

Key results from REGN-COV 2067 study (P3)

	1,200 mg IV	placebo
	n=736	n=748
Patients with ≥ 1 COVID-19-related hospitalization or death through day 29		
Risk reduction	70% (p=0.0024)	
Number of patients with events	7 (1.0%)	24 (3.2%)
Time to COVID-19 symptom resolution		
Median (days)	10	14
Median reduction (days)	4 (p<0.0001)	

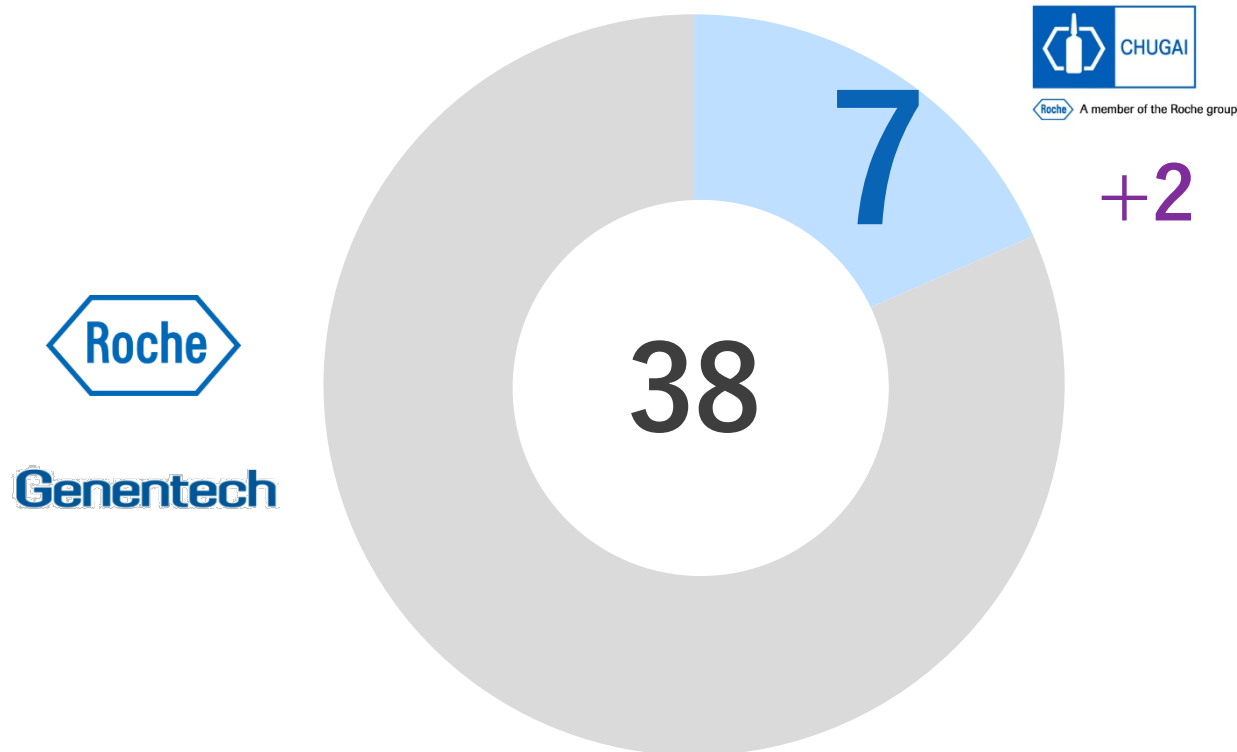
variant	activity
(α) detected in UK	no change
(β) detected in South Africa	no change
(γ) detected in Brazil	no change
(ϵ) detected in California	no change
(ι) detected in New York	no change
(δ / κ) detected in India	no change

Data from pre-clinical study conducted by Regeneron

Creation of Innovative Drugs

9 indications / 6 projects in in-house projects have been granted US BTB

Chugai originated products account for about 20 percent of Roche group's BTB products



year	product	indication
2021	VS-6766 (CKI27)*	recurrent LGSOC under development at Verastem Oncology
2019	nemolizumab	Prurigo nodularis under development at Galderma
2018	Enspryng	NMOSD
	Hemlibra	Hemophilia A (non-inhibitor)
2016	Actemra	giant cell arteritis
	Alecensa	ALK positive NSCLC [1st line]
2015	Actemra	Systemic sclerosis
	Hemlibra	Hemophilia A (inhibitor)
2013	Alecensa	ALK positive NSCLC [2nd line]

*in combination with FAK inhibitor (defactinib)

Major Licensed-out Projects

CKI27 and OWL833 made good progress

As of July 26, 2021

Development code Chugai/generic name (Partner code)	Licensee	Indication	Stage	Mode of Action	Progress
CKI27 (VS-6766)	Verastem Oncology	LGSOC	Global: P2	RAF/MEK inhibitor	• US FDA BTD★ (recurrent GSOC, in combination with defactinib)
		NSCLC			-
CIM331/ nemolizumab	Global (Galderma) Japan (Maruho)	Atopic dermatitis	Global: P3	Anti-IL-31 receptor A humanized monoclonal antibody	-
			Japan: filed		• Filed in Q3 2020 (Japan)
		Prurigo Nodularis	Global: P3		• US FDA BTD
			Japan: P2/3		-
OWL833 (LY3502970)	Eli Lilly and Company	Type 2 diabetes	Global: P1	Oral non-peptidic GLP-1 receptor agonist	<ul style="list-style-type: none"> • Results of P1a were presented at ADA2021★ - Clinical data support once-daily dosing with no food or water restrictions. • 12-week proof-of-concept study in patients with type 2 diabetes is ongoing★ • Potential for Phase 2 initiation in late 2021/early 2022★

SOF10 / RG6440 (Anti-latent TGF- β 1 monoclonal antibody)

Expected to improve response in the segment where cancer immunotherapy do not respond

● TGF- β 1

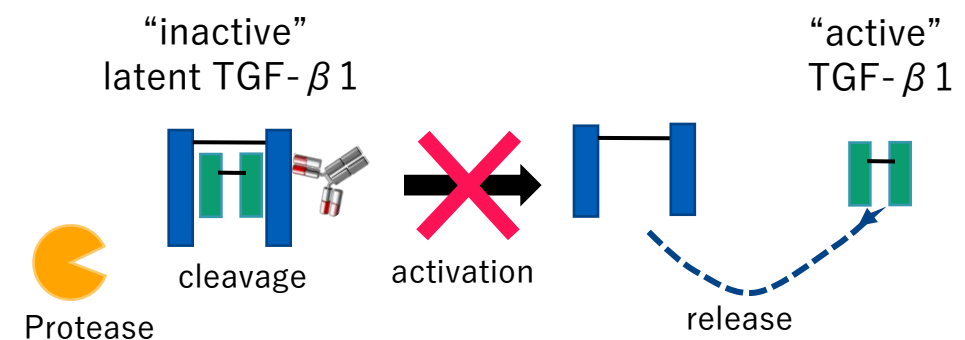
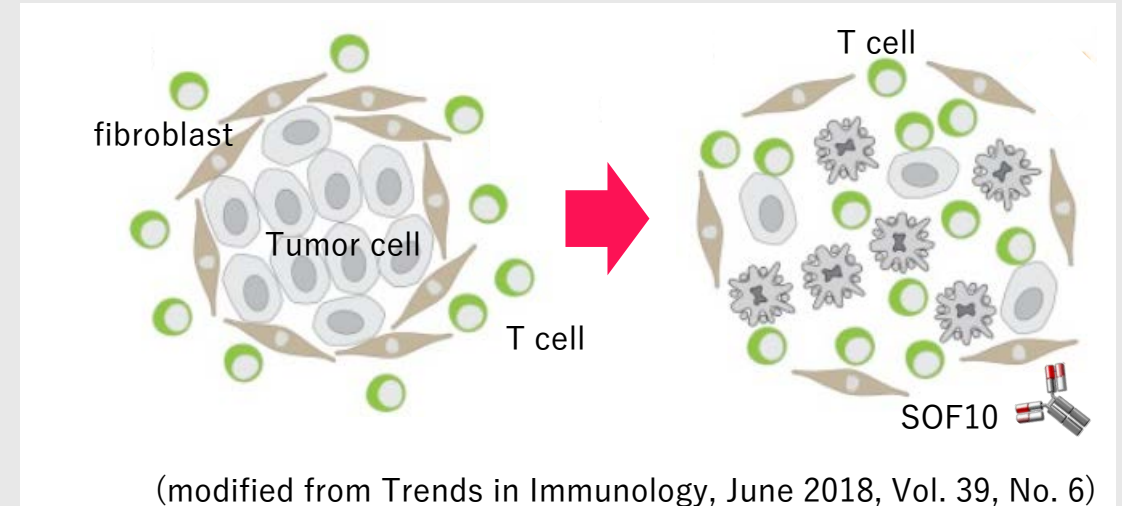
- ✓ Known as a key regulator of tumor microenvironment which forms a physical barrier for T cell infiltration.
- ✓ Expressed as inactive latent TGF- β 1, and then transformed into active TGF- β 1 by protease or via integrin and released

● SOF10

- ✓ Modified humanized monoclonal IgG1 antibody
- ✓ Bind to latent TGF- β 1 and inhibit the activation
- ✓ Due to the risk of toxicity* caused by Pan-TGF- β inhibition, we targeted the inhibition of latent TGF- β 1 activation via protease

*It is known in the literature that mice that inhibit the integrin pathway show inflammatory changes in multiple organs

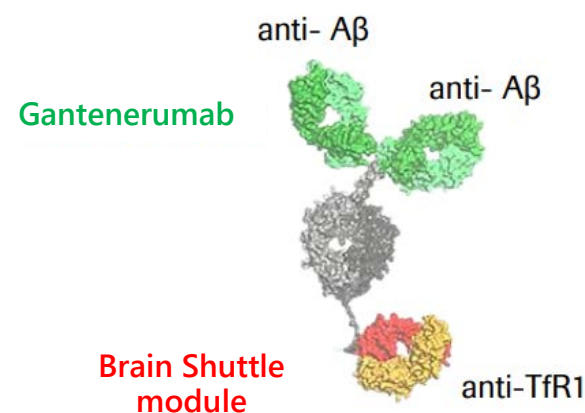
- ✓ By changing the immunosuppressive tumor microenvironment, such as developing fibrosis of tumor tissue, an anti-tumor effect is expected against cancers where anti-cancer drugs do not respond



Brain Shuttle Gantenerumab / RG6102

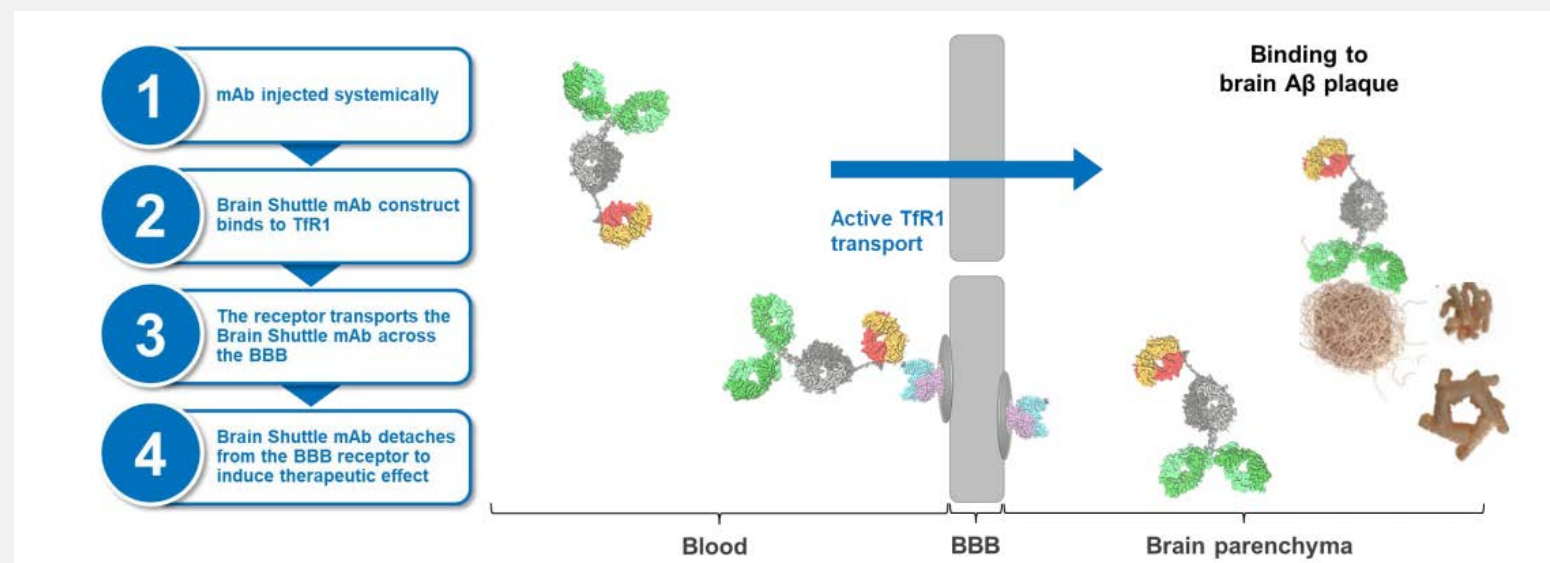
Potential for superior A β clearance in brain to delay progression of Alzheimer's disease

Anti-A β -TfR1 fusion protein



- Gantenerumab with a novel transferrin receptor (TfR1) binding Ab moiety to achieve efficient transport over the BBB and target A β engagement in the brain
- Brain shuttle technology could also be applied to other CNS disorders

Superior brain access through brain shuttle technology



Mechanism and evidences of Brain Shuttle Gantenerumab

- Microglia-mediated clearance of amyloid beta plaques in the brain
- Brain penetration is greatly enhanced through transferrin receptor-mediated transport across the BBB
- Preclinical work provides in vitro and in vivo evidence that binding to the TfR1 receptor facilitates transcellular transport across the BBB
- Phase 1 study in healthy subjects in overseas resulted in increase CSF/plasma ratio compared with gantenerumab alone

Tecentriq: IMpower010 Interim Analysis

First cancer immunotherapy which shows efficacy in adjuvant NSCLC

- Filed for adjuvant non-small cell lung cancer (July 2021)

Primary endpoint: DFS / OS

- Reduced the risk of disease recurrence or death (disease-free survival; DFS) by 34% (stratified log-rank p value =0.004; hazard ratio [HR]=0.66, 95% CI: 0.50–0.88) in randomized people with Stage II-IIIa non-small cell lung cancer (NSCLC), whose tumors express PD-L1 \geq 1%, compared with best supportive care (BSC)
- Reduced the risk of disease recurrence or death by 21% (stratified log-rank p value =0.02; HR=0.79, 95% CI: 0.64–0.96) in randomized Stage II-IIIa study participants
- Safety for Tecentriq was consistent with its known safety profile and no new safety signals were identified

Subgroup analysis: DFS <randomized Stage II-IIIa study participants>

- Decreased the risk of recurrence and death in PD-L1 TC \geq 50% population, compared with TC \geq 1% population (HR: 0.43, 95%CI: 0.27-0.68)
- Tecentriq did not show statistical significance in TC<1% population, compared with BSC

TC: tumor cells

Market Potential of Post PoC Projects

In-house project	★★★ Global (local) over 200 billion yen	★★ Global (local) over 100 billion yen	★ Global (local) below 100 billion yen
	<ul style="list-style-type: none"> • Enspryng • nemolizumab* 	<ul style="list-style-type: none"> • crovalimab 	-
In-licensed (Roche)	★★★ Domestic over 30 billion yen	★★ Domestic over 15 billion yen	★ Domestic below 15 billion yen
	<ul style="list-style-type: none"> • Tecentriq • Polivy • faricimab 	<ul style="list-style-type: none"> • gantenerumab • tiragolumab 	<ul style="list-style-type: none"> • Gazyva • Evrysdi • ipatasertib

NOTE: In addition to additional indications currently shown in the development pipeline, expected indications in the future are also considered
 *licensed out to Galderma (global) and Maruho (domestic) respectively. Based on the forecasts by Galderma and Maruho

Projected Submissions

(Post PoC NMEs and Products)

NME

Line extension

in-house

in-licensed (Roche)

Others



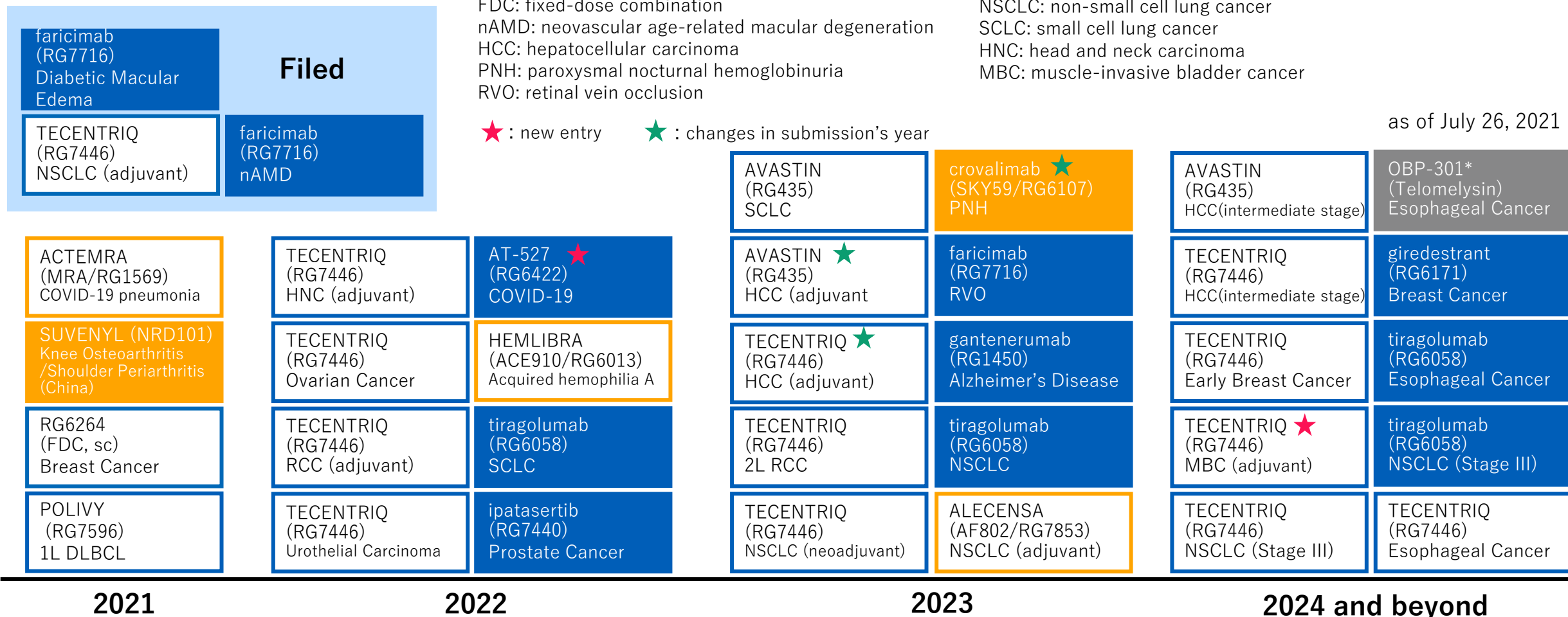
DLBCL: diffuse large B-cell lymphoma
FDC: fixed-dose combination
nAMD: neovascular age-related macular degeneration
HCC: hepatocellular carcinoma
PNH: paroxysmal nocturnal hemoglobinuria
RVO: retinal vein occlusion

RCC: renal cell carcinoma
NSCLC: non-small cell lung cancer
SCLC: small cell lung cancer
HNC: head and neck carcinoma
MBC: muscle-invasive bladder cancer

as of July 26, 2021

★ : new entry

★ : changes in submission's year



Projects under Development (1)

As of July 26, 2021

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

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

★: Projects with advances in stages since April 22, 2021

Letters in orange: in-house projects

Letters in blue: in-licensed (Roche)

*in-licensed (Oncolys BioPharma Inc.)

DLBCL: diffuse large B-cell lymphoma

HCC: hepatocellular carcinoma

SCLC: small cell lung cancer

RCC: renal cell carcinoma

NSCLC: non-small cell lung cancer

HNC: head and neck carcinoma

MIBC: muscle-invasive bladder cancer

TDB: T cell-dependent bispecific

Projects under Development (2)

As of July 26, 2021

	Phase I	Phase II	Phase III	Filed
Bone & Joint			NRD101 / Suvenyl (China) - knee osteoarthritis /shoulder peri arthritis	
Autoimmune	RG7880 (IL-22 fusion protein) - inflammatory bowel disease			
Neurology	RG7935 / prasinezumab - Parkinson's disease GYM329 (RG6237) - neuromuscular disease RG6100 / semorinemab - Alzheimer's disease RG6102 - Alzheimer's disease ★	RG7906 / ralmitaront - schizophrenia	RG1450 / gantenerumab - Alzheimer's disease RG6042 / tominersen - Huntington's disease	
Others	PCO371 - hypoparathyroidism AMY109 - endometriosis NXT007 - hemophilia A (PI/II) RG7992 - non-alcoholic steatohepatitis ★		RG7716 / faricimab - retinal vein occlusion MRA (RG1569) / Actemra (JPN) - COVID-19 pneumonia ACE910 (RG6013) / Hemlibra (JPN) - Acquired hemophilia A SKY59 (RG6107) / crovalimab - PNH RG6422 - COVID-19 ★	RG7716 / faricimab - DME ★ - nAMD ★

Letters in orange: in-house projects

Letters in blue: in-licensed (Roche)

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

★: Projects with advances in stages since April 22, 2021

PNH: paroxysmal nocturnal hemoglobinuria

nAMD: neovascular age-related macular degeneration

DME: diabetic macular edema

FoundationOne CDx Cancer Genomic Profile

Companion diagnostic indications

As of July 26, 2021

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

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

FoundationOne Liquid CDx Cancer Genomic Profile

Companion diagnostic indications

As of July 26, 2021

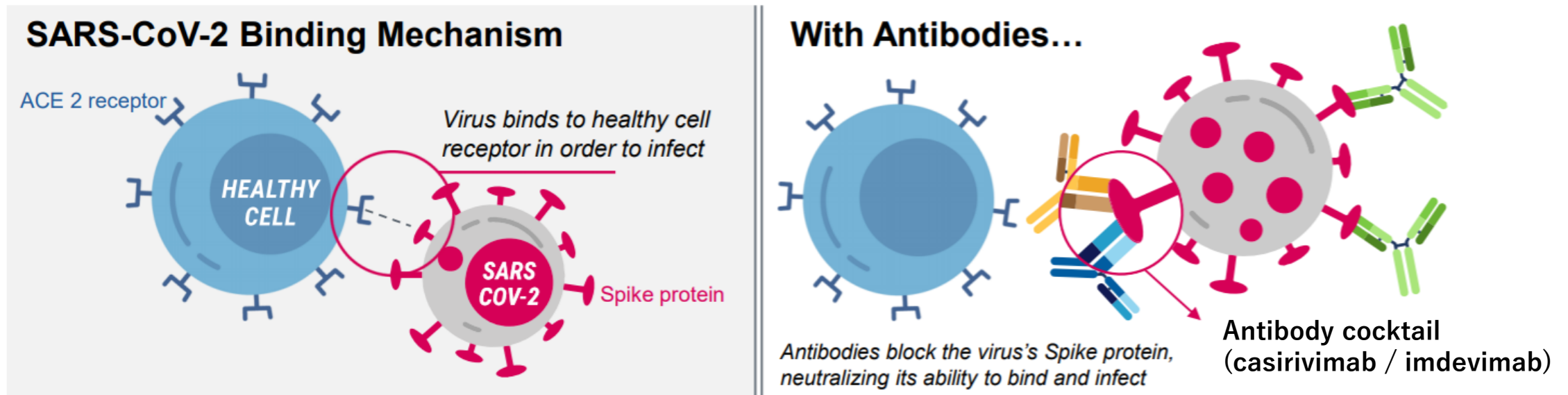
Alterations	Cancer type	Relevant drugs
Activated <i>EGFR</i> gene alterations	Non-small cell lung cancer (NSCLC)	afatinib dimaleate, erlotinib hydrochloride, gefitinib, osimertinib mesylate
<i>EGFR</i> exon 20 T790M alterations		osimertinib mesylate
<i>ALK</i> fusion genes		alectinib hydrochloride, crizotinib,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

Appendix

RONAPREVE : Anti-SARS-CoV-2 Monoclonal Antibody

SARS-CoV-2 binding mechanism and MoA of the antibody cocktail

Materials presented at the Regeneron IR call on 6 November 2020



- Two potent, virus-neutralizing Abs (nAb, casirivimab and imdevimab) binding non-competitively to the critical receptor-binding domain of the virus' spike protein
- Non-competitive binding to the receptor binding site of the viral spike protein was thought to show neutralizing activity against SARS-CoV-2, including viral strains with mutations in the spike protein generated in the human population (*in vitro*) *

* A. Baum et al., Science 10.1126/science.abd0831 (2020); In collaboration with Regeneron

RONAPREVE : Anti-SARS-CoV-2 Monoclonal Antibody

Results of overseas phase III study (COV-2067 study) for outpatients with aggravation risk factors

● Study design

- ✓ Phase I / II / III, placebo-controlled, randomized, double-blind, parallel-group comparative study for the purpose of evaluating the efficacy, safety, and tolerability of a single intravenous infusion of RONAPREVE in patients aged 18 years or older with SARS-CoV-2 infection.
- ✓ Eligible subjects of Phase III part: Patients with SARS-CoV-2 infection with aggravation risk factor* and oxygen saturation of 93% (room air) or higher
- ✓ Primary endpoint: Percentage of subjects with SARS-CoV-2 infection-related hospitalization or death (event) for any reason up to 29 days after randomization

Efficacy against infections caused by SARS-CoV-2 (Phase III part)

	RONAPREVE group**	Placebo group
mFAS *** Population	736	748
Risk reduction rate of SARS-CoV-2 infection-related hospitalization or death for any reason up to 29 days after randomization	70.4% (95% confidence interval: 31.6%-87.1%) (Cochran-Mantel-Haenszel test, p=0.0024)	
Number of patients with events	7 (1.0%)	24 (3.2%)

* Over 50 years old, obesity, cardiovascular disease, chronic lung disease, diabetes, chronic kidney disease, chronic liver disease, immunosuppressive state

** RONAPREVE group: casirivimab 600mg and imdevimab 600mg combination administration group

***mFAS: Patient population with a positive SARS-CoV-2 RT-qPCR test from nasopharyngeal swabs at baseline

**** Population for safety analysis with or without aggravation risk factors

Occurrence of adverse events (Phase III part)

	RONAPREVE group**	Placebo group
Number of safety analysis populations ****	827	1843
Serious adverse events	1.1% (9/827)	4.0% (74/1843)
Infusion reaction	0.2% (2/827)	0
Hypersensitivity reaction	0	Less than 0.1% (1/1843)
Adverse events leading to medical institution consultation (not related to SARS-CoV-2 infection)	0	0.3% (5/1843)
Adverse events leading to medical institution consultation (related to SARS-CoV-2 infection)	1.8% (15/827)	2.6% (47/1843)

RONAPREVE : Anti-SARS-CoV-2 Monoclonal Antibody

Obtained Special Approval for Emergency as the first treatment for mild to moderate COVID-19

Package insert information

- Product name: RONAPREVE for Intravenous Infusion Set 300/1332
- Generic name: casirivimab (genetical recombination)/imdevimab (genetical recombination)
- Indications: SARS-CoV-2 infection
- Dosage and administration: The usual dose for adults and children aged 12 years and older and weighing 40 kg or more is 600 mg casirivimab (genetical recombination) and 600 mg imdevimab (genetical recombination) given as a single intravenous dose
- Effect on mutant variants: Non-clinical pharmacological studies suggest retention of neutralizing activity
 - ✓ mutant variants : alpha, beta, gamma, delta, epsilon, zeta, eta, theta, iota, kappa
 - * The efficacy may not be expected for SARS-CoV-2 mutant variants with low neutralizing activity of this drug.

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INNOVATION BEYOND IMAGINATION