



TOP INNOVATOR  
**TOP i 2030**

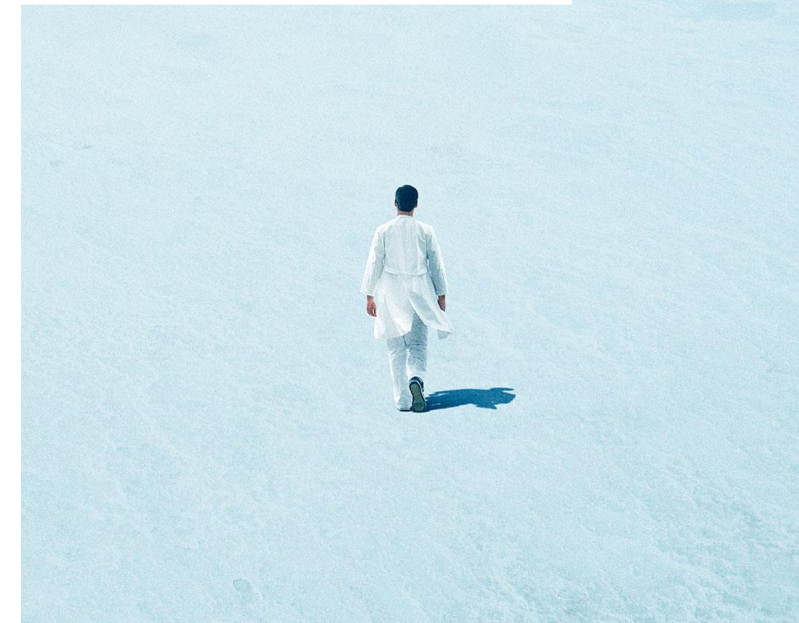
# Conference on FY2023.12 Financial Results

## CHUGAI PHARMACEUTICAL CO., LTD.

1 February 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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## FY2023 Overview and FY2024 Forecast

**Dr. Osamu Okuda**

President & CEO

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**Tetsuya Yamaguchi**

Executive Vice President  
Head of Foundation Medicine Unit

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**Toshiaki Itagaki**

Director, Executive Vice President & CFO

# FY2023 Overview and FY2024 Forecast

**Dr. Osamu Okuda**

President & CEO

# 2023 Financial Performance

- Revenue exceeded 1 trillion JPY for two consecutive fiscal years, and Core operating profit was comparable YoY. The company achieved YoY increases in revenue and profits, excluding the impact of decrease in sales of the COVID-19-related drug
- Core net income increased for seven consecutive fiscal years

Core (billions of JPY)	2022 Jan - Dec actual*	2023 Jan - Dec actual	Growth		2023 Jan - Dec forecast	Progress (%)
<b>Revenue</b>	<b>1167.8</b>	<b>1111.4</b>	<b>-56.4</b>	<b>-4.8%</b>	<b>1,070.0</b>	<b>103.9%</b>
Domestic sales	654.7	558.0	-96.7	-14.8%	541.7	103.0%
Overseas sales	384.6	416.5	+31.9	+8.3%	378.3	110.1%
Other revenue	128.6	136.9	+8.3	+6.5%	150.0	91.3%
<b>Operating profit</b>	<b>451.7</b>	<b>450.7</b>	<b>-1.0</b>	<b>-0.2%</b>	<b>415.0</b>	<b>108.6%</b>
Operating margin	38.7%	40.6%	+1.9pts	-	38.8%	-
<b>Net income</b>	<b>317.7</b>	<b>333.6</b>	<b>+15.9</b>	<b>+5.0%</b>	<b>306.0</b>	<b>109.0%</b>
<b>EPS (yen)</b>	<b>193.11</b>	<b>202.71</b>	<b>+9.60</b>	<b>+5.0%</b>	<b>186.00</b>	<b>109.0%</b>

- Domestic sales declined YoY due to the major decrease in sales for the supply of Ronapreve to the government, as well as the effects of the NHI drug price revisions and the market penetration of generic drugs, despite the favorable sales of the mainstay products including Enspryng, Hemlibra, and Tecentriq, in addition to the strong growth of new products such as Polivy and Vabysmo
- Overseas sales increased YoY due to the major increase in the exports of Hemlibra and Alecensa to Roche
- Other revenue increased YoY primarily due to the increase in income related to Hemlibra
- As a result, Core operating profit was comparable YoY to be 450.7 billion JPY, and Core net income increased for seven consecutive fiscal years to 333.6 billion JPY due to a decrease in corporate income tax etc.

\* Starting from FY2023, Chugai has excluded income from disposal of product rights from revenue. In conjunction with this change, the results for FY2022 have been restated accordingly.

# 2024 Forecast

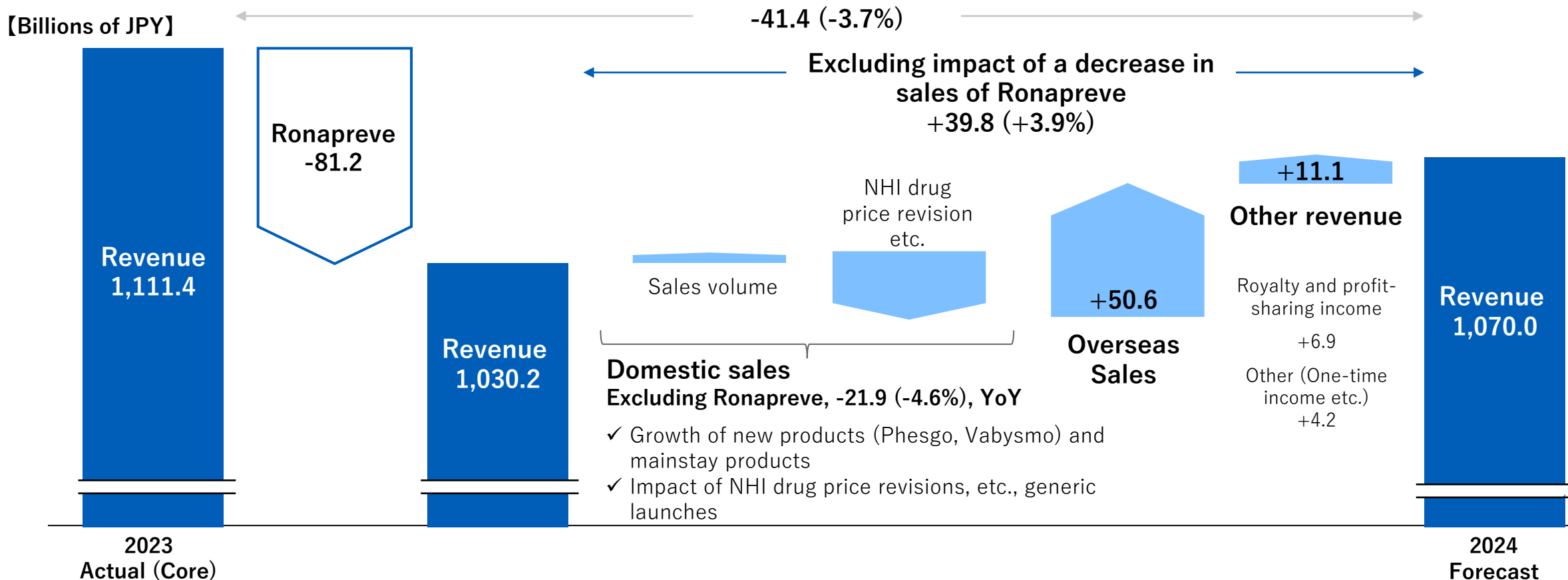
- Revenue is expected to exceed 1 trillion JPY for three consecutive fiscal years, driven by increase in overseas sales of mainstay products and royalties, despite the decrease in domestic sales due to the decrease in sales of Ronapreve and the impacts of NHI drug price revisions etc.
- Core operating profit and Core net income are expected to reach a record high

Core (billions of JPY)	2023 Jan - Dec actual	2024 Jan - Dec forecast	Growth (year on year)	
<b>Revenue</b>	<b>1,111.4</b>	<b>1,070.0</b>	<b>-41.4</b>	<b>-3.7%</b>
Domestic sales	558.0	454.9	-103.1	-18.5%
Overseas sales	416.5	467.1	+50.6	+12.1%
Other revenue	136.9	148.0	+11.1	+8.1%
<b>Operating profit</b>	<b>450.7</b>	<b>460.0</b>	<b>+9.3</b>	<b>+2.1%</b>
Operating margin	40.6%	43.0%	+2.4%pts	-
<b>Net income</b>	<b>333.6</b>	<b>335.5</b>	<b>+1.9</b>	<b>+0.6%</b>
<b>EPS (yen)</b>	<b>202.71</b>	<b>204.00</b>	<b>+1.29</b>	<b>+0.6%</b>

- Domestic sales are expected to decrease 18.5% due to the decrease in the supply of Ronapreve to the government and the impacts of NHI drug price revisions and the penetration of generics. Domestic sales excluding Ronapreve are expected to decrease by 4.6%
- Overseas sales are expected to increase significantly due to the major increase in export of Hemlibra, despite the decrease in export of Actemra due to the impact of the biosimilars etc.
- Other revenue is expected to increase due to the increase of Hemlibra-related income and one-time income

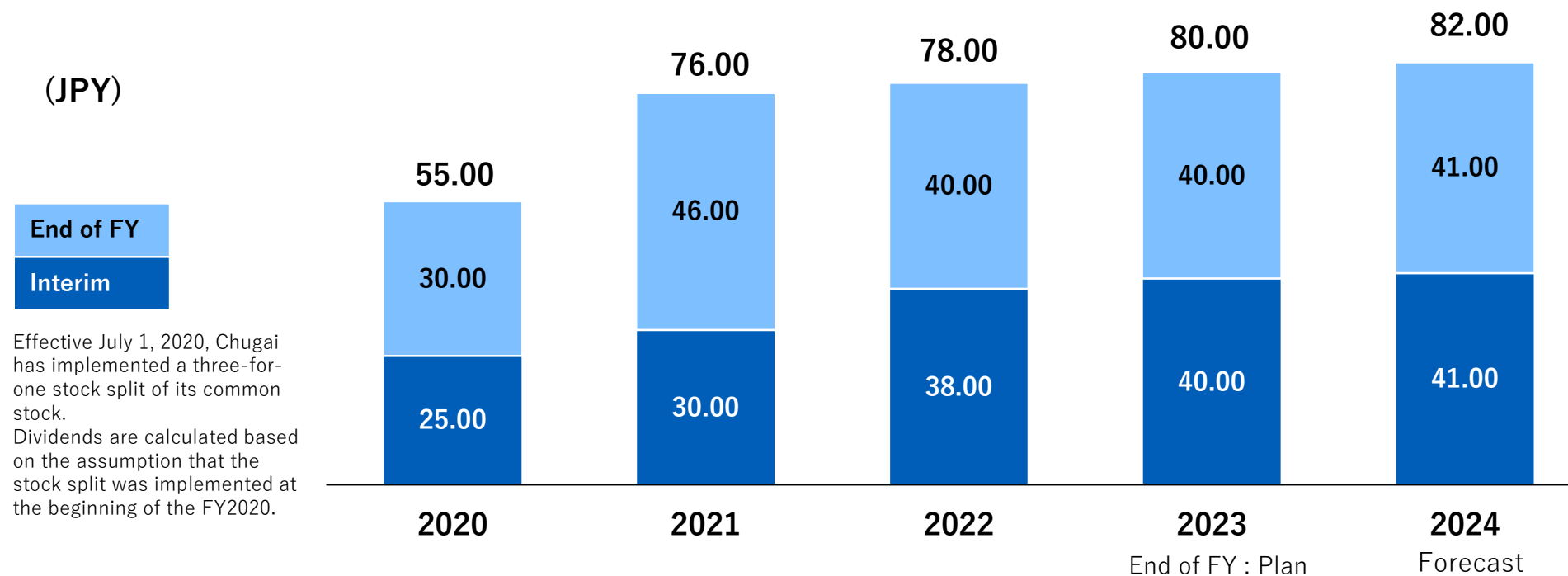
# Topline Analysis of 2024 Forecast

- Overseas sales and other revenue increased while domestic sales decreased mainly due to the impact of decrease in Ronapreve, the NHI drug price revisions and the market penetration of generics
- Increased revenues (+39.8 billion JPY, +3.9%, YoY) excluding the impact of a decrease in sales of Ronapreve (-81.2 billion JPY, YoY)



# Contribution to Shareholders

- Focusing on the continuous provision of stable dividends, we expect annual dividends of 82 JPY for FY2024
- Basic profit distribution principles
  - ✓ Taking into account strategic funding needs and earnings prospects, Chugai sets a target for a consolidated dividend payout ratio of 45% on average compared with Core EPS, to continuously provide a stable profit allocation of profit to all shareholders.



Core dividend payout ratio	5-year average	44.9%	42.9%	42.0%	40.9%	40.2%
	Single FY	41.2%	40.1%	40.4%	39.5%	40.2%

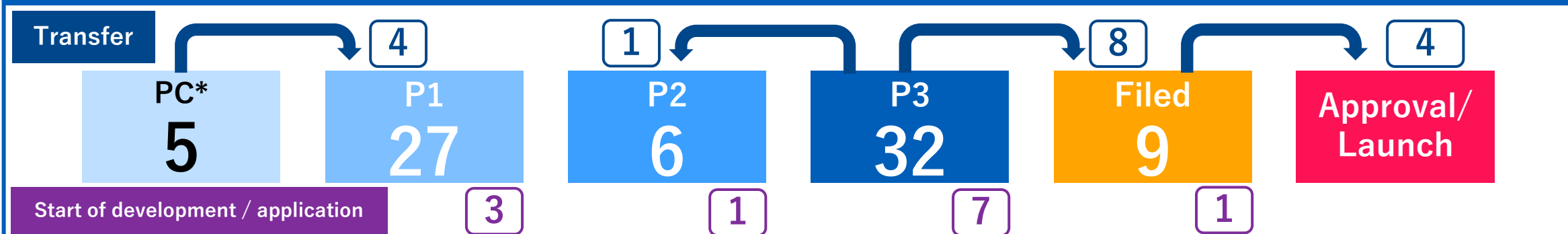
# Review of Strategic Policies for 2023 (1/2)

- Generally on track in late-stage, early-stage and preclinical-stage development, respectively

## Strengthening of RED Function

- **Development for mid-size molecule project:** Progressed in both quality and quantity despite some delay
  - ✓ Expected delay to obtain ePoC for LUNA18 from 2024
  - ✓ On the other hand, subsequent mid-size molecule projects have progressed, and 1 project achieved transfer to PC\*
- **Continuous creation of new projects and construction of technology infrastructure:** Progressed steadily in establishment of technology infrastructure. Open innovation and DX need to be further promoted toward challenging goals
- **Proof of value of in-house pre-PoC projects and strengthening of foundation:** Achieved bPoC/ePoC across multiple projects
- **Accelerating open innovation:** Established Chugai Venture fund (CVF) and completed its preparation for the full-scale start in 2024

## Changes in the number of R&D projects (from January 1 to December 31, 2023)



\*PC: Preclinical development

Development Discontinued: 6 projects, Temporarily suspended the development: 1 PJ, Withdrew the application: 1 PJ

# Review of Strategic Policies for 2023 (2/2)

## ■ Although some gaps remain, we are generally on track

<b>Maximize the value of growth drivers</b>	<ul style="list-style-type: none"> <li>● <b>Enhance value of post-PoC projects:</b> In-house products successfully achieved to file the regulatory applications as planned</li> <li>● <b>Maximizing value of new products and growth drivers:</b> Although Vabysmo did not achieve the challenging plan, Polivy and Enspryng are steadily growing more than expected</li> <li>● <b>Operation model evolution for futuristic business model:</b> Stable operation of SPIRITS, the digital foundation for production functions</li> </ul>
<b>Strengthen business foundation</b>	<ul style="list-style-type: none"> <li>● <b>Foster an organizational culture that continues to produce innovation:</b> Implementation of Early retirement incentive program and promotion of career recruitment/dialogue between supervisors and subordinates, expansion of digital human resource development contents, implementation of measures to improve company-wide digital literacy</li> <li>● <b>Resource creation by business process reform:</b> While ASPIRE* progressed, we are midway through resolving the lack of resources raised as an issue in the employee awareness survey</li> <li>● <b>Sophistication of risk management functions:</b> Progress in building a system to establish a company-wide third-party risk management</li> <li>● <b>Promotion of autonomous management of affiliated companies:</b> Changes to the decision-making process</li> <li>● <b>Measures to address mid-term environmental goals:</b> Decided to implement the measures for Halogenated Hydrocarbon-Free in UK3</li> </ul>

\*ASPIRE: The name of a business and digital transformation program that will deliver cutting edge global standard processes and the next-generation ERP platforms across Chugai Group

### Hemlibra: Trends of domestic hemophilia A patient share

Q4 2022	Q1 2023	Q2 2023	Q3 2023	Q4 2023
29.2%	30.0%	30.8%	31.7%	32.5%

# Strategic Policies for 2024

- Continue to focus on strengthening of RED functions, maximizing the value of growth drivers, and strengthening business foundation
- In regard to strengthening business foundation, the strategic policy items were reviewed based on changes in the environment inside and outside the company

## 1) Strengthening of RED Function

- Promotion and expansion of development of mid-size molecule projects
- Continuous creation of new projects and construction of technology infrastructure
- Proof of value of in-house pre-PoC projects and strengthening of Foundation
- Accelerating promotion system of Open Innovation

## 2) Maximize the value of growth drivers

- Enhance value of post-PoC projects
- Maximizing value of new products and growth drivers
- Operation Model Evolution for futuristic business model

## 3) Strengthen business foundation

- Strengthen HR strategy and business foundation that continues to produce innovation
- Further promotion of sustainability
- Organize related systems and reform business processes to introduce ASPIRE
- New insight business promotion policy

# Outlook of Mid- to Long-term Growth to Achieve TOP I 2030

- In the mid term, overcome the impact of overseas Actemra BS and domestic BS/NHI drug price revisions by expanding the indications of in-house products and launching new products, and view sustainable growth
- In the long term, continuous development success of in-house projects will drive further growth

[Hemlibra] Further continuous growth

[Alecensa] Expected to obtain additional indication for postoperative adjuvant therapy for NSCLC within 2024

[Enspryng] Following NMOSD, expected to file and obtain approvals for 4 other additional indications sequentially in 2024 and beyond

[crovalimab] PNH: Expected to be approved and launch in Japan/U.S./EU/China in 2024. In 2025 and beyond, expected to file and obtain approvals for 3 other indications sequentially

[Projects out-licensed to 3rd parties] Expected to contribute to revenue through filing, approval, and launch of multiple projects sequentially

[In-house projects] Expected revenue contribution from global launch

[In-licensed from Roche] Stable contribution to revenue from exclusive marketing of Roche products in Japan

[Domestic: Impacts of BS/NHI drug price revisions] [Overseas: Impact of Actemra BS]

2024	2025	2026	2027	2028	2029	2030 and beyond
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# Expand Research Function in Chugai Pharmabody Research

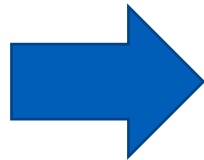
- Expanding the mid-size molecule drug discovery function of CPR, and repositioning it as a permanent overseas drug discovery research function
- Aim to further promote the provision of innovative new drugs to patients through continuous creation of projects, including joint research with research institutions in Singapore

## Chugai LSP Yokohama:

Creation of development candidate compounds  
Mid-size molecule technology development



Technology  
Transfer



## CPR :

Primary screening  
Hit generation



New!

Provision of primary lead molecules for antibodies and mid-size molecules

CPR original research

+

External joint research:

- Provision of tools necessary for deep cultivation of disease biology
- New drug discovery targets



Technology transfer for screening of mid-size molecule drug discovery to CPR  
Chugai LSP Yokohama focuses on mid-size molecule drug discovery technology development



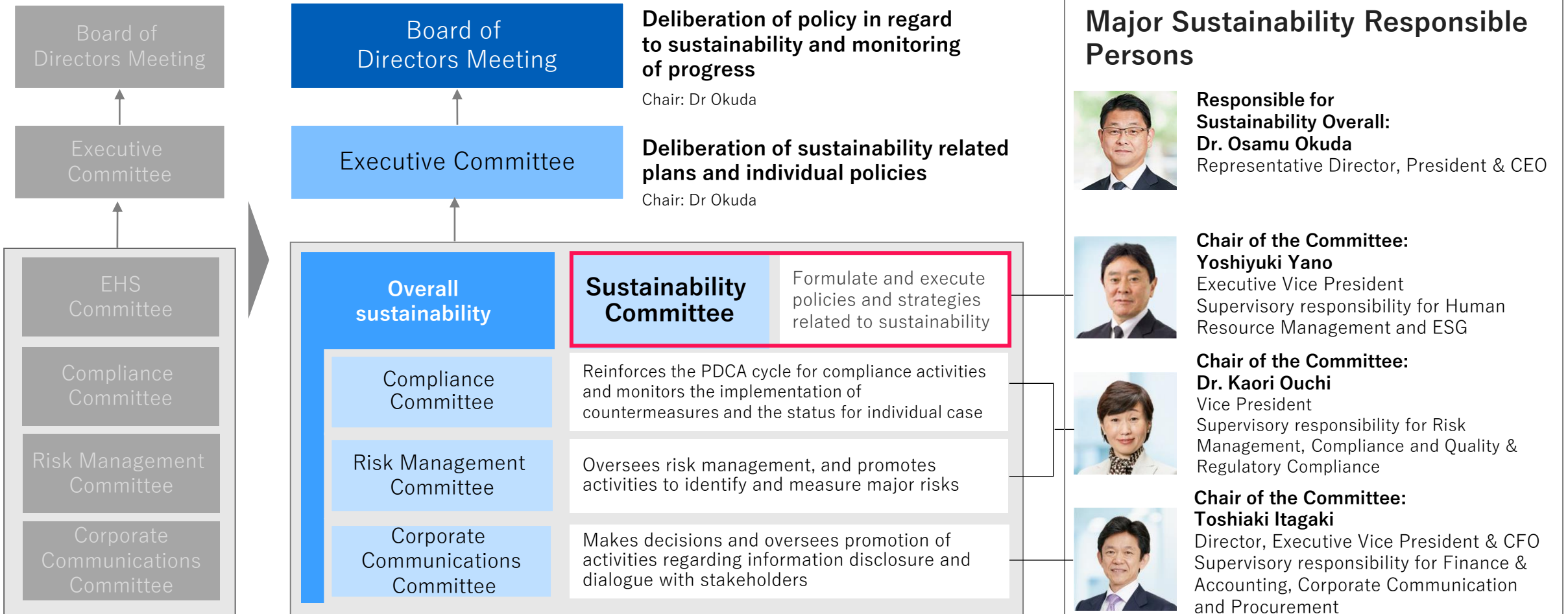
Continuous drug  
discovery  
Project creation

*Evaluation of novel drug  
discovery targets*

# Sustainability Promotion System - Review of Management Advisory Committees -

- Established a new management committee to consolidate functions and enable cross-organizational management to further strengthen sustainability initiatives as a key management issue

Since February 2024



# New Management Structure

Underline: new position/role  
Excluding removal effective on April 1, 2024

Name	Rank	Supervisory responsibility
Dr. Osamu Okuda	Representative Director, President CEO	Chair of the Board of Directors Chair of the Executive Committee External Affairs and Audit
Iwaaki Taniguchi	<u>Director</u> , Executive Vice President <u>CFO</u>	<u>Finance &amp; Accounting, Corporate Communication and Procurement</u>
Dr. Hitoshi Iikura	<u>Director</u> , <u>Executive Vice President</u> Head of Translational Research Div.	<u>Research, Translational Research, Clinical Development</u>

- Iwaaki Taniguchi and Dr. Hitoshi Iikura are scheduled to be appointed as directors upon approval at the 113th Annual General Meeting of Shareholders to be held on March 28, 2024
- Dr. Hisafumi Yamada, Director, Executive Vice President, and Toshiaki Itagaki, Director, Executive Vice President & CFO, will retire on March 28, 2024

# Summary

- In 2023, revenue exceeded 1 trillion JPY for two consecutive fiscal years, and Core operating profit was comparable YoY. The company achieved YoY increase in revenue and profits, excluding the impact of decrease in sales of the COVID-19-related drug. Core net income increased for seven consecutive fiscal years
- In 2024, we continue to promote RED SHIFT under the three frameworks of Strengthening of RED function, Maximize the value of growth drivers, and Strengthen business foundation. Chugai aims to promote further provision of innovative new drugs to patients through expansion of CPR functions, etc.
- Revenue for 2024 is expected to exceed 1 trillion JPY for three consecutive fiscal years, driven by increase in overseas sales of mainstay products and royalties, despite the decrease in domestic sales due to the decrease in sales of Ronapreve and the impacts of NHI drug price revisions etc. Core operating profit and Core net income are expected to reach a record high
- In the mid term, we will overcome the impact of overseas Actemra BS and domestic BS/NHI drug price revisions by expanding the indications of in-house products and launching new products, and view sustainable growth. In the long term, we aim for further growth through continuous development success of in-house projects

# Updates on Mid-term Milestones Targeting 2023

- Mid-term milestones will be revised in line with current business environment and progress

Letters in pink: KPI not met

Drug Discovery	<p><b>Developing Next-Generation Antibody Technologies to Solve Drug-Wants</b></p> <ul style="list-style-type: none"> <li>• PC transition of new antibody engineering technologies that work selectively with tissue and cells following Switch-Ig</li> </ul> <p><b>Establishment of a Technology Platform and New Modality Research Platform Comprising Multiple Modalities with Competitive Advantages</b></p> <ul style="list-style-type: none"> <li>• PoC of new technologies through a combination of protein engineering technology and new modalities</li> </ul> <p><b>Strengthening the Drug Discovery Process by Utilizing Digital Technology</b></p> <ul style="list-style-type: none"> <li>• Antibodies: Increased efficiency of the discovery process through machine learning technology</li> </ul>
Development	<p><b>Accelerate Value Expansion of in-House Developed Products through the Simultaneous Development of Multiple Diseases</b></p> <ul style="list-style-type: none"> <li>• Simultaneous development of multiple diseases in multiple projects based on science and business feasibility</li> </ul> <p><b>Evolution of Late-Stage Development Operations</b></p> <ul style="list-style-type: none"> <li>• Increase workforce productivity</li> </ul>
Pharmaceutical Technology	<p><b>Establishment of an Efficient Manufacturing System for CPMC</b></p> <ul style="list-style-type: none"> <li>• Strengthen core manufacturing technologies, establish a cost-competitive CPMC system, and firmly establish operations</li> <li>• Establish a CMO management system for future product portfolio</li> <li>• Launch a new operational model at other sites through the development of digital and IT infrastructure</li> </ul>
Value Delivery	<p><b>Building an Engagement Model to Meet Diversifying Customer Needs</b></p> <ul style="list-style-type: none"> <li>• Implement a precise individual strategy that combines in-person, remote, and digital channels <ul style="list-style-type: none"> <li>✓ Customer satisfaction (cancer): No. 1 in obtaining information other than Medical Reps</li> <li>✓ Customer satisfaction (MA Priority Activity Disease Area Assessment): Top 3 in all areas</li> <li>✓ Customer satisfaction (providing safety information): No. 1</li> </ul> </li> </ul> <p><b>Functional Reforms Through Resource Shifts and Digital Use, etc.</b></p> <ul style="list-style-type: none"> <li>• Systematically withdraw from mature areas and invest resources in new areas</li> </ul>
Foundation for Growth	<p><b>Acceleration and Penetration of D&amp;I</b></p> <ul style="list-style-type: none"> <li>• Ratio of female managers/Ratio of female managers with subordinates: 17% / 17% achieved</li> </ul>

# Overview of Development Pipeline

**Tetsuya Yamaguchi**

Executive Vice President, Head of Foundation Medicine Unit

# Q4 Topics (1/2)



As of February 1, 2024

Launched	<b>Phesgo</b>	“HER2+ BC” and “advanced or recurrent HER2+ CC that has progressed following cancer chemotherapy and is not amenable to curative resection”	November 2023
Approved	<b>Rituxan</b>	Suppression and treatment of antibody-mediated rejection in organ transplantation	December 2023
Filed	<b>Alecensa</b>	Postoperative adjuvant therapy for <i>ALK</i> fusion gene-positive non-small cell lung cancer	November 2023 (US/EU/China) December 2023 (Japan)
Initiation of study	<b>avutometinib/VS-6766</b> <b>REVN24</b>	Recurrent LGSOC (combination with defactinib) * Acute diseases	P3 study (December 2023) P1 study (October 2023)
Phase Transition	<b>AMY109</b>	Endometriosis	P1 study→P2 study (January 2024)
Readout	<b>RG6356/SRP-9001</b> <b>Tecentriq</b>	EMBARK study (DMD) did not meet its primary endpoint (favorable secondary endpoints) IMvoke010 study (head and neck carcinoma) did not meet its primary endpoint	October 2023 2023 Q4
Removed from pipeline	<b>Tecentriq</b> <b>semorinemab</b>	IMvoke010 study (head and neck carcinoma): development discontinued Domestic P1 (Alzheimer’s disease): development discontinued	

# Q4 Topics (2/2)

As of February 1, 2024

Medical conference	Hemlibra	HAVEN 7 study (babies with severe hemophilia A): American Society of Hematology (ASH)	December 2023
	Kadcyla	KATHERINE study (HER2+ early-stage breast cancer): San Antonio Breast Cancer Symposium (SABCS)	December 2023
Literature publication	nemolizumab	OLYMPIA 2 study* (prurigo nodularis): New England Journal of Medicine (NEJM)	October 2023
	NXT007	Non-clinical research results: Journal of Thrombosis and Haemostasis	November 2023
	DONQ52	Non-clinical research results: Nature Communications	December 2023
Orphan drug designation	Alecensa	Postoperative adjuvant therapy for <i>ALK</i> fusion gene-positive non-small cell lung cancer	December 2023 (Japan)
Priority review designation	Alecensa	Postoperative adjuvant therapy for <i>ALK</i> fusion gene-positive non-small cell lung cancer	January 2024 (US)
Exercise of option rights by out-licensing partners	EOS789	Worldwide exclusive license to develop, manufacture, and commercialize: Alebund Pharmaceuticals Ltd.	October 2023
Business Transfer	Xeloda	Transfer of the business in Japan: CHEPLAPHARM K.K.	November 2023

# 2023: Key R&D Milestones

Underlined and bolded are new progress since October 24, 2023

	Product	Indication/Study name	Progress
Projects to be approved	<b>Actemra</b>	Systemic sclerosis with interstitial lung disease (SSc-ILD) (EU)	<b>withdrawal</b>
	<b>Hemlibra</b>	Moderate hemophilia A (EU)	<b>approved</b>
	<b>crovalimab</b>	PNH (China)	<b>2024</b>
	<b>Phesgo</b>	<b><u>HER2+ breast cancer/colorectal cancer</u></b>	<b>Approved/launched</b>
P3/Pivotal readouts	<b>Alecensa</b>	<b><u>ALINA study: NSCLC [adjuvant]</u></b>	<b>met PE/<u>filed</u></b>
	<b>crovalimab</b>	COMMODORE 1/2 study: PNH	<b>met PE/filed</b>
	<b>nemolizumab</b>	ARCADIA 1/2 study <sup>1</sup> : Atopic dermatitis	<b>met PE</b>
	<b>Tecentriq + Avastin</b>	IMbrave050 study: Hepatocellular carcinoma [adjuvant]	<b>met PE</b>
	<b>Tecentriq</b>	IMpassion030: early breast cancer [adjuvant]	<b>Development discontinued</b>
	<b>Tecentriq</b>	<b><u>IMvoke010 study: Head and neck carcinoma [adjuvant]</u></b>	<b>did not meet PE /development discontinued</b>
	<b>Tecentriq+ tiragolumab</b>	SKYSCRAPER-01 study: NSCLC [1st line]	<b>H2 2024<sup>2</sup></b>
	<b>mosunetuzumab+Polivy</b>	SUNMO study: r/r aggressive B-cell non-Hodgkin's lymphoma	<b>2024</b>
	<b>delandistrogene</b>	<b><u>EMBARK study: Duchenne muscular dystrophy (DMD)</u></b>	<b><u>did not meet PE (favorable secondary endpoints)</u></b>
	<b>moxeparvovec</b>		

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

1. Conducted by Galderma, an overseas licensee 2. 2024→H2 2024

# 2024: Key R&D Milestones

	Product	Indication/Study name	Progress
Projects to be approved	<b>crovalimab</b> <b>Alecensa</b> <b>Vabysmo</b>	Paroxysmal nocturnal hemoglobinuria (Japan/US/EU) NSCLC (adjuvant) (Japan/US/EU) Retinal vein occlusion	
P3/Pivotal readouts	<b>Enspryng</b> <b>Tecentriq + tiragolumab</b> <b>mosunetuzumab</b> <b>mosunetuzumab + Polivy</b> <b>Vabysmo</b>	Luminesce study: generalized myasthenia gravis SKYSCRAPER-01 study: NSCLC(1st Line) Domestic P1 (Expansion cohort): Follicular lymphoma (3rd Line) SUNMO study: r/r aggressive B-cell non-Hodgkin's lymphoma NIHONBASHI study: Angioid streaks	
P2 readouts	<b>GYM329</b> + <b>Evrysdi</b>	MANATEE study: Spinal muscular atrophy (SMA)	

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

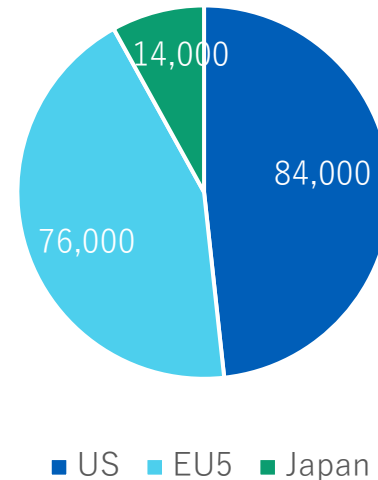
# Market Opportunity of Enspryng

- Launched in 2020 for the indication of NMOSD. Global sales in 2023 total 256mCHF
- Readout of Global P3 study for gMG and regulatory filing are expected in 2024. Four indications are simultaneously under development
- First antibody utilizing Chugai's proprietary Recycling Antibody® technology which enables convenient every four-week subcutaneous injection. Confirmed favorable safety profile in the data from clinical studies for NMOSD

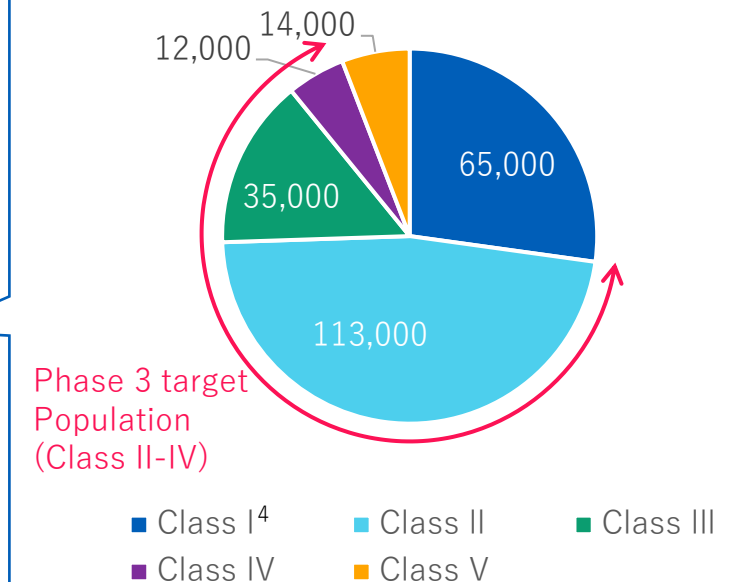
## Diagnosed prevalence in 2025 (# of patients in US/EU5/Japan)

MOGAD	26,000
TED	69,000 <sup>2</sup>
AIE	3,000-12,000 <sup>1</sup>
gMG	174,000
NMOSD	24,000

### gMG prevalence by regions



### MG MGFA<sup>3</sup> Classification



1. AIE; Incidence-based with ranges 2. TED: Incidence-based

Source: Citeline data as of Dec. 2023, numbers are rounded

NMOSD: neuromyelitis optica spectrum disorder, gMG: generalized myasthenia gravis, AIE: autoimmune encephalitis, TED: thyroid eye disease, MOGAD: myelin oligodendrocyte glycoprotein antibody-associated disease

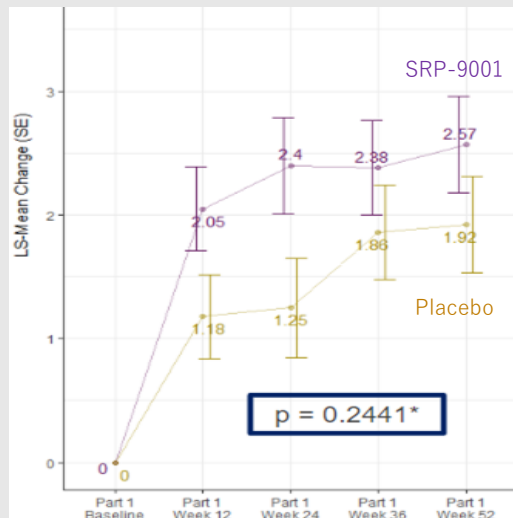
3. MGFA: Myasthenia Gravis Foundation of America

4. Class I is not included in gMG

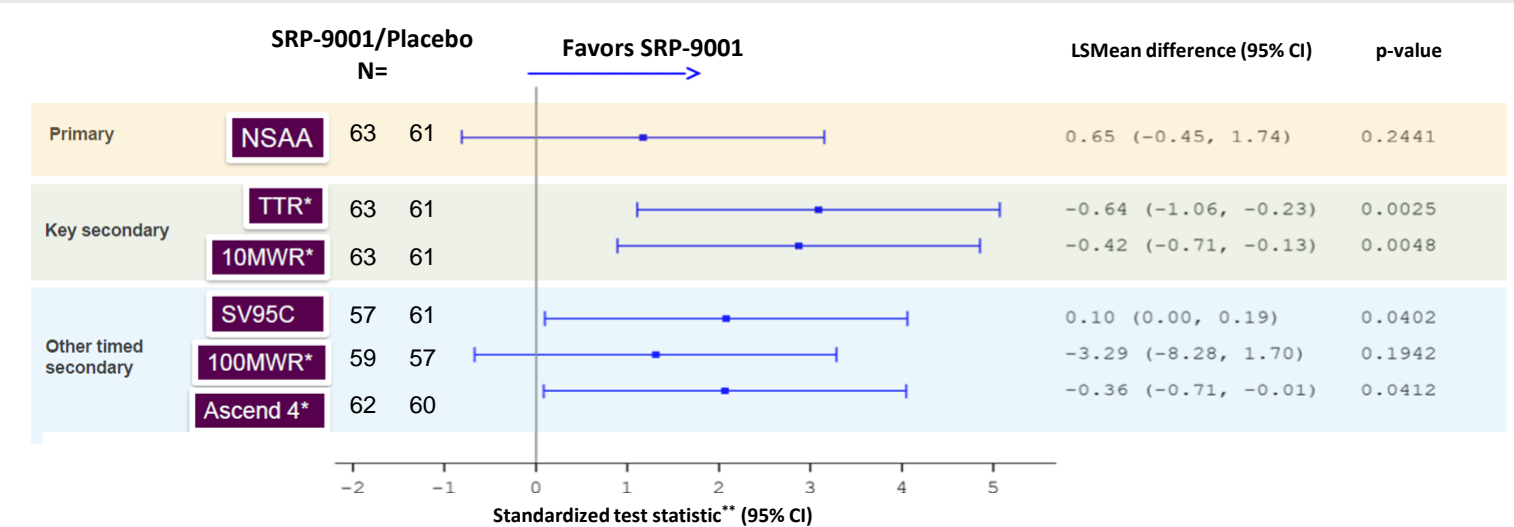
# delandistrogene moxeparvovec (RG6356/SRP-9001)

Global Phase 3 EMBARK study did not reach the primary endpoint, but shows positive efficacy outcomes on all timed functional key endpoints.

## Primary Endpoint (NSAA)



## Key secondary functional EPs (TTR, 10MWR) with clinically significant treatment benefit



- SRP-9001-treated patients improved 2.6 points on their NSAA total score at 52 weeks compared to 1.9 points in placebo-treated patients (0.65; n=125; p=0.24).
- The NSAA is a 17-item rating scale used to measure functional motor abilities in ambulant children with DMD. It is used to monitor the progression of the disease and treatment effects in clinical studies for DMD.

- Both key pre-specified functional secondary endpoints demonstrated robust evidence for a clinically meaningful treatment benefit across age groups in SRP-9001-treated patients (age of 4-7) compared to placebo at 52 weeks.
  - TTR (Time To Rise) predicts altered trajectories for the time to loss of ambulation in natural history. At 52w, 3% of SRP-9001-treated patients showed a TTR >5sec compared to 16% in the placebo group (n=124, p=0.0135)<sup>a</sup>.
  - Safety: Pattern and severity of AE/SAE were consistent with prior studies, no deaths and no discontinuations occurred.
  - Based on the results, Chugai will work together with Sarepta and Roche to consult with regulatory authority in Japan.
- <sup>a</sup>.post hoc analysis

NSAA:North Star Ambulatory Assessment, TTR:Time To rise from floor, 10MWR:10m walk run test, SV96C: stride velocity 95C measured with ankle pedometer Syde, 100MWR:100m walk run test, Ascend 4: time to climb 4 stairs

\*\*Lines plot standardized t-test statistic (+/- 1.96) after dividing LSM (95%CI) by standard error; t-test statistic signs reversed to align favorable directions among effect endpoints (endpoints with \*)

Source: Sarepta Therapeutics Update\_30 Oct 2023 <https://investorrelations.sarepta.com/static-files/4871976b-aebc-4ab1-b598-b9ad15c660bf> (Accessed Jan 2024)

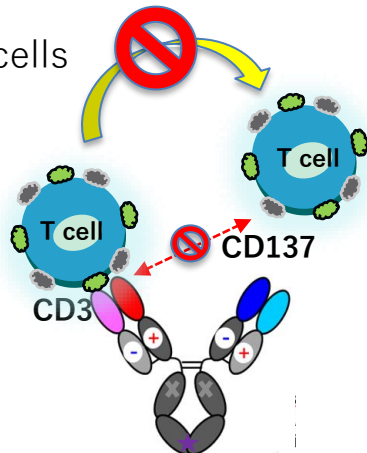
# SAIL66: Anti-CLDN6/CD3/CD137 trispecific (Dual-Ig<sup>®</sup>)

## Next Generation T-cell Redirecting Antibody Targeting Claudin 6 using our Dual-Ig<sup>®</sup> Technology

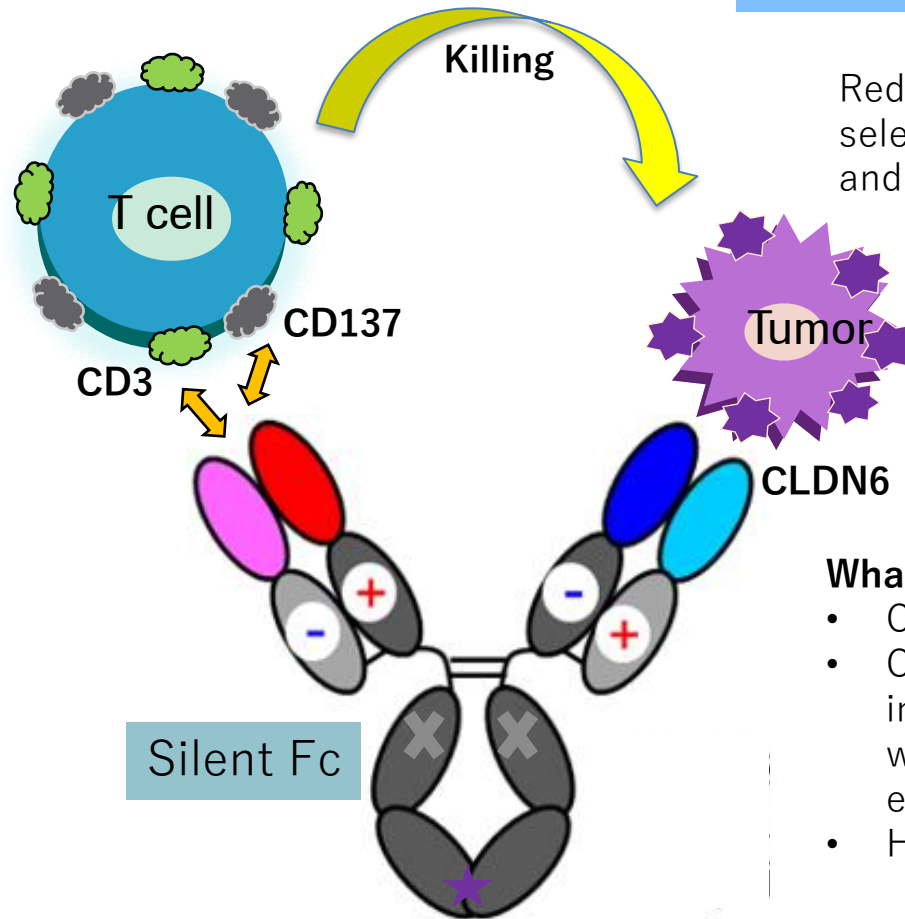
Phase 1 study in patients with CLDN6-positive solid tumors is currently ongoing.

### Dual-Ig<sup>®</sup>

- Non-simultaneous binding to CD3 and CD137 and induction of potent T cell activation stimuli in the presence of tumor antigen
- The potential for long-term efficacy through T cell proliferation and the inhibition of exhausted T cell by CD137 costimulatory signals
- Non-simultaneous binding to CD3 and CD137 avoids activation of T cell in a tumor antigen independent manner and killing of immune cells



### Anti-CLDN6

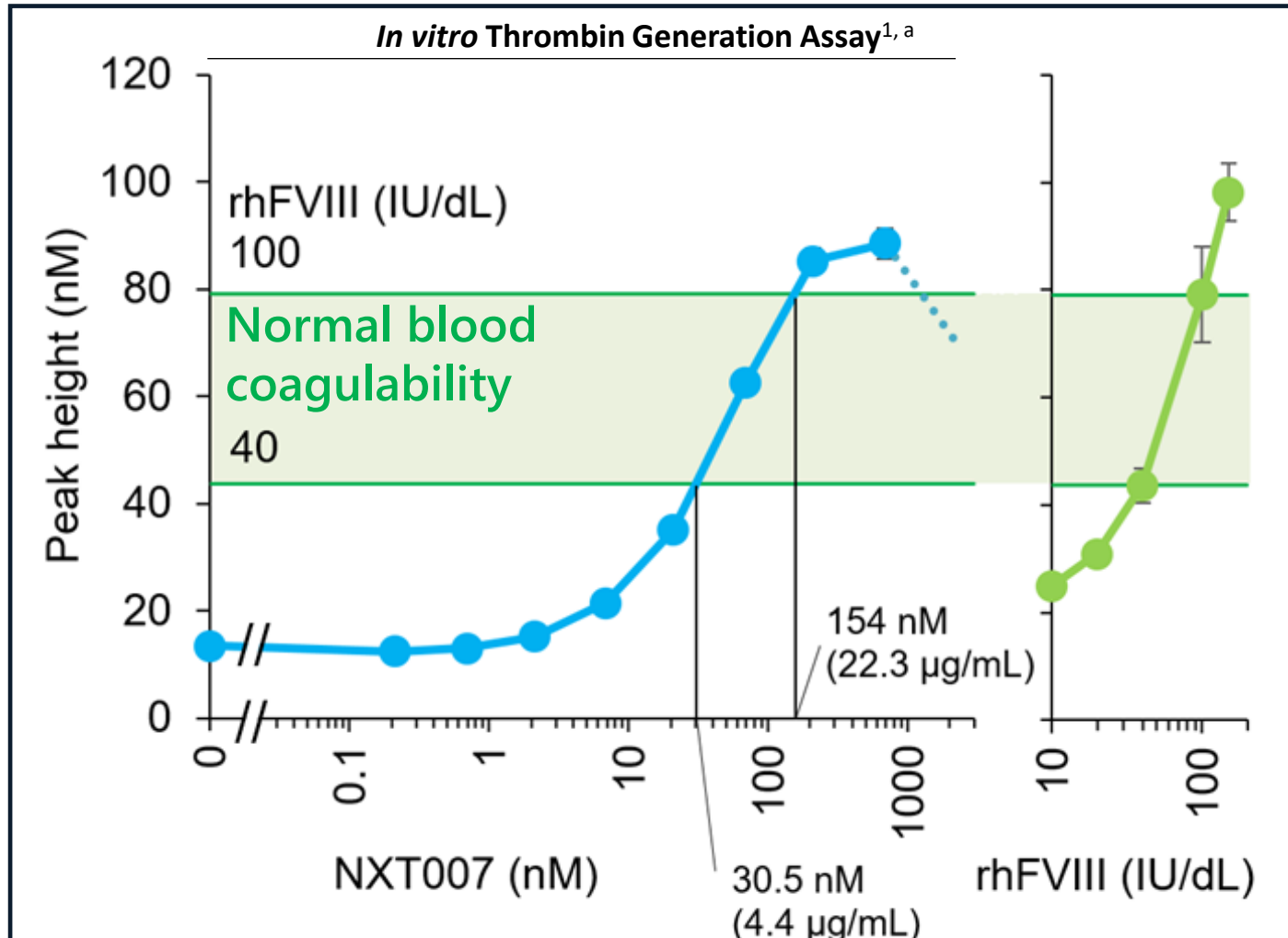


Reduce safety risk by having high selectivity for Claudin 6 (CLDN6) and not binding to CLDN3/4/9

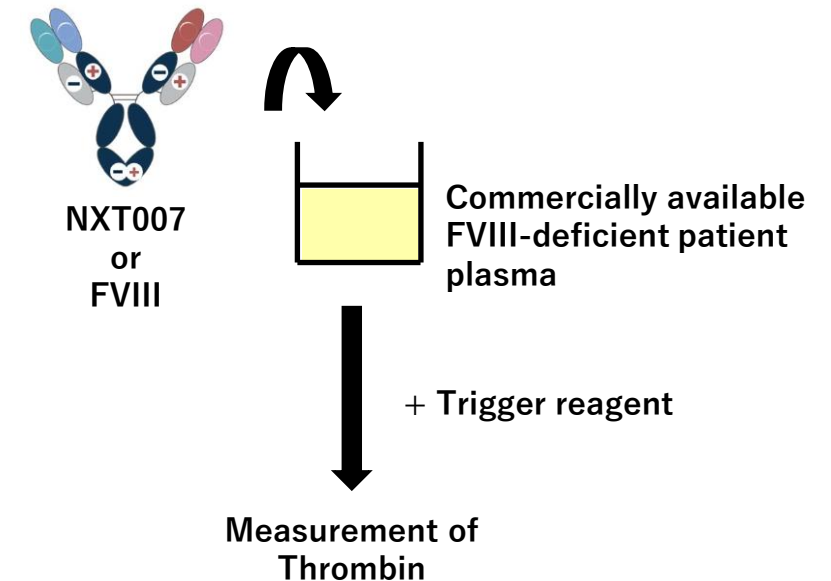
### What is Claudin 6 ?

- One of the tight junction proteins
- Overexpressed in some malignancies including ovarian cancer and NSCLC, while showing almost silent expression in normal tissues
- High tumor specificity expected

# NXT007 Demonstrated Possibility of Maintaining Blood Coagulability Equivalent to Healthy Individuals in People with Hemophilia A



## Non-clinical research data (*in vitro*)

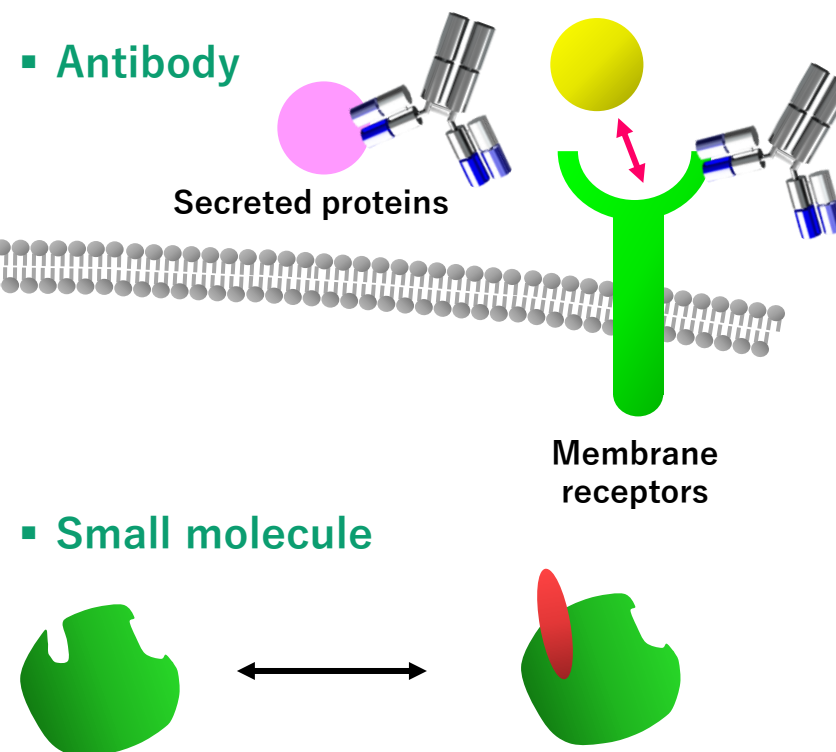
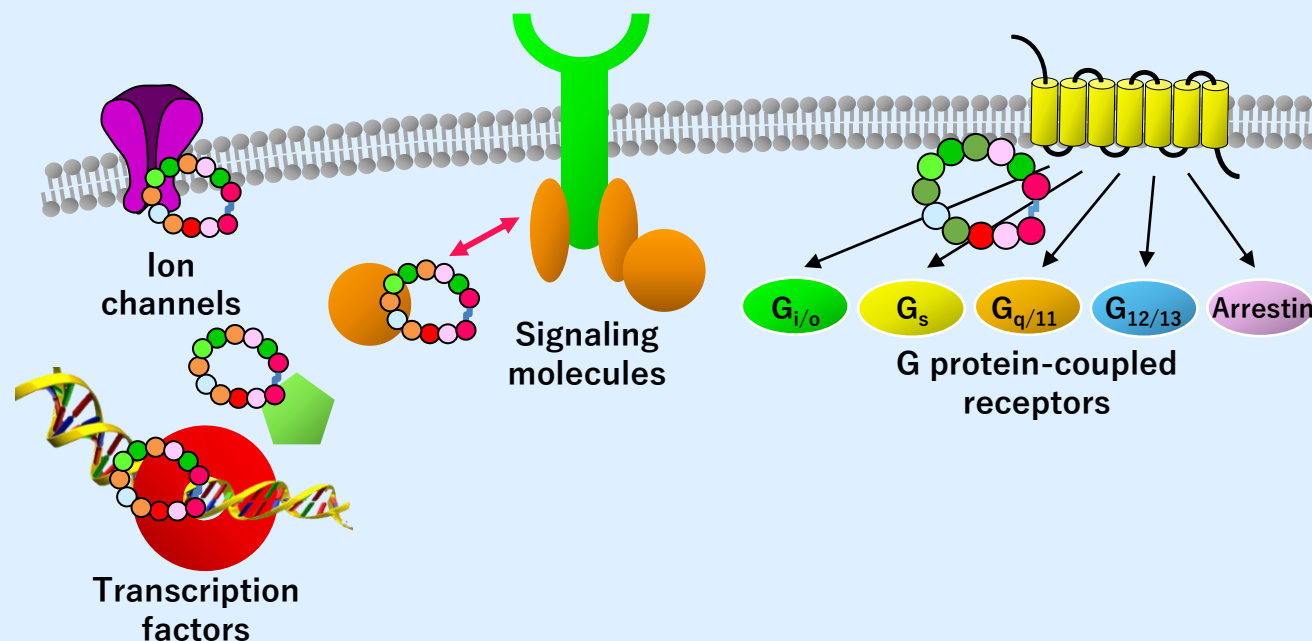


<sup>1</sup> Yuri Teranishi-Ikawa et. al *Journal of Thrombosis and Haemostasis* 2023 (partially modified)

<sup>a</sup> tissue factor triggered

# Chugai's Mid-Size Molecule Can Address Intracellular Tough Targets Undruggable by Small Molecules and Antibodies

## ■ Mid-size molecule



- ✓ Antibodies can be applied targets only extracellular molecules (approx. 20% of the total proteins)
- ✓ Small molecules can only be applied to targets with clear pockets (approx. 20% of proteins)

# Chugai has Established Unique Mid-Size Molecules Technology

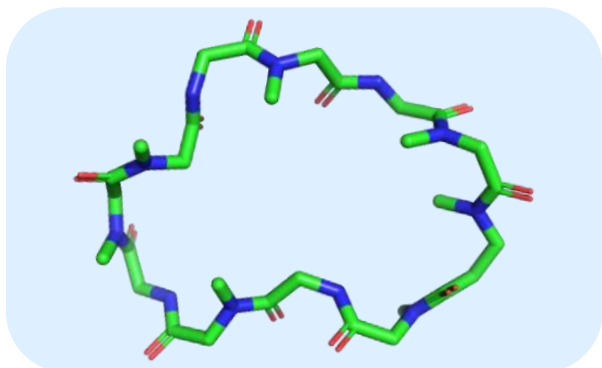
“Chugai Criteria” to create drug-like mid-size molecule beyond “Rule of 5”

Oral bioavailability

Intracellular targeting

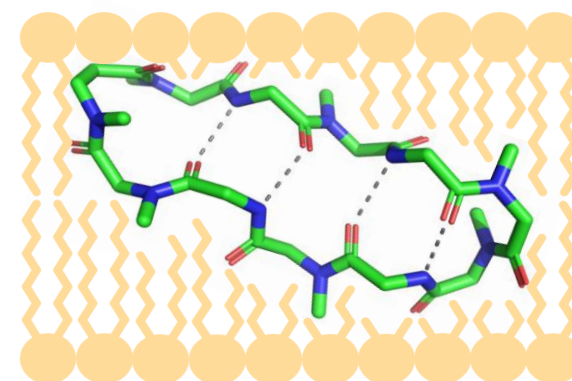
High affinity binding

Cyclic peptides with 9-11 amino acids, more than half should be N-alkylated



**Metabolically stable**  
(hydrophilic and water soluble)

Structure flip  
↔  
Conformational change



**Membrane permeable**  
(lipophilic only inside the cell membrane)

As of February 1, 2024

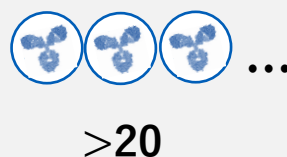
## Drug Discovery

## Pre-clinical development

## Clinical

## Launched

### Antibody drugs, cellular and gene therapy products



GC33  
ERY974  
AMY109  
GYM329  
NXT007  
STA551  
SOF10  
DONQ52  
RAY121  
ALPS12  
SAIL66  
ROSE12



Enspryng  
(gMG, MOGAD, AIE, TED)  
crovalimab  
(PNH\*, aHUS, SCD, LN)



Enspryng  
Hemlibra  
Actemra

### Developments licensed out to 3rd parties excl. Roche

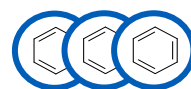


nemolizumab  
(AD(overseas), PN)

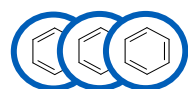


Mitchga (JPN)

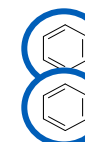
### Small molecule drugs



Screening  
3



Selection of candidates  
8



SPYK04  
REVN24



Alecensa  
(NSCLC adjuvant\*)

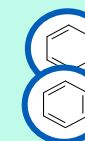


Alecensa  
Edirol  
Oxarol

### Developments licensed out to 3rd parties excl. Roche



EOS789

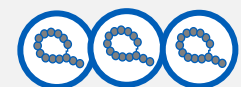


orforglipron  
(T2D, obesity)  
avutometinib  
(LGSOC, NSCLC)



Deberza

### Mid-size molecule drugs



Screening  
17



Selection of candidates  
11



LUNA18

# Projected Submissions (Post PoC NMEs and Products)

as of February 1, 2024

Filed			NME			Line extension		
			in-house			★ : new entry	★ : changes in submission year	
			in-licensed (Roche)			*Before obtaining PoC		
crovalimab (SKY59/RG6107) PNH (China)	ALECENSA (AF802/RG7853) NSCLC (adjuvant)(US)	VABYSMO (RG7716) RVO						
crovalimab (SKY59/RG6107) PNH (Japan)	ALECENSA (AF802/RG7853) NSCLC (adjuvant)(EU)							
crovalimab (SKY59/RG6107) PNH (US)	ALECENSA (AF802/RG7853) NSCLC (adjuvant)(China)							
crovalimab (SKY59/RG6107) PNH (EU)	ALECENSA (AF802/RG7853) NSCLC (adjuvant)(Japan)							
		giredestrant (RG6171) 1L - 3L breast cancer		Vabysmo (RG7716) Angioid streaks	tiragolumab + TECENTRIQ (RG6058 + RG7446) 1L NSQ NSCLC	giredestrant (RG6171) 1L breast cancer		GAZYVA (RG7159) Extra renal lupus
		tiragolumab + TECENTRIQ (RG6058 + RG7446) NSCLC (Stage III)		TECENTRIQ+AVASTIN (RG7446 + RG435) HCC (intermediate stage)	ENSPRYNG (SA237/RG6168) MOGAD	giredestrant (RG6171) breast cancer (adj)		GAZYVA (RG7159) Pediatric nephrotic syndrome
		tiragolumab (RG6058) 1L NSCLC + TECENTRIQ	★	TECENTRIQ (RG7446) MIBC (adjuvant)	ALECENSA (AF802/RG7853) NSCLC (Stage III)	RG6179 UME		GAZYVA (RG7159) Lupus nephritis
		ENSPRYNG (SA237/RG6168) TED	★	ranibizumab(PDS) (RG6321) DME	crovalimab (SKY59/RG6107) SCD* (US/EU)	mosunetuzumab (RG7828) 2L Follicular lymphoma		TECENTRIQ (RG7446) 2L HCC
SRP-9001 (RG6356) DMD		ENSPRYNG (SA237/RG6168) Autoimmune encephalitis		ranibizumab(PDS) (RG6321) nAMD	GYM329/RG6237 FSHD*	tiragolumab(RG6058) 1L HCC TECENTRIQ + AVASTIN	★	TECENTRIQ (RG7446) early breast cancer (neoadjuvant)
mosunetuzumab (RG7828) 3L Follicular lymphoma	AVASTIN (RG435) 1L SCLC + TECENTRIQ							
ENSPRYNG (SA237/RG6168) gMG	TECENTRIQ+AVASTIN (RG7446 + RG435) HCC(adjuvant)	crovalimab (SKY59/RG6107) aHUS		mosunetuzumab+ POLIVY (RG7828+RG7596) r/r aNHL	GYM329/RG6237 SMA* + EVRYSDI	tiragolumab + TECENTRIQ (RG6058 + RG7446) Esophageal cancer		TECENTRIQ (RG7446) NSCLC (neoadjuvant)
2024			2025			2026 and beyond		

# Projects under Development (1/2)

As of February 1, 2024

	Phase I		Phase II	Phase III		Filed
Cancer	<b>LUNA18</b> - solid tumors	<b>RG7421 / cobimetinib</b> - solid tumors	<b>RG6396 / pralsetinib</b> - NSCLC (2L) - solid tumors	<b>AF802 (RG7853) / Alecensa</b> - NSCLC (stage III)*	<b>RG6058 / tiragolumab + RG7446 / Tecentriq</b> - NSCLC (1L) - NSCLC (stage III) - NSQ NSCLC (1L) - Esophageal cancer	<b>AF802 (RG7853) / Alecensa</b> - NSCLC (adjuvant) (US/EU/China/Japan)★
	<b>GC33 / codrituzumab</b> - HCC	<b>RG6026 / glofitamab</b> - hematologic tumors		<b>RG7446 / Tecentriq</b> - NSCLC (neoadjuvant) - MIBC (adjuvant) - Ealy BC (neoadjuvant) - HCC (2L) - Prostate cancer (2L)	<b>RG6058 / tiragolumab+RG7446 / Tecentriq+RG435 / Avastin</b> - HCC (1L)	
	<b>ERY974</b> - solid tumors	<b>RG6194 / runimotamab</b> - solid tumors		<b>RG7446 / Tecentriq +RG435 / Avastin</b> - SCLC (1L) - HCC (adjuvant) - HCC (intermediate stage)	<b>RG6171 / giredestrant</b> - BC (adjuvant) - BC (1L) - BC (1L-3L)	
	<b>STA551</b> - solid tumors	<b>RG6330 / KRAS G12C inhibitor</b> - solid tumors			<b>RG7828 / mosunetuzumab</b> - Follicular lymphoma (2L)	
	<b>SOF10 (RG6440)</b> - solid tumors	<b>RG6433 / SHP2 inhibitor</b> - solid tumors			<b>RG7828 / mosunetuzumab + RG7596 / Polivy</b> - r/r aNHL	
	<b>SPYK04</b> - solid tumors	<b>RG6160 / cevostamab</b> - r/r multiple myeloma			<b>RG6396 / pralsetinib</b> - NSCLC (1L)	
	<b>ALPS12 (RG6524)</b> - solid tumors	<b>RG6139 / tobemstomig</b> - solid tumors				
	<b>SAIL66</b> - CLDN6 positive solid tumors					
	<b>ROSE12</b> - solid tumors					
	<b>RG7828 / mosunetuzumab</b> - Follicular lymphoma (3L)					

**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 October 24, 2023

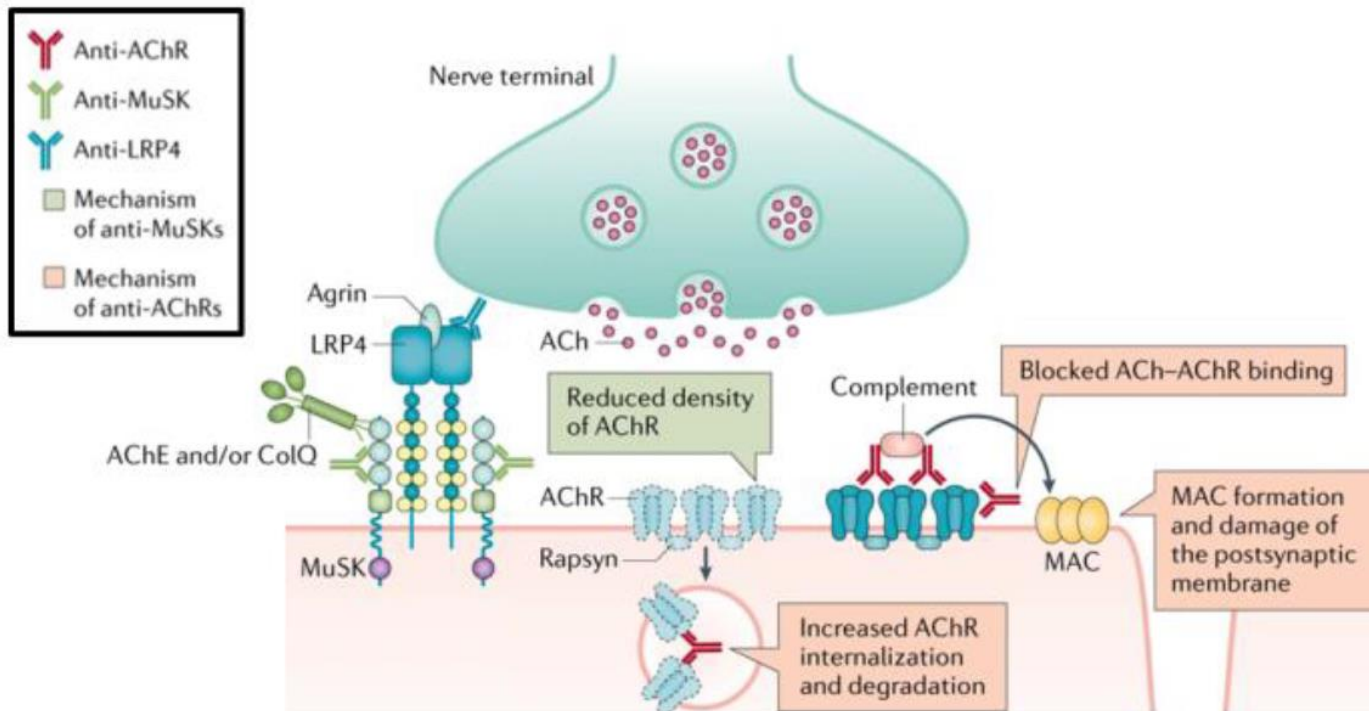
# Projects under Development (2/2)

As of February 1, 2024

	Phase I	Phase II	Phase III	Filed
Immunology	<b>DONQ52</b> - Celiac disease <b>RAY121</b> - Autoimmune disease	<b>SKY59(RG6107)/crovalimab</b> - Lupus nephritis	<b>RG7159 / Gazyva</b> - Lupus nephritis - Pediatric nephrotic syndrome - Extra renal lupus	
Neurology	<b>RG7935 / prasinezumab</b> - Parkinson's disease <b>RG6102 / trontinemab</b> - Alzheimer's disease (PI/II)	<b>GYM329 (RG6237) + Evrysdi</b> - SMA (PII/III) - FSHD <b>RG6042 / tominersen</b> - Huntington's disease	<b>SA237 (RG6168) / Enspryng</b> - gMG - MOGAD - AIE <b>SRP-9001(RG6356) / delandistrogene moxeparvovec</b> -DMD*	
Hematology	<b>NXT007 (RG6512)</b> - hemophilia A (PI/II)	<b>SKY59 (RG6107) / crovalimab (US/EU)</b> - SCD	<b>SKY59 (RG6107) / crovalimab</b> - aHUS	<b>SKY59 (RG6107) / crovalimab (Japan, US, EU)</b> - PNH <b>SKY59 (RG6107) / crovalimab (China)</b> - PNH
Ophthalmology	<b>RG6321 / PDS</b> - nAMD (PI/II) - DME (PI/II)		<b>SA237 (RG6168) / Enspryng</b> - TED ★ <b>RG7716 / Vabysmo</b> - Angioid streaks	<b>RG6179</b> - UME <b>RG7716 / Vabysmo</b> - RVO
Other	<b>REVN24</b> - acute diseases ★	<b>AMY109</b> - Endometriosis ★		

# Generalized Myasthenia Gravis (gMG)

## Enspryng: IL-6 blockade may reduce pathogenic autoantibody production



Source: Roche Pharma Day materials (September 14, 2021)

- 1) Myasthenia gravis clinical practice guideline 2014 (supervisor: Japanese Society of Neurology), Nankodo
- 2) Kerty E, Elsaïs A, Argov Z, et al. EFNS/ENS Guidelines for the treatment of ocular myasthenia. European Journal of Neurology 2014;21:687-93.
- 3) Gilhus N, Tzartos S, Evoli A, et al. Myasthenia gravis. Nat Rev Dis Primers 2019;5(30). Available from the Internet: <https://www.nature.com/articles/s41572-019-0079-y>
- 4) Health and Labor Sciences Research Grants Policy Research Project for Intractable Diseases (Policy Research Project for Intractable Diseases) Verification of Diagnostic Criteria, Severity Classification, Guidelines and Patient QOL Based on Evidence of Neuroimmune Diseases Summary / Sharing Research report (2018)

- gMG is a chronic autoimmune disease against molecules on the postsynaptic membrane of the neuromuscular junction and is characterized by painless muscle loss with easy fatiguability of skeletal muscle.<sup>1)</sup>
- Transition from initial symptoms such as ptosis and diplopia to systemic type is observed. gMG with cervical limb weakness, dysarthria, dysphagia, breathing disability, etc. accounts for 85% of the total.<sup>1) 2)</sup>
- Although the autoantibody positive rate varies slightly depending on the report, it is reported that 80-85% of the total are acetylcholine receptor (AChR) antibody positive and about 5% are muscle specific kinase (MuSK) antibody positive.<sup>3)</sup>
- In Japan, the 2018 National Epidemiological Survey estimates that there are 29,210 MG patients, or 23.1 per 100,000.<sup>4)</sup>

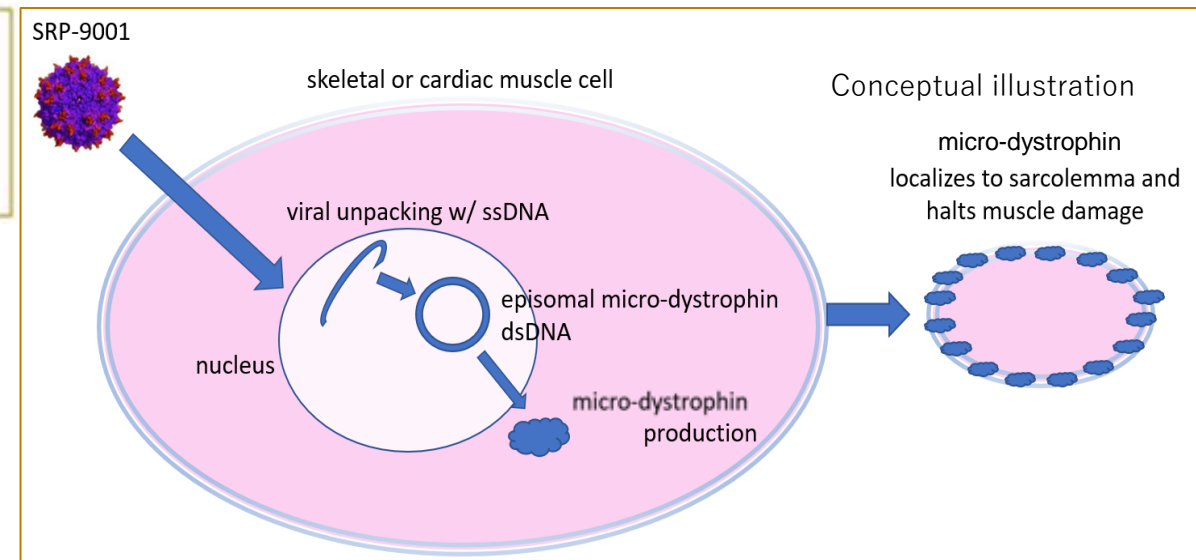
# Delandistrogene moxeparvovec (RG6356/SRP-9001)

Gene transfer therapy developed for targeted muscle expression of micro-dystrophin, a shortened, functional dystrophin protein

Delandistrogene moxeparvovec (SRP-9001/ RG6356) is an investigational gene transfer therapy developed for targeted muscle expression of micro-dystrophin, a shortened, functional dystrophin protein, that addresses the genetic cause of DMD.



- Aims to express **micro-dystrophin** – a smaller but still functional version of dystrophin, used because naturally-occurring dystrophin is too large to fit in an AAV vector<sup>1</sup>.
- Employs the **AAVrh74 vector**, which has a robust affinity for muscle cells, making it an ideal choice for delivering the micro-dystrophin transgene. AAVrh74 also has a relatively low level of pre-existing immunity<sup>1</sup>.
- The **MHCK7 promoter** drives the expression of the micro-dystrophin transgene selectively in skeletal and cardiac muscle, and contains an  **$\alpha$ -MHC enhancer** that has been shown to drive high protein expression, particularly in cardiac muscle.<sup>1,2</sup>



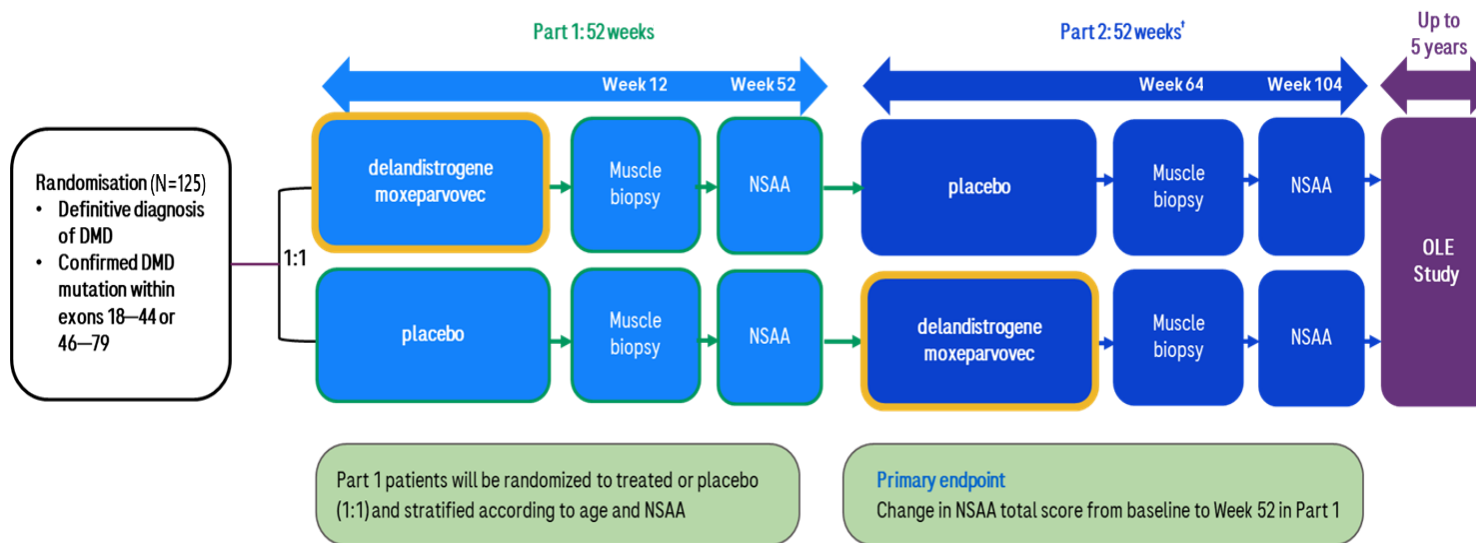
Source: Roche internal materials

1. Asher D, et al. Clinical development on the frontier: gene therapy for duchenne muscular dystrophy. Expert Opinion on Biological Therapy. 2020; 20:263-274;  
2. Salva MZ, et al. Design of Tissue-specific Regulatory Cassettes for High-level rAAV-mediated Expression in Skeletal and Cardiac Muscle. Mol Ther. 2007; 15:320-9;

# Delandistrogene moxeparvovec (RG6356/SRP-9001)

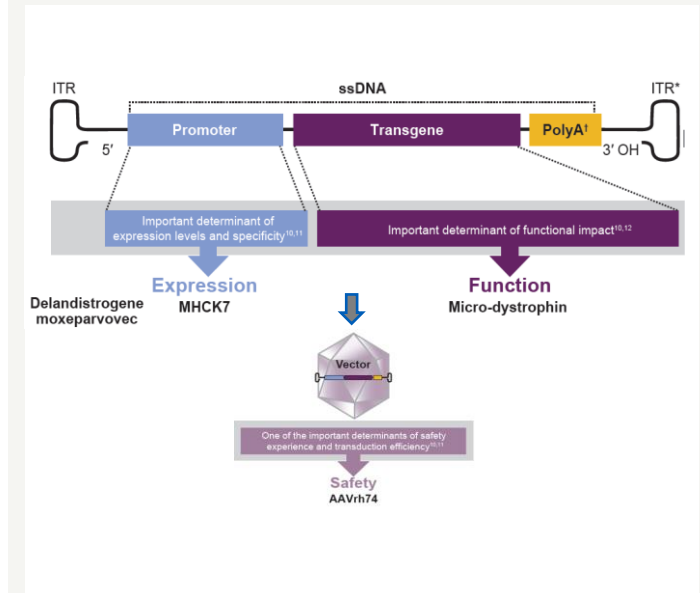
Phase 3 EMBARK study in ambulatory boys ( $\geq 4$  to  $< 8$  yrs) with DMD, design and mode of action

## Ph III EMBARK study design<sup>1</sup>



- The EMBARK study is a double-blind, placebo-controlled trial in ambulatory 4-7 year-old boys with DMD (n=125, 1:1; Part1, 52 week observation period)
- † Patients, caregivers, investigators, and site staff remain blinded. Only a subset of patients will receive a muscle biopsy for expression assessments.

## Mode of Action

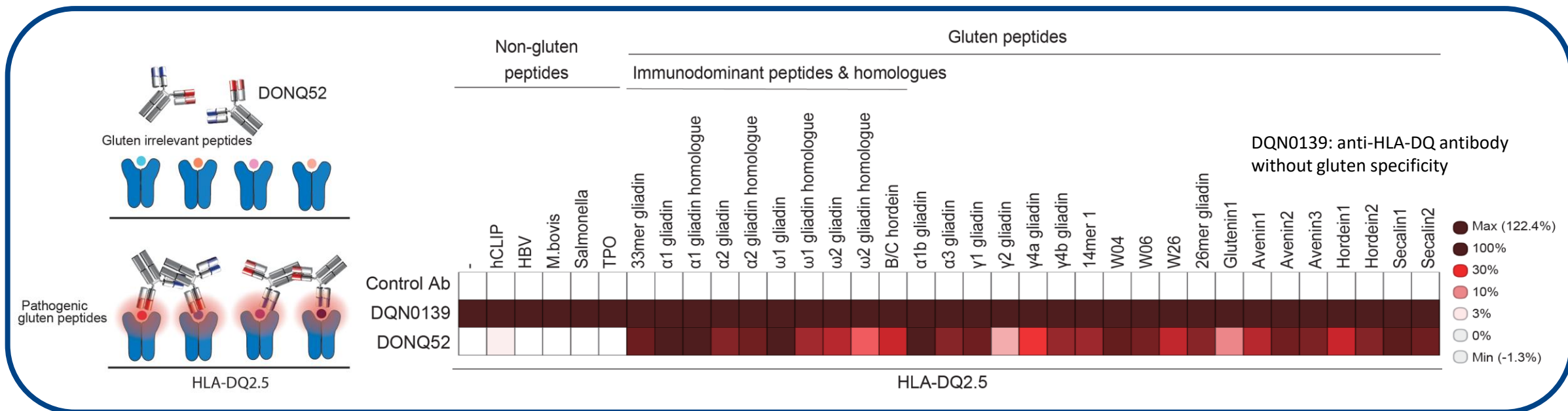


- Targeted delivery of micro-dystrophin transgene to key muscle tissue can enable meaningful and durable functional response
- AAVrh74 vector: low likelihood of pre-existing immunity and high tropism for skeletal & cardiac muscles
- Expression potentiated by the MHCK7 promoter in cardiac & skeletal muscle

## DONQ52: Non-Clinical Research Results Published in Nature Communications

### DONQ52 binds to more than 25 types of gluten peptides that cause celiac disease

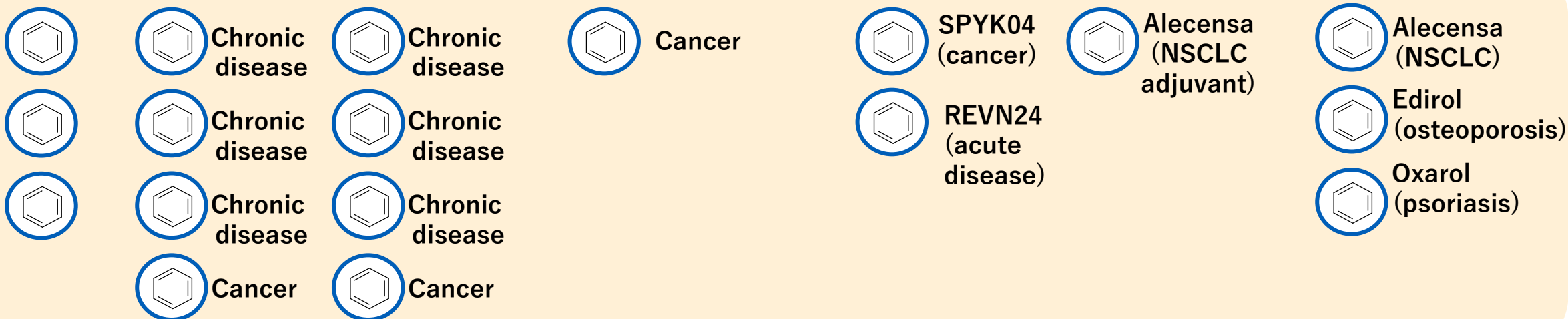
- Specific binding to complex of HLA-DQ2.5/gluten peptides. No binding to HLA molecule itself or complex of HLA-DQ2.5/irrelevant peptides.
- Binding to more than 25 peptides responsible for celiac disease by flexibly recognizing the unique motif of gluten epitopes



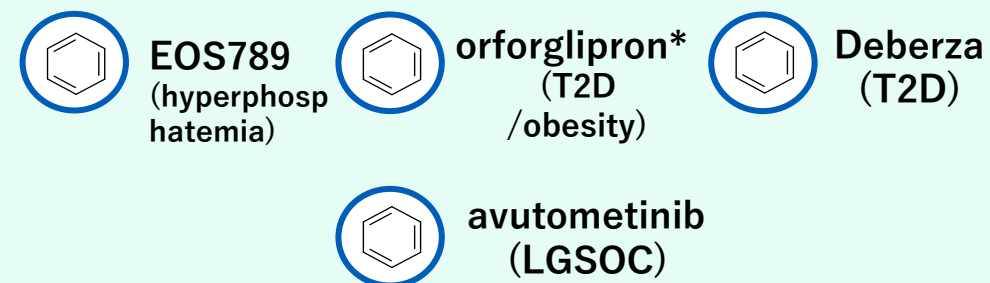
# Small Molecule Drug Discovery: Portfolio

As of February 1, 2024

## In-house molecule



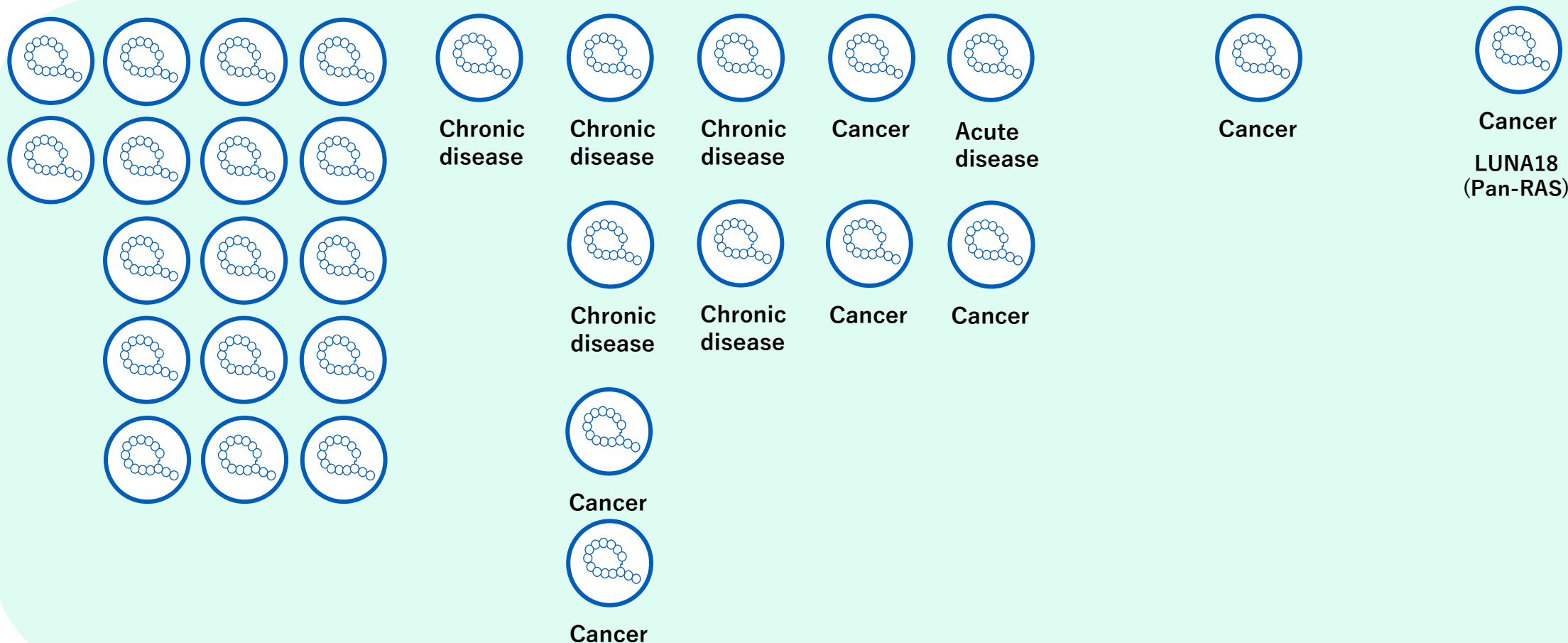
## Outsourced to a third party other than Roche



\*The worldwide development and commercialization rights have been licensed out to Eli Lilly

# Mid-Size Molecule Drug Discovery: Portfolio

As of February 1, 2024



Screening

Selection of candidates

Pre-clinical development

Clinical

# Antibody Drug, Cellular and Gene Therapy Product: Portfolio

\* Projects that utilize multiple technologies are displayed in each technology.

As of February 1, 2024

Recycling Antibody®  
Sweeping Antibody®  
etc.



chronic  
disease



AMY109  
(endometriosis/P2)



Enspryng



GYM329  
(SMA/P2/3))



RAY121  
(Autoimmune disease/P1)



crovalimab  
(PNH/Filed)

Multispecific antibody



chronic  
disease



NXT007 (hemophilia A/P1/2)



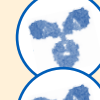
DONQ52 (Celiac disease/P1)



ERY974 (cancer/P1)



ALPS12 (cancer/P1)



SAIL66 (cancer/P1)



Hemlibra

Switch Antibody™

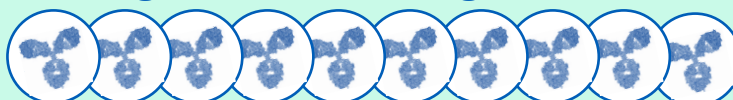


STA551 (cancer/P1)



ROSE12 (cancer/P1)

PAC-Ig®, new technologies, etc. *and more incl CAR-T*



infectious  
disease



SOF10 (cancer/P1)



GC33 (cancer/P1)



nemolizumab  
(atopic  
dermatitis/prurigo  
nodularis)



Actemra



Mitchga  
(atopic dermatitis  
/JPN)

Discovery

Pre-clinical development

Clinical

Launched

# Advances in Major Chugai Originated Projects Out Licensed to 3rd Parties

As of February 1, 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"> <li>US FDA BTd (recurrent LGSOC in combination with defactinib)</li> <li>RAMP301 trial initiated★</li> </ul>
				NSCLC	global: P2	—
					global: P1/2	<ul style="list-style-type: none"> <li>RAMP 203 trial (in combination with KRAS G12C inhibitor sotorasib) initiated</li> <li>RAMP 204 trial (in combination with KRAS G12C inhibitor, adagrasib) initiated</li> </ul>
nemolizumab	Anti-IL-31 receptor A humanized monoclonal antibody	Global (Galderma) Japan (Maruho)	Galderma exclusive global license for the development and marketing excluding Japan and Taiwan Maruho rights for development and marketing in the skin disease area for the Japanese market	Atopic dermatitis	global: P3 Japan: filed	<ul style="list-style-type: none"> <li>Two P3 studies met primary endpoints</li> <li>Filed for additional indication for pruritus associated with atopic dermatitis (pediatric)</li> </ul>
				Prurigo nodularis	global: P3 Japan: filed	<ul style="list-style-type: none"> <li>US FDA BTd</li> <li>Two P3 studies met primary endpoints</li> <li>Filed for additional indication for prurigo nodularis</li> </ul>
				CKDaP	global: P2/3	—
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"> <li>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 The Lancet*</li> </ul>
				Obesity	global: P3	<ul style="list-style-type: none"> <li>In the other phase 2 study, orforglipron demonstrated up to 14.7% weight reduction at 36 weeks. The results were published in the New England Journal of Medicine**</li> </ul>

\* 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.

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

★ Changes from the last announcement on October 24, 2023

# FoundationOne CDx Cancer Genomic Profile -Companion diagnostic indications-

\* Underlined are the companion diagnostic features and relevant drugs currently under application for regulatory approval

As of February 1, 2024

Alterations	Cancer type	Relevant drugs
Activated <i>EGFR</i> gene alterations	NSCLC	afatinib dimaleate, erlotinib hydrochloride, gefitinib, osimertinib mesilate, dacomitinib hydrate
<i>EGFR</i> exon 20 T790M alterations		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>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 gene		entrectinib, larotrectinib sulfate
<u><i>RET</i> fusion genes</u>		<u>selpercatinib</u>
<i>BRCA1/2</i> alterations	Ovarian cancer	olaparib
<i>BRCA1/2</i> alterations	Prostate cancer	olaparib, <u>talazoparib tosilate</u>
<i>FGFR2</i> fusion genes	Biliary tract cancer	pemigatinib

# FoundationOne Liquid CDx Cancer Genomic Profile

## Companion diagnostic indications

As of February 1, 2024

Alterations	Cancer type	Relevant drugs
Activated <i>EGFR</i> gene alterations	Non-small cell lung cancer (NSCLC)	afatinib dimaleate, erlotinib hydrochloride, gefitinib, osimertinib mesilate
<i>EGFR</i> exon 20 T790M alterations		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 gene	Solid tumors	entrectinib
<i>BRCA1/2</i> alterations	Prostate cancer	olaparib

# FY2023 Consolidated Financial Overview(Core)

**Toshiaki Itagaki**

Director, Executive Vice President & CFO

# P/L Jan – Dec (Non-core adjustment)

(Billions of JPY)	IFRS results	Non-core items		Core results
		Intangible assets	Others	
<b>Revenue</b>	<b>1,111.4</b>			<b>1,111.4</b>
Sales	974.5			974.5
Other revenue	136.9			136.9
Cost of sales	-413.3	+1.2	+0.1	-412.0
Research and development	-174.9	+5.4	+6.7	-162.8
Selling, general and administration	-112.6		+10.6	-102.0
Other operating income (expense)	28.6		-12.5	16.1
<b>Operating profit</b>	<b>439.2</b>	<b>+6.6</b>	<b>+4.9</b>	<b>450.7</b>
Financial account balance	4.6			4.6
Income taxes	-118.3	-2.0	-1.4	-121.8
<b>Net income</b>	<b>325.5</b>	<b>+4.6</b>	<b>+3.5</b>	<b>333.6</b>
<b>EPS (JPY)</b>	<b>197.80</b>			<b>202.71</b>

## Non-core items

(Billions of JPY)

### Intangible assets

Amortization	+1.6
Impairment	+5.1

### Others

Restructuring expenses, etc. including gain on disposal of assets	-5.5
Early retirement incentive program	+10.3

# P/L Jan – Dec (Year on Year)

(Billions of JPY)	2022	2023	Growth	
<b>Revenue</b>	<b>1,167.8</b>	<b>1,111.4</b>	<b>- 56.4</b>	<b>- 4.8%</b>
Sales	1,039.2	974.5	- 64.7	- 6.2%
Domestic	654.7	558.0	- 96.7	- 14.8%
Overseas	384.6	416.5	+ 31.9	+ 8.3%
Other revenue	128.6	136.9	+ 8.3	+ 6.5%
Cost of sales	-475.0	-412.0	+ 63.0	- 13.3%
(cost to sales ratio)	45.7%	42.3%	-3.4%pts	-
Research and development	-143.7	-162.8	- 19.1	+ 13.3%
Selling, general and administration	-98.8	-102.0	- 3.2	+ 3.2%
Other operating income (expense)	1.4	16.1	+ 14.7	12 times
<b>Operating profit</b>	<b>451.7</b>	<b>450.7</b>	<b>- 1.0</b>	<b>- 0.2%</b>
(operating margin)	38.7%	40.6%	+1.9%pts	-
Financial account balance	-2.1	4.6	+ 6.7	-
Income taxes	-131.8	-121.8	+ 10.0	- 7.6%
<b>Net income</b>	<b>317.7</b>	<b>333.6</b>	<b>+ 15.9</b>	<b>+ 5.0%</b>
<b>EPS (JPY)</b>	<b>193.11</b>	<b>202.71</b>	<b>+9.60</b>	<b>+ 5.0%</b>

## Domestic sales

Decrease in the supply of Ronapreve to the government

## Overseas sales

Significant increase in sales of Hemlibra and Alecensa

## Other revenue

Increase in income of Hemlibra and 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, including start of operations at Chugai Life Science Park Yokohama and progress of development projects

## Selling, general and administration expenses

Increase in various expenses

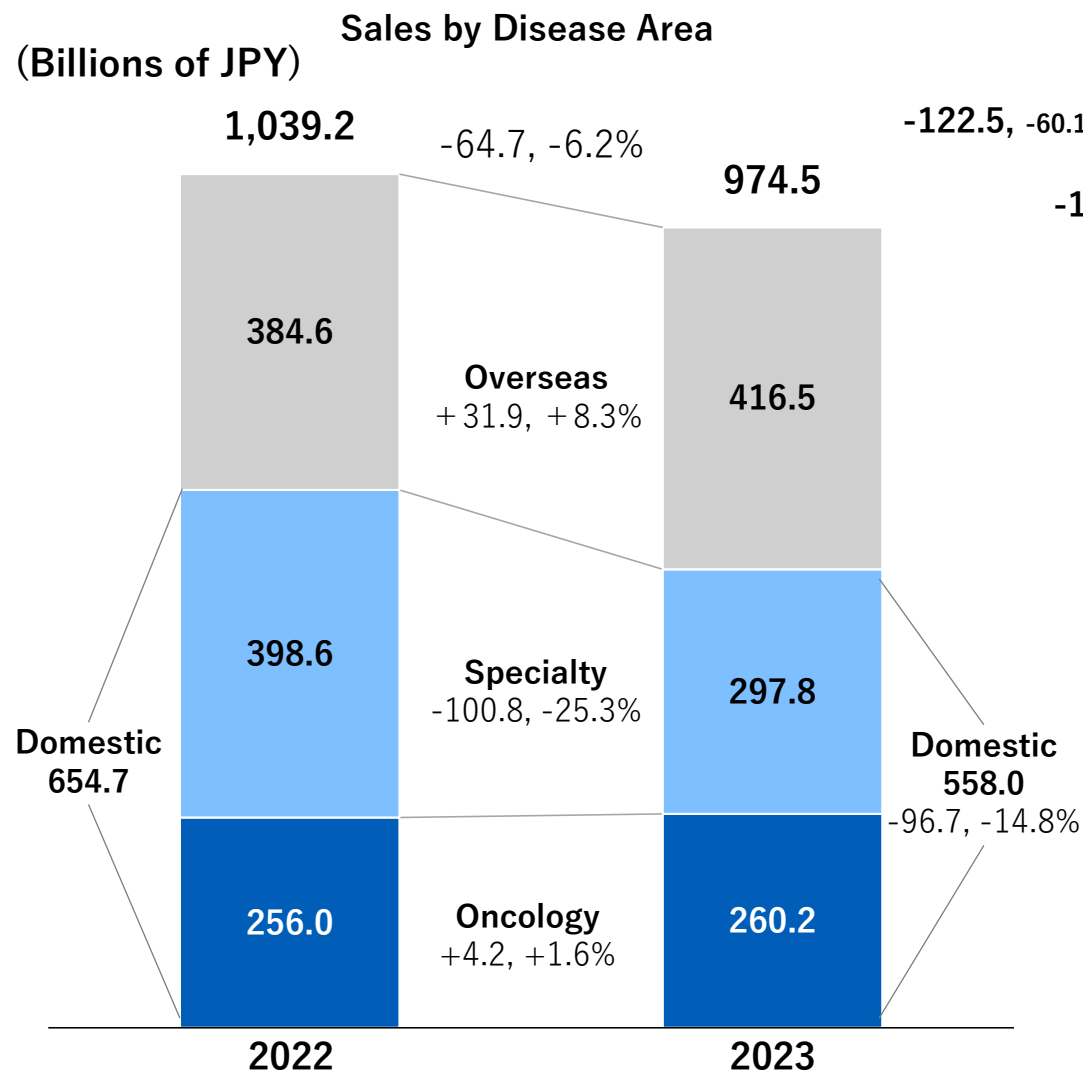
## Other operating income (expense)

Increase in income from disposal of product rights and gain on sales of property, plant and equipment, etc.

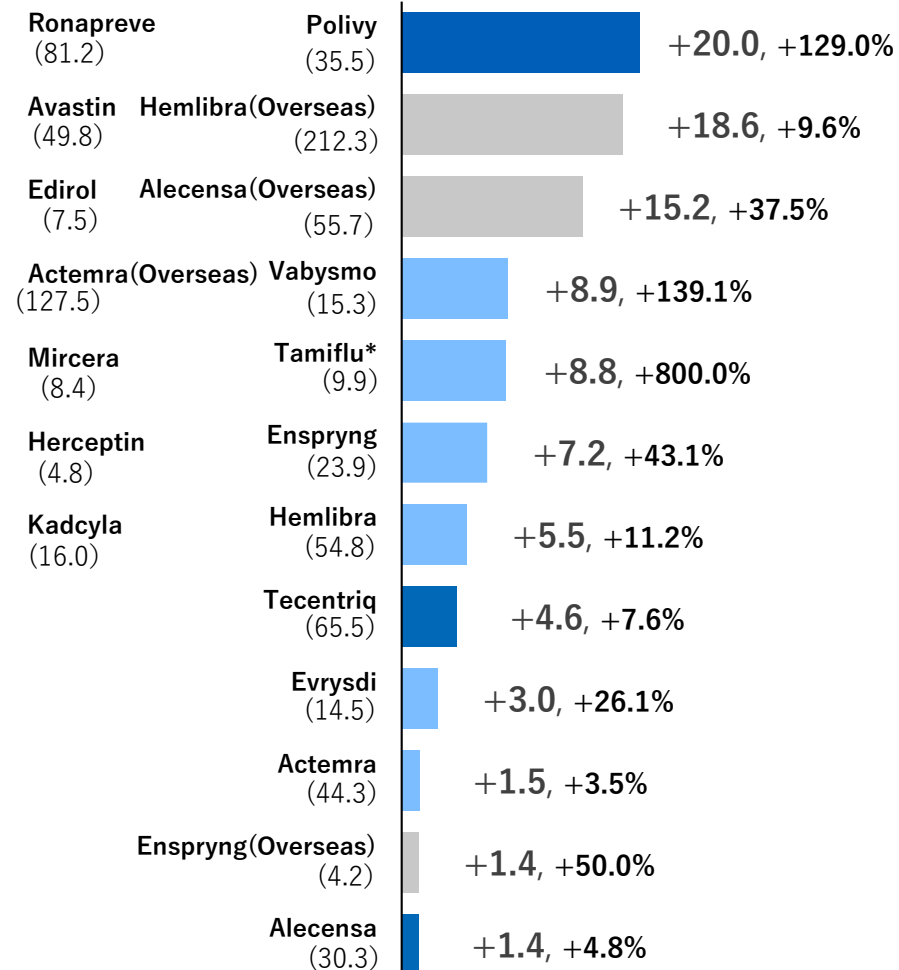
## Net income

Increase due to decrease in income taxes and improvement in financial account balance, etc.

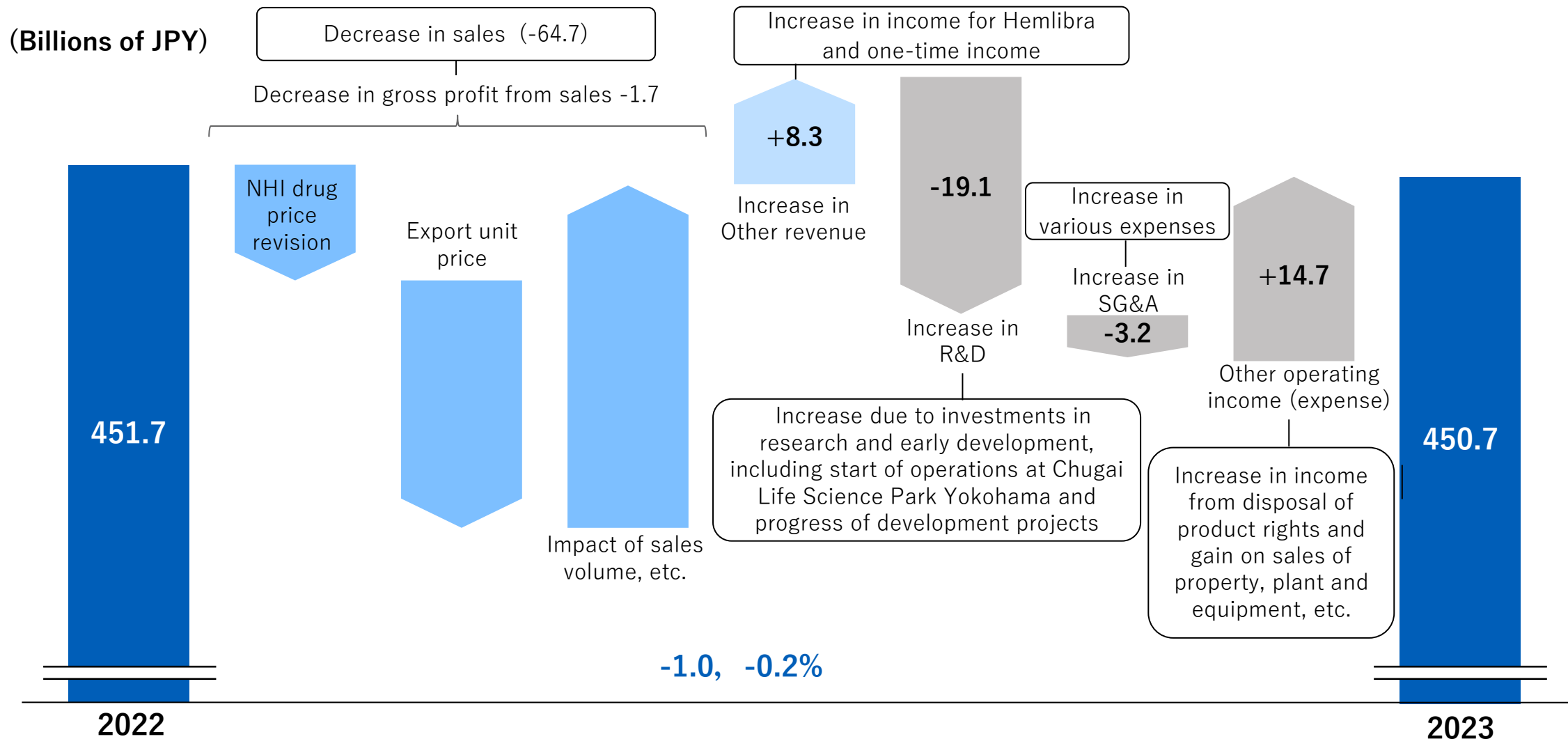
# Sales Jan – Dec (Year on Year)



## Sales by Product

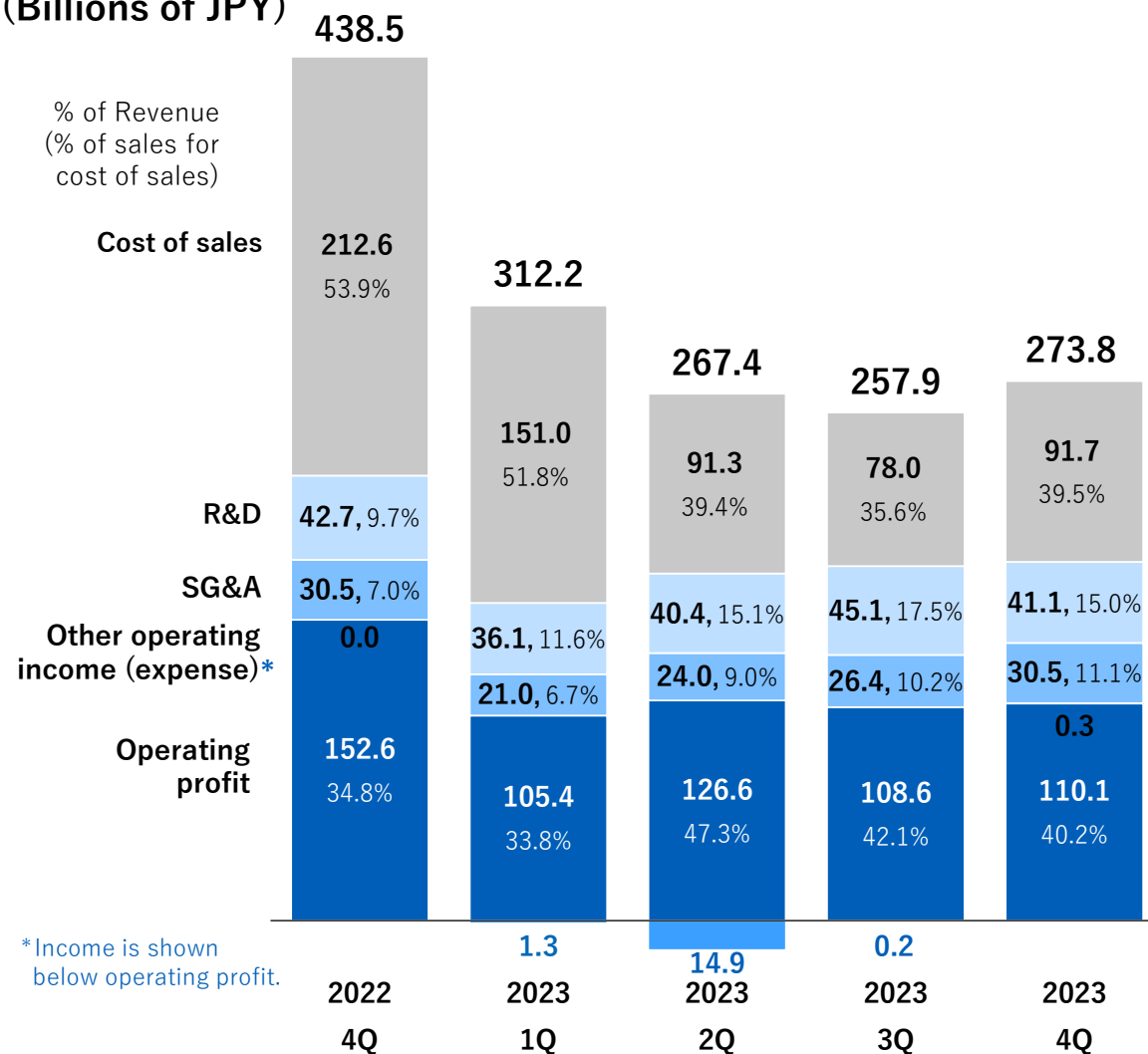


# Operating Profit Jan – Dec (Year on Year)



# Structure of Costs and Profit by Quarter

(Billions of JPY)



## Year on Year (vs. 2022 Q4)

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

**R&D:** difference from the timing of incurred expenses

**SG&A:** same level as the same period of the previous year

**Other operating income (expense):** same level as the same period of the previous year

**Operating profit:** -42.5 billion JPY, -27.9%

## Quarter on Quarter (vs. 2023 Q3)

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

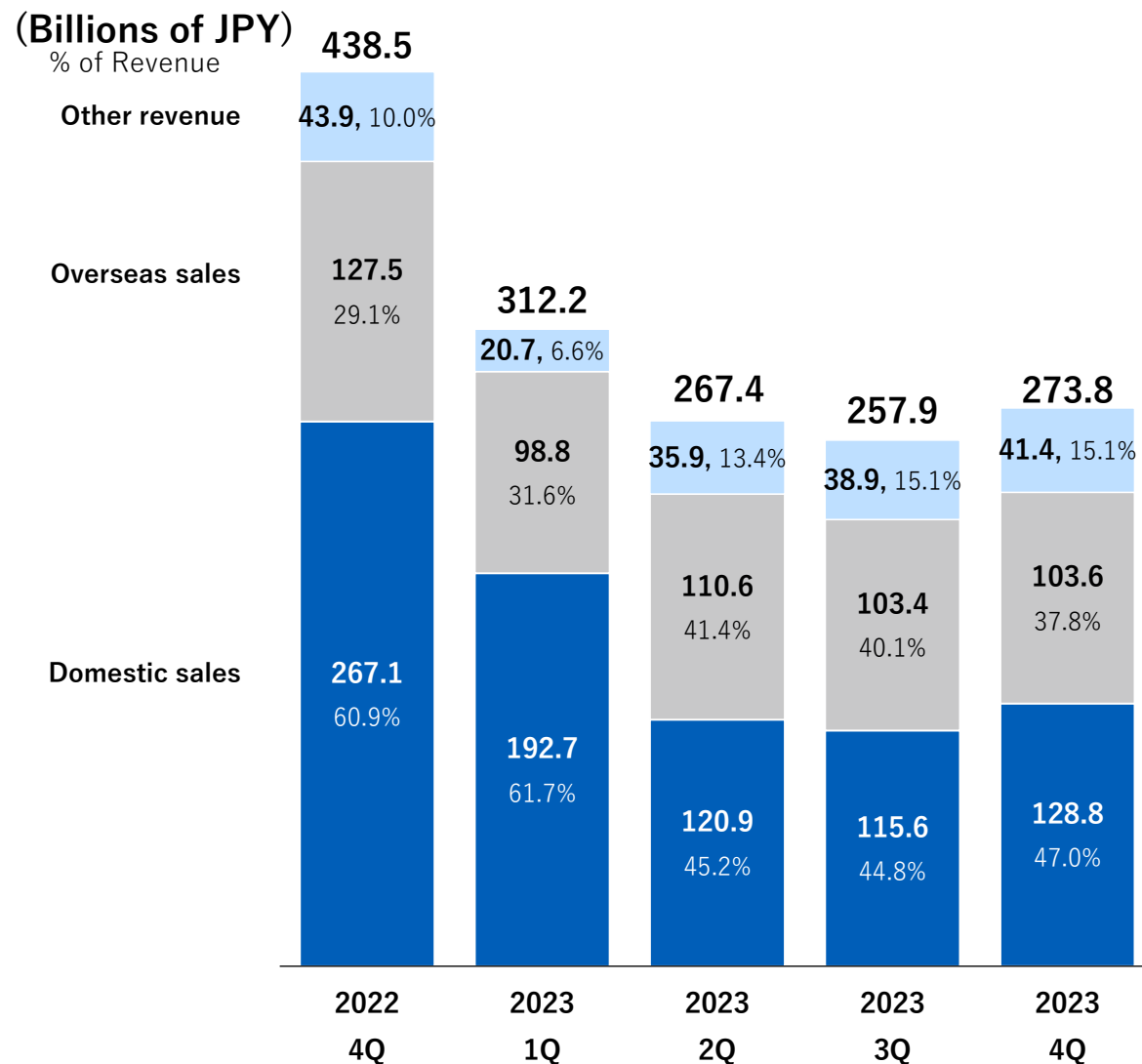
**R&D:** difference from the timing of incurred expenses

**SG&A:** increase due to the annual upward trend of cost

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

**Operating profit:** +1.5 billion JPY, +1.4%

# Structure of Revenue by Quarter



## Year on Year (vs. 2022 Q4)

**Domestic sales:** decrease due to the absence of Ronapreve supplied to the government

**Overseas sales:** decrease in sales of Hemlibra and Actemra

**Other revenue:** decrease in royalty income of Actemra, etc.

## Quarter on Quarter (vs. 2023 Q3)

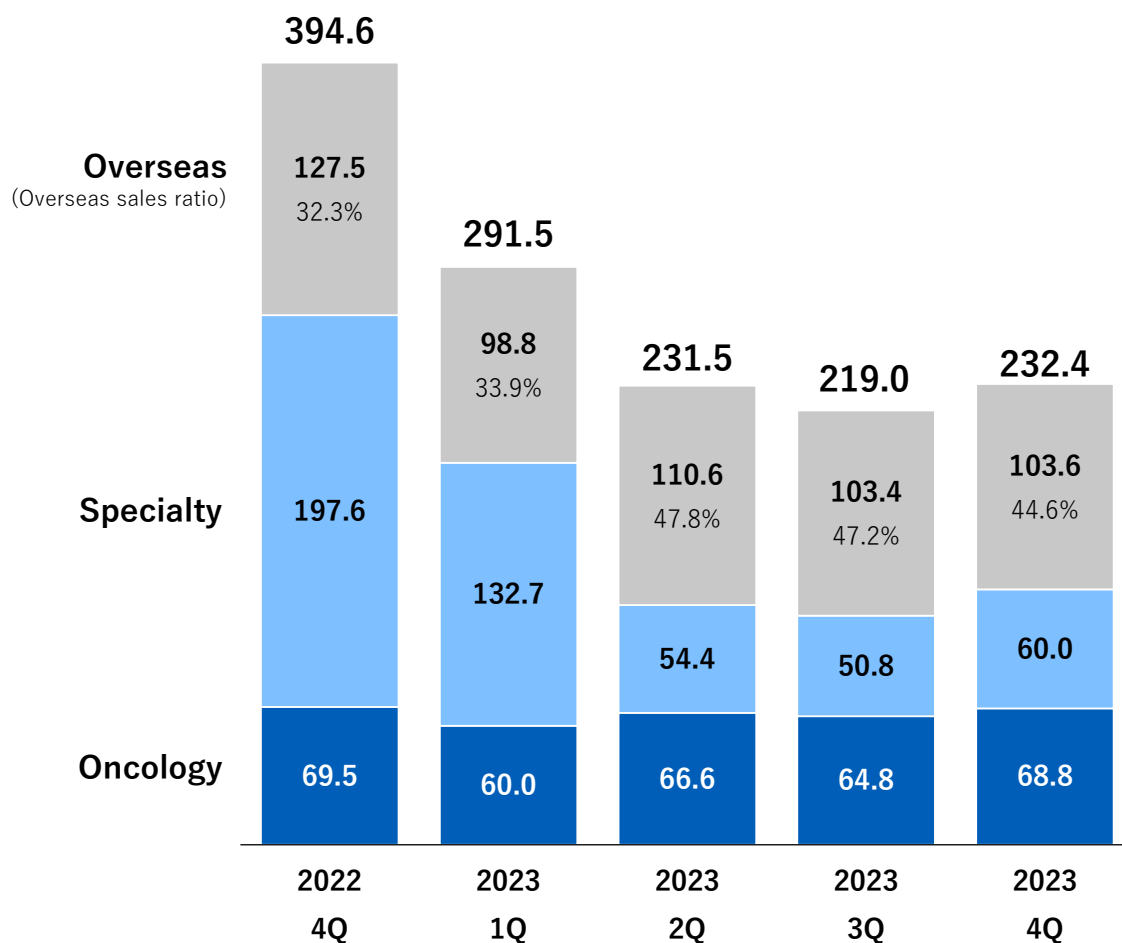
**Domestic sales:** increase due to growth of mainstay and new products

**Overseas sales:** increase in sales of Actemra and Alecensa, offsetting the decrease in sales of Hemlibra due to the timing of shipment

**Other revenue:** increase in royalty income of Hemlibra, etc.

# Structure of Sales by Quarter

(Billions of JPY)



Year on Year (vs. 2022 Q4)

Oncology	Avastin:	-5.1	Polivy:	+3.6
	Phesgo:	+0.7		
Specialty	Ronapreve:	-142.8	Tamiflu*:	+3.6
	Enspryng:	+1.9	Vabysmo:	+1.4
Overseas	Hemlibra:	-18.2	Actemra:	-9.3
	Alecensa:	+4.3		

Quarter on Quarter (vs. 2023 Q3)

Oncology	Tecentriq:	+1.3	Alecensa:	+0.7
	Phesgo:	+0.7		
Specialty	Tamiflu*:	+3.0	Enspryng:	+1.1
	Actemra:	+0.9	Vabysmo:	+0.6
Overseas	Actemra:	+19.5	Alecensa:	+11.3
	Hemlibra:	-27.4	Enspryng:	-3.3

\*included in Other products of Speciality

# P/L Jan – Dec (vs. Forecast)

(Billions of JPY)	2023		+/-	Achiev.
	Forecast	Actual		
<b>Revenue</b>	<b>1,070.0</b>	<b>1,111.4</b>	<b>+ 41.4</b>	<b>103.9%</b>
Sales	920.0	974.5	+ 54.5	105.9%
Domestic	541.7	558.0	+ 16.3	103.0%
Overseas	378.3	416.5	+ 38.2	110.1%
Other revenue	150.0	136.9	- 13.1	91.3%
Cost of sales	- 405.0	- 412.0	- 7.0	101.7%
(cost to sales ratio)	44.0%	42.3%	-1.7%pts	-
Research and development	- 165.0	- 162.8	+ 2.2	98.7%
Selling, general and administration	- 100.0	- 102.0	- 2.0	102.0%
Other operating income (expense)	15.0	16.1	+ 1.1	107.3%
<b>Operating profit</b>	<b>415.0</b>	<b>450.7</b>	<b>+ 35.7</b>	<b>108.6%</b>
(operating margin)	38.8%	40.6%	+1.8%pts	-
<b>Net income</b>	<b>306.0</b>	<b>333.6</b>	<b>+ 27.6</b>	<b>109.0%</b>
<b>EPS (JPY)</b>	<b>186.00</b>	<b>202.71</b>	<b>+ 16.71</b>	<b>109.0%</b>

## Domestic sales

Various products outperformed the forecast (see next slide)

## Overseas sales

Sales of Hemlibra, Actemra and Alecensa exceeded the forecast

## Other revenue

One-time income and income for Hemlibra were lower than the forecast

## Cost of sales

Cost to sales ratio improved compared to the forecast due to the impact of product mix, etc.

## Research and development expenses

Mostly in line with the forecast

## Selling, general and administration expenses

Mostly in line with the forecast

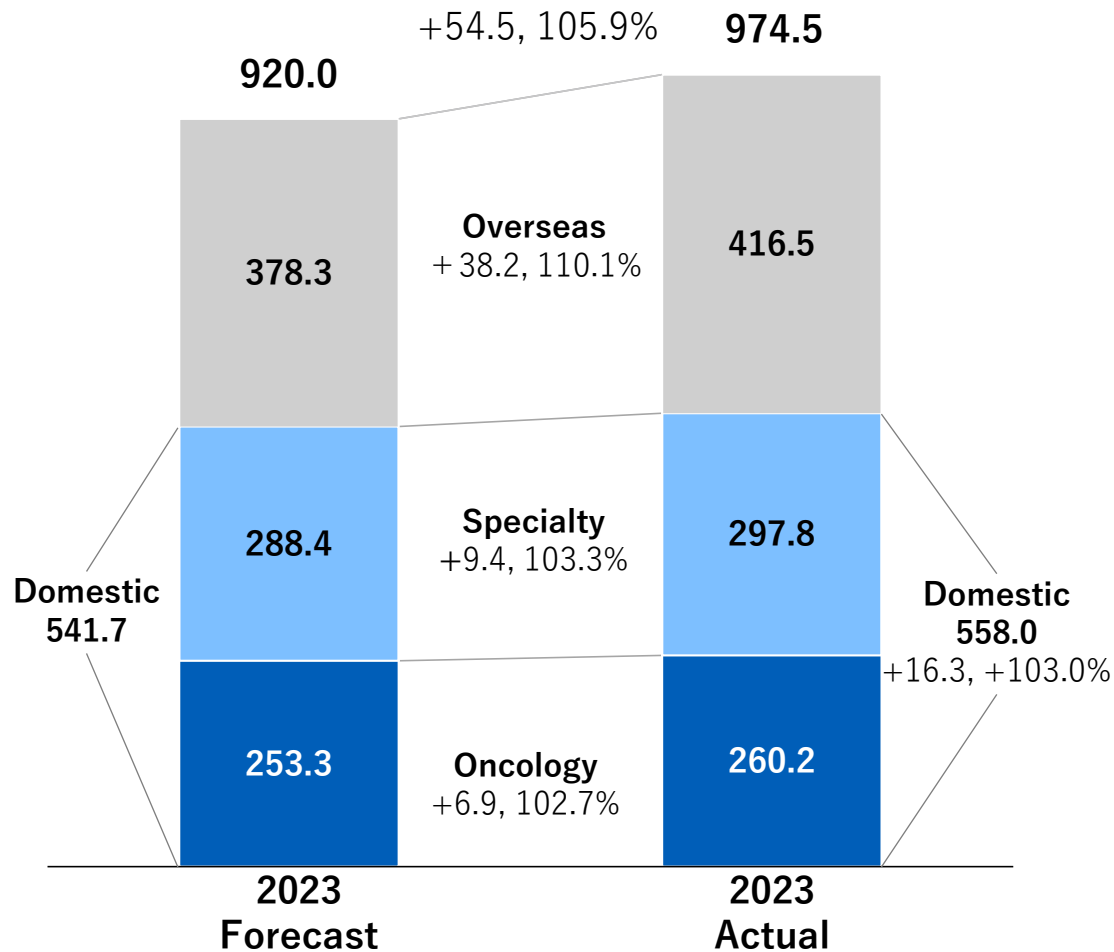
## Other operating income (expense)

Mostly in line with the forecast

# Sales Jan – Dec (vs. Forecast)

## Sales by Disease Area

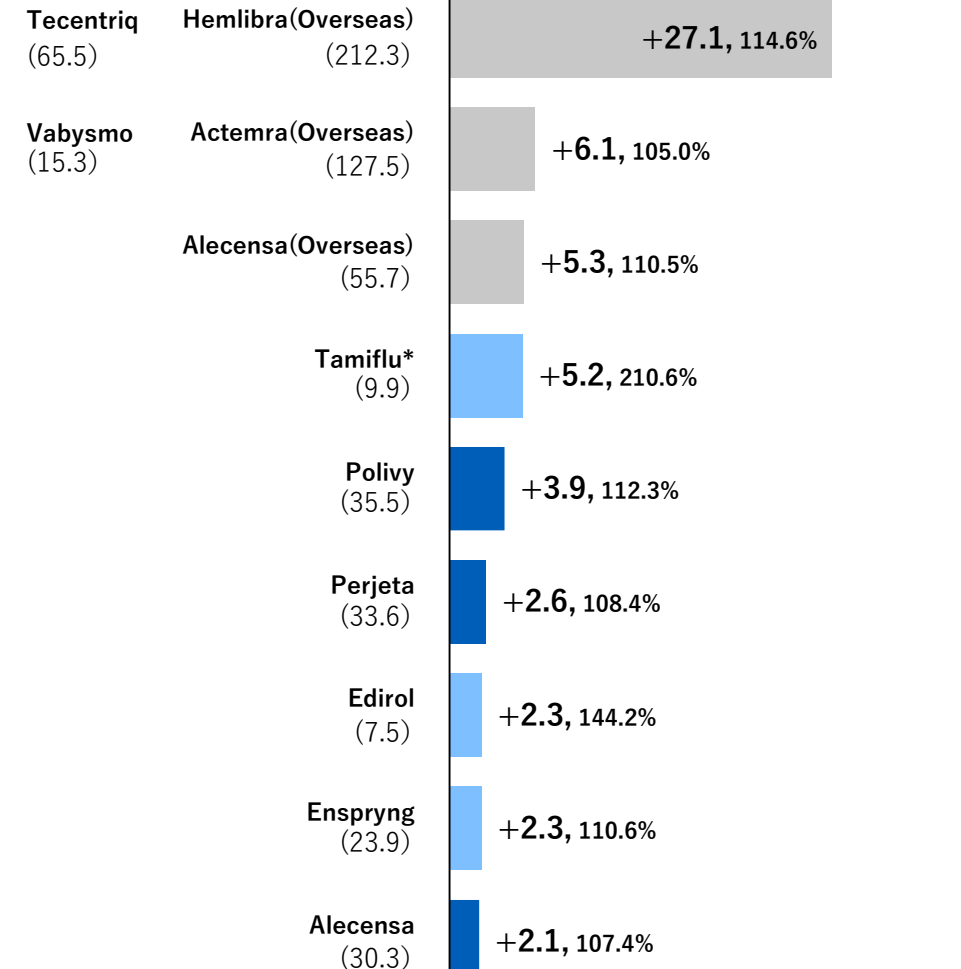
(Billions of JPY)



## Sales by Product

-2.2, 96.8%

-2.1, 87.9%



( ): Actual sales in FY2023

%: Achievement

\*included in Other products of Speciality

# Impact from Foreign Exchange Jan – Dec

(Billions of JPY)	vs. 2022 Actual rate	vs. 2023 Forecast rate <sup>*1</sup>
<b>Revenue</b>	<b>+51.9</b>	<b>+10.3</b>
Sales	+41.4	+8.9
Other revenue	+10.5	+1.4
<b>Cost of sales</b>	<b>-26.1</b>	<b>-0.6</b>
<b>Other than above<sup>*2</sup></b>	<b>-4.6</b>	<b>-2.8</b>
<b>Operating profit</b>	<b>+21.2</b>	<b>+7.0</b>

Exchange rate (JPY)	2022 Jan - Dec Actual rate <sup>*3</sup>	2023 Jan - Dec Actual rate <sup>*3</sup>
1CHF	125.17	140.31
1EUR	137.67	151.38
1USD	116.27	134.21

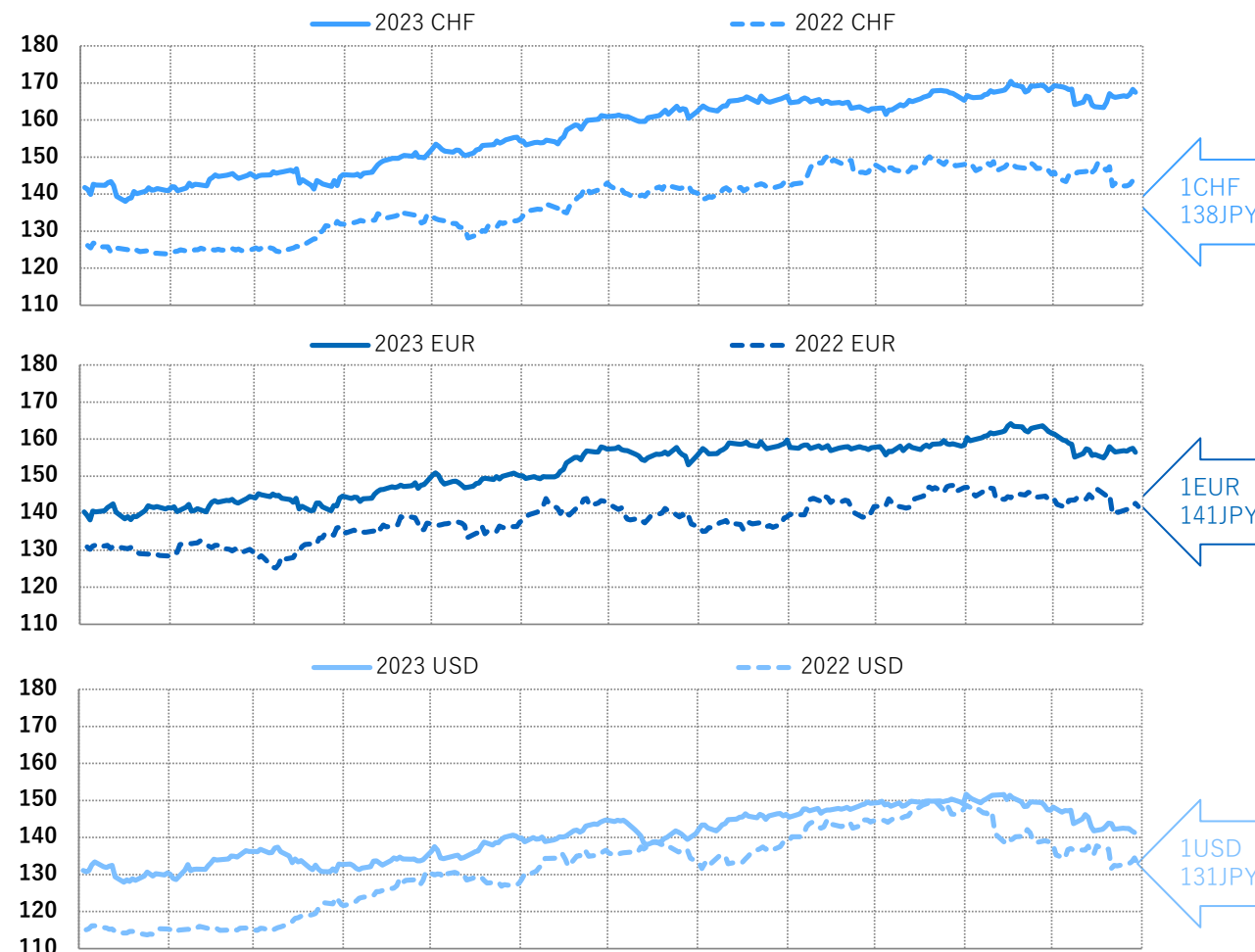
<sup>\*1</sup> Foreign Exchange effect from Jan-Dec Forecast rate(2023)

<sup>\*2</sup> Total of R&D, SG&A and other operating income (expense)

<sup>\*3</sup> Weighted average of the exchange rates used to record foreign currency transactions included in categories from revenue to operating profit

## Historical exchange rate to the JPY

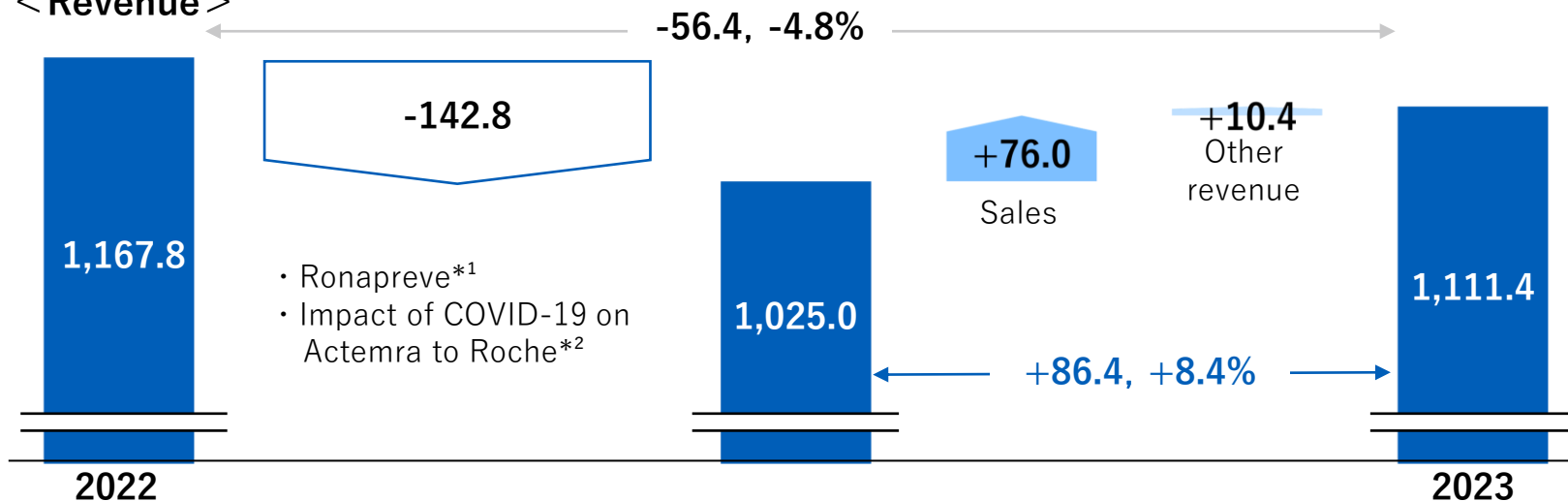
◀ : Full-year Forecast rate(2023)



# P/L Analysis Jan – Dec (Year on Year)

(Billions of JPY)

## &lt; Revenue &gt;

\*<sup>1</sup>Ronapreve sales

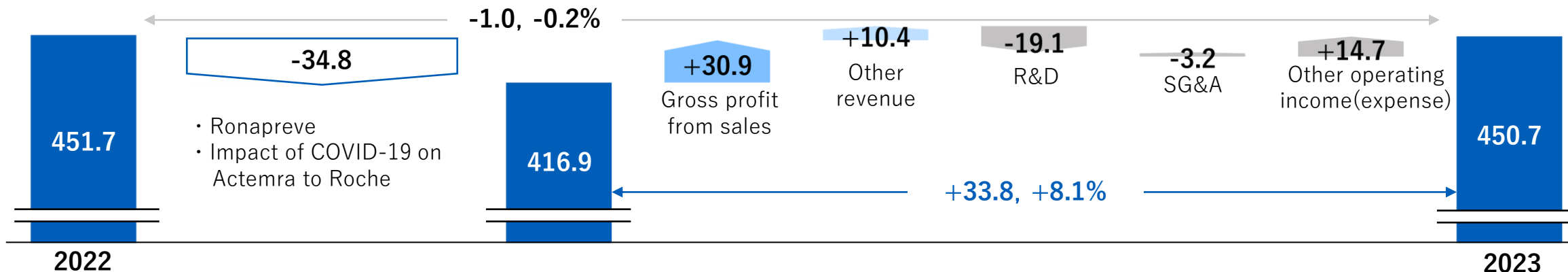
2022 Jan-Dec	203.7
2023 Jan-Dec	81.2
Year on Year	-122.5

\*<sup>2</sup>Impact of COVID-19 on Actemra to Roche

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

2022 Jan-Dec	60.3
2023 Jan-Dec	39.9
Year on Year	-20.4

## &lt; Operating profit &gt;



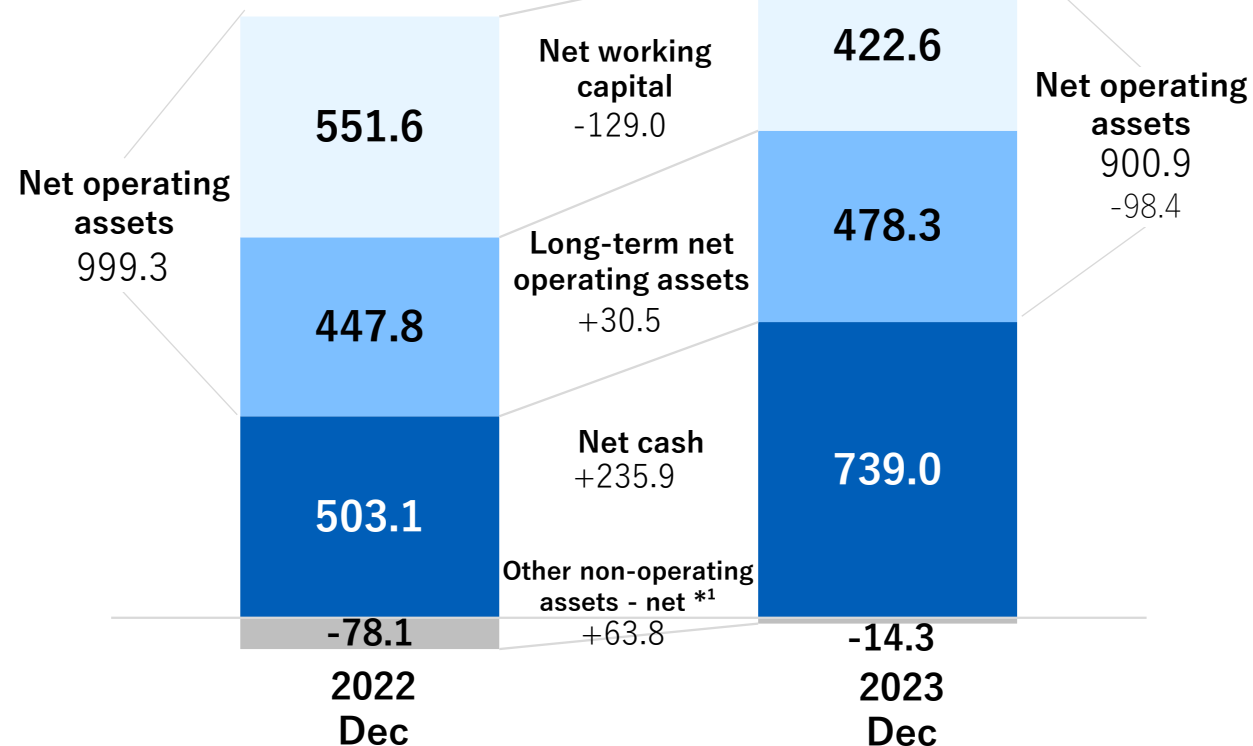
# Financial Position (vs. 2022 Year End)

(Billions of JPY)

Total assets	1,869.8	+62.7	1,932.5
Total liabilities	-445.4	+138.4	-307.0

**1,424.4** **Total net assets** **1,625.6**

+201.2



## Decrease in net working capital

Decrease in trade accounts receivable including Ronapreve

## Increase in long-term net operating assets

Increase in property, plant and equipment mainly due to the investment in manufacturing building for active pharmaceutical ingredients(FJ3) at Fujieda Plant

## Increase in net cash

(See next slide)

## Increase in other non-operating assets – net

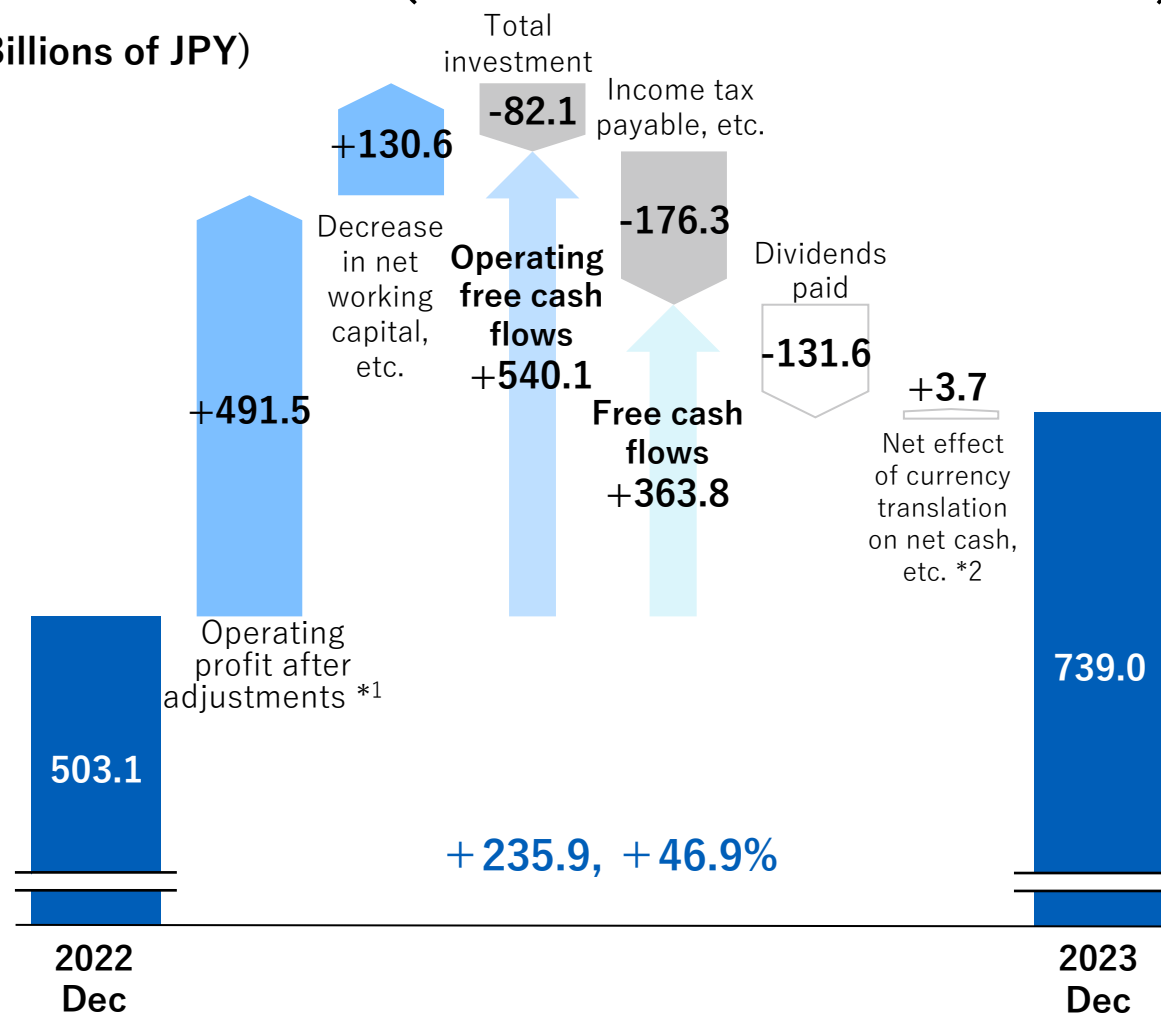
Decrease mainly due to a decrease in accrued corporate tax

Ratio of equity attributable to Chugai shareholders	76.2%	+7.9%pts	84.1%
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\* 1 E.g., deferred income tax assets, accrued corporate tax, etc.

# Net Cash (vs. 2022 Year End)

(Billions of JPY)



<b>Operating profit after adjustment <sup>*1</sup></b>	<b>+491.5</b>
Operating profit <sup>*1</sup>	+439.2
Depreciation, amortization and impairment <sup>*1</sup>	+37.5
<b>Decrease in net working capital, etc.</b>	<b>+130.6</b>
Trade accounts receivable, accounts payable and inventory of Ronapreve	+107.3
<b>Total investment</b>	<b>-82.1</b>
Property, plant and equipment	-71.9
Payment for lease liabilities	-7.9
Intangible assets	-2.3
<b>Operating free cash flows</b>	<b>+540.1</b>
<b>Income tax payable, etc.</b>	<b>-176.3</b>
Income tax payable	-176.1
<b>Free cash flows</b>	<b>+363.8</b>
<b>Dividends paid</b>	<b>-131.6</b>
<b>Net effect of currency transaction on net cash, etc. <sup>*2</sup></b>	<b>+3.7</b>

<sup>\*1</sup> Including Non-Core (IFRS results)

<sup>\*2</sup> Net effect of currency translation on net cash, etc. = Transaction in own equity instruments + Net effect of currency translation on net cash(<sup>\*3</sup>)

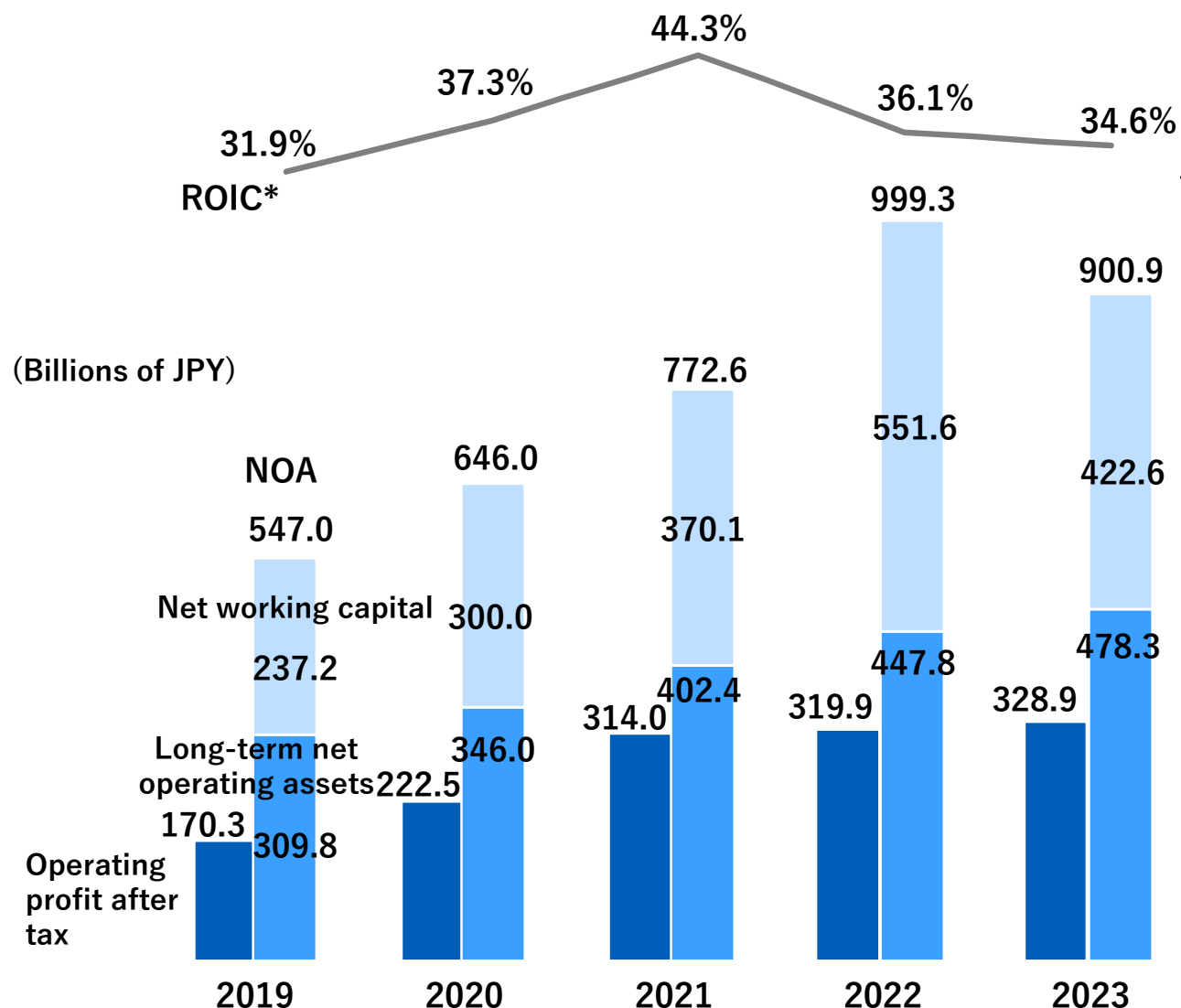
<sup>\*3</sup> Results from using different types of exchange rates when consolidating overseas subsidiaries in financial statements, i.e. net cash using end of period exchange rate and free cash flows using average exchange rate. (Chugai defines this term based on IAS 7 and IAS 21)

# Current Status / Plan for Major Investments

			~2022	2023	2024	2025	2026	2027	2028~	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	47.3	billion JPY	2021	2024
	Ukima site	UK4: Manufacture bio-APIs for early-stage clinical development								12.1	10.7	billion JPY	2021	2023
	Utsunomiya plant	UT3: Manufacture bio-APIs for middle to later- stage clinical development and early commercial use								37.4	5.6	billion JPY	2023	2026
	Utsunomiya plant	UTA: Manufacture sterile injectables for early commercial use								19.0	5.3	billion JPY	2023	2025
	Ukima plant	UK3(modification): Manufacture bio-APIs								20.3	-	billion JPY	2024	2027
Research and development	CPR	Accelerate creation of clinical candidates utilizing proprietary antibody technologies								758	558	million SGD	2012	2026
										of which, capital investment: 82	77			
		Move and renovate facilities to enhance research functions								60	-	million SGD	2024	2026
	Chugai LSP Yokohama	Building of state-of-the-art R&D site to create innovative new drug candidates								128.8	124.9	billion JPY	2019	2022
										- Land of 43.0 billion JPY excluded		- Start of operation: Apr. 2023		
	IFReC	Funding to IFReC per comprehensive collaboration agreement								10.0	6.8	billion JPY	2017	2027
Environment	Environmental investment*	Equipment upgrade to achieve Mid-Term Environmental Goals 2030								109.5	2.9	billion JPY	2022	2033
										estimated total amount				

\* incl. part of Chugai LSP Yokohama and UK3(modification)

## ROIC



● Core operating profit after tax [A]

Steady increase due to sales growth of new products and mainstay products and export and royalty income for Hemlibra

● NOA [B]

Increase mainly in long-term net operating assets due to aggressive capital investment, such as Chugai Life Science Park Yokohama

Significant movement in net working capital in 2022 and 2023 due to supply of Ronapreve to the government



● ROIC [= A/the average of opening and ending of B]

ROIC has risen continuously as a result of the growth rate of core operating profit after tax exceeding that of net operating assets (NOA) until 2021

In 2023, ROIC slightly decreased to 34.6% compared to the previous year due to the increase in averaged NOA, while Core operating profit after tax increased

\*ROIC = core operating profit after tax / the average of opening and ending NOA balances  
Opening balance as of FY2019 was adjusted by the adoption of IFRS16 Leases.

# P/L 2024 Forecast

(Billions of JPY)	2023 Actual	2024 Forecast	Growth	
<b>Revenues</b>	<b>1,111.4</b>	<b>1,070.0</b>	<b>- 41.4</b>	<b>- 3.7%</b>
Sales	974.5	922.0	- 52.5	- 5.4%
Domestic	558.0	454.9	- 103.1	- 18.5%
Overseas	416.5	467.1	+ 50.6	+ 12.1%
Other revenue	136.9	148.0	+ 11.1	+ 8.1%
Cost of sales	- 412.0	- 337.5	+ 74.5	- 18.1%
(cost to sales ratio)	42.3%	36.6%	-5.7%pts	-
Research and development	- 162.8	- 171.0	- 8.2	+ 5.0%
Selling, general and administration	- 102.0	- 102.0	0	0.0%
Other operating income (expense)	16.1	0.5	- 15.6	- 96.9%
<b>Operating profit</b>	<b>450.7</b>	<b>460.0</b>	<b>+ 9.3</b>	<b>+ 2.1%</b>
(operating margin)	40.6%	43.0%	+2.4%pts	-
<b>Net income</b>	<b>333.6</b>	<b>335.5</b>	<b>+ 1.9</b>	<b>+ 0.6%</b>
<b>EPS (JPY)</b>	<b>202.71</b>	<b>204.00</b>	<b>+ 1.29</b>	<b>+ 0.6%</b>

## Domestic sales

Decrease in supply of Ronapreve to the government, the NHI price revisions and market penetration of generic drugs

## Overseas sales

Significant increase in sales of Hemlibra, decrease in sales of Actemra

## Other revenue

Increase in income for Hemlibra and one-time income

## Cost of sales

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

## Research and development

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

## Selling, general and administration expenses

The same level as the previous year

## Other operating income (expense)

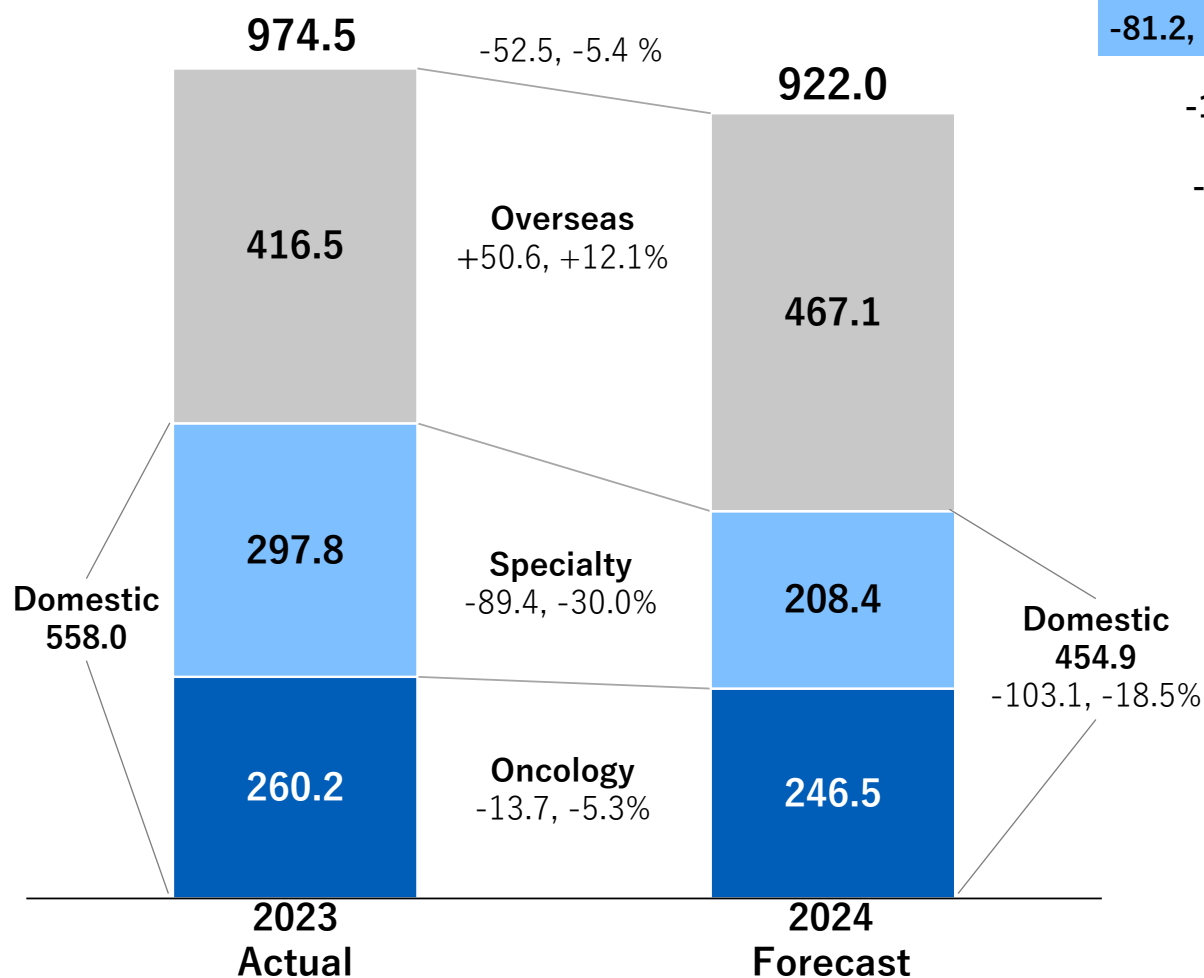
Income from disposal of product rights to decrease

Exchange rate (JPY)	2023 Actual	2024 Assumption
1CHF	140.31	159.00
1EUR	151.38	157.00
1USD	134.21	136.00

# Sales 2024 Forecast

(Billions of JPY)

Sales by Disease Area

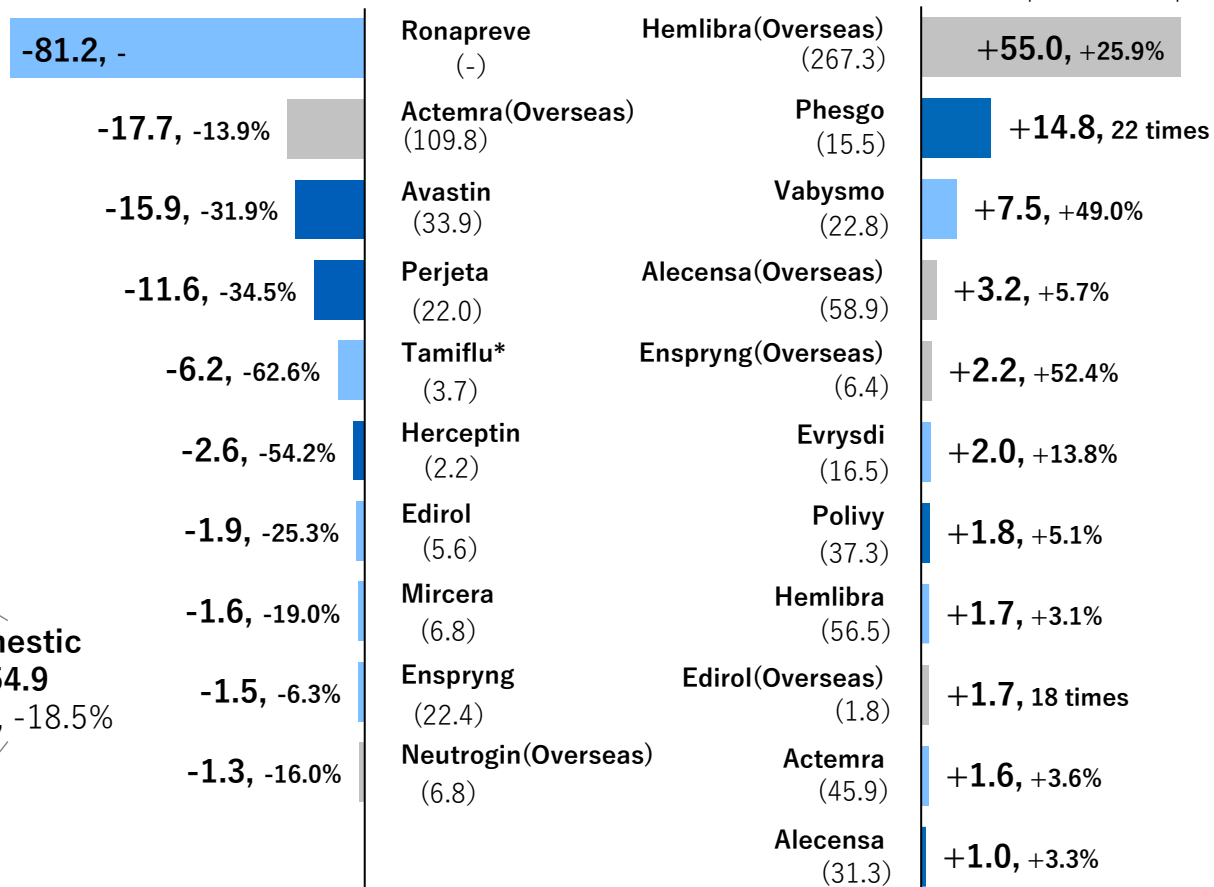


Sales by Product

(): Forecast sales in FY2024

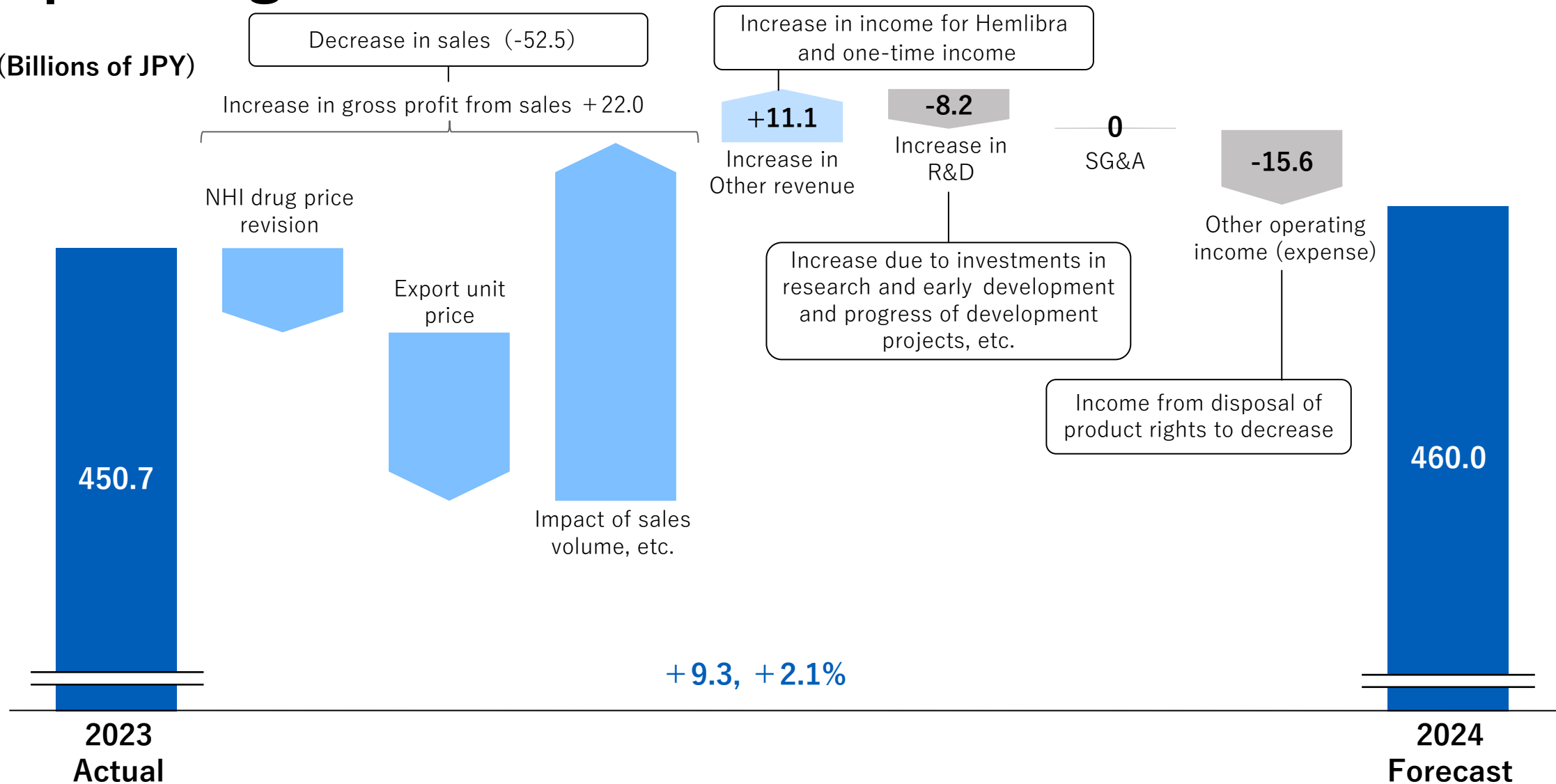
%: Year-on-year percentage change

\*included in Other products of Speciality



# Operating Profit 2024 Forecast

(Billions of JPY)



# Abbreviations

<b>AD</b>	atopic dermatitis	<b>LN</b>	lupus nephritis
<b>adj</b>	adjuvant	<b>LSP</b>	Life Science Park
<b>AE</b>	adverse events	<b>MIBC</b>	muscle-invasive bladder cancer
<b>API</b>	active pharmaceutical ingredient	<b>MM</b>	multiple myeloma
<b>aHUS</b>	atypical hemolytic uremic syndrome	<b>MOGAD</b>	myelin oligodendrocyte glycoprotein antibody-associated disease
<b>AIE</b>	autoimmune encephalitis	<b>nAMD</b>	neovascular age-related macular degeneration
<b>aNHL</b>	aggressive B-cell non-Hodgkin lymphoma	<b>NHI</b>	national health insurance
<b>BC</b>	breast cancer	<b>NME</b>	new molecular entity
<b>bPoC</b>	biology proof of concept	<b>NMOSD</b>	neuromyelitis optica spectrum disorder
<b>BS</b>	biosimilars	<b>NSCLC</b>	non-small cell lung cancer
<b>CC</b>	colorectal cancer	<b>NSQ</b>	non-squamous
<b>CKDaP</b>	Chronic kidney disease associated pruritus	<b>PDS</b>	port delivery system with ranibizumab
<b>CLDN</b>	Claudin	<b>PE</b>	primary endpoint
<b>CPR</b>	Chugai Pharmabody Research	<b>PN</b>	prurigo nodularis
<b>CRC</b>	colorectal cancer	<b>PNH</b>	paroxysmal nocturnal hemoglobinuria
<b>CRS</b>	cytokine release syndrome	<b>PS</b>	profit share
<b>DMD</b>	duchenne muscular dystrophy	<b>QOL</b>	quality of life
<b>DME</b>	diabetic macular edema	<b>r/r</b>	relapsed or refractory
<b>eBC</b>	early breast cancer	<b>RED</b>	research & early development
<b>EC</b>	esophageal cancer	<b>ROY</b>	royalty
<b>EHA</b>	European Hematology Association	<b>RVO</b>	retinal vein occlusion
<b>ePoC</b>	early proof of concept	<b>SAE</b>	severe adverse events
<b>FL</b>	follicular lymphoma	<b>sc</b>	subcutaneous
<b>FSHD</b>	facioscapulohumeral muscular dystrophy	<b>SCD</b>	sickle cell disease
<b>GLP</b>	Good Laboratory Practice	<b>SCLC</b>	small cell lung cancer
<b>gMG</b>	generalized myasthenia gravis	<b>SMA</b>	spinal muscular atrophy
<b>HCC</b>	hepatocellular carcinoma	<b>SSc-ILD</b>	systemic sclerosis with interstitial lung disease
<b>HNC</b>	head and neck carcinoma	<b>TED</b>	thyroid eye disease
<b>HR</b>	human resources	<b>UME</b>	uveitic macular edema
<b>IV</b>	intravenous	<b>T2D</b>	type 2 diabetes
<b>LGSOC</b>	low-grade serous ovarian cancer		

# Contacts

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