



CHUGAI

TOP INNOVATOR
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Roche Group

Q1 Results (Jan - Mar 2021) Conference Call

CHUGAI PHARMACEUTICAL CO., LTD.

22 April 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

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Dr. Osamu Okuda

President & CEO

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Toshiaki Itagaki

Executive Vice President & CFO

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Tetsuya Yamaguchi

Senior Vice President, Head of Project & Lifecycle Management Unit

FY2021 Q1 Overview

Dr. Osamu Okuda

President & CEO

Financial Overview

- YoY decrease in revenues and profits due to NHI drug price revision and timing of exports to Roche, etc., but the progress was in line with the initial forecast
- No change in outlook for earnings growth from April, and expect increase in revenues and profits as initially forecasted

Core (billions of JPY)	2020	2021	Growth		2021	Progress (%)
	Jan -Mar actual	Jan -Mar actual			Jan - Dec forecast	
Revenues	179.4	168.8	-10.6	-5.9%	800.0	21.1%
Domestic sales	101.9	94.9	-7.0	-6.9%	393.7	24.1%
Overseas sales	42.6	35.4	-7.2	-16.9%	237.3	14.9%
ROOI	34.9	38.6	+3.7	+10.6%	169.0	22.8%
Operating profit	74.1	65.4	-8.7	-11.7%	320.0	20.4%
Operating margin	41.3%	38.7%	-2.6%pts		40.0%	-
Net income	52.7	48.4	-4.3	-8.2%	232.0	20.9%
EPS (yen)*	32.04	29.42	-2.62	-8.2%	141.00	20.9%

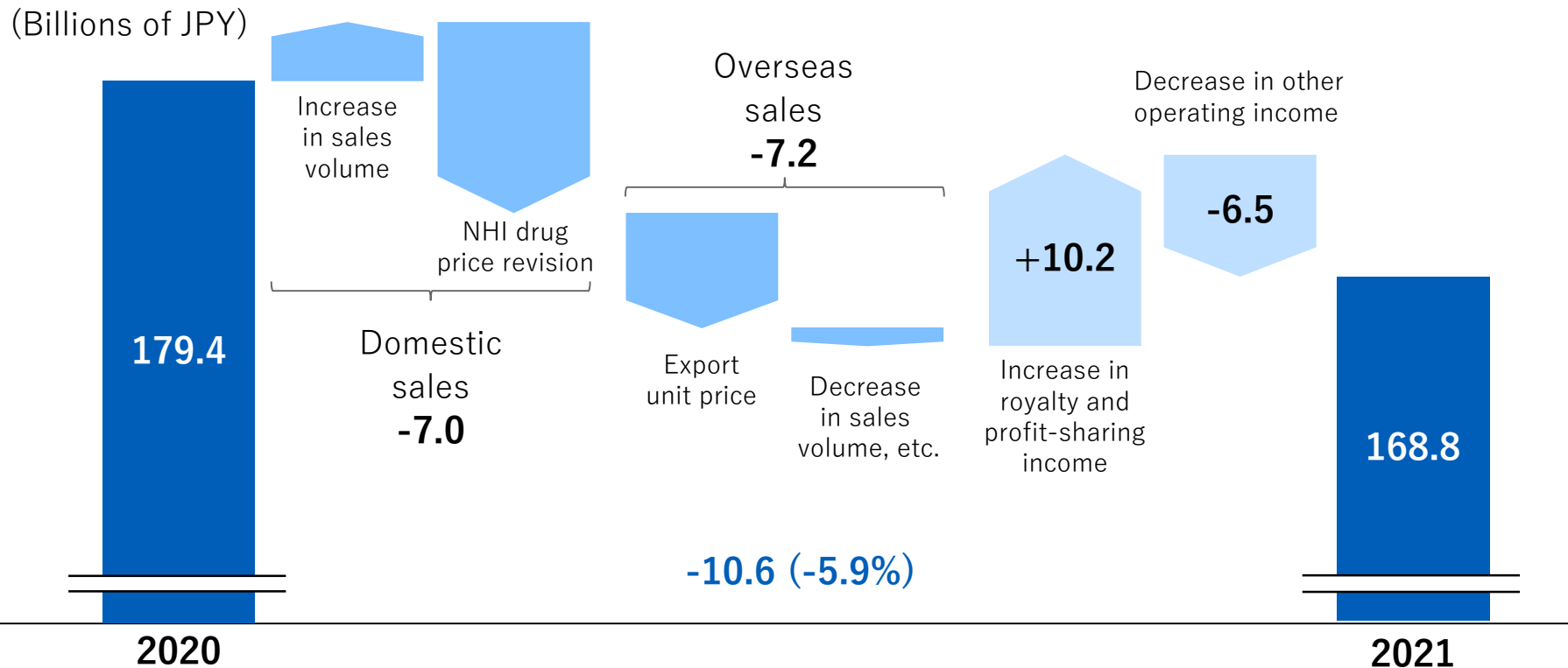
- ✓ No major negative impact on financial performance due to COVID-19
- ✓ Domestic sales decreased due to NHI drug price revision in April last year, but the progress was in line with the initial forecast
- ✓ As for overseas sales, exports to Roche are not evenly distributed each quarter, and the low progress was in line with the initial forecast
- ✓ ROOI increased due to growth in overseas local sales as expected

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 the previous fiscal year.

Topline Overview

- Domestic sales decreased due to NHI drug price revision, despite an increase in sales volume amid the impact of generic products
- Overseas sales decreased due to lower export unit price and timing of exports to Roche
- Royalty income increased due to growth in overseas local sales of in-house products



- ✓ Domestic sales for Tecentriq, Kadcyra, and Enspryng exceeded expectations. Impact of generics on some products and impact of NHI drug price revision were significant. Overall sales declined, but progress was in line with the initial forecast.
- ✓ Overseas sales decreased due to decline in export unit price and timing of exports of Actemra to Roche as expected
- ✓ Royalty income increased due to growth in overseas local sales of Hemlibra and Actemra as expected

R&D Overview

- **Obtained approval for multiple first-in-class products in Japan, which is expected to contribute to sales this year**
 - ✓ Polivy: Aiming for early market penetration through obtaining approval and launch for relapsed / refractory indication prior to 1st line treatment
 - ✓ FoundationOne Liquid CDx*: Preparing for launch to address diverse needs with complementary use
- **Progress of development pipelines for COVID-19**
 - ✓ Actemra: REMDACTA study did not meet its primary endpoint
Collaborating with Roche to evaluate clinical study results obtained to date
 - ✓ Antibody Cocktail: Achieved primary endpoints in multiple Phase 3 trials conducted overseas.
Domestic Phase 1 study initiated, scheduled to file in 2021
 - ✓ AT-527: Oral new drug candidate in-licensed from Roche, preparing for development in Japan

(As of April 22, 2021)

Approved	Actemra	Adult patients with SSc-ILD**	Mar. 2021 (US)
	Polivy	Relapsed or Refractory Diffuse Large B-cell Lymphoma	Mar. 2021
	FoundationOne Liquid CDx*	Blood-based Comprehensive Genomic Profiling Test for Solid Tumors	Mar. 2021
Filed	Enspryng	Neuromyelitis Optica Spectrum Disorder	Aug. 2019 (EU)
	nemolizumab	atopic dermatitis	Q3 2020***
	Risdiplam	Spinal Muscular Atrophy	Oct. 2020

Letters in orange: in-house projects

* FoundationOne Liquid CDx Cancer Genomic Profile **SSc-ILD: Systemic sclerosis-associated interstitial lung disease ***Filed by Maruho Co., Ltd., the licensee in Japan

FY2021 Q1 Consolidated Financial Overview (Core)

Toshiaki Itagaki

Executive Vice President & CFO

P/L Jan - Mar (Year on Year)

(Billions of JPY)	2020	2021	Growth	
Revenues	179.4	168.8	- 10.6	- 5.9%
Sales	144.5	130.3	- 14.2	- 9.8%
Domestic	101.9	94.9	- 7.0	- 6.9%
Overseas	42.6	35.4	- 7.2	- 16.9%
Royalties and other operating income	34.9	38.6	+ 3.7	+ 10.6%
Royalty and profit-sharing income	26.4	36.6	+ 10.2	+ 38.6%
Other operating income	8.5	2.0	- 6.5	- 76.5%
Cost of sales	-61.0	-55.0	+ 6.0	- 9.8%
(cost to sales ratio)	42.2%	42.2%	-	-
Operating expenses	-44.4	-48.5	- 4.1	+ 9.2%
M&D and G&A * ¹	-19.4	-19.7	- 0.3	+ 1.5%
Research and development	-25.0	-28.7	- 3.7	+ 14.8%
Operating profit	74.1	65.4	- 8.7	- 11.7%
(operating margin)	41.3%	38.7%	-2.6%pts	-
Financial account balance	-1.2	0.3	+ 1.5	-
Income taxes	-20.2	-17.2	+ 3.0	- 14.9%
Net income	52.7	48.4	- 4.3	- 8.2%
EPS (JPY) * ²	32.04	29.42	-2.62	- 8.2%

Domestic sales

Decrease due to NHI drug price revision and launch of generic drugs

Overseas sales

Decrease in export of Actemra

Royalty and profit-sharing income

Increase in income for Hemlibra

Other operating income

Decrease in one-time income

Cost of sales

Cost to sales ratio remained unchanged from 2020 Q1

Operating expenses

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

Operating profit

Decrease due to lower revenues, including a decrease in one-time income, and an increase in research and development expenses

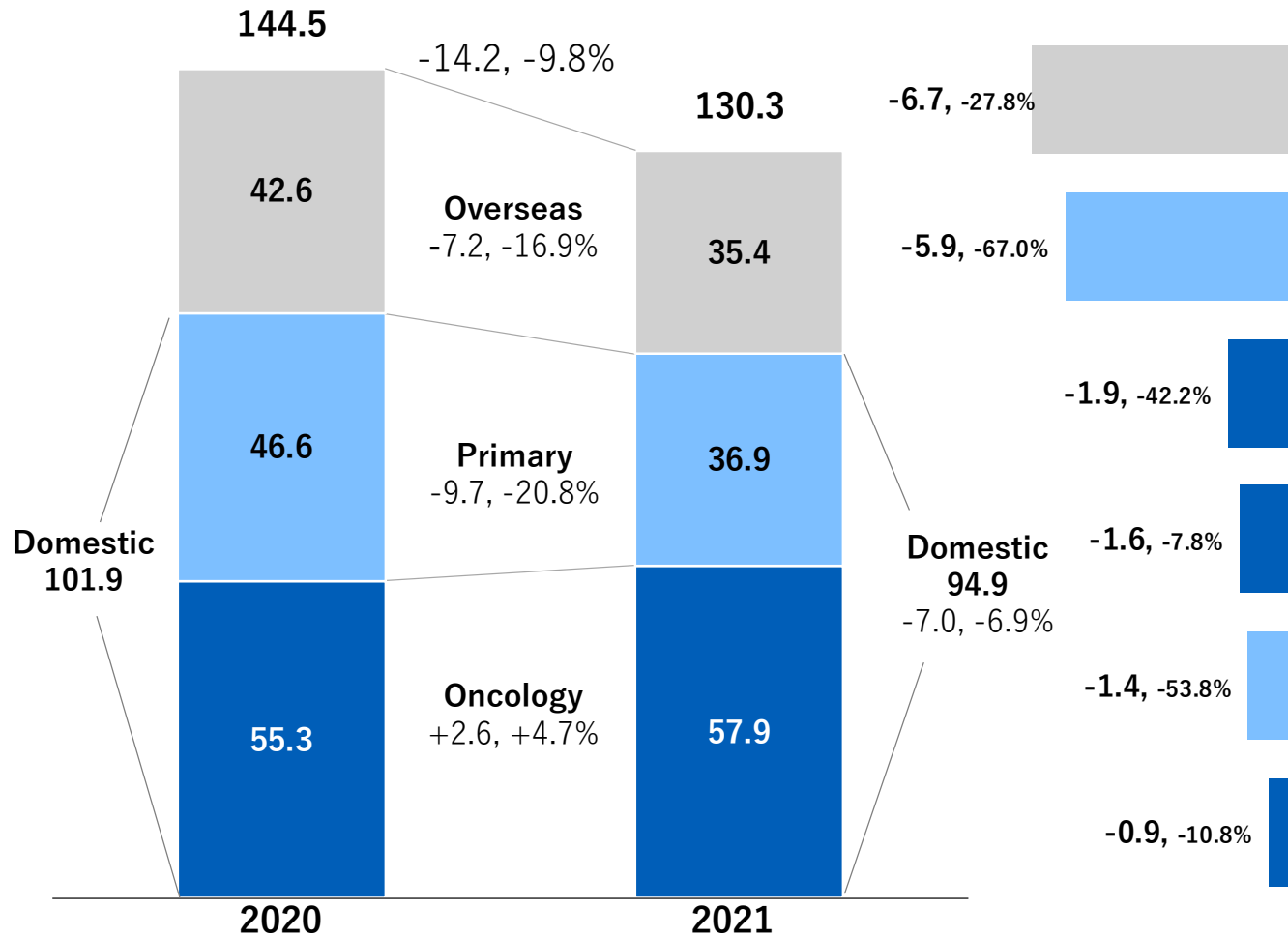
*1 M&D: Marketing and distribution, G&A: General and administration

*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.

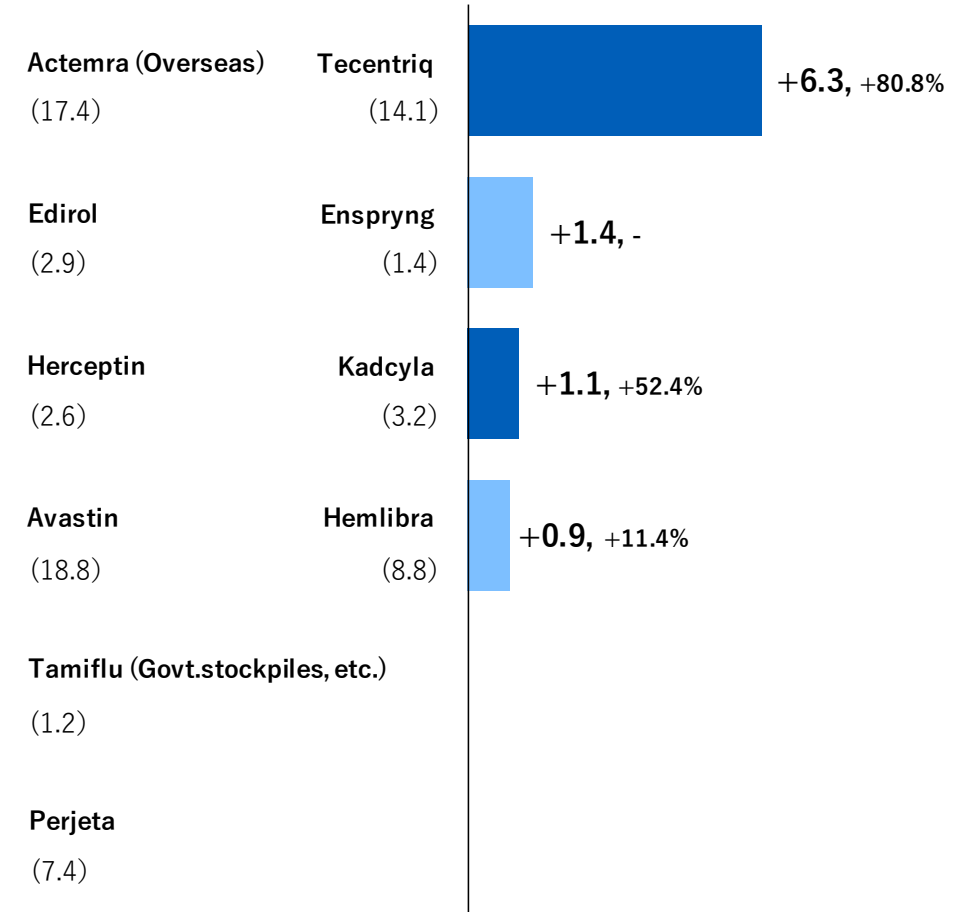
Sales Jan - Mar (Year on Year)

Sales by Disease Area,
Year on Year Comparisons

(Billions of JPY)

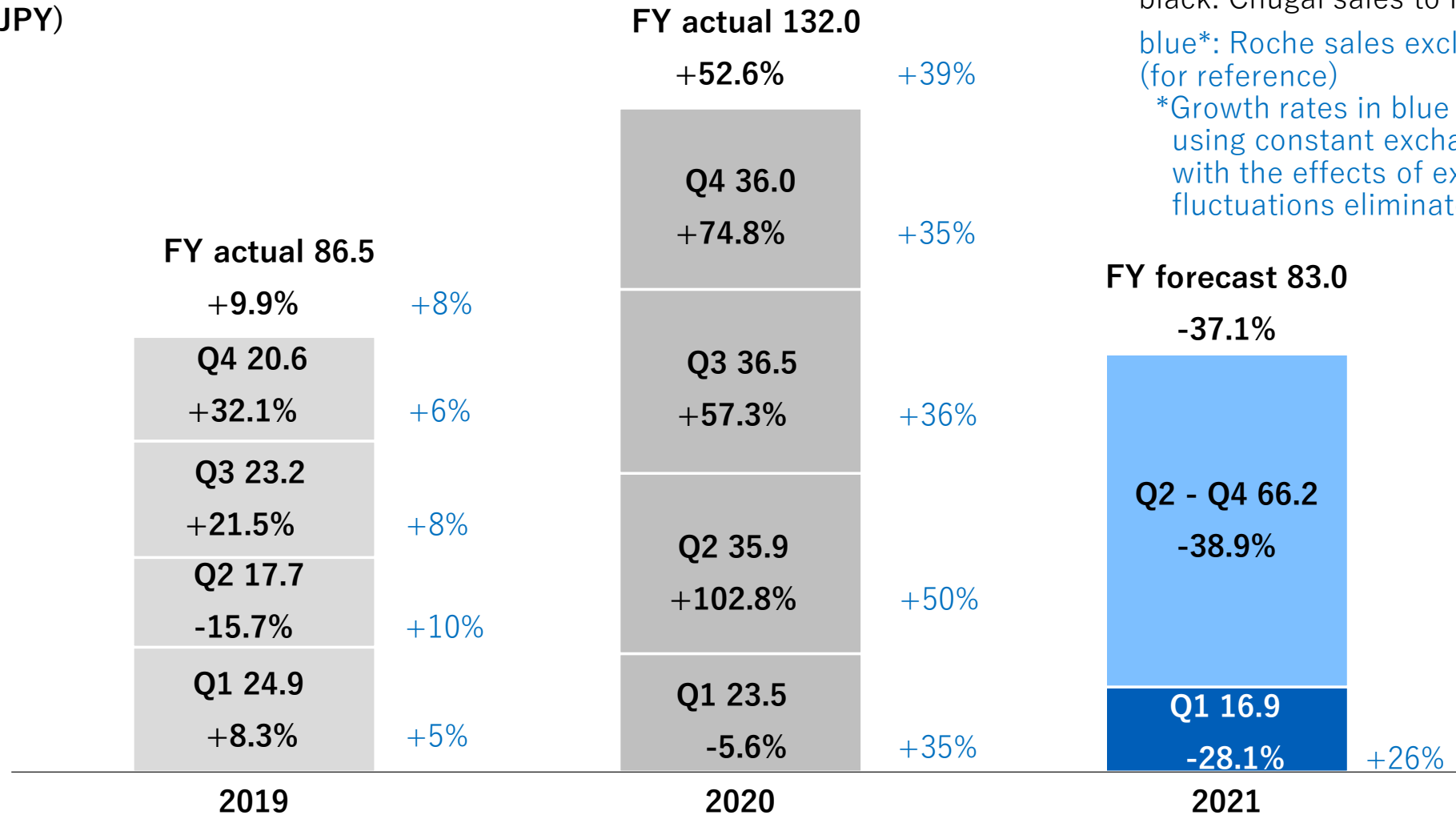


Sales by Products,
Year on Year Changes
(): Actual sales in FY2021
%: Year-on-year percentage change



Export of Actemra to Roche

(Billions of JPY)



%: year on year growth

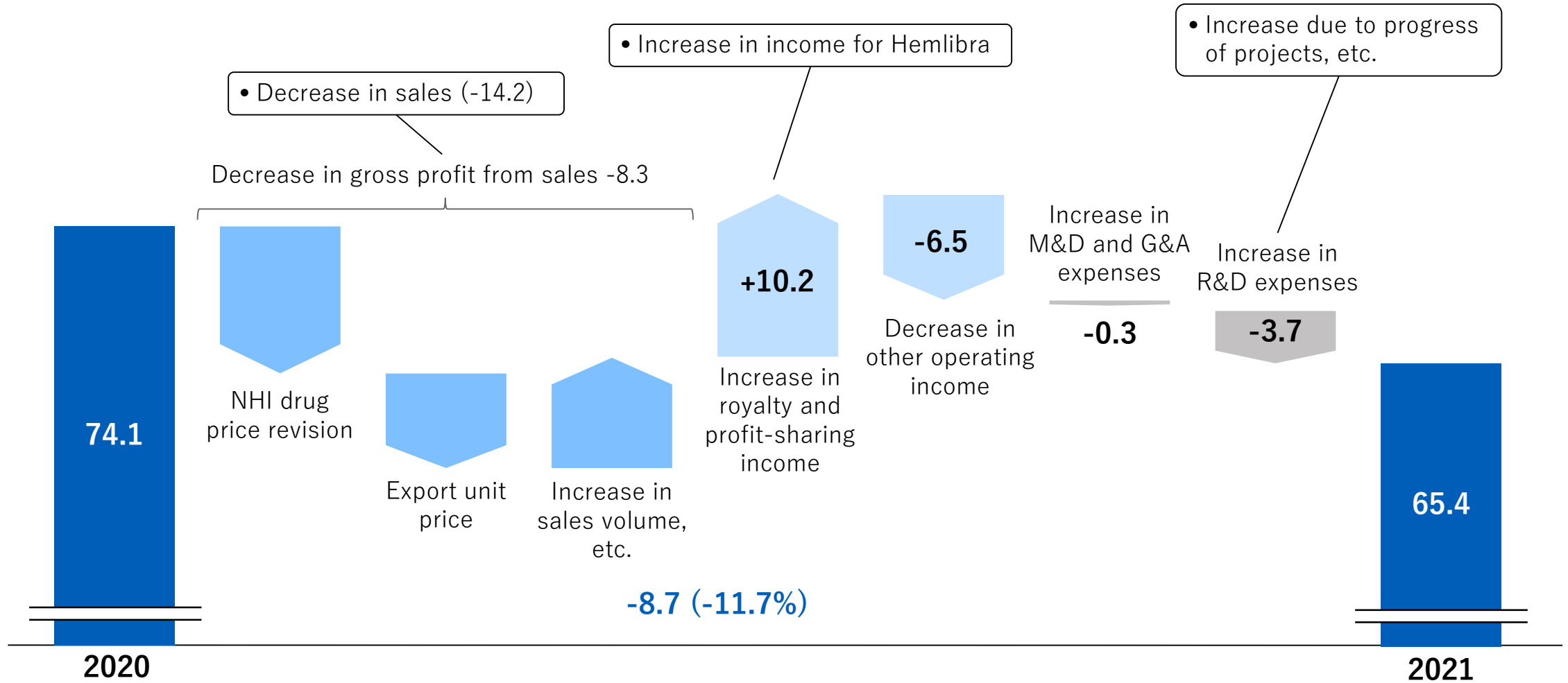
black: Chugai sales to Roche

blue*: Roche sales excluding Japan (for reference)

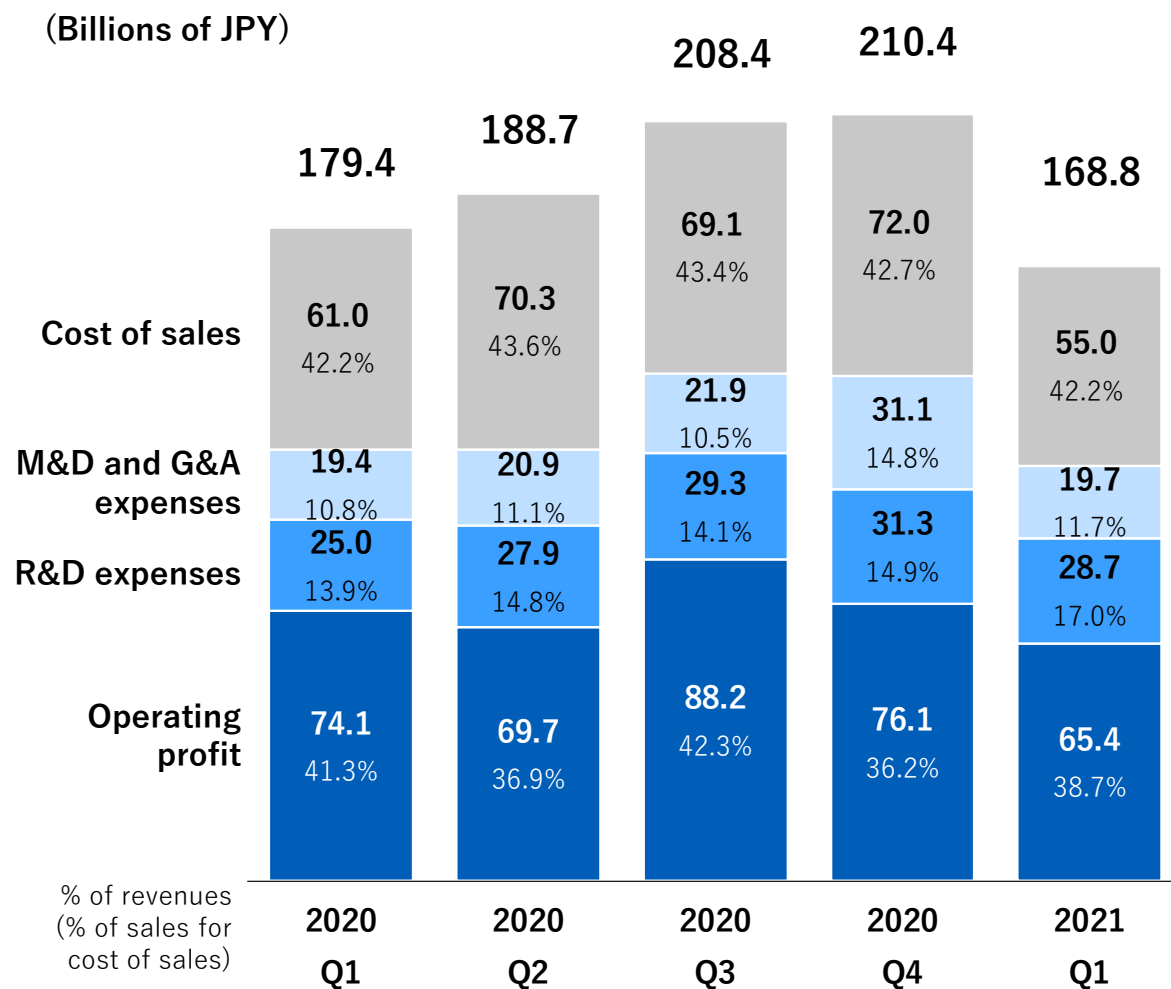
*Growth rates in blue are calculated using constant exchange rates (CER), with the effects of exchange rate fluctuations eliminated.

Operating Profit Jan - Mar (Year on Year)

(Billions of JPY)



Structure of Costs and Profit by Quarter



vs. Year on Year (2020 Q1)

Cost of sales ratio: unchanged from 2020 Q1

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

Operating profit: decrease of -8.7 (-11.7%)

vs. Previous Quarter (2020 Q4)

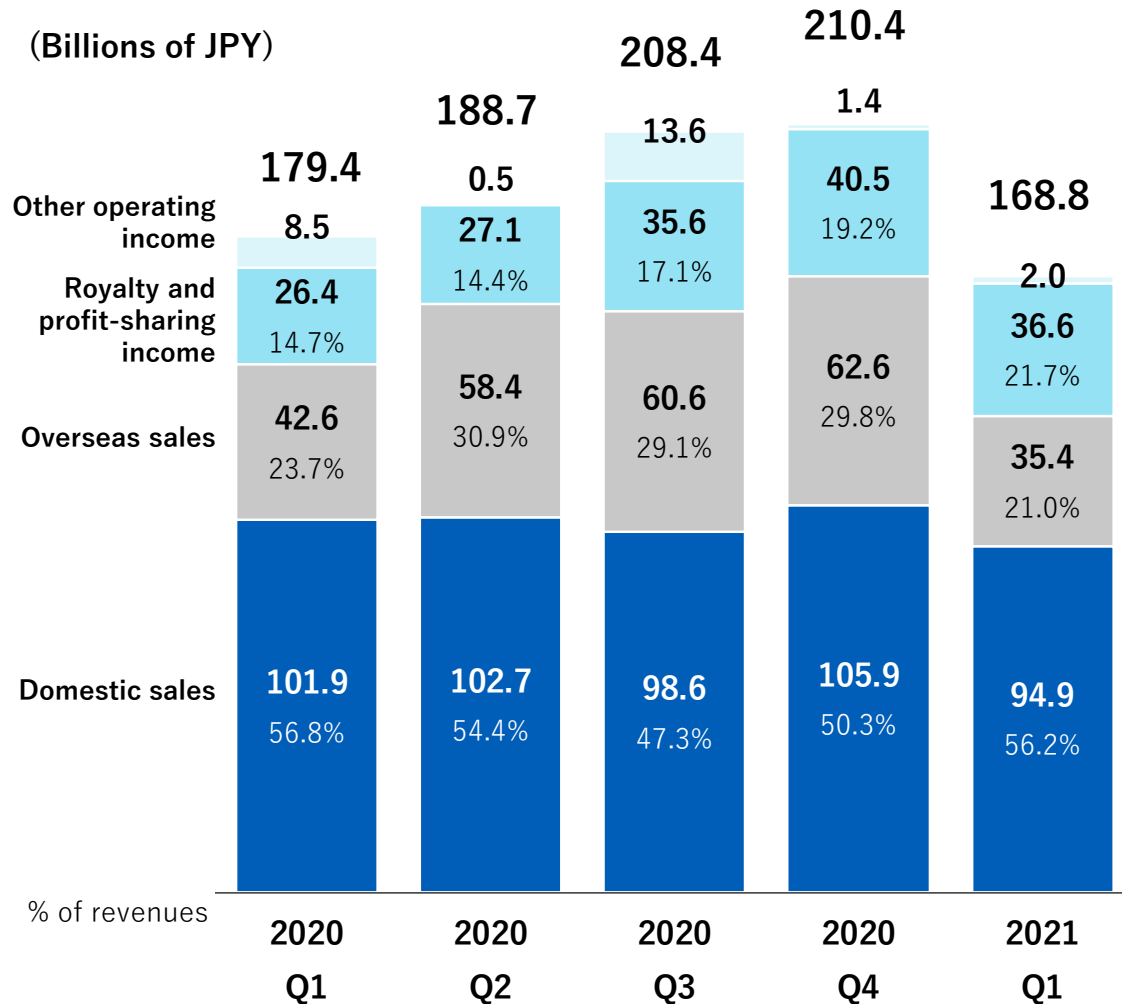
Cost of sales ratio: no significant change (-0.5%pts)

M&D and G&A expenses: decrease in line with the trend of previous years

R&D expenses: despite progress of projects, decrease according to the trend of costs incurred in previous years

Operating profit: decrease of -10.7 (-14.1%)

Structure of Revenues by Quarter



vs. Year on Year (2020 Q1)

Domestic sales: decrease due to NHI drug price revision and launch of generic drugs, etc.

Overseas sales: decrease in sales of Actemra

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

Other operating income: decrease in one-time income

vs. Previous Quarter (2020 Q4)

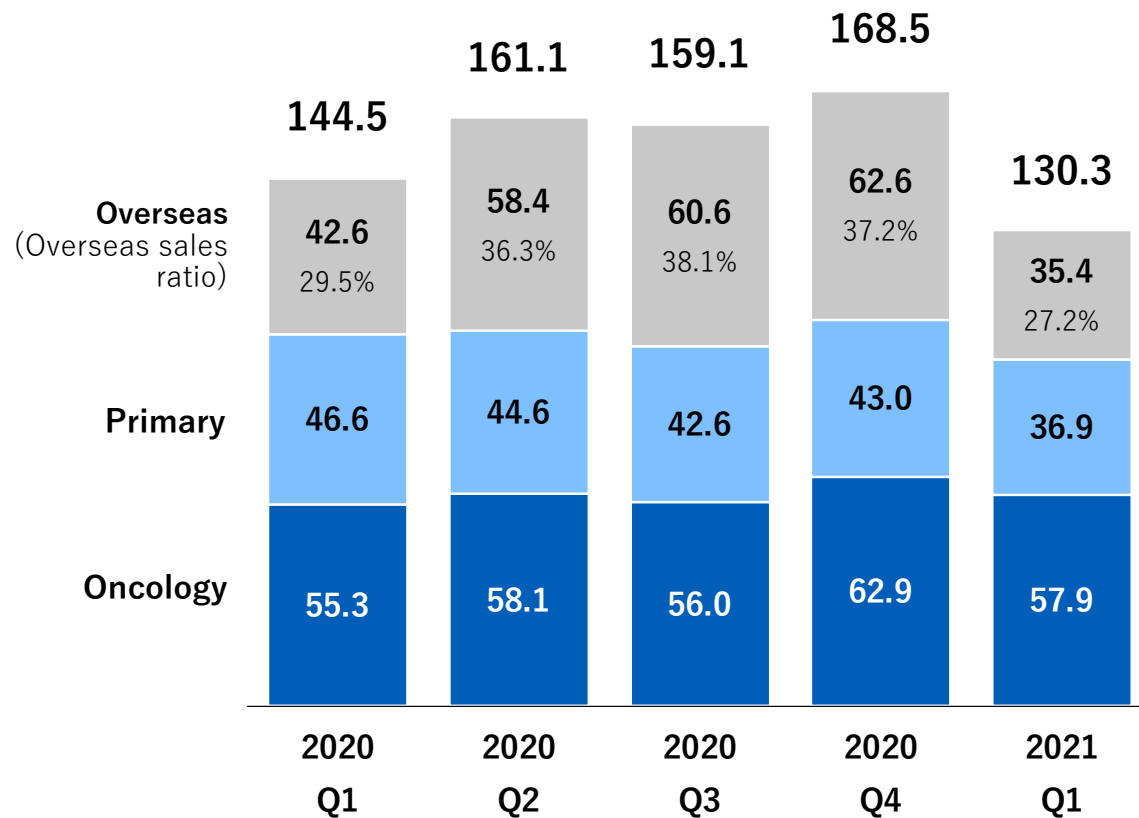
Domestic sales: decrease due to impact from launch of generic drugs in addition to the trend in previous years

Overseas sales: decrease in sales of Actemra, Alecensa, etc.

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

Structure of Sales by Quarter

(Billions of JPY)



vs. Year on Year (2020 Q1)

- Overseas** Actemra: -6.7
- Oncology** Tecentriq: +6.3, Kadcylla: +1.1
Herceptin: -1.9, Avastin: -1.6
Perjeta: -0.9
- Primary** Ediolol: -5.9, Tamiflu (Govt. stockpiles, etc.): -1.4
Enspryng: +1.4, Hemlibra: +0.9

vs. Previous Quarter (2020 Q4)

- Overseas** Actemra: -19.4, Alecensa: -7.6
Enspryng: -4.0, Hemlibra: +4.0
- Oncology** Avastin: -2.3, Perjeta: -1.3
Alecensa: -1.3, Herceptin: -1.0
Tecentriq: +2.1
- Primary** Actemra: -1.5, Mircera: -1.2

P/L Jan - Mar (vs. Forecast)

(Billions of JPY)	Actual	Forecast		2020
	2021 Jan - Mar	2021 Jan - Dec	Progress	Progress *1
Revenues	168.8	800.0	21.1%	22.8%
Sales	130.3	631.0	20.6%	22.8%
Domestic	94.9	393.7	24.1%	24.9%
Overseas	35.4	237.3	14.9%	19.0%
Royalties and other operating income	38.6	169.0	22.8%	22.7%
Royalty and profit-sharing income	36.6	163.0	22.5%	20.4%
Other operating income	2.0	6.0	33.3%	35.3%
Cost of sales	- 55.0	- 252.5	21.8%	22.4%
(cost to sales ratio)	42.2%	40.0%	-	-
Operating expenses	- 48.5	- 227.5	21.3%	21.5%
M&D and G&A	- 19.7	- 96.0	20.5%	20.8%
Research and development	- 28.7	- 131.5	21.8%	22.0%
Operating profit	65.4	320.0	20.4%	24.1%
(operating margin)	38.7%	40.0%	-	-
Net income	48.4	232.0	20.9%	24.0%
EPS (JPY) *2	29.42	141.00	20.9%	24.0%

Domestic Sales

Progress nearly in line with forecast as total

Overseas sales

Progress nearly in line with forecast

Royalty and profit-sharing income

Progress nearly in line with forecast

Other operating income

Progress nearly in line with forecast

Cost of Sales

Cost to sales ratio nearly in line with Q1 forecast

Operating expenses

Progress nearly in line with forecast

Operating profit

Progress nearly in line with forecast

*1 Jan – Mar progress versus Jan – Dec

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

Sales Jan - Mar (vs. Forecast)

(Billions of JPY)	Actual	Forecast		2020
	2021 Jan - Mar	2021 Jan - Dec	Progress	Progress *
Sales	130.3	631.0	20.6%	22.8%
Domestic	94.9	393.7	24.1%	24.9%
Oncology	57.9	226.7	25.5%	23.8%
Avastin	18.8	60.5	31.1%	25.0%
Tecentriq	14.1	49.2	28.7%	20.8%
Perjeta	7.4	31.8	23.3%	24.8%
Alecensa	6.0	27.0	22.2%	21.5%
Kadcyla	3.2	13.3	24.1%	20.6%
Herceptin	2.6	10.9	23.9%	28.3%
Gazyva	1.0	5.7	17.5%	21.7%
Rituxan	1.2	5.2	23.1%	26.4%
Xeloda	0.6	2.7	22.2%	30.6%
Rozlytrek	0.1	0.9	11.1%	0.0%
Foundation Medicine	1.0	7.2	13.9%	21.4%
Other	1.8	12.3	14.6%	22.0%

(Billions of JPY)	Actual	Forecast		2020
	2021 Jan - Mar	2021 Jan - Dec	Progress	Progress *
Primary	36.9	167.0	22.1%	26.4%
Hemlibra	8.8	51.7	17.0%	23.2%
Actemra	9.2	38.5	23.9%	24.2%
Edirol	2.9	17.3	16.8%	31.7%
Mircera	3.4	11.7	29.1%	24.0%
Bonviva	2.0	8.5	23.5%	23.6%
CellCept	2.0	8.3	24.1%	24.2%
Oxarol	1.4	5.5	25.5%	21.9%
Enspryng	1.4	4.0	35.0%	0.0%
Tamiflu(Ordinary use)	-0.1	0.8	-12.5%	75.0%
Tamiflu(Govt. stockpiles, etc.)	1.2	1.2	100.0%	70.3%
Other	4.7	19.6	24.0%	25.8%
Overseas	35.4	237.3	14.9%	19.0%
Hemlibra	8.5	89.7	9.5%	33.0%
Actemra	17.4	85.3	20.4%	17.9%
Alecensa	6.0	44.2	13.6%	14.0%
Enspryng	-	3.9	0.0%	1.8%
Neutrogin	2.2	8.7	25.3%	27.8%
Other	1.2	5.4	22.2%	22.9%

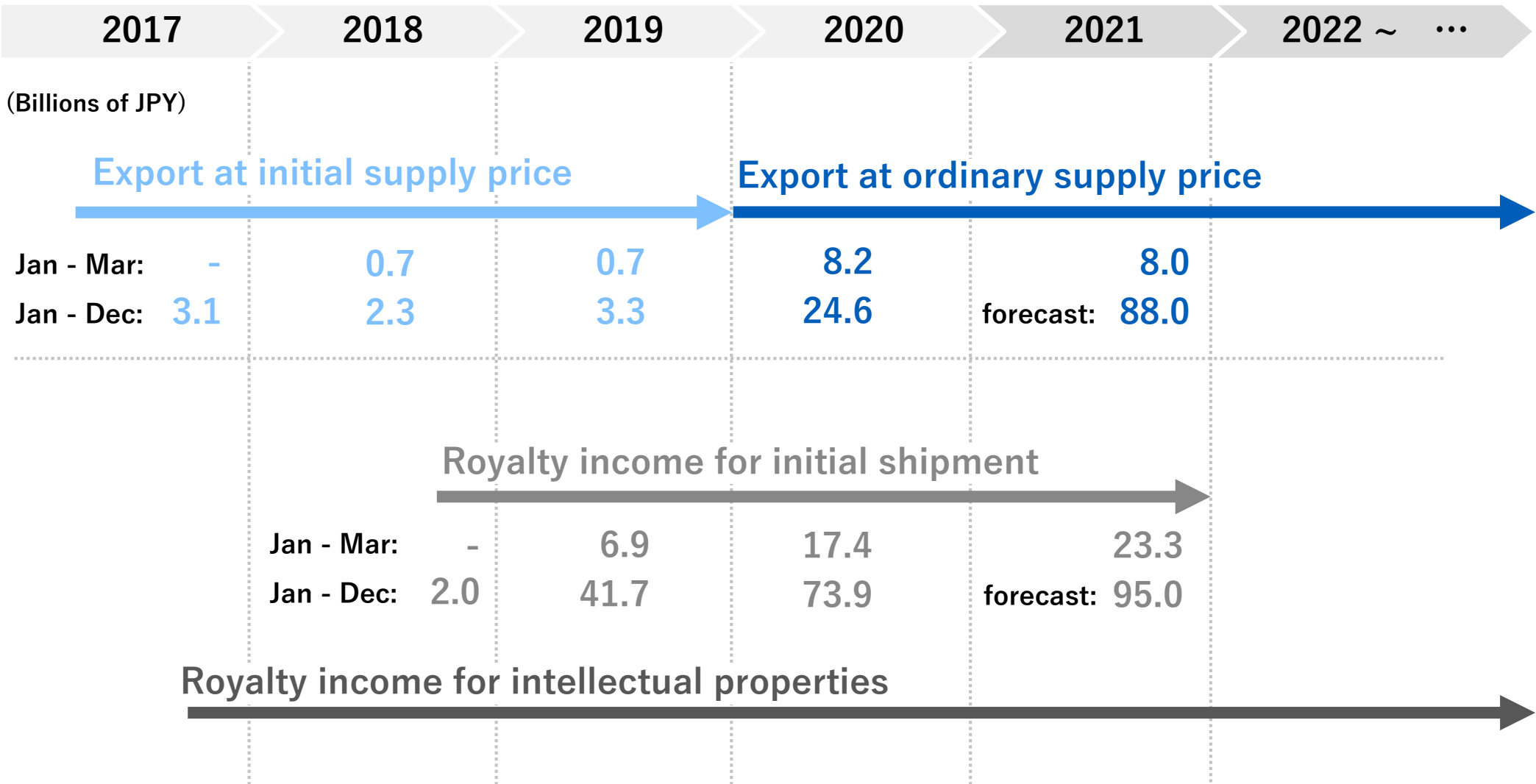
* Jan - Mar progress versus Jan - Dec

Outline of Hemlibra Sales to Roche

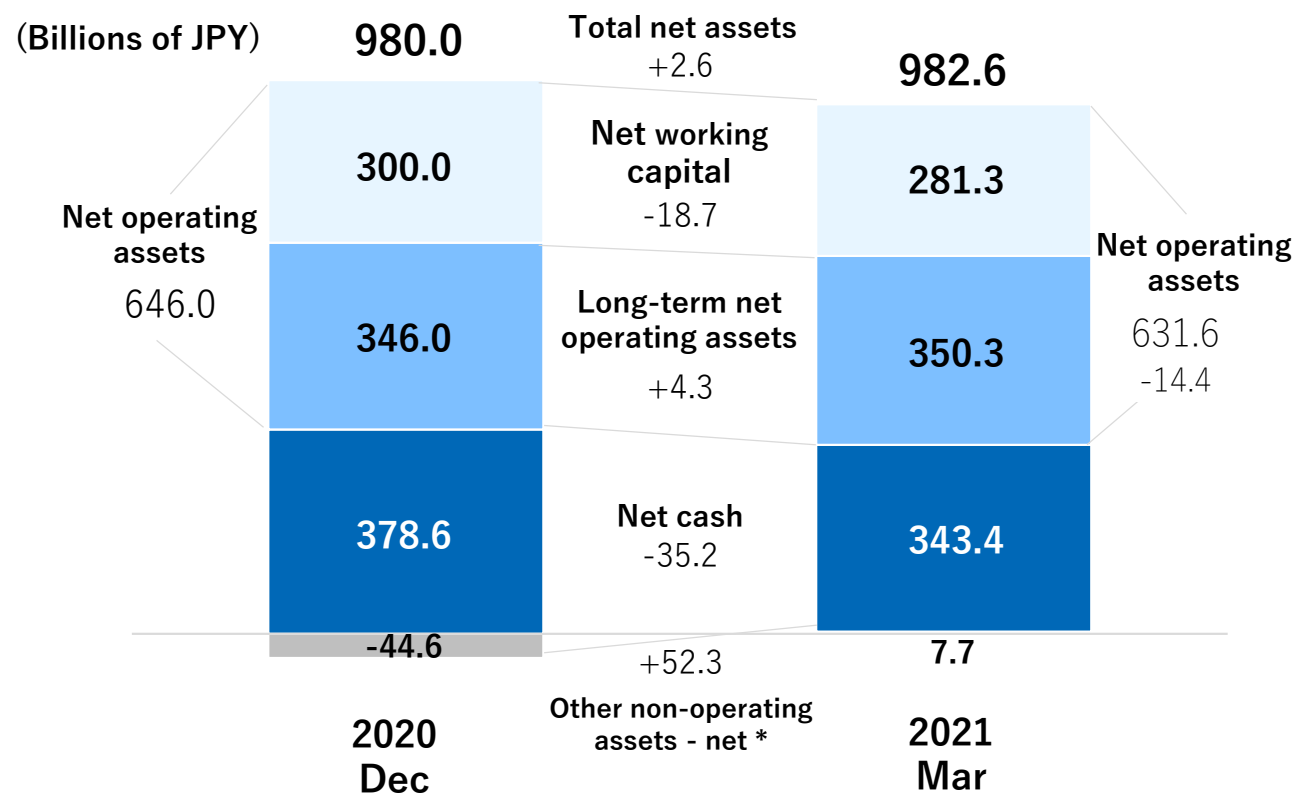
(Excluding profit-sharing income and expenses in co-promotion countries)

Export sales

Royalty income



Financial Position (vs. 2020 Year End)



Decrease in net working capital

Decrease mainly in trade accounts receivable

Increase in long-term net operating assets

Mainly increase in Property, plant and equipment

Decrease in net cash

(Please refer to the next slide)

Increase in other non-operating assets – net

Decrease in accrued corporate tax

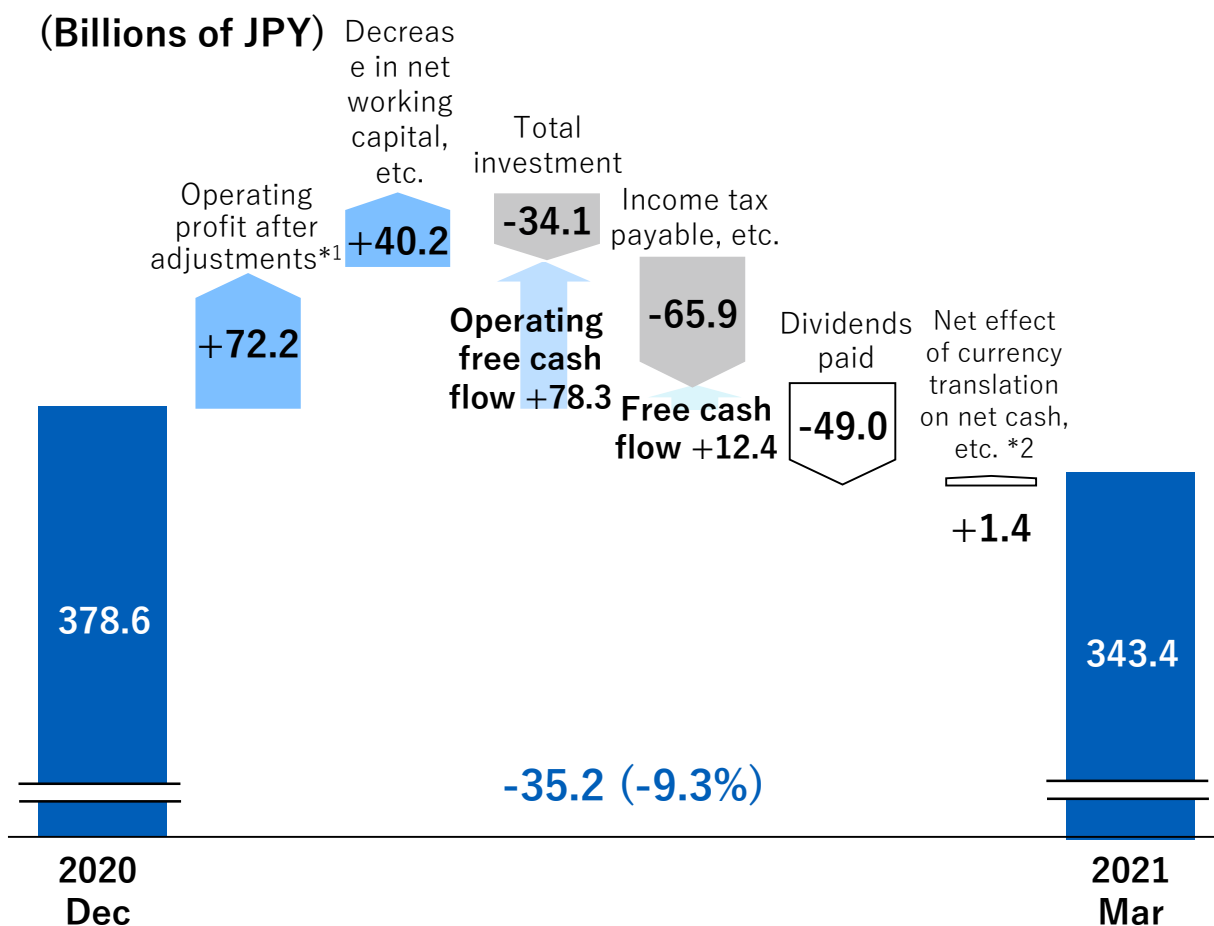
* e.g. deferred income tax assets, accrued corporate tax, etc.

Total assets	1,235.5	-90.9	1,144.6
Total liabilities	-255.5	+93.5	-162.0
Total net assets	980.0	+2.6	982.6
Ratio of equity attributable to Chugai shareholders	79.3%	+6.5%pts	85.8%

FX rate to the JPY (end of period)

	2020 Actual	2021 Actual
1CHF	117.10	117.14
1EUR	126.89	129.30
1USD	103.19	110.37
1SGD	77.98	81.87

Net Cash (vs. 2020 Year End)



Operating profit after adjustment *1	+72.2
Operating profit *1	+64.0
Depreciation, amortization and impairment *1	+7.3
Decrease in net working capital, etc.	+40.2
Total investment	-34.1
Property, plant and equipment	-28.9
Payment for lease liabilities	-2.2
Intangible assets	-2.9
Operating free cash flow	+78.3
Income tax payable, etc.	-65.9
Income tax payable	-63.3
Free cash flow	+12.4
Dividends paid	-49.0
End of FY 2020	-49.0
Net effect of currency translation on net cash, etc.	+1.4

*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)



Appendix

IFRS and Core Results Jan - Mar

(Billions of JPY)	IFRS results	Non-core items		Core results
		Intangible assets	Others	
Revenues	168.8			168.8
Sales	130.3			130.3
Royalties and other operating income	38.6			38.6
Cost of sales	-55.3	+0.3		-55.0
Operating expenses	-49.5	+0.0	+1.1	-48.5
M&D and G&A	-19.8		+0.1	-19.7
Research and development	-29.7	+0.0	+1.0	-28.7
Operating profit	64.0	+0.3	+1.1	65.4
Financial account balance	0.3			0.3
Income taxes	-16.8	-0.1	-0.3	-17.2
Net income	47.4	+0.2	+0.8	48.4
EPS (JPY)	28.82			29.42

Non-Core items

(Billions of JPY)

Intangible assets

Amortization +0.3

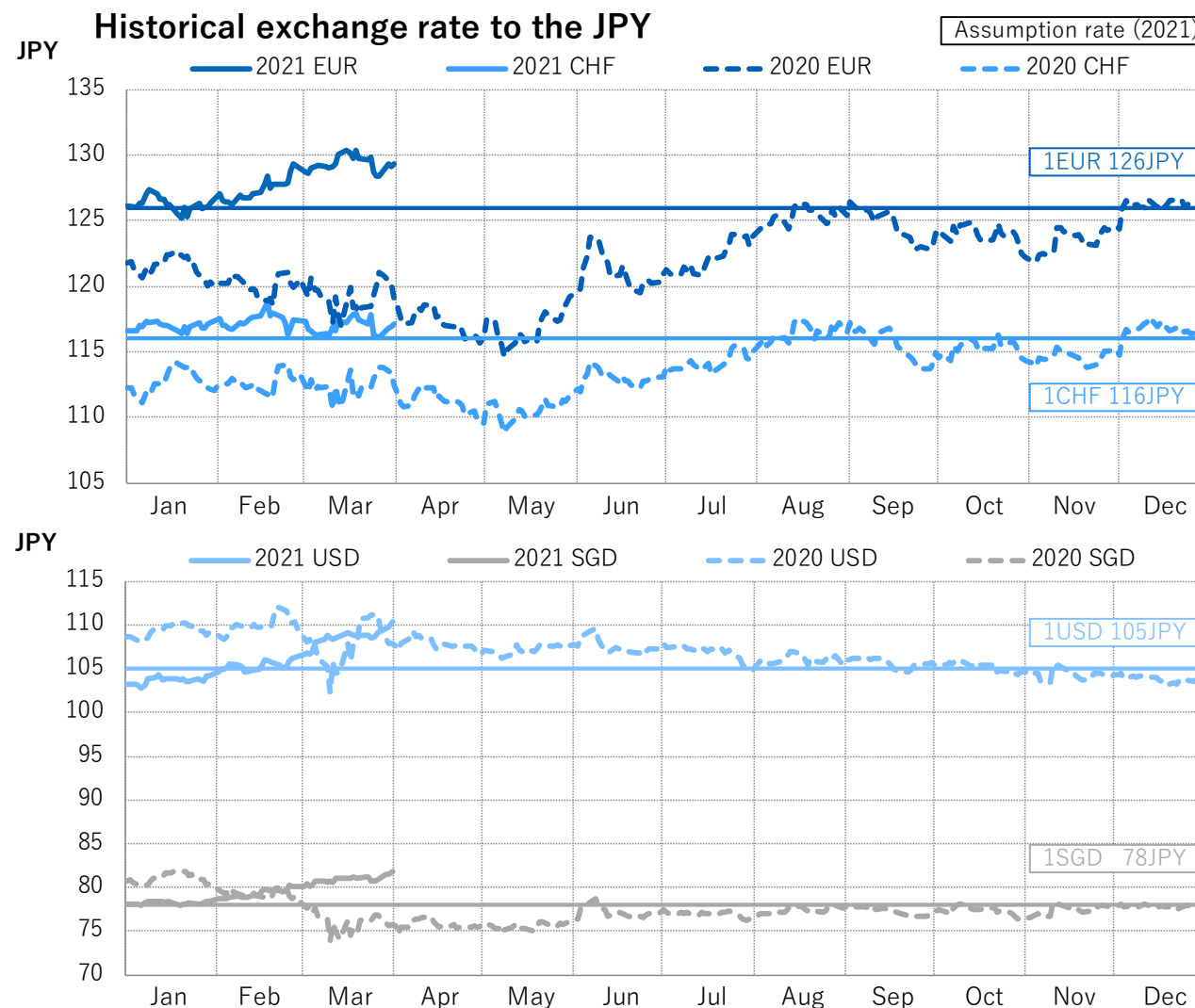
Others

Restructuring expenses +1.1

Impact from Foreign Exchange (vs. Forecast)

(billions of JPY)	FX impact 2021 (FX impact vs. Assumption)	
Revenues	Sales	+0.0
	Royalties and other operating income	+0.0
Cost of sales & Operating expenses	Cost of sales	-0.0
	Operating expenses	-0.2
Operating profit	-0.2	

Market average exchange rate(JPY)	2020 Actual	2021 Assumption	2021 Actual
1CHF	112.61	116.00	117.08
1EUR	120.19	126.00	127.65
1USD	109.02	105.00	105.83
1SGD	78.72	78.00	79.47



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

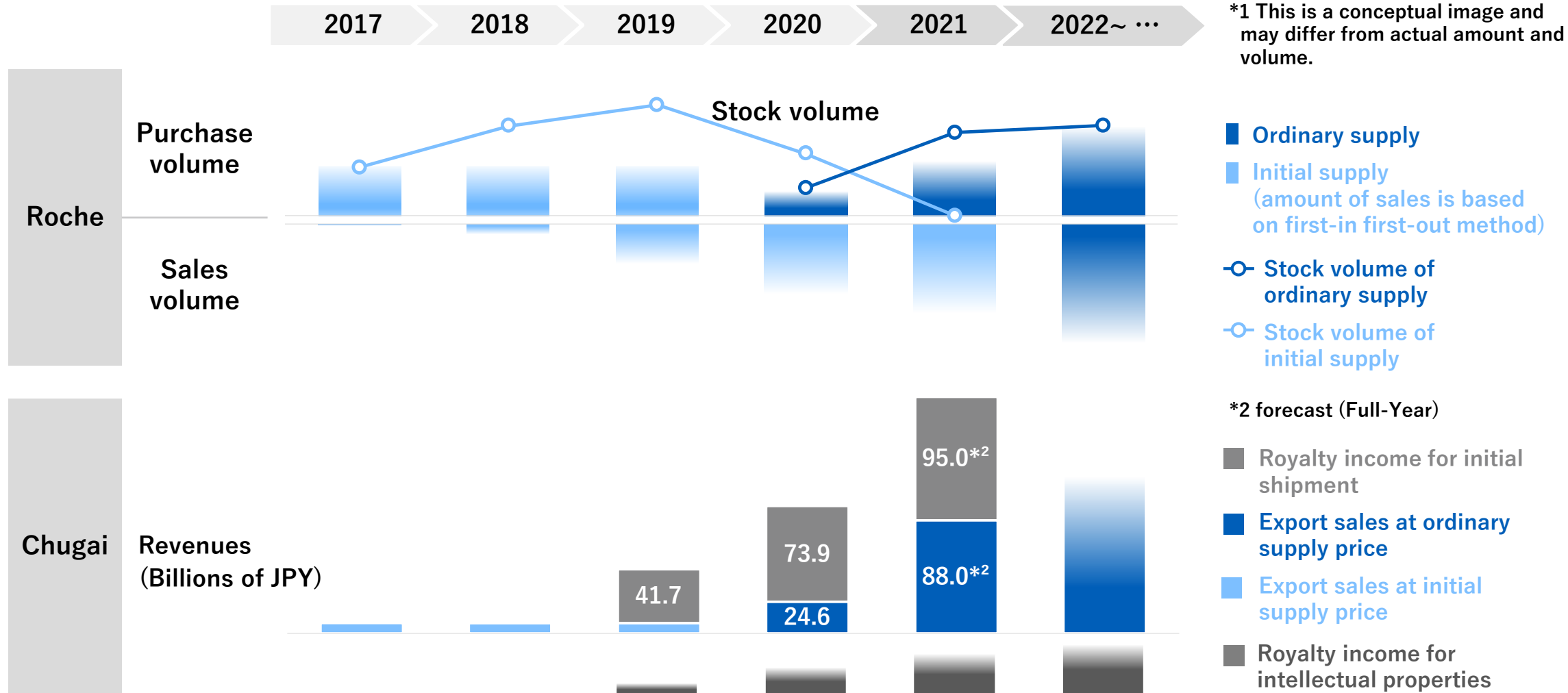
*2 Main co-promotion countries are as follows:

- 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



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

Overview of Development Pipeline

Tetsuya Yamaguchi

Senior Vice President, Head of Project & Lifecycle Management Unit

Projects under Development (1)

As of April 22, 2021

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

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

★: Projects with advances in stages since February 4, 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

TDB: T cell-dependent bispecific

Projects under Development (2)

PNH: paroxysmal nocturnal hemoglobinuria
 nAMD: neovascular age-related macular degeneration
 DME: diabetic macular edema
 NMOSD: neuromyelitis optica spectrum disorder



As of April 22, 2021

	Phase I	Phase II	Phase III	Filed
Bone & Joint			NRD101 / Suvenyl (China) - knee osteoarthritis /shoulder periartthritis	
Renal	EOS789 - Hyperphosphatemia			
Autoimmune	RG7880 (IL-22 fusion protein) - inflammatory bowel disease			
Neurology	RG7935 / prasinezumab - Parkinson's disease GYM329 (RG6237) - neuromuscular disease RG6100 / semorinemab - Alzheimer's disease	RG7906 / ralmitaront - schizophrenia	RG1450 / gantenerumab - Alzheimer's disease RG6042 / tominersen - Huntington's disease	SA237 (RG6168) / Enspryng (EU) - NMOSD RG7916 / risdiplam - spinal muscular atrophy
Others	PCO371 - hypoparathyroidism AMY109 - endometriosis NXT007 - hemophilia A (PI/II) RG6413+RG6412 / casiribimab+imdevimab - COVID-19★		RG7716 / faricimab - DME - nAMD - retinal vein occlusion★ MRA (RG1569) / Actemra (JPN) - COVID-19 pneumonia	ACE910 (RG6013) / Hemlibra (JPN) - Acquired hemophilia A SKY59 (RG6107) / crovalimab - PNH

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

★: Projects with advances in stages since February 4, 2021

Letters in orange: in-house projects

Letters in blue: in-licensed (Roche)

Key News Flows in Q1

As of April 22, 2021

Approved	Actemra	Adult patients with SSc-ILD	March, 2021 (US)
	Polivy	Relapsed or refractory diffuse large B-cell lymphoma	March, 2021
	FoundationOne Liquid CDx¹	Blood-based comprehensive genomic profiling test for solid tumors	March, 2021
	FoundationOne CDx²	Pemigatinib: biliary tract cancer (<i>FGFR2</i> fusion genes)	February, 2021
New to pipeline	Tecentriq + Avastin	Hepatocellular carcinoma (intermediate stage: combination with TACE)	P3 study (TALENTACE)
	faricimab	Retinal vein occlusion (CRVO / BRVO)	P3 study
	casirivimab/imdevimab³	COVID-19	P1 study
Development Discontinued	Tecentriq	Early breast cancer (HER2+, neoadjuvant)	P3 study (IMpassion050)
Late-stage Readout	Actemra	COVID-19 pneumonia: primary endpoint not met	P3 study (REMDACTA)
	Tecentriq	Non small cell lung cancer (adjuvant): primary endpoint met	P3 study (IMpower010)
	casirivimab/imdevimab³	COVID-19: primary endpoint met	P3 study (2067, 2069)
Medical Conference	risdiplam	P2/3 SUNFISH study (2-year data)	March, 2021 (MDA)
	faricimab	P2/3 FIREFISH study (2-year data) Results of P3 studies (YOSEMITE, RINE / TENAYA, LUCERNE)	April, 2021 (AAN) February, 2021 (AED)
Others	AT-527	New oral treatment against COVID-19 in-licensed from Roche	February, 2021

Letters in orange: in-house projects

Letters in blue : in-licensed (Roche)

1: FoundationOne Liquid CDx Cancer Genomic Profile

2: FoundationOne CDx Cancer Genomic Profile

3: antibody cocktail

SSc-ILD: Systemic Sclerosis-associated Interstitial Lung Disease

TACE: Transarterial chemoembolization

CRVO: Central Retinal Vein Occlusion

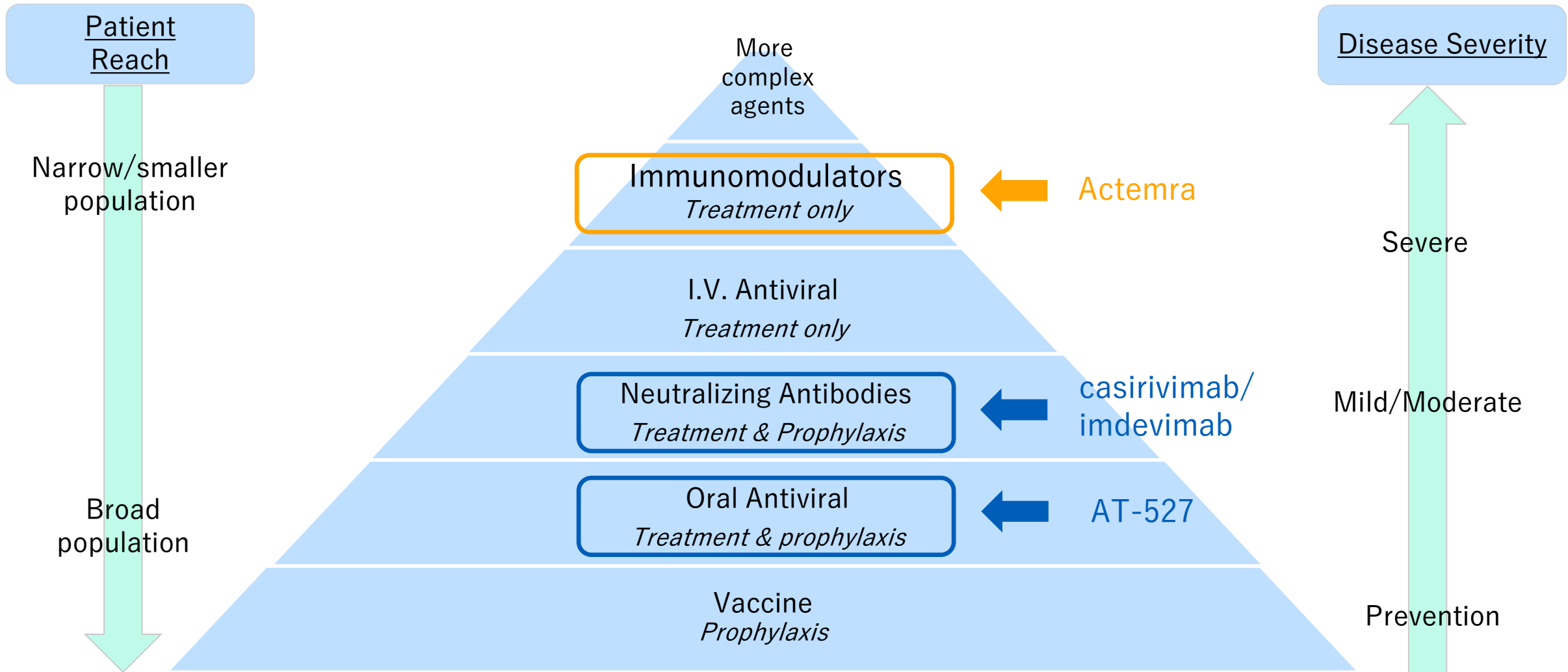
BRVO: Branch Retinal Vein Occlusion

MDA: Muscular Dystrophy Association

AAN: American Academy of Neurology

AED: Angiogenesis, Exudation, and Degeneration

Overview of COVID-19 Treatment Pathway



Summary of Clinical Trials of Actemra against COVID-19

Clinical trials sponsored by Roche / Chugai

Study	Sponsor / Region	Population	Dosing regimen	Results
J-COVACTA (Phase 3)	Chugai / Japan	Hospitalized severe patients >10	Single 8mg/kg IV dose; up to one additional dose may be given	—
COVACTA (Phase 3)	Roche / Global	Hospitalized severe patients 450	Same as above	Primary endpoint not met
EMPACTA (Phase 3)	Roche / Global	Hospitalized patients 379	Same as above	Primary endpoint met
REMDACTA (Phase 3)	Roche* / Global * collaboration with Gilead Sciences, Inc.	Hospitalized severe patients 650	Same as above** ** combination with remdesivir	Primary endpoint not met

< Next Action >

Analyze accumulated results so far in details and evaluate overall risk / benefit profile of Actemra

SARS-CoV-2 Antibody Cocktail (casirivimab / imdevimab) (1) P3 (Study 2067) for high-risk* non-hospitalized patients with COVID-19: Reduce hospitalization or death by 70%

- Chugai starts P1 study in Japan in March, 2021 and plans to file the application during 2021

< REGN-COV 2067 study >

- Meet primary endpoint
 - ✓ Antibody cocktail(1,200 mg / 2,400 mg intravenous administration) significantly reduced the risk of hospitalization or death by 70 % (p=0.0024), 71% (p<0.0001) respectively
- Meet all major secondary points
 - ✓ Both doses reduced the duration with symptom from 14 days to 10 days (median numbers) (p<0.0001)
- No new or serious safety signals were observed

< REGN-COV 20145 study >

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

*All patients in this analysis had at least one risk factor in progressing to severe, including obesity (58%), age 50 years (51%) and cardiovascular disease, including hypertension (36%). 32

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

SARS-CoV-2 Antibody Cocktail (casirivimab / imdevimab) (2) P3 (Study 2069) for household contacts of individuals infected with SARS-CoV-2* : Reduce the risk of symptomatic COVID-19 infections by 81%

< REGN-COV 2069 study >

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

*Individuals without any COVID-19 symptoms who lived in the same household as an individual who tested positive to SARS-CoV-2 within the prior four days. Individuals who tested negative to RT-qPCR test and negative to antibody test.
symptomatic infection: infection with symptom

Characteristics of Tissue and Blood Samples

CGP by Liquid and Tissue Builds on the Strengths of Each Type of Assay



Tissue

- Enable pathology assessment of overall tumor fraction before testing
- Both morphological and molecular assessments are possible¹⁻³⁾
- Invasive procedure is required when taking samples^{1,2)}
- If the quality and quantity of sample is insufficient, it might not be accurate result⁴⁾



Blood

CGP: Comprehensive Genomic Profiling
ctDNA: circulating tumor DNA

- Capturing the inpatient genomic heterogeneity⁵⁾
- Minimally invasive and easier to obtain sample^{1,6)}
- If the amount of ctDNA in the blood is insufficient, it might not be accurate result

1) Francis G et al.: Int J Mol Sci 2015; 16(6): 14122-42 2) De Rubis G et al.: Trends Pharmacol Sci 2019; 40(3): 172-86
3) Chouaid C et al.: Lung Cancer 2014; 86(2): 170-3 4) Corcoran RB et al.: Nat Med 2020; 26(12): 1815-6 34
5) Scherer F: Recent Results Cancer Res 2020; 215: 213-30 6) Bardelli A et al.: Cancer Cell 2017; 31(2): 172-9

Overview of Development Pipeline

Projected Submissions (Post PoC NMEs and Products)

NME

Line extension

in-house

in-licensed (Roche)

Others



RCC: renal cell carcinoma
NSCLC: non-small cell lung cancer
PNH: paroxysmal nocturnal hemoglobinuria
SCLC: small cell lung cancer
HNC: head and neck carcinoma

Filed

ENSPRYNG
(SA237/RG6168)
NMOSD(EU)

risdiplam
(RG7916)
Spinal Muscular
Atrophy

DLBCL: diffuse large B-cell lymphoma
NMOSD: neuromyelitis optica spectrum disorder
FDC: fixed-dose combination
nAMD: neovascular age-related macular degeneration
HCC: hepatocellular carcinoma
RVO: retinal vein occlusion

faricimab
(RG7716)
RVO

gantenerumab
(RG1450)
Alzheimer's Disease

ipatasertib
(RG7440)
Breast Cancer

as of April 22, 2021

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

casirivimab/imdevimab
(RG6413/RG6412)
COVID-19

AVASTIN
(RG435)
HCC (adjuvant)

crovalimab
(SKY59/RG6107)
PNH

tiragolumab
(RG6058)
NSCLC

TECENTRIQ
(RG7446)
Esophageal Cancer

tominersen
(RG6042)
Huntington's
Disease

RG6264
(FDC, sc)
Breast Cancer

faricimab
(RG7716)
nAMD

TECENTRIQ
(RG7446)
HCC (adjuvant)

HEMLIBRA
(ACE910/RG6013)
Acquired hemophilia A

ALECENSA
(AF802/RG7853)
NSCLC (adjuvant)

AVASTIN
(RG435)
HCC(intermediate stage)

OBP-301*
(Telomelysin)
Esophageal Cancer

TECENTRIQ
(RG7446)
NSCLC (adjuvant)

faricimab
(RG7716)
Diabetic Macular
Edema

TECENTRIQ
(RG7446)
Ovarian Cancer

tiragolumab
(RG6058)
SCLC

AVASTIN
(RG435)
SCLC

TECENTRIQ
(RG7446)
HCC(intermediate stage)

giredestrant
(RG6171)
Breast Cancer

POLIVY
(RG7596)
1L DLBCL

ACTEMRA
(MRA/RG1569)
COVID-19 pneumonia

TECENTRIQ
(RG7446)
RCC (adjuvant)

ipatasertib
(RG7440)
Prostate Cancer

TECENTRIQ
(RG7446)
2L RCC

TECENTRIQ
(RG7446)
Early Breast Cancer

tiragolumab
(RG6058)
Esophageal Cancer

TECENTRIQ
(RG7446)
Urothelial Carcinoma

TECENTRIQ
(RG7446)
HNC (adjuvant)

TECENTRIQ
(RG7446)
NSCLC (neoadjuvant)

TECENTRIQ
(RG7446)
NSCLC (Stage III)

tiragolumab
(RG6058)
NSCLC (Stage III)

2021

2022

2023

2024 and beyond

*in-licensed (Oncolys BioPharma Inc.)

FoundationOne CDx Cancer Genomic Profile

Companion diagnostic indications

As of April 22, 2021

Alterations	Cancer type	Relevant drugs
Activated <i>EGFR</i> gene alterations	Non-small cell lung cancer (NSCLC)	afatinib dimaleate, erlotinib hydrochloride, gefitinib, osimertinib mesylate
<i>EGFR</i> exon 20 T790M alterations		osimertinib mesylate
<i>ALK</i> fusion genes		alectinib hydrochloride, crizotinib, ceritinib
<i>ROS1</i> fusion genes		entrectinib
<i>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)
<u>Microsatellite Instability-High</u>		<u>nivolumab (genetical recombination)</u>
<u>Microsatellite Instability-High</u>	Solid tumors	<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

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

FoundationOne Liquid CDx Cancer Genomic Profile

Companion diagnostic indications

As of April 22, 2021

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

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INNOVATION BEYOND IMAGINATION