



TOP INNOVATOR
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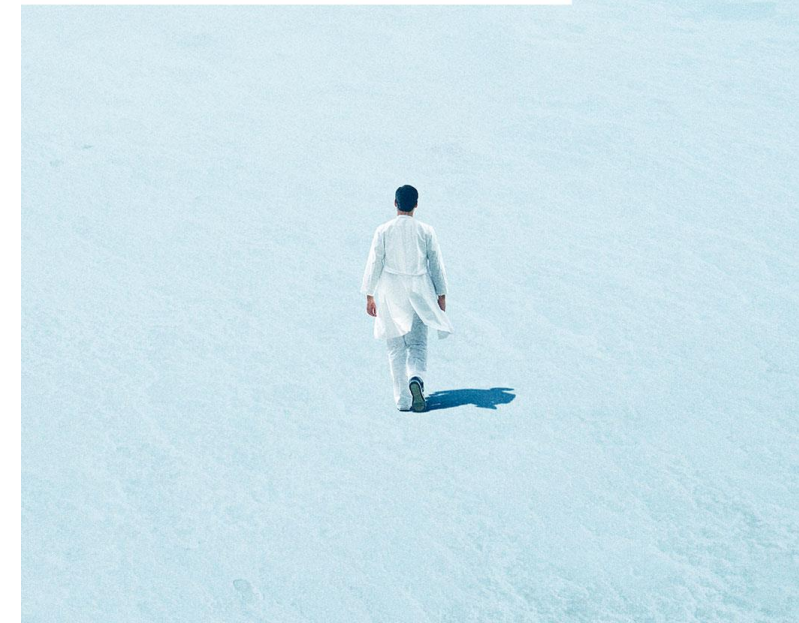
Conference on FY2024.12 Q1 Financial Results

CHUGAI PHARMACEUTICAL CO., LTD.

24 April 2024



INNOVATION BEYOND IMAGINATION



Important Reminder

Forward-Looking Statements

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

Core Results

Chugai discloses its results on a Core basis from 2013 in conjunction with its transition to IFRS. Core results are the results after adjusting non-recurring items recognized by Chugai to IFRS results. Chugai’s recognition of non-recurring items may differ from that of Roche due to the difference in the scale of operations, the scope of business and other factors. Core results are used by Chugai as an internal performance indicator, for explaining the status of recurring profits both internally and externally, and as the basis for payment-by-results.

Note:

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

Agenda

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Dr. Osamu Okuda

President & CEO

02

Overview of Development Pipeline

Tsukasa Kusano

Executive Vice President
Head of Project & Lifecycle Management Unit

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FY2024 Q1 Consolidated Financial Overview (Core)

Iwaaki Taniguchi

Director, Executive Vice President & CFO



FY2024 Q1 Overview

Dr. Osamu Okuda

President & CEO

Financial Overview

- Significantly decreased in revenue due to the completion of supply of Ronapreve to the government and the NHI drug price revisions etc.
- Achieved high profitability, significantly surpassing last year, resulting in a slight decrease in profit
- Earnings forecast remain unchanged for record high core operating profit and core net income

Core (billions of JPY)	2023 Jan - Mar actual	2024 Jan - Mar actual	Growth		2024 Jan - Dec forecast	Progress (%)
Revenue	312.2	236.9	-75.3	-24.1%	1,070.0	22.1%
Domestic sales*	192.7	103.2	-89.5	-46.4%	454.9	22.7%
Overseas sales	98.8	101.3	+2.5	+2.5%	467.1	21.7%
Other revenue	20.7	32.5	+11.8	+57.0%	148.0	22.0%
Operating profit	105.4	102.1	-3.3	-3.1%	460.0	22.2%
Operating margin	33.8%	43.1%	+9.3%pts	-	43.0%	-
Net income	78.4	76.0	-2.4	-3.1%	335.5	22.7%
EPS (yen)	47.66	46.16	-1.50	-3.1%	204.00	22.6%

- Domestic sales declined due to the impact of the decrease in Ronapreve* sales, the NHI drug price revisions, and the market penetration of generic drugs, despite the growth of new and mainstay products. As expected
- Regarding overseas sales, the increase in Hemlibra exports to Roche exceeded the decrease in Actemra exports. Mostly as expected
- Other revenue increased mainly due to the increase in one-time incomes. Mostly as expected
- With the completion of supply of Ronapreve to the government, profitability significantly improved, securing an operating profit margin of 43.1% as a core business. Mostly as expected

* Recorded sales of ¥81.2 billion for the supply of Ronapreve to the government in the same period of previous year

Summary of Chugai Originated Global Products

- Despite the BS impact on Actemra, we expect continued growth in overseas sales, primarily driven by Hemlibra
- We are dedicated to delivering the value that patients truly need through our unique, proprietary medicines

Product (Billions of yen)	FY2024 Q1 Results		Year on Year	Full Year Forecast	Comments	
Hemlibra [®]	Domestic:	12.5	+0.8%	56.5	• Japan: Sales are flat YoY due to last year's drug price revision ^{*1} . Domestic market share steadily increased • Overseas: Increased overseas sales, especially in the EU and International. No change in export forecast - • We provide value to patients worldwide through convenience and accumulated clinical evidence	
	Export:	57.8	+25.7%			267.3
	Overseas local:	961 mCHF	+9%			
Actemra [®]	Domestic:	10.2	+3.0%	45.9	• Japan: Continued to obtain new prescriptions for rheumatoid arthritis. Other indications also penetrated • Overseas: Overseas sales decreased slightly due to biosimilars impact. No change in export forecast - • We provide value to patients through the established evidence as an originator of IL-6 inhibitors	
	Export:	23.4	-26.4%			109.8
	Overseas local:	550 mCHF	-3%			
Alecensa [®]	Domestic:	6.6	+0.0%	31.3	• Japan: Competitors entered first-line therapy since 2021, but maintained a high market share (78.3% ^{*2}) • Overseas: Continued market penetration in all regions. No change in export forecast - • We anticipate that the expanded indication for NSCLC adj. will further contribute to the treatment of patients	
	Export:	14.0	-16.2%			58.9
	Overseas local:	311 mCHF	+5%			
Enspryng [®]	Domestic:	5.8	+23.4%	22.4	• Japan: De-steroidization treatment is gaining ground. Sales are increasing due to its earlier introduction • Overseas: Sales are growing in the US and international. No change in export forecast at this point - • We provide a convenient treatment option for patients who wish to avoid steroids	
	Export:	2.1	+200.0%			6.4
	Overseas local:	31 mCHF	+55%			

* "Export" in the table includes Taiwan local sales in the Chugai territory. 'Overseas local' refers to overseas local sales by Roche, and Year on Year (%) is on a constant exchange rate basis.

*1 Market expansion re-pricing in November 2023 (-9.4%)

*2 Drug price-based share (lung cancer: ALK TKI) IQVIA JPM 2024 March

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[Hemlibra] Domestic Hemophilia A Patient Share Trends

Q1 2023	Q2 2023	Q3 2023	Q4 2023	Q1 2024
30.0%	30.8%	31.7%	32.5%	33.2%

Introduction of New Management Members (Supervisory Responsibility)



Dr. Osamu Okuda
Representative Director,
President & CEO

Supervisory responsibility for
External Affairs and Audit



Iwaaki Taniguchi
Director, Executive Vice
President & CFO

Supervisory responsibility for
Finance & Accounting, Corporate
Communication and Procurement

Head of Finance Supervisory Div.



Dr. Hitoshi Iikura
Director, Executive Vice
President

Supervisory responsibility for
Research, Translational Research
and Clinical Development

Head of Translational Research
Div.



Tetsuya Yamaguchi
Executive Vice President

Supervisory responsibility for PHC
Solution, Partnering and Special
Mission for CVF

Head of PHC Solution Unit



Junichi Ebihara
Executive Vice President

Supervisory responsibility for Legal
and Intellectual Property



Shinji Hidaka
Executive Vice President

Supervisory responsibility for
Marketing & Sales, Drug Safety,
and Medical Affairs



Yoshiyuki Yano
Executive Vice President

Supervisory responsibility for
Human Resource Management
and ESG



Tsukasa Kusano
Executive Vice President

Supervisory responsibility for
Project & Lifecycle Management

Head of Project & Lifecycle
Management Unit



Dr. Kaori Ouchi
Executive Vice President

Supervisory responsibility for Risk
Management, Compliance and
Quality & Regulatory Compliance,
Pharmaceutical Technology and
Manufacturing Technology



Norihisa Onozawa
Executive Vice President

Supervisory responsibility for
Corporate Planning, ASPIRE
Transformation, Business
Transformation and Digital
Transformation

Overview of Development Pipeline

Tsukasa Kusano

Executive Vice President, Head of Project & Lifecycle Management Unit

Q1 Topics (1/2)



As of April 24, 2024

Approved	Piasky	Paroxysmal nocturnal hemoglobinuria (PNH)	February 2024 (China) March 2024 (Japan)
	Alecensa	ALK-positive early-stage NSCLC (adjuvant)	April 2024 (U.S.)
	Mitchga	Pruritus associated with atopic dermatitis (children aged ≥ 6 and < 13 years), Prurigo nodularis* ¹	March 2024 (Japan)
	Vabysmo	Macular edema associated with retinal vein occlusion (RVO)	March 2024
	FoundationOne Liquid CDx	Talazoparib for <i>BRCA</i> gene mutation-positive castration-resistant prostate cancer with distant metastases	February 2024
	FoundationOne Liquid CDx	Selpercatinib for <i>RET</i> fusion-positive solid tumors	February 2024
	FoundationOne Liquid CDx	Capivasertib for advanced HR-positive, HER2-negative breast cancer with <i>PIK3CA</i> , <i>AKT1</i> or <i>PTEN</i> alterations	March 2024
Filed	nemolizumab	Prurigo nodularis, Atopic dermatitis* ²	February 2024 (filing accepted in U.S./EU)
	CellCept	Systemic sclerosis with interstitial lung disease (SSc-ILD)	February 2024
	Evrysdi	Pre-symptomatic spinal muscular atrophy (SMA)	February 2024
	mosunetuzumab	FL (3rd line)	March 2024
	Tecentriq	Alveolar soft part sarcoma	March 2024

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

*¹ Conducted by Maruho, a domestic licensee, *² Conducted by Galderma, an overseas licensee

Q1 Topics (2/2)



As of April 24, 2024

Initiation of study	RG6299(ASO Factor B)	IgA nephropathy	P1 study (February 2024)
	RG6356/SRP-9001	Duchenne muscular dystrophy (Non-ambulatory)	P3 study (March 2024)
	glofitamab+Polivy	Previously untreated large B-cell lymphoma	P3 study (April 2024)
Readout	Enspryng	Luminesce study (gMG) met its primary endpoint (the results did not reach our expectations on the degree of clinical benefit)	March 2024
	mosunetuzumab	Domestic phase I study in expansion cohort for FL (3rd line) met its primary endpoint	February 2024
	Vabysmo	NIHONBASHI study (AS) met its primary endpoint	April 2024
Removed from pipeline	Enspryng	Luminesce study (gMG): Development discontinued	
Medical conference	nemolizumab	OLYMPIA LTE study(Prurigo nodularis), ARCADIA 1&2 maintenance study (Atopic dermatitis)*: American Academy of Dermatology (AAD)	March 2024
	Vabysmo	BALATON study, COMINO study (RVO): Angiogenesis Exudation and Degeneration 2024	February 2024
Priority review designation	nemolizumab	Prurigo nodularis*	February 2024 (U.S.)
License-in agreement	zilebesiran (RNAi Therapeutic)	Hypertension (created by Alnylam Pharmaceuticals, Inc. and license-in from Roche)	April 2024

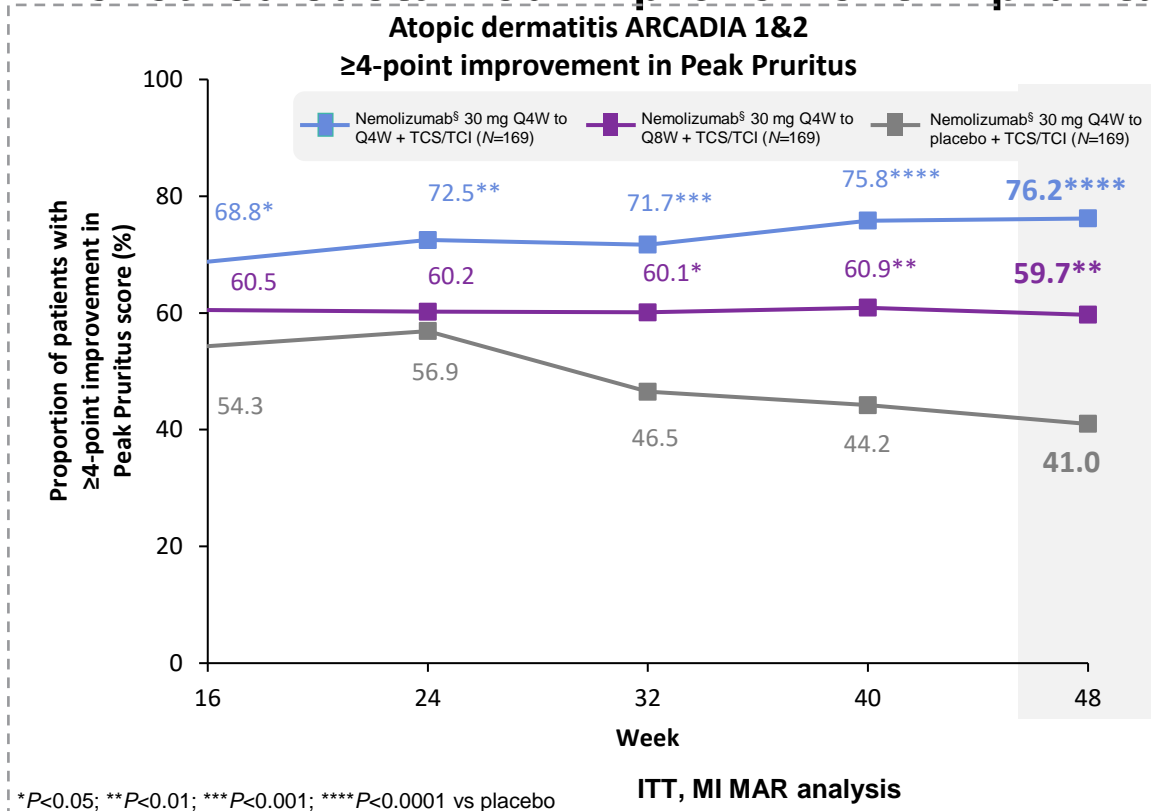
2024: Key R&D Milestones

Underlined and bolded are new progress since February 1, 2024

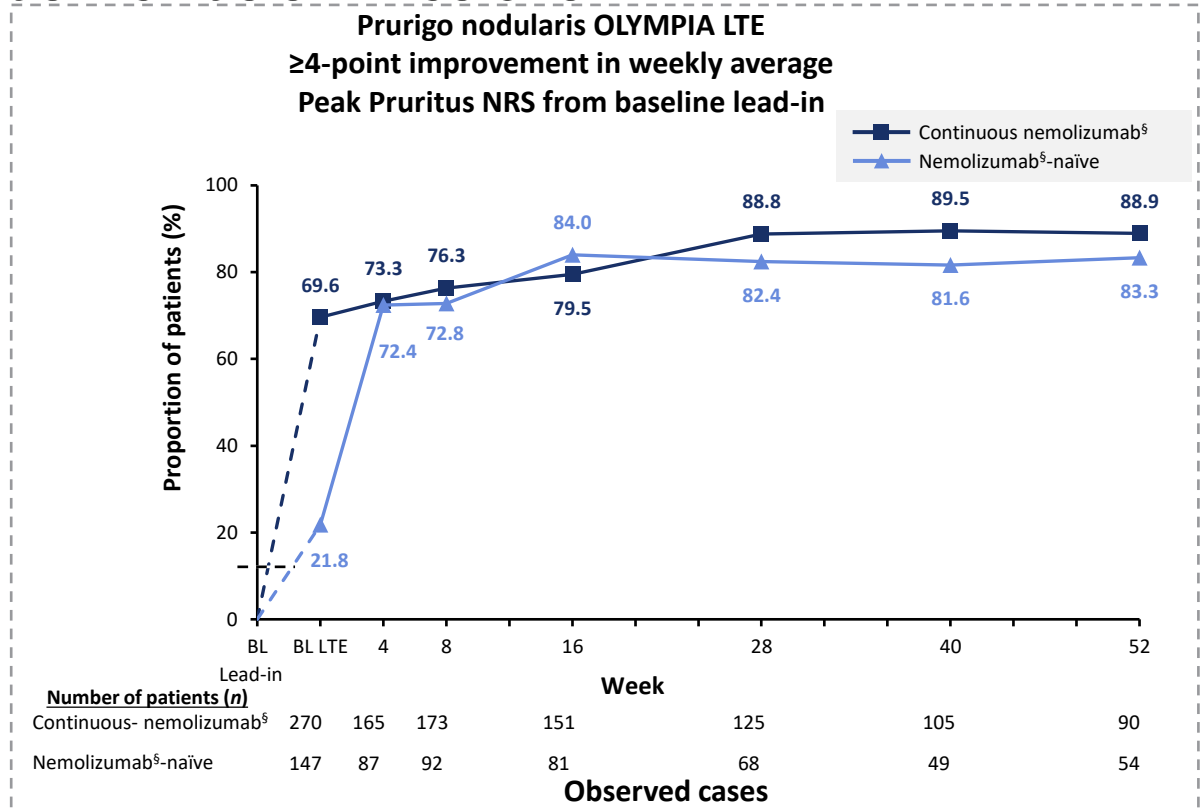
	Product	Indication/Study name	Progress
Projects to be approved	crovalimab	Paroxysmal nocturnal hemoglobinuria (Japan/EU/U.S.)	<u>Approved (Japan)</u>
	Alecensa	NSCLC (adjuvant) (U.S./EU/Japan)	<u>Approved (U.S.)</u>
	Vabysmo	Retinal vein occlusion	<u>Approved</u>
P3/Pivotal readouts	Enspryng	Luminesce study: generalized myasthenia gravis	<u>Achieved PE</u> (the results did not reach our expectations on the degree of clinical benefit) <u>/Development discontinued</u>
	Tecentriq + tiragolumab	SKYSCRAPER-01 study: NSCLC (1st Line)	
	mosunetuzumab	Domestic P1 (Expansion cohort): Follicular lymphoma (3rd Line)	<u>Achieved PE</u>
	mosunetuzumab + Polivy	SUNMO study: r/r aggressive B-cell non-Hodgkin's lymphoma	
	Vabysmo	NIHONBASHI study: Angioid streaks	<u>Achieved PE</u>
P2 readouts	GYM329 + Evrysdi	MANATEE study: Spinal muscular atrophy (SMA)	

Overview of Development Pipeline

Nemolizumab: Global Ph3 ARCADIA 1&2 maintenance and OLYMPIA LTE studies revealed sustained improvement in pruritus as well as skin lesions*1, *2



The safety profile was consistent across treatment arms and most treatment-related adverse events were non-serious and mild/moderate in intensity.



Long-term safety data were consistent with the previously reported safety profiles in the Phase 3 pivotal trials.

*1 IGA0/1 and EASI-75 success rates in ARCADIA1&2 at 48wk were, IGA0/1: 49.7% (placebo), 60.4% (Q8W, P<0.05) and 61.5% (Q4W, P<0.05), and EASI-75: 63.9% (placebo), 75.7% (Q8W, P<0.05) and 76.3% (Q4W, P<0.05)
 *2 IGA0/1 success rates in OLYMPIA LTE at 52wk were 69.2% (Continuous nemolizumab) and 64.5% (Nemolizumab-naïve)

ITT, intent-to-treat; MAR, missing at random; MI, multiple imputation; N, total number of patients in the treatment group; NRS, Numerical Rating Scale; Q4/8W, every 4/8 weeks; TCI, topical calcineurin inhibitors; TCS, topical corticosteroids
 Weekly PP NRS score was calculated using 7 consecutive days' diary data and set to missing if less than 4 days' data were available. Percentage (%) was calculated using the number of patients with available data (n) at the analysis visit as the denominator. Week 16 measurements serve as maintenance baseline measurements. Strata adjusted P-values were from Cochran-Mantel-Haenszel test adjusting for the stratification variable study. The estimates were from 50 complete datasets by MI with MAR assumption.
[§]Week 16 data were from non-responder imputation.
[§]Galderna is investigating the use of nemolizumab and has not received approval for any indication in any country.
 Nemolizumab or corresponding placebo onto background TCS/TCI. Nemolizumab responder at 16wk were rerandomized to placebo, nemolizumab Q4W or Q8W arms.

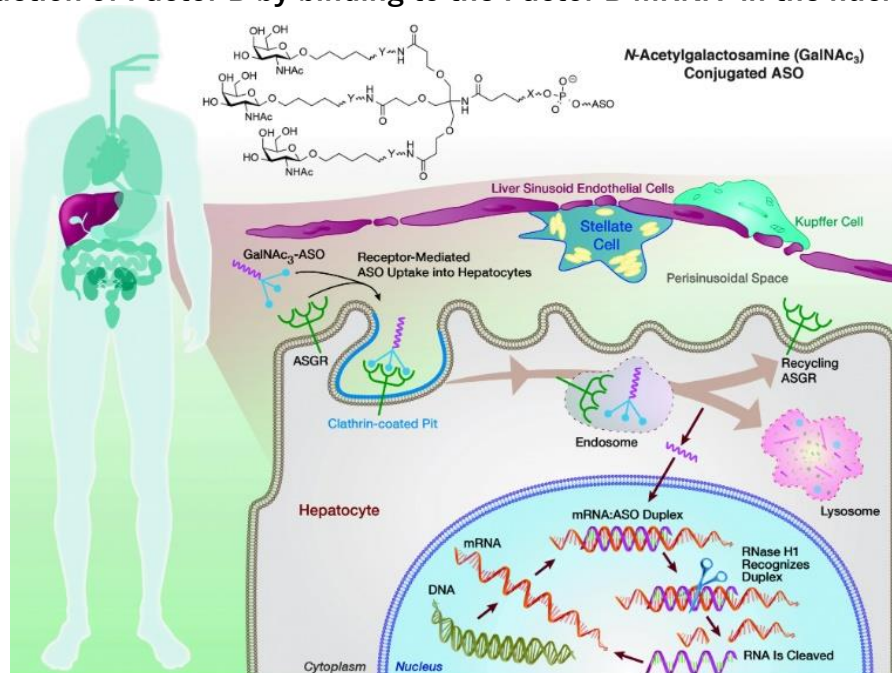
BL, baseline; LTE, long-term extension; n, number of patients with available data based on observed cases for each cohort at the respective visit; NRS, Peak Pruritus Numerical Rating Scale
 Weekly values were calculated as average of 7 consecutive days data up to the actual visit day or target study day (excluding) and set to missing, if <4 days data were available. Baseline Lead-in is defined as the last non-missing value before the first dose of study drug in Lead-in study. Baseline/Day 1 (Baseline LTE) is the last non-missing value prior to first dose of study drug in this study. Observed cases are presented where all observed data even after use of rescue therapy are included; No imputations for missing data. **Continuous nemolizumab[§]**: Patients with a <12-week interval between the last nemolizumab[§] dose in the lead-in study and the first dose in LTE. (Patients could have different exposure duration before entering LTE). **Nemolizumab[§]-naïve**: Patients who never received nemolizumab[§] before LTE
[§]Galderna is investigating the use of nemolizumab and has not received approval for any indication in any country.

ASO(AntiSense Oligonucleotide) Factor B (RG6299)

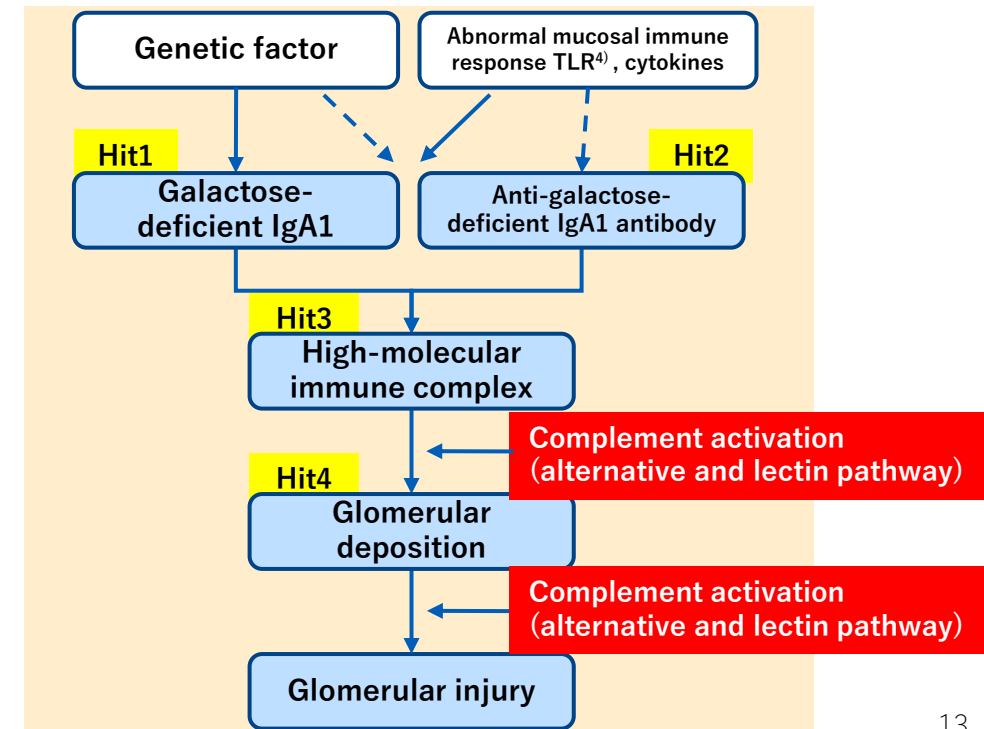
Oligonucleotide therapeutics, selectively taken up by hepatocytes to inhibit complement factor B production

- IgA nephropathy (IgAN) is characterized by persistent abnormalities in urinalysis such as glomerular hematuria and proteinuria, and deposition of IgA and complements in the glomeruli. The complement alternative pathway is thought to contribute to the development of IgAN, and complement factor B is involved in the activation of the alternative pathway.
- ASO Factor B is being developed for the treatment of IgAN and is an oligonucleotide therapeutics that inhibits the production of complement factor B and thereby suppressing the activation of the alternative complement pathway.

N-acetylgalactosamine (GalNAc)-conjugated ASO is selectively taken up into hepatocytes by binding to ASGPR¹. (figure below²) GalNAc-ASO is metabolized and free-ASO Factor B inhibits the production of Factor B by binding to the Factor B mRNA in the nucleus.



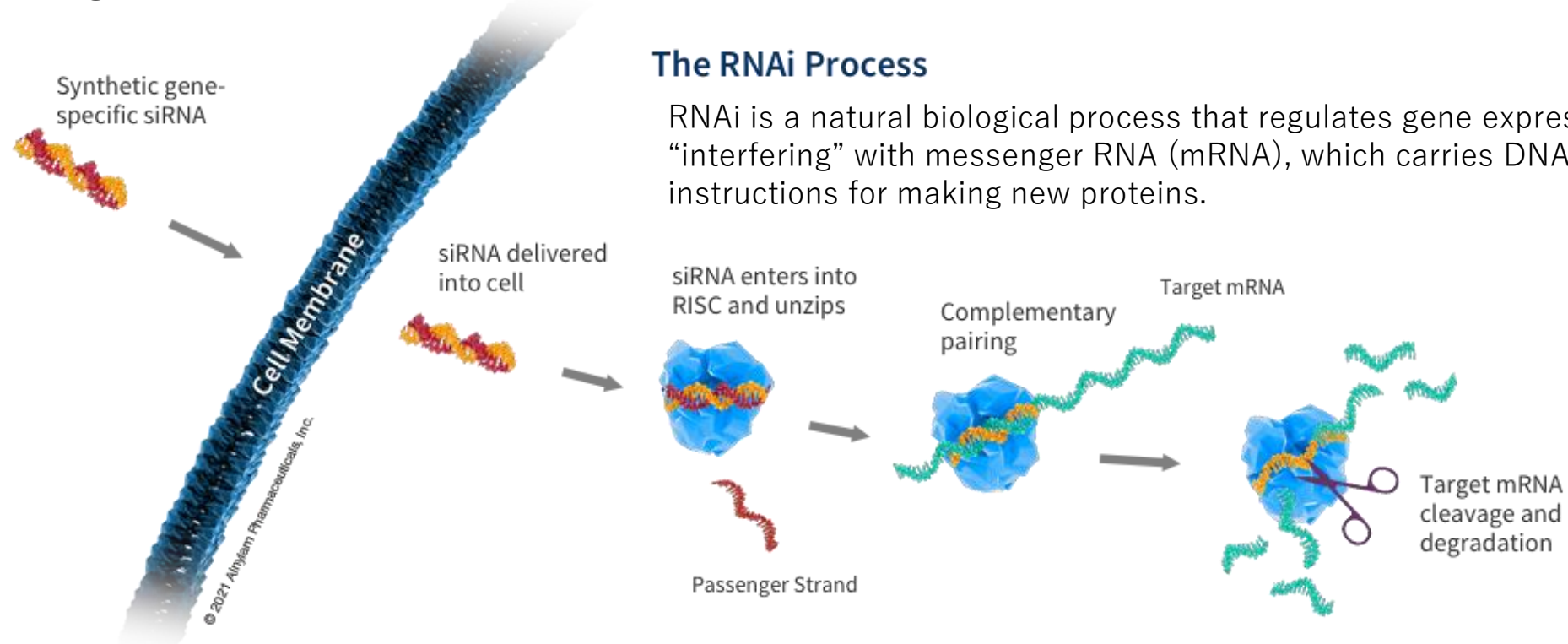
The Multi Hit Hypothesis for the development of IgAN³ and complement



1) Abbreviation for asialoglycoprotein receptor; 2) Nucleic Acid Ther. 2019;29(1):16-32; 3) Adapted from Nihon jinzo gakkai shi2015; 57(8) 4) Abbreviation for toll-like receptor

Zilebesiran, an RNAi Therapeutic Agent as a New Modality

RNAi is an RNA interference mechanism by which genes are naturally regulated in cells, and one of the innovative drugs based on RNAi is an siRNAs



The RNAi Process

RNAi is a natural biological process that regulates gene expression by “interfering” with messenger RNA (mRNA), which carries DNA’s instructions for making new proteins.

- Zilebesiran, a siRNA^{*1}, is internalized into hepatocytes and forms a protein complex with RISC ^{*2}. Protein complexes bind to target mRNAs and degrade them, thereby inhibiting the synthesis of disease-causing proteins.
- The protein complex of siRNA and RISC can degrade target mRNA multiple times, which is expected to enable treatment once every six months.
- GalNAc^{*3} conjugation technology for siRNA, etc. increased the delivery rate into hepatocytes and enabled the formulation for subcutaneous injection.

*1 siRNA: small interfering RNA

*2 RISC: a complex of intracellular proteins known as RNA-induced silencing complex, which recognizes and uses double-stranded RNA to play an important role in gene regulation (inhibition of protein synthesis)

*3 GalNAc: ligand for the Asialoglycoprotein receptor (ASGPR), which is highly expressed in hepatocytes

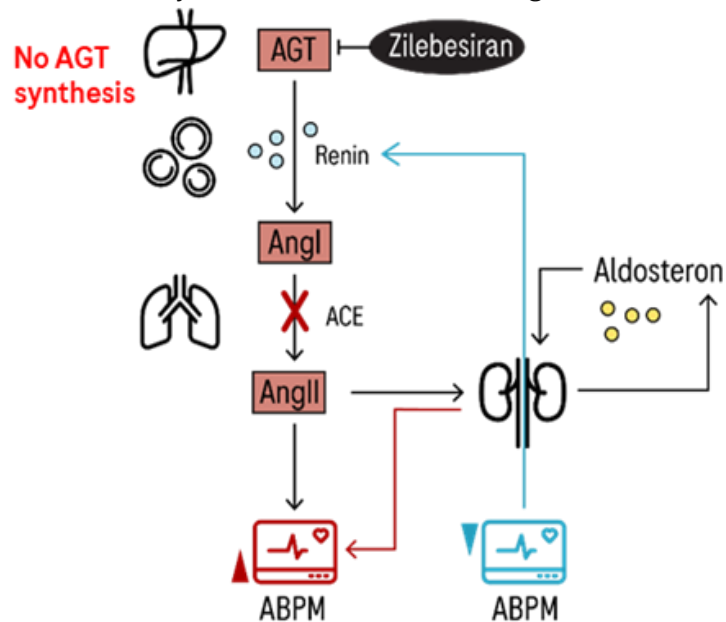
Source: Alnylam website; <https://www.alnylam.com/our-science/the-science-of-rnai> (searched in March 2024)

About Zilebesiran

- Zilebesiran, an RNAi therapy for hypertension, achieve sustained suppression of angiotensinogen (AGT) expression and is expected to be a promising solution to unmet medical needs in hypertensive patients with poor blood pressure control and a high risk of cardiovascular events

Zilebesiran targets the most upstream part of RAAS

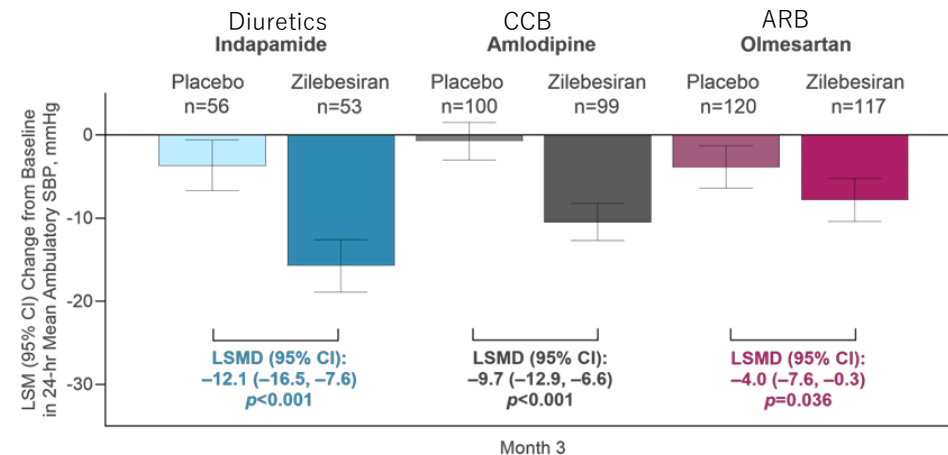
RAAS system: renin-angiotensin-aldosterone system
 AngI/II=Angiotensin I/II
 ACE=angiotensin-converting enzyme
 ABPM:Ambulatory Blood Pressure Monitoring



It continuously inhibits the synthesis of AGT, the highest precursor of the renin-angiotensin-aldosterone system involved in blood pressure regulation, by degrading mRNA, and finally shows an antihypertensive effect by reducing angiotensin II.

Overseas phase II clinical study results*

Mean 24 hour ambulatory systolic blood pressure: from baseline
 Mean change up to three months post-dose (primary endpoint)



CCB, calcium channel blocker; ARB, angiotensin receptor blocker

Study Design

- After randomization to three cohorts - on top of a diuretic, a CCB, or an ARB- the efficacy and safety of a single subcutaneous dose of zilebesiran or placebo were evaluated in hypertensive patients with an inadequate response to each treatment.

Result

- Serum AGT decreased by $\geq 95\%$ and persist for six months
- Clinically significant reductions in 24 hour ambulatory systolic blood pressure at three months compared with placebo
- There were no deaths or AEs leading to study discontinuation, and the AE of hypotension was transient.

* Presented at the American College of Cardiology Annual Scientific Session & Expo , April 6-8, 2024, Atlanta, GA, USA

Potential Market Sales of Main Projects

as of April 24, 2024

Domestic Sales

In-house Products	Indications	Domestic Sale* ¹	Roche products		Domestics Sales* ¹	Peak Sales Year		Changes from previous disclosure
			Roche products	Indications		Peak Sales Year	Peak Sales Year	
Hemlibra	Hemophilia A, Acquired Hemophilia A	50 bn+ JPY	Tecentriq	LC, BC, HCC, Urological cancer, and others	100 bn+ JPY	~2030		Reschedule of the filing timing for multiple indications and discontinuation of development
Alecensa	NSCLC, ALCL	30 bn+ JPY	Polivy	DLBCL, aNHL	50 bn+ JPY		2031 and beyond	Added SKYGLO study
Enspryng	NMOSD, AIE, MOGAD, TED	20 bn+ JPY	Vabysmo	nAMD, DME, RVO, AS	30 bn+ JPY		2031 and beyond	Changes of disclosure policy* ²
Piasky	PNH, aHUS	10 bn+ JPY	Phesgo	BC, Colorectal cancer	20 bn+ JPY	~2030		Changes of disclosure policy* ²
GYM329	SMA	< 10 bn JPY	Evrysdi	SMA	15 bn+ JPY	~2030		Changes of disclosure policy* ²
			mosunetuzumab	FL, aNHL	20 bn+ JPY		2031 and beyond	—
			glofitamab	LBCL	20 bn+ JPY		2031 and beyond	—
			tiragolumab	NSCLC, Esophageal cancer	15 bn+ JPY		2031 and beyond	Changes of disclosure policy* ²
			giredestrant	BC	10 bn+ JPY		2031 and beyond	Changes in competitive landscape
			ranibizumab (PDS)	nAMD, DME	< 10 bn JPY		2031 and beyond	—

*¹ without considering the development success rate

*² Changes associated with the revision of the amount category

Overseas Sales

[Products out-licensed to Roche] based on the forecast by Roche

- **Enspryng** (NMOSD, AIE, MOGAD, TED) : 1bn+ CHF
- **crovalimab** (PNH, aHUS, SCD, LN) : 1bn+ CHF
- **GYM329** (FSHD, SMA) : 1bn+ CHF

[Out-Licensed to 3rd Parties]

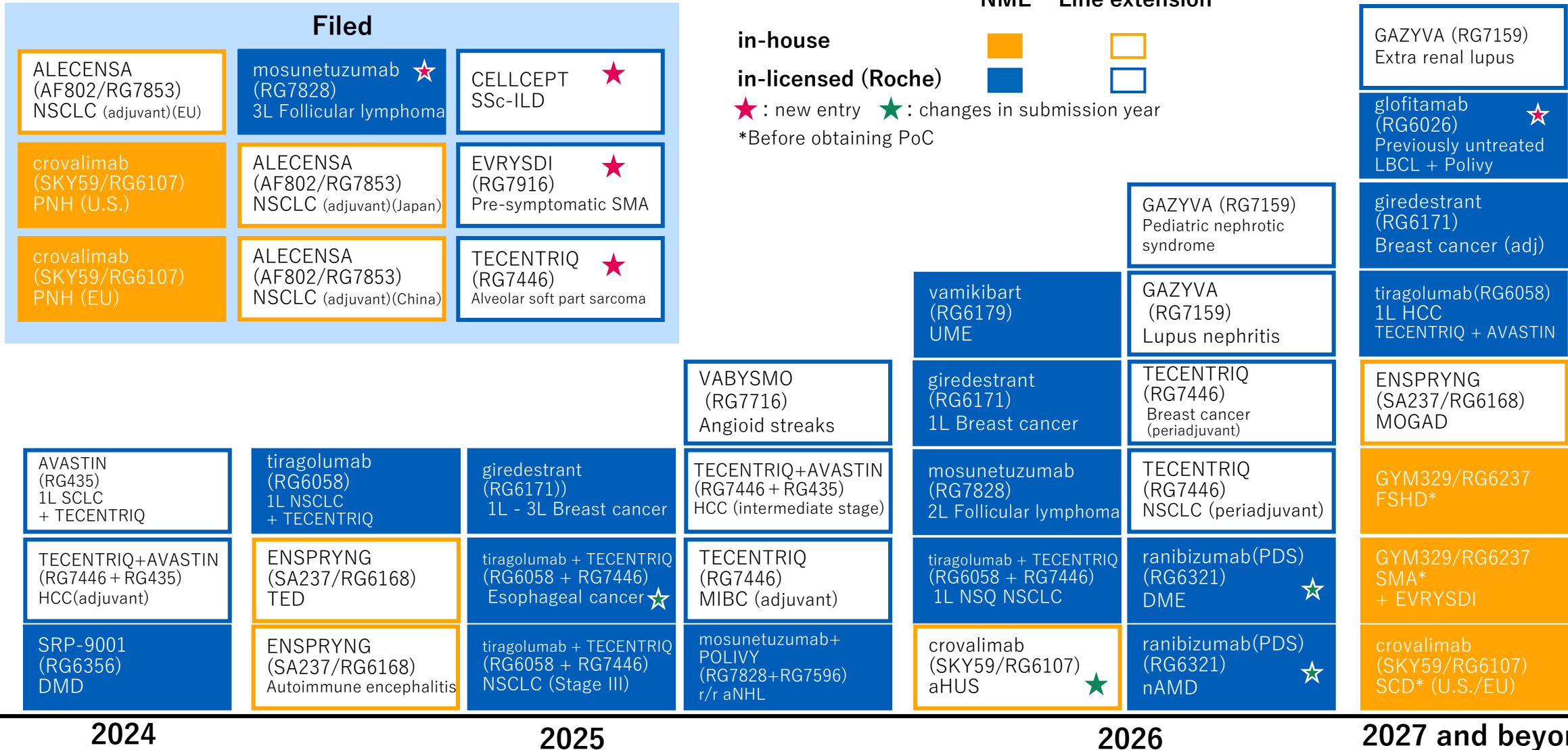
- **nemolizumab***³ (AD, PN) : 2bn+ USD

*³ based on the forecast by Galderma without considering the development success rate

Projected Submissions (Post PoC NMEs and Products)



as of April 24, 2024



Projects under Development (1/2)

As of April 24, 2024

	Phase I	Phase II	Phase III	Filed		
Cancer	LUNA18 - Solid tumors	RG7421 / cobimetinib - Solid tumors	RG6396 / pralsetinib - NSCLC (2L) - Solid tumors	AF802 (RG7853) / Alecensa - NSCLC (stage III)* RG7446 / Tecentriq - NSCLC (periadjuvant) - MIBC (adjuvant) - BC (periadjuvant) - HCC (2L) - Prostate cancer (2L) RG7446 / Tecentriq +RG435 / Avastin - SCLC (1L) - HCC (adjuvant) - HCC (intermediate stage) RG6058 / tiragolumab + RG7446 / Tecentriq - NSCLC (1L) - NSCLC (stage III) - NSQ NSCLC (1L) - Esophageal cancer	RG6058 / tiragolumab+RG7446 / Tecentriq+RG435 / Avastin - HCC (1L) RG6171 / giredestrant - BC (adjuvant) - BC (1L) - BC (1L-3L) RG7828 / mosunetuzumab - Follicular lymphoma (2L) RG7828 / mosunetuzumab + RG7596 / Polivy - r/r aNHL RG6396 / pralsetinib - NSCLC (1L) RG6026 / glofitamab +RG7596 / Polivy - Previously untreated large B-cell lymphoma ★	AF802 (RG7853) / Alecensa - NSCLC (adjuvant) (EU/China/Japan) RG7446 / Tecentriq - Alveolar soft part sarcoma★ RG7828 / mosunetuzumab - Follicular lymphoma (3L)★
	GC33 / codrituzumab - HCC	RG6026 / glofitamab - Hematologic tumors				
	ERY974 - Solid tumors	RG6194 / runimotamab - Solid tumors				
	STA551 - Solid tumors	RG6330 / divarasib - Solid tumors				
	SOF10 (RG6440) - Solid tumors	RG6433 / migoprotafib - Solid tumors				
	SPYK04 - Solid tumors	RG6160 / cevostamab - r/r multiple myeloma				
	ALPS12 (RG6524) - Solid tumors	RG6139 / tobemstomig - Solid tumors				
	SAIL66 - CLDN6 positive solid tumors					
	ROSE12 - Solid tumors					

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

* maintenance therapy after chemoradiation

In principle, completion of first dose is regarded as pipeline entry into each phase of clinical studies. ★: Projects with advances in stages since February 1, 2024

Projects under Development (2/2)

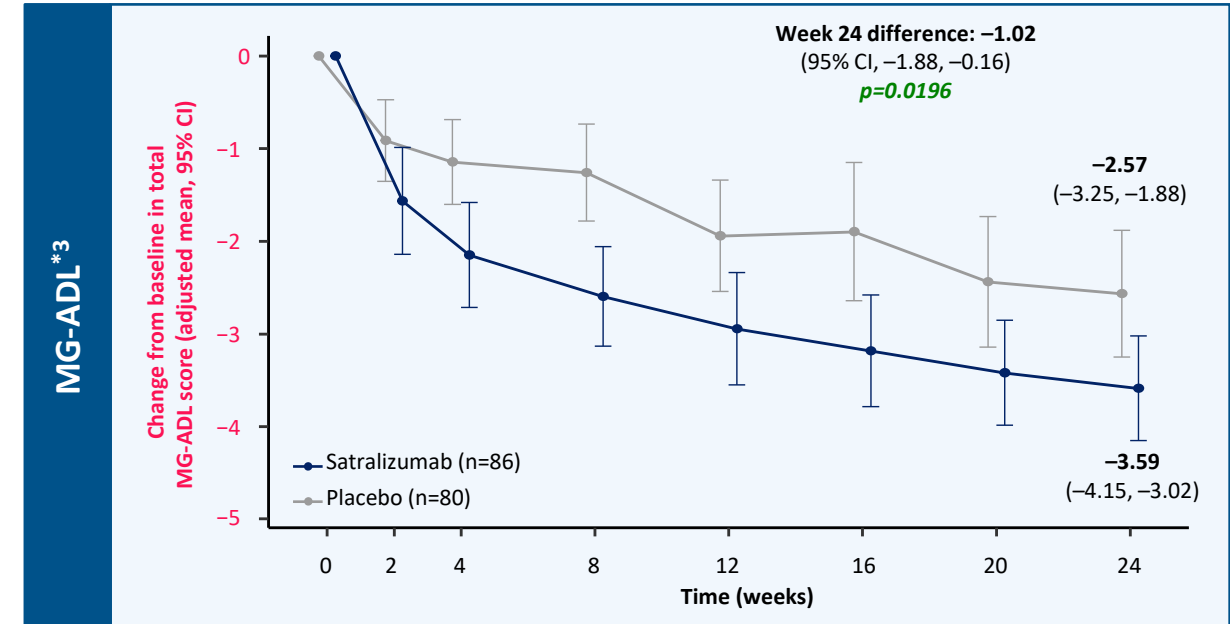
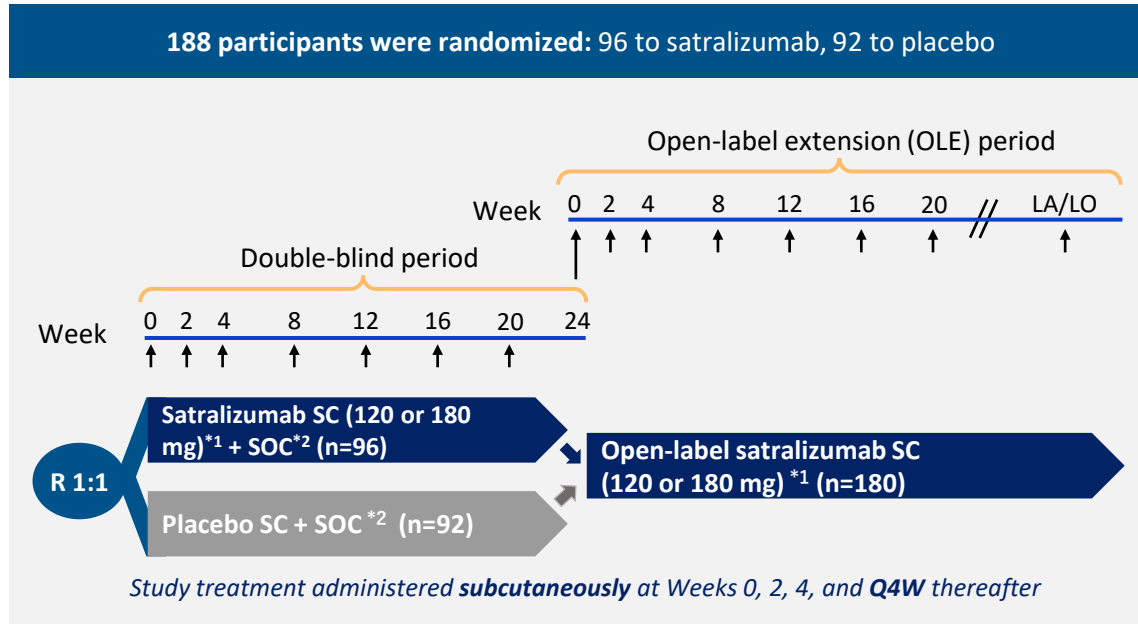
As of April 24, 2024

	Phase I	Phase II	Phase III	Filed
Immunology	DONQ52 - Celiac disease RAY121 - Autoimmune disease SKY59(RG6107)/crovalimab - Lupus nephritis RG6299 -IgA nephropathy ★		RG7159 / Gazyva - Lupus nephritis - Pediatric nephrotic syndrome - Extra renal lupus	CellCept - SSc-ILD ★
Neurology	RG7935 / prasinezumab - Parkinson's disease RG6102 / trontinemab - Alzheimer's disease (PI/II)	GYM329 (RG6237) + Evrysdi - SMA (PII/III) - FSHD RG6042 / tominersen - Huntington's disease	SA237 (RG6168) / Enspryng - MOGAD - AIE SRP-9001(RG6356) / delandistrogene moxeparvovec -DMD*	RG7916 / Evrysdi - Pre-symptomatic SMA ★
Hematology	NXT007 (RG6512) - Hemophilia A (PI/II)	SKY59 (RG6107) / crovalimab (U.S./EU) - SCD	SKY59 (RG6107) / crovalimab - aHUS	SKY59 (RG6107) / crovalimab (EU/U.S.) - PNH
Ophthalmology	RG6321 / PDS - nAMD (PI/II) - DME (PI/II)		SA237 (RG6168) / Enspryng - TED RG7716 / Vabysmo - Angioid streaks	RG6179/ vamikibart - UME
Other	REVN24 - Acute diseases	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 pipeline entry into each phase of clinical studies. ★: Projects with advances in stages since February 1, 2024

Enspryng: Generalized Myasthenia Gravis

Ph III study (LUMINESCE): met primary endpoint, but did not reach our expectations



- LUMINESCE, which compared the use of satralizumab + SOC vs placebo + SOC, investigated the available pre-clinical and clinical data hypothesizing the role of IL-6 inhibition in gMG. It demonstrated a statistically significant improvement in mean change from baseline in total MG-ADL score at Week 24 in patients with AChR-IgG+ gMG, although the effect size was small and did not reach our expectations on the degree of clinical benefit across various endpoints.
- Safety of satralizumab in gMG was consistent with established data in NMOSD with no new safety signals emerging. Satralizumab has a favorable safety profile and is generally well tolerated.
- Results from LUMINESCE do not impact the long-term experience of satralizumab's benefit:risk profile in NMOSD. Additionally, satralizumab continues to be evaluated in clinical trials in other neurological autoimmune and inflammatory diseases that may benefit from inhibition of IL-6 signaling, including AIE, MOGAD and TED.

↑ Administration of SC satralizumab or placebo. *1 Satralizumab 120 mg for patients with a body weight ≤ 100 kg or 180 mg for patients with a body weight > 100 kg. *2 Background therapies permitted were AChEI monotherapy or the following therapies (with or without AChEI): OCS, one IST, or an OCS in combination with one IST. *3 Analysis of covariance model fitted per visit adjusted for stratification factors on a data set that has been imputed using a mixed model repeated measures approach based on the protocol defined estimand.

Advances in Major Chugai Originated Projects Out-Licensed to 3rd Parties (1/2)



As of April 24, 2024

Generic name/development code	Mode of Action	Licensee	Granted rights to licensee	Indication	Stage	Progress
avutometinib /VS-6766	RAF/MEK inhibitor	Verastem Oncology	exclusive global license for the manufacturing, development and marketing	Recurrent LGSOC	global: P3	<ul style="list-style-type: none"> US FDA BTB (recurrent LGSOC in combination with defactinib) US orphan drug designation (avutometinib alone or in combination with defactinib in recurrent LGSOC) ★ RAMP301 trial (P3) initiated
				NSCLC	Global/U.S. : P1/2	<ul style="list-style-type: none"> RAMP 203 trial (P1/2 in combination with KRAS G12C inhibitor sotorasib with or without defactinib) ongoing globally U.S. FDA fast track designation of avutometinib in combination with sotorasib ★ RAMP 204 trial (P1/2 in combination with KRAS G12C inhibitor, adagrasib) ongoing in the U.S.
				metastatic Pancreatic Ductal Adenocarcinoma (mPDAC)*	US: Phase 1/2	<ul style="list-style-type: none"> RAMP 205 trial (P1/2 evaluating avutometinib and defactinib in combination with gemcitabine and nab-paclitaxel) ongoing
nemolizumab	Anti-IL-31 receptor A humanized monoclonal antibody	Galderma	exclusive global license for the development and marketing excluding Japan and Taiwan	Atopic dermatitis	FDA BLA / EMA MAA review	<ul style="list-style-type: none"> FDA BLA / EMA MAA accepted in Feb 2024 ★
				Prurigo nodularis	FDA BLA / EMA MAA review	<ul style="list-style-type: none"> FDA BLA / EMA MAA accepted in Feb 2024 ★
				Chronic kidney disease associated pruritus (CKDaP)	global: P2/3	<ul style="list-style-type: none"> On-going

* Newly added according to the progress of the project ★ Changes from the last announcement on February 1, 2024

Advances in Major Chugai Originated Projects Out-Licensed to 3rd Parties (2/2)



As of April 24, 2024

Generic name/development code	Mode of Action	Licensee	Granted rights to licensee	Indication	Stage	Progress
orforglipron/ LY3502970	Oral non-peptidic GLP-1 receptor agonist	Eli Lilly and Company	worldwide development and commercialization rights	T2D	global: P3	<ul style="list-style-type: none"> In a phase 2 study, orforglipron achieved HbA1c reduction up to 2.1% and 10.1 kg of weight reduction at 26 weeks. The results were published in <i>The Lancet</i>*¹
				Obesity	global: P3	<ul style="list-style-type: none"> In the other phase 2 study, orforglipron demonstrated up to 14.7% weight reduction at 36 weeks. The results were published in the <i>New England Journal of Medicine</i>*²
-/AP306 (EOS789)*³	Oral inhibitor of phosphate transporters	Alebund	Exclusive global license for the manufacturing, development and marketing	Hyperphosphatemia	China: P2	<ul style="list-style-type: none"> In a phase 2 study, AP306 showed a clinically significant reduction in serum phosphorus levels at the end of treatment

*¹ Juan PF, et al. Efficacy and safety of oral orforglipron in patients with type 2 diabetes: a multicentre, randomised, dose-response, phase 2 study. *Lancet* 2023.

*² Sean W, et al. Daily Oral GLP-1 Receptor Agonist Orforglipron for Adults with Obesity. *NEJM* 2023.

*³ Newly added according to the progress of the project

FoundationOne CDx Cancer Genomic Profile -Companion diagnostic indications-

As of April 24, 2024

Alterations	Cancer type	Relevant drugs
Activating <i>EGFR</i> alterations	NSCLC	afatinib maleate, erlotinib hydrochloride, gefitinib, osimertinib mesilate, dacomitinib hydrate
<i>EGFR</i> exon 20 T790M alteration		osimertinib mesilate
<i>ALK</i> fusion genes		alectinib hydrochloride, crizotinib, ceritinib, brigatinib
<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, encorafenib, binimetinib
<i>ERBB2</i> copy number alterations (HER2 gene amplification positive)	BC	trastuzumab (genetical recombination)
<i>AKT1</i> alterations		capiwasertib
<i>PIK3CA</i> alterations		
<i>PTEN</i> alterations		
<i>KRAS/NRAS</i> 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)
<i>NTRK1/2/3</i> fusion genes		entrectinib, larotrectinib sulfate
<i>RET</i> fusion genes		selpercatinib
<i>BRCA1/2</i> alterations	Ovarian cancer	olaparib
<i>BRCA1/2</i> alterations	Prostate cancer	olaparib, talazoparib tosilate
<i>FGFR2</i> fusion genes	Biliary tract cancer	pemigatinib

FoundationOne Liquid CDx Cancer Genomic Profile

Companion diagnostic indications

As of April 24, 2024

Alterations	Cancer type	Relevant drugs
Activating <i>EGFR</i> alterations	Non-small cell lung cancer (NSCLC)	afatinib maleate, erlotinib hydrochloride, gefitinib, osimertinib mesilate
<i>EGFR</i> exon 20 T790M alteration		osimertinib mesilate
<i>ALK</i> fusion genes		alectinib hydrochloride, crizotinib, ceritinib
<i>ROS1</i> fusion genes		entrectinib
<i>MET</i> exon14 skipping alterations		capmatinib hydrochloride hydrate
<i>NTRK1/2/3</i> fusion genes	Solid tumors	entrectinib
<i>BRCA1/2</i> alterations	Prostate cancer	olaparib

Upcoming events:

Information Meeting on Piasky June 27, 1:00-2:30 p.m. (JST)

FY2024 Q1 Consolidated Financial Overview(Core)

Iwaaki Taniguchi

Executive Vice President & CFO

P/L Jan – Mar (Year on Year)

(Billions of JPY)	2023	2024	Growth	
Revenue	312.2	236.9	- 75.3	- 24.1%
Sales	291.5	204.5	- 87.0	- 29.8%
Domestic	192.7	103.2	- 89.5	- 46.4%
Overseas	98.8	101.3	+ 2.5	+ 2.5%
Other revenue	20.7	32.5	+ 11.8	+ 57.0%
Cost of sales	-151.0	-72.6	+ 78.4	- 51.9%
(cost to sales ratio)	51.8%	35.5%	-16.3%p	-
Research and development	-36.1	-41.2	- 5.1	+ 14.1%
Selling, general and administration	-21.0	-21.2	- 0.2	+ 1.0%
Other operating income (expense)	1.3	0.2	- 1.1	- 84.6%
Operating profit	105.4	102.1	- 3.3	- 3.1%
(operating margin)	33.8%	43.1%	+9.3%p	-
Financial account balance	1.4	0.0	- 1.4	-
Income taxes	-28.3	-26.2	+ 2.1	- 7.4%
Net income	78.4	76.0	- 2.4	- 3.1%
EPS (JPY)	47.66	46.16	-1.50	- 3.1%

Domestic sales

Decrease due to the absence of supply of Ronapreve to the government recorded in the same period of the previous year, the NHI drug price revision and market penetration of generic drugs

Overseas sales

Decrease in sales of Actemra and significant increase in sales of Hemlibra

Other revenue

Increase mainly in one-time income

Cost of sales

Cost to sales ratio improved due to product mix, etc.

Research and development expenses

Increase due to investments in research and early development, and progress of development projects

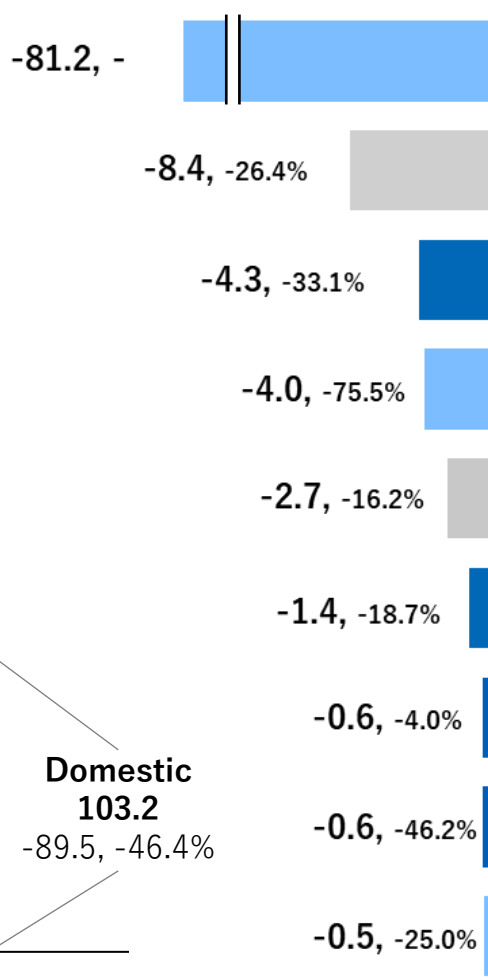
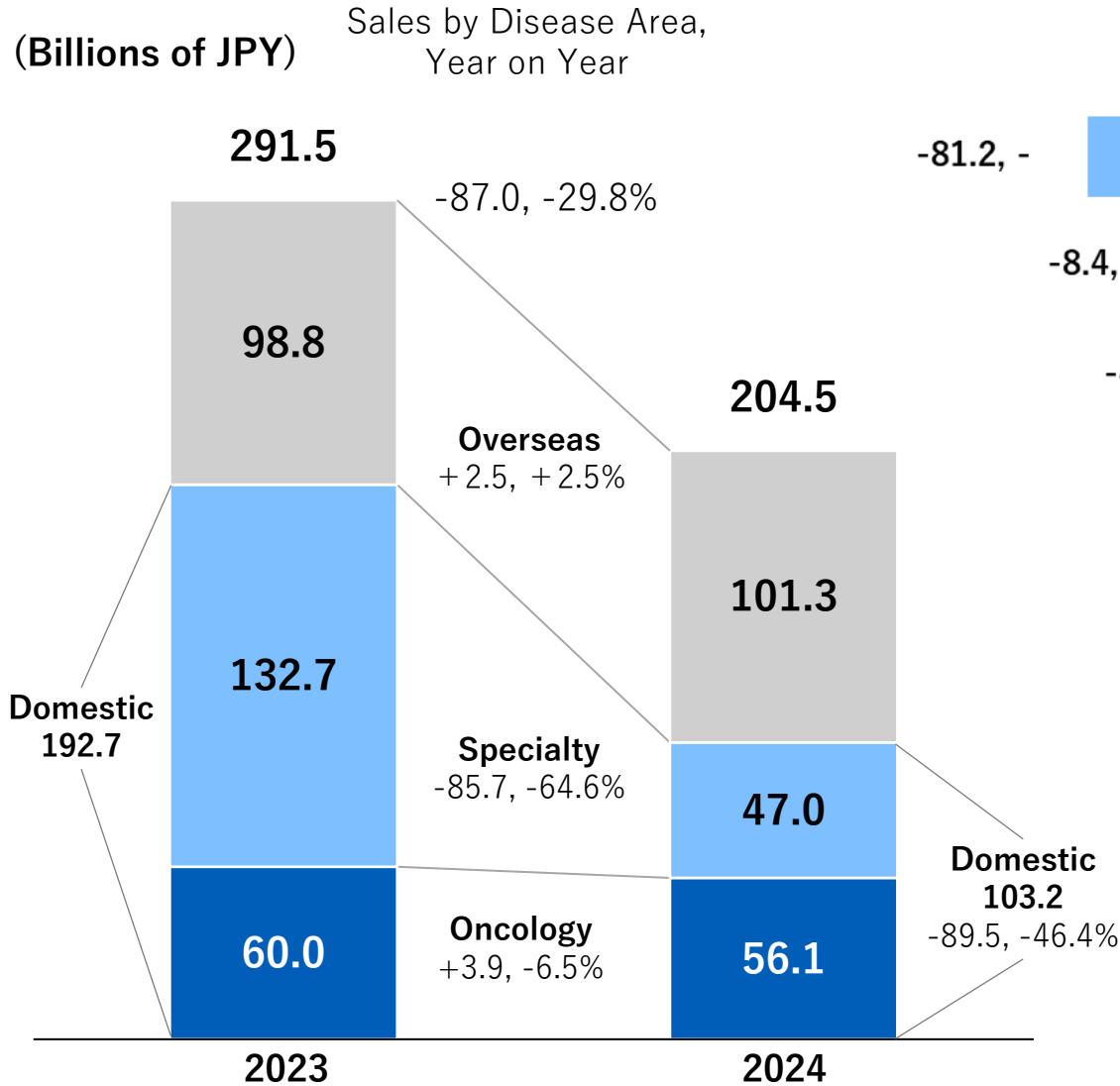
Selling, general and administration expenses

Same level as the same period of the previous year

Other operating income (expense)

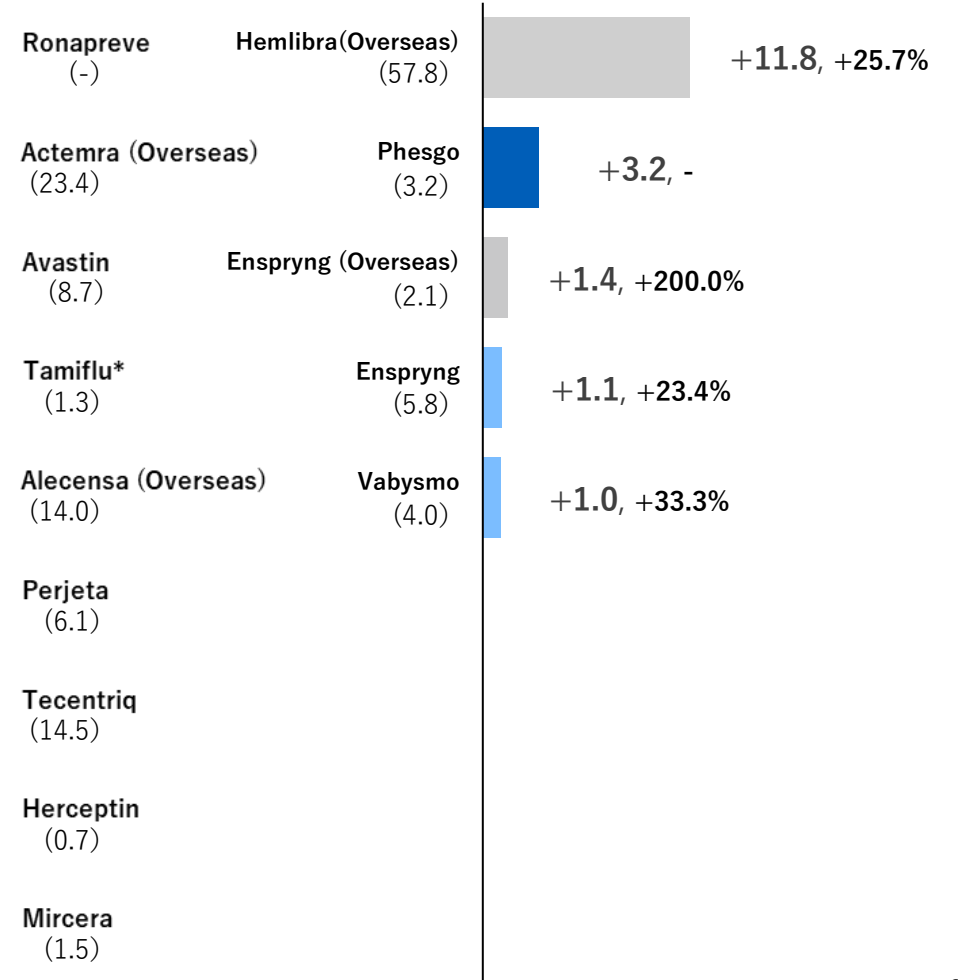
Decrease due to the absence of gain on sales of property, plant and equipment, etc. recorded in the same period of the previous year

Sales Jan – Mar (Year on Year)



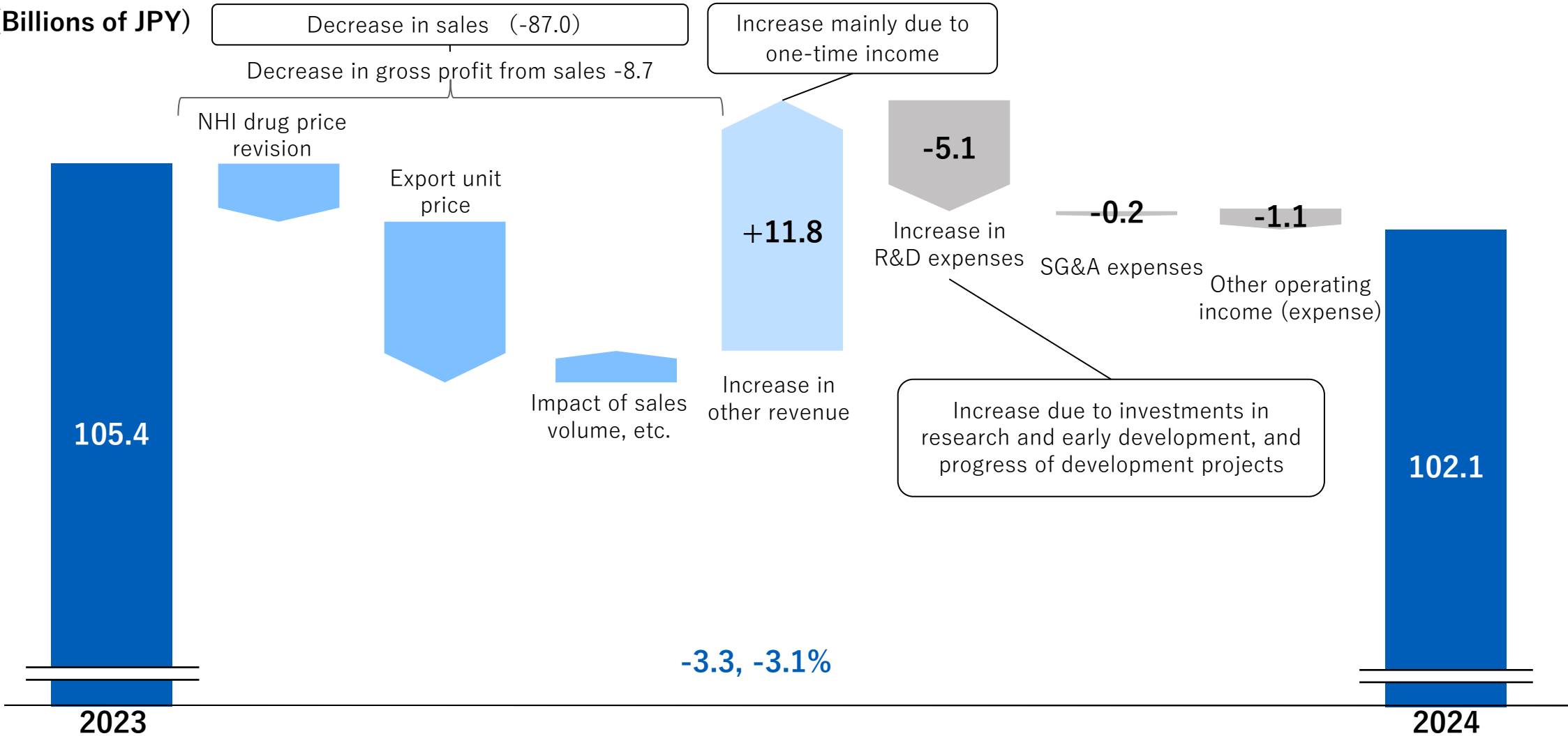
Sales by Product, Year on Year

(): Actual sales in FY2024
 %: Year-on-year percentage change
 *included in Other products of Specialty



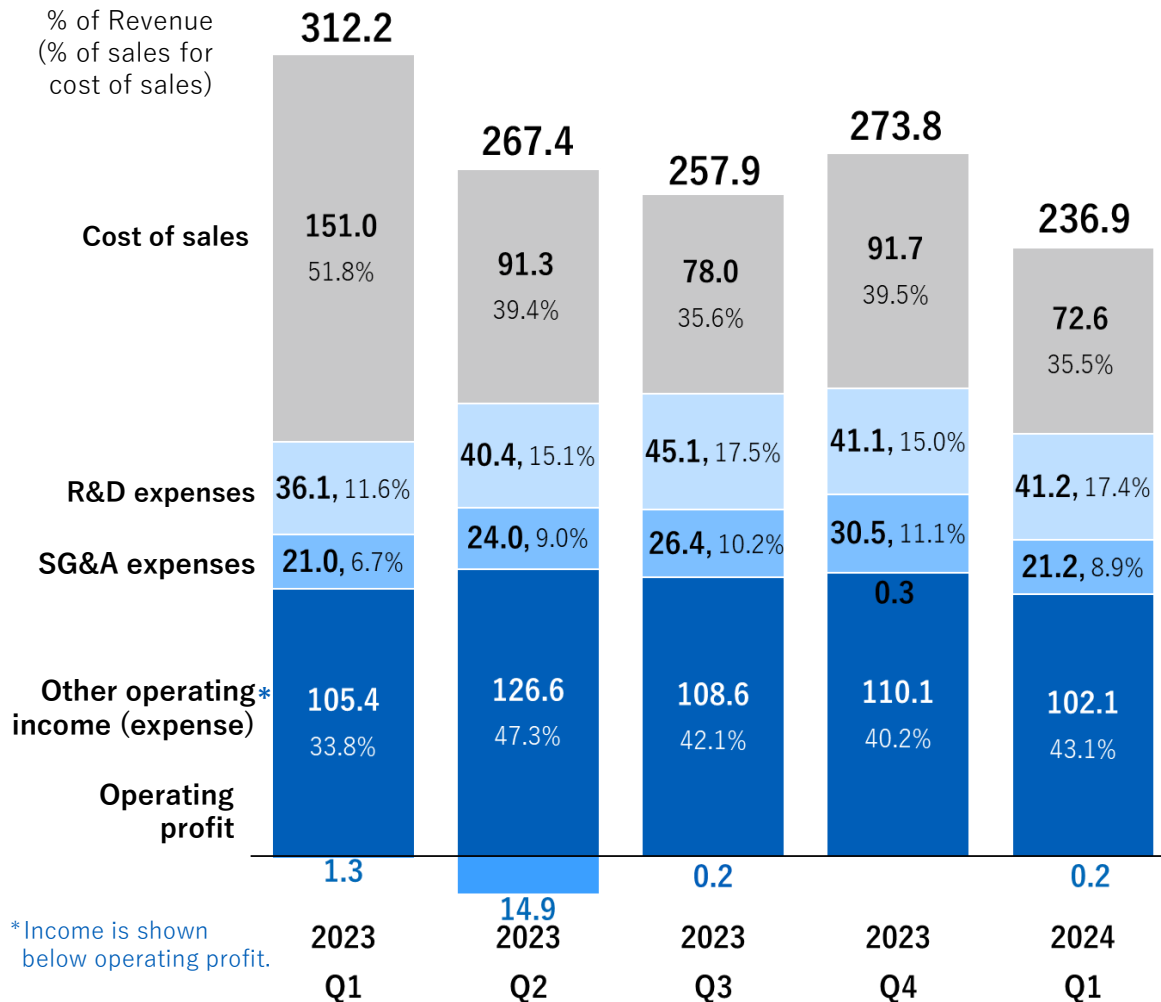
Operating Profit Jan – Mar (Year on Year)

(Billions of JPY)



Structure of Costs and Profit by Quarter

(Billions of JPY)



Year on Year (vs. 2023 Q1)

See the page “P/L Jan – Mar (Year on Year)”

Quarter on Quarter (vs. 2023 Q4)

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

R&D: same level as the previous quarter

SG&A: decrease due to seasonal factors, etc.

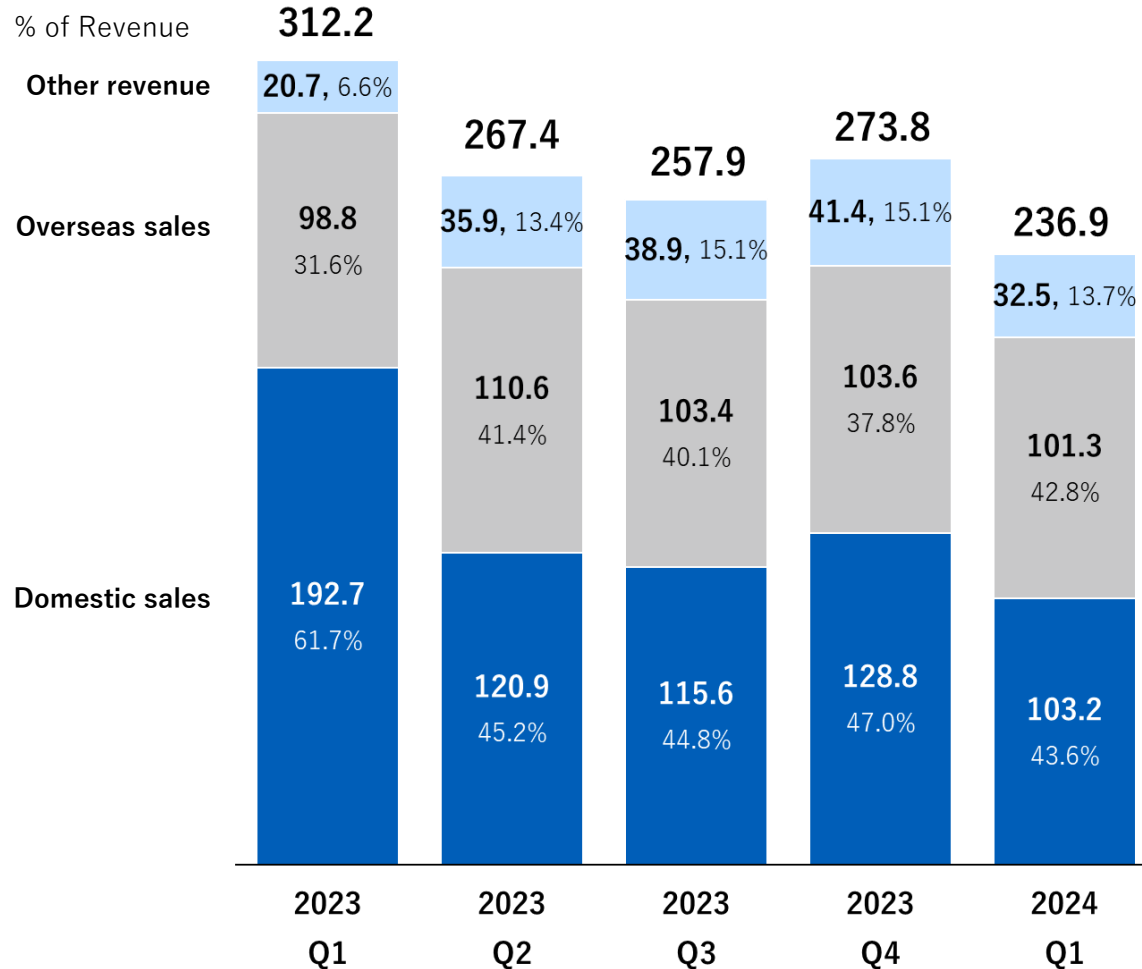
Other operating income (expense): same level as the previous quarter

Operating profit: -8.0 billion JPY, -7.3%

* Income is shown below operating profit.

Structure of Revenue by Quarter

(Billions of JPY)



Year on Year (vs. 2023 Q1)

See the page “P/L Jan – Mar (Year on Year)”

Quarter on Quarter (vs. 2023 Q4)

Domestic sales: decrease due to the difference of number of business days, the NHI drug price revision and decrease in sales of Tamiflu

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

Other revenue: increase in one-time income and decrease in royalty income of Hemlibra

P/L Jan – Mar (vs. Forecast)

(Billions of JPY)	Actual	Forecast		2023
	2024 Jan - Mar	2024 Jan - Dec	Progress	Progress*
Revenue	236.9	1,070.0	22.1%	28.1%
Sales	204.5	922.0	22.2%	29.9%
Domestic	103.2	454.9	22.7%	34.5%
Overseas	101.3	467.1	21.7%	23.7%
Other revenue	32.5	148.0	22.0%	15.1%
Cost of sales	- 72.6	- 337.5	21.5%	36.7%
(cost to sales ratio)	35.5%	36.6%	-	-
Research and development	- 41.2	- 171.0	24.1%	22.2%
Selling, general and administration	- 21.2	- 102.0	20.8%	20.6%
Other operating income (expense)	0.2	0.5	40.0%	8.1%
Operating profit	102.1	460.0	22.2%	23.4%
(operating margin)	43.1%	43.0%	-	-
Net income	76.0	335.5	22.7%	23.5%
EPS (JPY)	46.16	204.00	22.6%	23.5%

Domestic sales

Progress in line with forecast of domestic sales
(2023 progress excluding Ronapreve: 24.2%)

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 expenses

Progress nearly in line with forecast

Selling, general and administration expenses

Progress nearly in line with forecast

Other operating income (expense)

Progress nearly in line with forecast

* Jan - Mar progress versus Jan – Dec actual

Sales Jan – Mar (vs. Forecast)

(Billions of JPY)	Actual	Forecast		2023
	2024 Jan - Mar	2024 Jan - Dec	Progress	Progress *
Sales	204.5	922.0	22.2%	29.9%
Domestic	103.2	454.9	22.7%	34.5%
Oncology	56.1	246.5	22.8%	23.1%
Tecentriq	14.5	66.2	21.9%	23.1%
Polivy	7.4	37.3	19.8%	20.3%
Avastin	8.7	33.9	25.7%	26.1%
Alecensa	6.6	31.3	21.1%	21.8%
Perjeta	6.1	22.0	27.7%	22.3%
Kadcyla	3.6	16.2	22.2%	23.8%
Phesgo	3.2	15.5	20.6%	0.0%
Herceptin	0.7	2.2	31.8%	27.1%
Foundation Medicine	1.8	7.1	25.4%	25.7%
Other	3.4	14.8	23.0%	21.7%

(Billions of JPY)	Actual	Forecast		2023
	2024 Jan - Mar	2024 Jan - Dec	Progress	Progress *
Specialty	47.0	208.4	22.6%	44.6%
Hemlibra	12.5	56.5	22.1%	22.6%
Actemra	10.2	45.9	22.2%	22.3%
Vabysmo	4.0	22.8	17.5%	19.6%
Enspryng	5.8	22.4	25.9%	19.7%
Evrysdi	3.4	16.5	20.6%	20.7%
Mircera	1.5	6.8	22.1%	23.8%
CellCept	1.5	6.3	23.8%	22.9%
Edirol	1.4	5.6	25.0%	24.0%
Ronapreve	-	-	-	100.0%
Other	6.7	25.7	26.1%	32.0%
Overseas	101.3	467.1	21.7%	23.7%
Hemlibra	57.8	267.3	21.6%	21.7%
Actemra	23.4	109.8	21.3%	24.9%
Alecensa	14.0	58.9	23.8%	30.0%
Enspryng	2.1	6.4	32.8%	16.7%
Neutrogen	2.1	6.8	30.9%	23.5%
Edirol	0.1	1.8	5.6%	0.0%
Other	1.8	16.1	11.2%	21.2%

* Jan - Mar progress versus Jan - Dec actual

Impact from Foreign Exchange Jan – Mar

(Billions of JPY)	vs.2023 Actual rate 【C】 vs. 【A】	vs.2024 Actual rate 【C】 vs. 【B】
Revenue	+19.8	+1.2
Sales	+15.2	+1.3
Other revenue	+4.6	-0.1
Cost of sales	-1.0	-0.0
Other than above^{*1}	-1.1	-0.1
Operating profit	+17.7	+1.1

Exchange Rate (JPY)	2023 Actual rate ^{*2} Jan - Mar 【A】	2024 Forecast rate Jan - Mar 【B】	2024 Forecast rate Jan - Dec	2024 Actual rate ^{*2} Jan - Mar 【C】
1CHF	137.05	160.57	159.00	162.70
1EUR	141.96	157.00	157.00	161.10
1USD	132.79	137.46	136.00	131.49

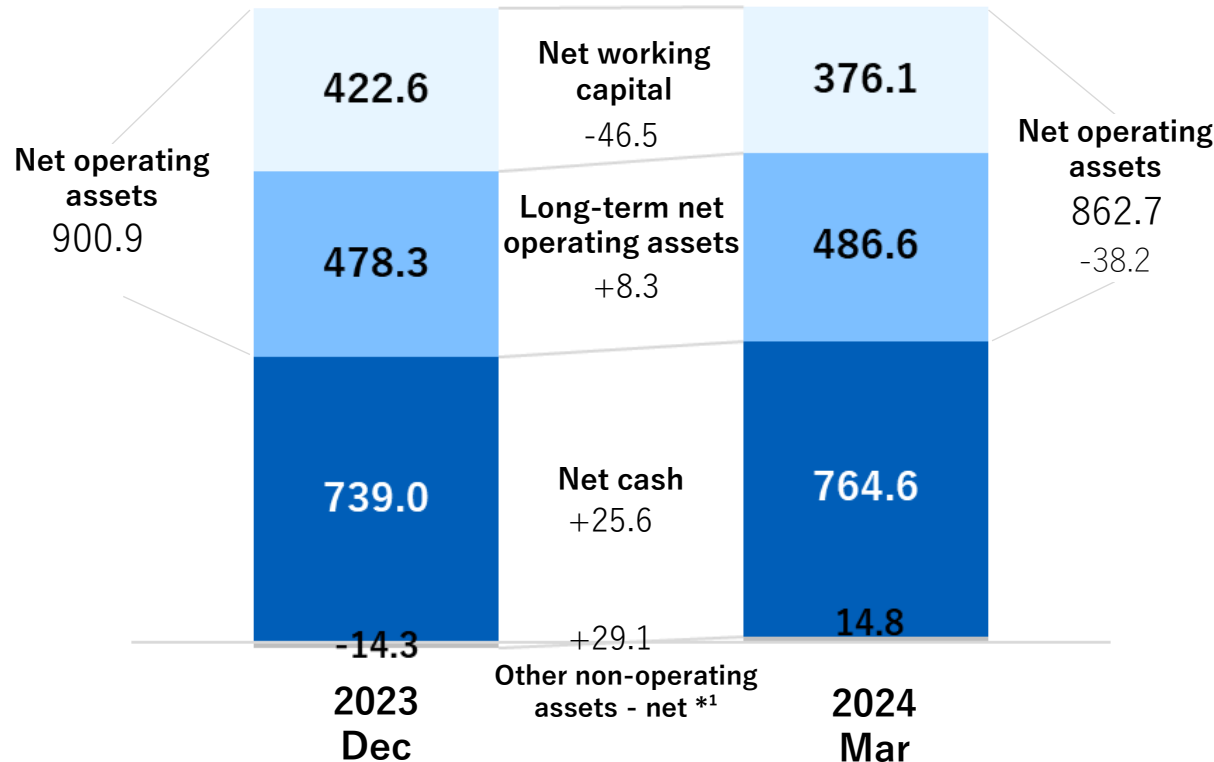
*1 Total of R&D, SG&A and other operating income (expense)

*2 Weighted average of the exchange rates used to record foreign currency transactions included in categories from revenue to operating profit

Financial Position (vs. 2023 Year End)

(Billions of JPY)

Total assets	1,932.5	-34.7	1,897.8
Total liabilities	-307.0	+51.3	-255.7
	1,625.6	Total net assets +16.4	1,642.0



Ratio of equity attributable to Chugai shareholders

84.1%

+2.4%p

86.5%

Decrease in net working capital

Decrease mainly due to a decrease in accounts receivable

Increase in long-term net operating assets

Increase in property, plant and equipment mainly due to the investment in

- the manufacturing building for bio drug substance (UT3) at Utsunomiya Plant
- the manufacturing building for active pharmaceutical ingredients (FJ3) at Fujieda Plant

Increase in net cash

(See next page)

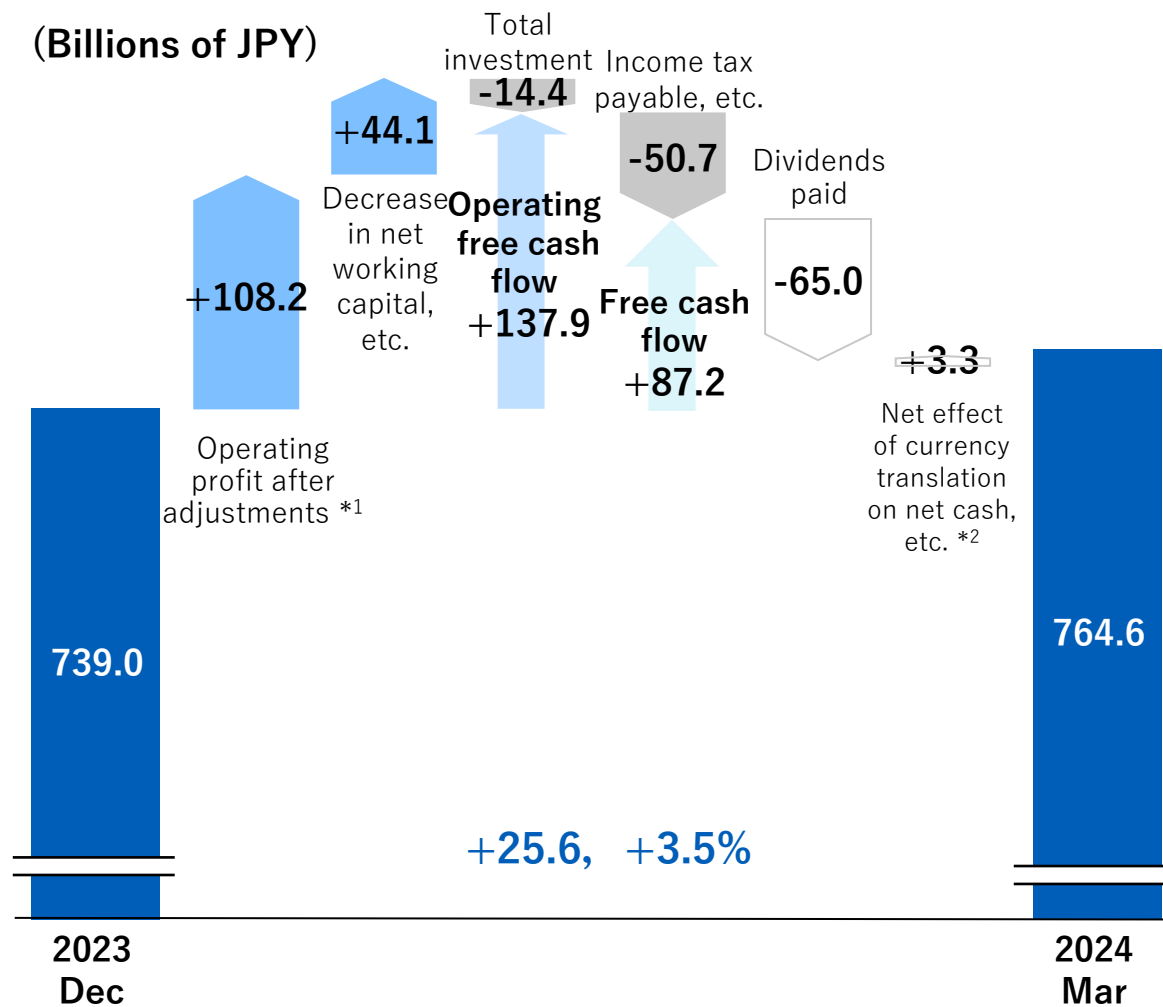
Increase in other non-operating assets – net

Decrease in current income tax liabilities and other items

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

Net Cash (vs. 2023 Year End)

(Billions of JPY)



Operating profit after adjustment *1	+108.2
Operating profit *1	+99.9
Depreciation, amortization and impairment *1	+8.0
Decrease in net working capital, etc.	+44.1
Total investment	-14.4
Property, plant and equipment	-12.4
Payment for lease liabilities	-2.0
Intangible assets	-0.1
Operating free cash flows	+137.9
Income tax payable, etc.	-50.7
Income tax payable	-41.0
Free cash flows	+87.2
Dividends paid	-65.0
Net effect of currency transaction on net cash, etc. *2	+3.3

*1 Including Non-Core (IFRS results)

*2 Net effect of currency translation on net cash, etc. = Transaction in own equity instruments + 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

		~2023	2024	2025	2026	2027	2028	2029~	Planned investment			Start of investment	Planned completion
									Total amount	Investment to-date	Unit		
Manufacturing	Fujieda plant	FJ3: Manufacture APIs of small and mid-size molecule drugs for late-stage clinical development and early commercial use						55.5	51.7	billion JPY	2021	2024	
	Utsunomiya plant	UT3: Manufacture bio drug substance for middle to later- stage clinical development and early commercial use						37.4	10.3	billion JPY	2023	2026	
	Utsunomiya plant	UTA: Manufacture sterile injectables for early commercial use						19.0	5.7	billion JPY	2023	2025	
	Ukima plant	UK3(modification): Manufacture bio drug substance						20.3	0.0	billion JPY	2024	2027	
Research and development	CPR	Move and renovate facilities to enhance research functions						60	-	million SGD	2024	2026	
	IFReC	Funding to IFReC per comprehensive collaboration agreement						10.0	7.0	billion JPY	2017	2027	
Environment	Environmental investment*	Equipment upgrade to achieve Mid-Term Environmental Goals 2030						109.5 estimated total amount	3.0	billion JPY	2022	2033	

* incl. part of investments described in the schedule above

P/L Jan – Mar (Non-core adjustment)

(Billions of JPY)	IFRS results	Non-core items		Core results
		Intangible assets	Others	
Revenue	236.9			236.9
Sales	204.5			204.5
Other revenue	32.5			32.5
Cost of sales	-72.9	+0.3		-72.6
Research and development	-41.4	+0.2	+0.0	-41.2
Selling, general and administration	-22.6		+1.4	-21.2
Other operating income (expense)	-0.2		+0.4	0.2
Operating profit	99.9	+0.5	+1.8	102.1
Financial account balance	0.0			0.0
Income taxes	-25.5	-0.1	-0.5	-26.2
Net income	74.4	+0.3	+1.2	76.0
EPS (JPY)	45.21			46.16

Non-core items

(Billions of JPY)

Factors affected operating profit

Intangible assets

Amortization	+0.4
Impairment	+0.1

Others

Business rebuilding expenses	+1.4
Restructuring expenses	+0.4

Abbreviations



AD	atopic dermatitis	MIBC	muscle-invasive bladder cancer
adj	adjuvant	MM	multiple myeloma
aHUS	atypical hemolytic uremic syndrome	MOGAD	myelin oligodendrocyte glycoprotein antibody-associated disease
AIE	autoimmune encephalitis	nAMD	neovascular age-related macular degeneration
aNHL	aggressive B-cell non-Hodgkin lymphoma	NHI	national health insurance
AS	angioid streaks	NME	new molecular entity
BC	breast cancer	NMOSD	neuromyelitis optica spectrum disorder
BS	biosimilars	NSCLC	non-small cell lung cancer
CKDaP	Chronic kidney disease associated pruritus	NSQ	non-squamous
CLDN	Claudin	PDAC	pancreatic ductal adenocarcinoma
CRC	colorectal cancer	PDS	port delivery system with ranibizumab
DLBCL	diffuse large B-cell lymphoma	PE	primary endpoint
DMD	duchenne muscular dystrophy	PN	prurigo nodularis
DME	diabetic macular edema	PNH	paroxysmal nocturnal hemoglobinuria
eBC	early breast cancer	PS	profit share
EC	esophageal cancer	r/r	relapsed or refractory
ePoC	early proof of concept	ROY	royalty
FL	follicular lymphoma	RVO	retinal vein occlusion
FSHD	facioscapulohumeral muscular dystrophy	SCD	sickle cell disease
gMG	generalized myasthenia gravis	SCLC	small cell lung cancer
HCC	hepatocellular carcinoma	SMA	spinal muscular atrophy
HNC	head and neck carcinoma	SSc-ILD	systemic sclerosis with interstitial lung disease
IV	intravenous	TED	thyroid eye disease
LBCL	large B-cell lymphoma	UME	uveitic macular edema
LGSOC	low-grade serous ovarian cancer	T2D	type 2 diabetes
LN	lupus nephritis		

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INNOVATION BEYOND IMAGINATION