

# Conference on FY2024.12 Q2 Financial Results

**CHUGAI PHARMACEUTICAL CO., LTD.**

25 July 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

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President & CEO

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Executive Vice President  
Head of Project & Lifecycle Management Unit

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**Iwaaki Taniguchi**

Director, Executive Vice President & CFO

# **FY2024 Q2 Overview and Refinement of Five Reforms on “TOP I 2030”**

**Dr. Osamu Okuda**

President & CEO

# Financial Overview

- Despite the completion of Ronapreve supply to the government and the NHI drug price revisions etc., strong exports to Roche offset these effects, leading to a slight decrease in revenue
- Operating profit significantly exceeded the previous year, resulting in double-digit growth
- Earnings forecast remains unchanged for record high operating profit and net income

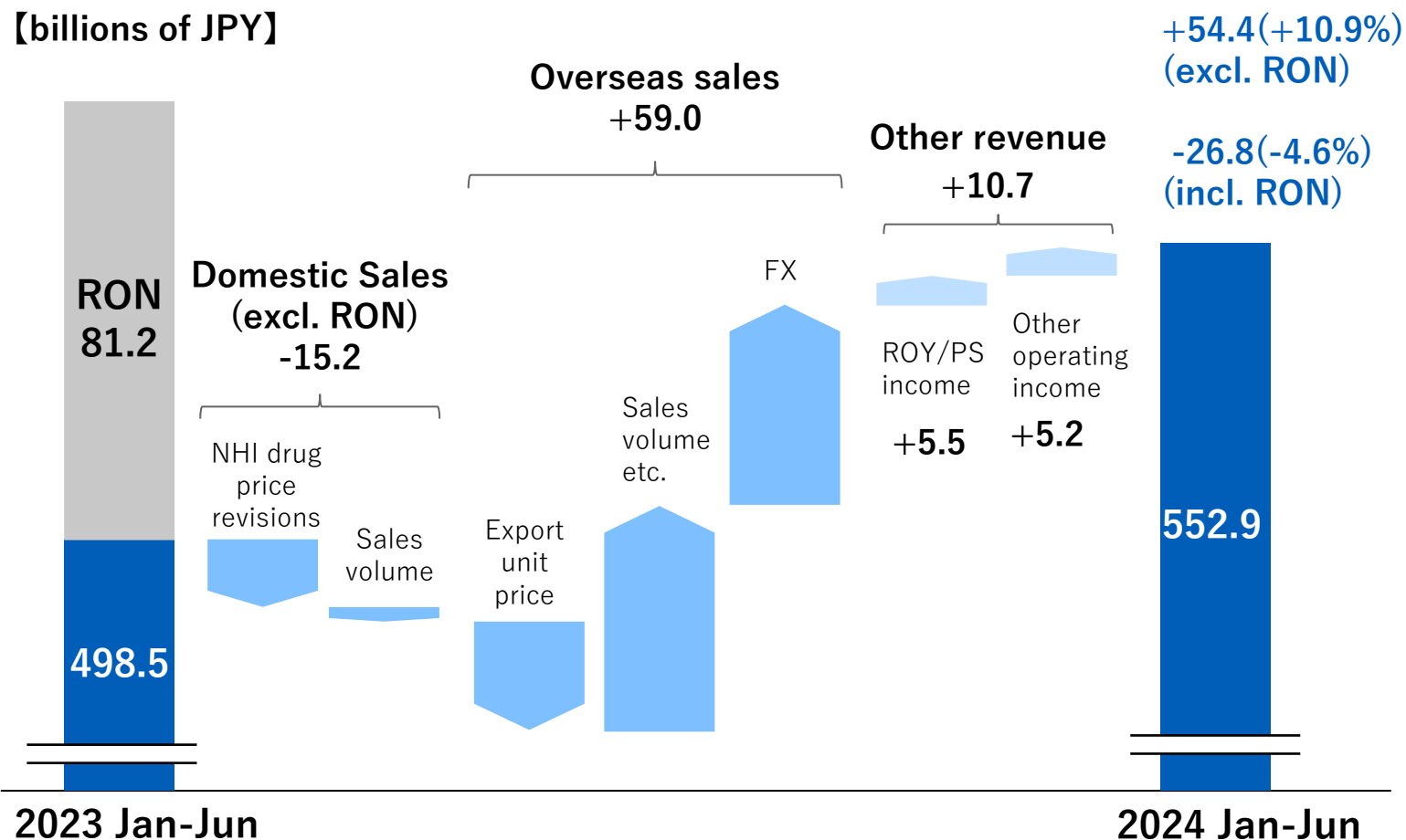
Core (billions of JPY)	2023 Jan -Jun actual	2024 Jan -Jun actual	Growth		2024 Jan - Dec forecast	Progress (%)
<b>Revenue</b>	<b>579.7</b>	<b>552.9</b>	<b>-26.8</b>	<b>-4.6%</b>	<b>1,070.0</b>	<b>51.7%</b>
Domestic sales*	313.6	217.2	-96.4	-30.7%	454.9	47.7%
Overseas sales	209.4	268.4	+59.0	+28.2%	467.1	57.5%
Other revenue	56.6	67.3	+10.7	+18.9%	148.0	45.5%
<b>Operating profit</b>	<b>232.0</b>	<b>262.8</b>	<b>+30.8</b>	<b>+13.3%</b>	<b>460.0</b>	<b>57.1%</b>
Operating margin	40.0%	47.5%	+7.5pts	-	43.0%	-
<b>Net income</b>	<b>171.4</b>	<b>189.5</b>	<b>+18.1</b>	<b>+10.6%</b>	<b>335.5</b>	<b>56.5%</b>
<b>EPS (yen)</b>	<b>104.19</b>	<b>115.15</b>	<b>+10.96</b>	<b>+10.5%</b>	<b>204.00</b>	<b>56.4%</b>

- 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, Hemlibra exports to Roche significantly increased. Progress was better than expected
- Other revenue increased mainly due to the increase in Hemlibra related revenue and one-time incomes. Mostly as expected
- With the completion of Ronapreve supply to the government and strong overseas sales, profitability significantly improved, achieving an operating profit margin of 47.5% as a core business.

\* Recorded sales of ¥81.2 billion for Ronapreve supply to the government in the first quarter of previous year

# Topline Overview

【billions of JPY】



- Domestic Sales (excl. RON):**

Declined due to the impact of the NHI drug price revisions, and the market penetration of generic drugs, despite growth in new products such as Phesgo and Vabysmo, and the favorable sales of the mainstay product like Actemra. As expected

- Overseas sales:**

Increased significantly by higher sales volume and FX impact, surpassing the decline in export unit price. Progress of Actemra and Hemlibra exports was better than expected.

- Other revenue:**

Increased mainly due to the increase in Hemlibra related royalty income as well as one-time income. Mostly as expected

RON: Ronapreve, ROY: Royalty, PS: Profit Share

# Hemlibra: Progress in Hemophilia A Treatment

## <Accumulated Evidence>

- Hemlibra has >10 years of clinical trial experience in approx. 1,000 participants, plus real-world evidence\* from more than >26,000<sup>1</sup> people worldwide
  - Bleed protection observed in clinical trials (upper right figure) was confirmed in real-world settings, with a mean annual bleeding rate (ABR) of 0.4 and zero treated bleeds in approx. 80% of people<sup>2-4</sup>
  - Target joints resolution observed with approx. 88% reduction in annual joint bleeding rate in real-world settings (lower right figure)<sup>5</sup>
  - Long-term safety profile accumulated in diverse patient populations from clinical trials and real-world settings<sup>6</sup>
  - Flexible subcutaneous administration options: once weekly, once every two weeks, or once every four weeks

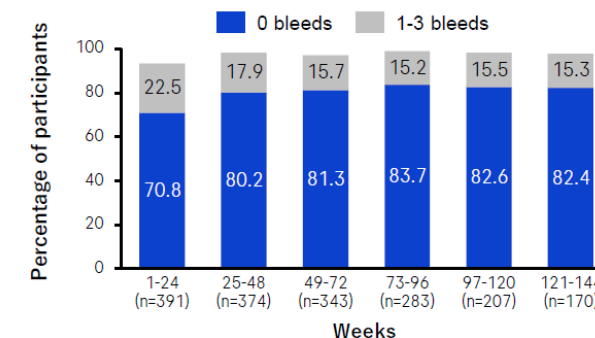
\*Extensive real world evidence base of >100 publications with data for >10,000 patients

## <Future Initiatives>

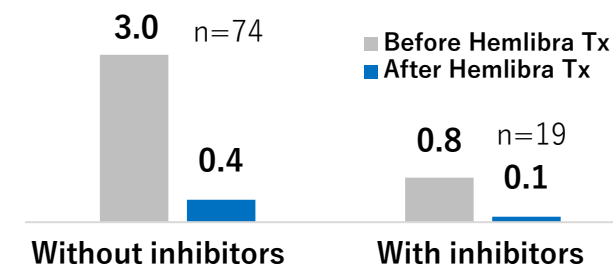
- Efforts to improve user experience
  - Addition of new vial sizes, improvement of administration kits, development of auto-injectors

### Clinical Trials : HAVEN 1-4 long-term analysis<sup>2</sup>

Proportion of patients with 0 or 1-3 treated bleeds over time (n=400)



### Real World Data: Annual joint bleeding rate<sup>5</sup>



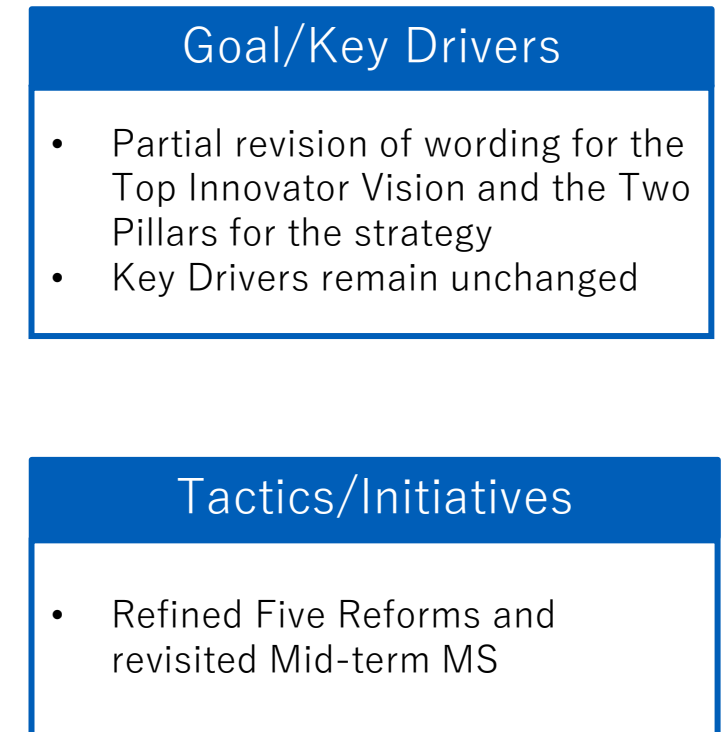
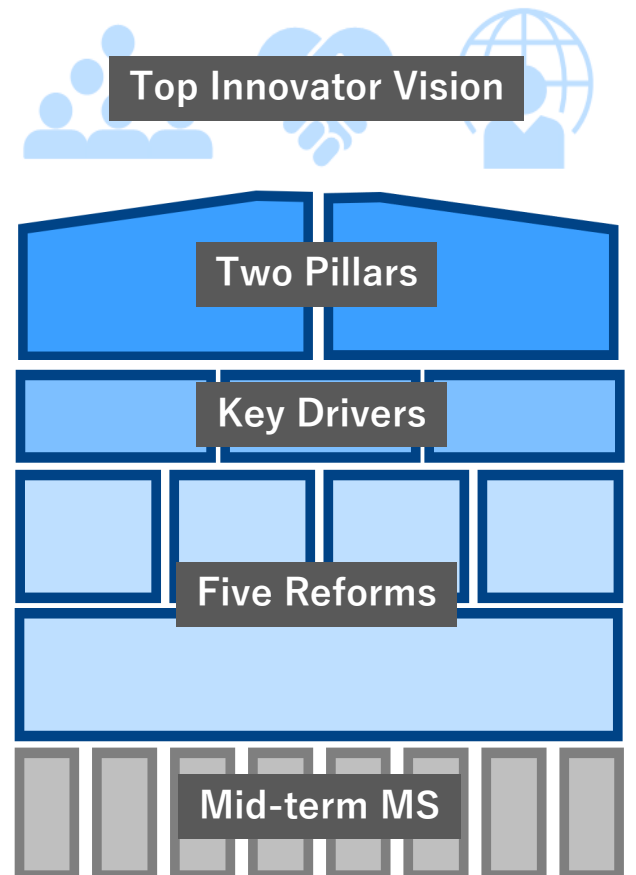
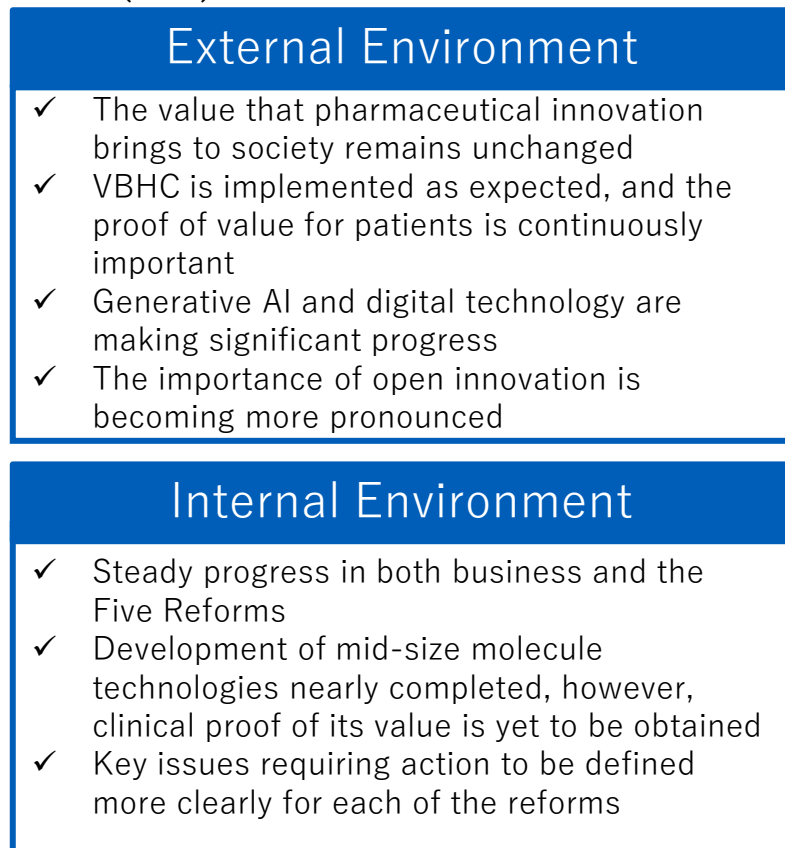
We remain committed to the hemophilia field through Hemlibra, which has a wealth of evidence regarding its efficacy and safety and aim to maximize the value of our portfolio, including NXT007.





# Progress of TOP I 2030 and Overview of Refinement of Five Reforms

- Chugai made steady progress with TOP I 2030. Issues to be resolved have been clarified given environmental changes and progress so far
- The framework of TOP I 2030 remains unchanged with no changes in strategic fundamentals
- Refining Five Reforms for tactical addition/strengthening/concretization, and updating mid-term milestones (MS)





# Two Pillars (**Revised**)

- ✓ **Global First-class Drug Discovery:** Since the same expression was used for the goal and the means, the description was revised to indicate early development and pharmaceutical technology function in RED function.
- ✓ **Building Futuristic Business Model:** Revised to reflect the direction of insight business toward PHC solutions

"Double R&D output" & "Launch global in-house products every year"

## Global First-class Drug Discovery

- ▶ Expansion of existing technological bases and building a new technological foundation to materialize unique drug discovery ideas
- ▶ **Maximization of the value of development projects by pursuing translational research and pharmaceutical technologies**
- ▶ Accelerating innovation opportunities by strengthening collaboration with leading global players and leveraging digital technologies

## Futuristic Business Model

- ▶ Dramatic improvement in product / patient value by restructuring business model, having digital utilization as a core
- ▶ Improve productivity of entire value chain by leveraging digital technologies.
- ▶ **Development of PHC solutions** to maximize the value of pharmaceuticals

Key Drivers

▶ **DX**

▶ **RED SHIFT**

▶ **Open Innovation**

# Five Reforms (Progress and Challenges) R&D

## Progress


## Challenges



**Drug  
Discovery**

- » Steady progress in building drug discovery technologies for mid-size molecules and antibodies
- » Smooth progress in utilizing digital and robotics technologies

- » **Continuous creation of high-quality development candidates**
  - Refinement of mid-size molecule and new antibody engineering technologies
  - Further deepening of non-clinical research and fundamental technologies
  - Promotion of open innovation



**Development**

- » Success in confirming absorption of mid-size molecule
- » Increase in development pipeline, and initiation of simultaneous development for multiple diseases
- » Progress in transforming the operational model, including the use of RWD

- » **Shortening development periods and improving success rates**
  - Accurate assessment of project potential and strategic prioritization
  - Advancement of human predictive models
- » **Thorough utilization of digital technologies and RWD for efficiency**



**Pharmaceutical  
Technology**

- » Success in manufacturing highly complex substances including those with high potency and mid-size molecules
- » Established supply system through expansion of mid-size molecule manufacturing facilities
- » Progress in building digital infrastructure to support new production functions and improving efficiency

- » **Improving speed in mid-size molecule manufacturing**
  - Platforming of pharmaceutical technologies
- » **Increasing geopolitical risks**
  - Building a robust supply system

# Five Reforms ① Drug Discovery

Pursue drug discovery based on the R&D principles, and establish unique technologies and produce output by strengthening open innovation



## Direction of Reform

## Goal

### Technology-driven drug discoveries

- Sustainable drug discoveries that could not be achieved with previous technologies, regardless of disease area, by enhancing and building on existing and new modality technologies

Commit to drug discovery that only Chugai can achieve and double R&D output

### Quality-centric drug discoveries

- Realization of (i) development molecules evidencing a high level of completeness, (ii) high probability of clinical success, and (iii) high productivity, by enhancing and building up non-clinical research, basic technologies, and biological research

Establish new proprietary technologies to enable growth for 2030 and beyond

### Open Innovation

- Expansion of the scope and output of in-house drug discovery by moving away from purely self-reliant drug discovery and incorporating external strengths

Expand drug discovery opportunities by shifting from purely self-reliant research

Maintain high productivity

# Five Reforms ② Development

Pursue strengthening Go/No-Go decision-making, maximizing project value and increasing of productivity by continuous transformation of operational model

## Direction of Reform

## Goal

Early Stage	<u>Appropriate and rapid Go/No-Go decisions by integrating clinical development and human predictive capabilities</u>	<ul style="list-style-type: none"> <li>Focus on improving detection and intricate understanding of biological responses and modeling &amp; simulation</li> <li>Strategic planning and implementation of development options by utilizing internal/external insights</li> </ul>	<div>Set highly reliable standards for Go/No-Go decisions and rapid execution</div> <div>Early estimation of overall project value</div>
	<u>Creation of unprecedented added value resulting from early-stage clinical trials</u>	<ul style="list-style-type: none"> <li>Setting true endpoint hypotheses</li> <li>Simultaneous development of multiple indications through early identification of candidate disease targets</li> </ul>	
Late Stage	<u>Transformation of operational model</u>	<ul style="list-style-type: none"> <li>Pursuit of innovative clinical development model by utilizing digital and RWD</li> <li>Maximizing global product value through close collaboration with Roche</li> </ul>	Maximize project value and increase productivity

## Five Reforms ③ Pharmaceutical Technology

Pursue world-class technologies to deliver drug discovery ideas to patients as pharmaceutical products; realize highly competitive pharmaceutical technologies in terms of quality, speed, and cost



### Direction of Reform

### Goal

#### Pursuit of world-class technologies

- Manufacture highly unique compounds by strengthening collaboration with drug discovery and making full use of state-of-the-art technology
- Evolution of the world’s most advanced antibody/mid-size molecule technology and realization of development speed

#### Establishment of robust and competitive supply systems

- Further efficiency gains by strengthening the manufacturing technology function, including the use of digital technologies and robotics
- Pursuing stable supply and global standard quality through implementation of dual-site strategy

Establish competitive pharmaceutical technologies

World-class development speed

Apply production technologies and achieve world-class productivity and quality

Establish supply systems that ensure both stable supply and high quality

# Summary of Five Reforms (**Revised**)

## 1) Drug Discovery

- ▶ Expansion of existing technological platforms to realize unique drug discovery ideas and establish new technology platform.
- ▶ Acceleration of innovation opportunities by leveraging digital technologies and strengthening collaboration with leading global players.

## 2) Development

- ▶ Enhancement of Go/No-Go decision making and maximization of project value by integrating clinical development and human prediction capabilities
- ▶ Realization of advanced and efficient clinical development operations using digital technologies

## 3) Pharmaceutical Technology

- ▶ Establishment of world-class pharmaceutical technologies for antibody and mid-size molecule and acceleration of development
- ▶ Applying manufacturing technology to achieve world-class productivity and quality
- ▶ Establishment of supply systems that ensure both stable supply and high quality

## 4) Value Delivery

- ▶ Realization of further personalized medical care by the creation of unique evidence that addresses unmet healthcare needs in actual clinical practice
- ▶ Maximize customer value by innovative digital-based customer engagement model

## ⑤ Foundation for Growth


- ▶ Realization of human resource management that encourages discovery, growth, and exercise of diverse individuals; acquisition, retention, and development of highly specialized human resources
- ▶ Realization of CHUGAI DIGITAL VISION 2030
- ▶ Realization of Mid-term Environment Goals 2030; enhancement of sustainability platform
- ▶ Achievement of QUALITY VISION 2030
- ▶ Provision of advanced proof and maximum value of pharmaceuticals through PHC solution

# Toward Realizing “Double R&D output” and “Launch global in-house products every year”

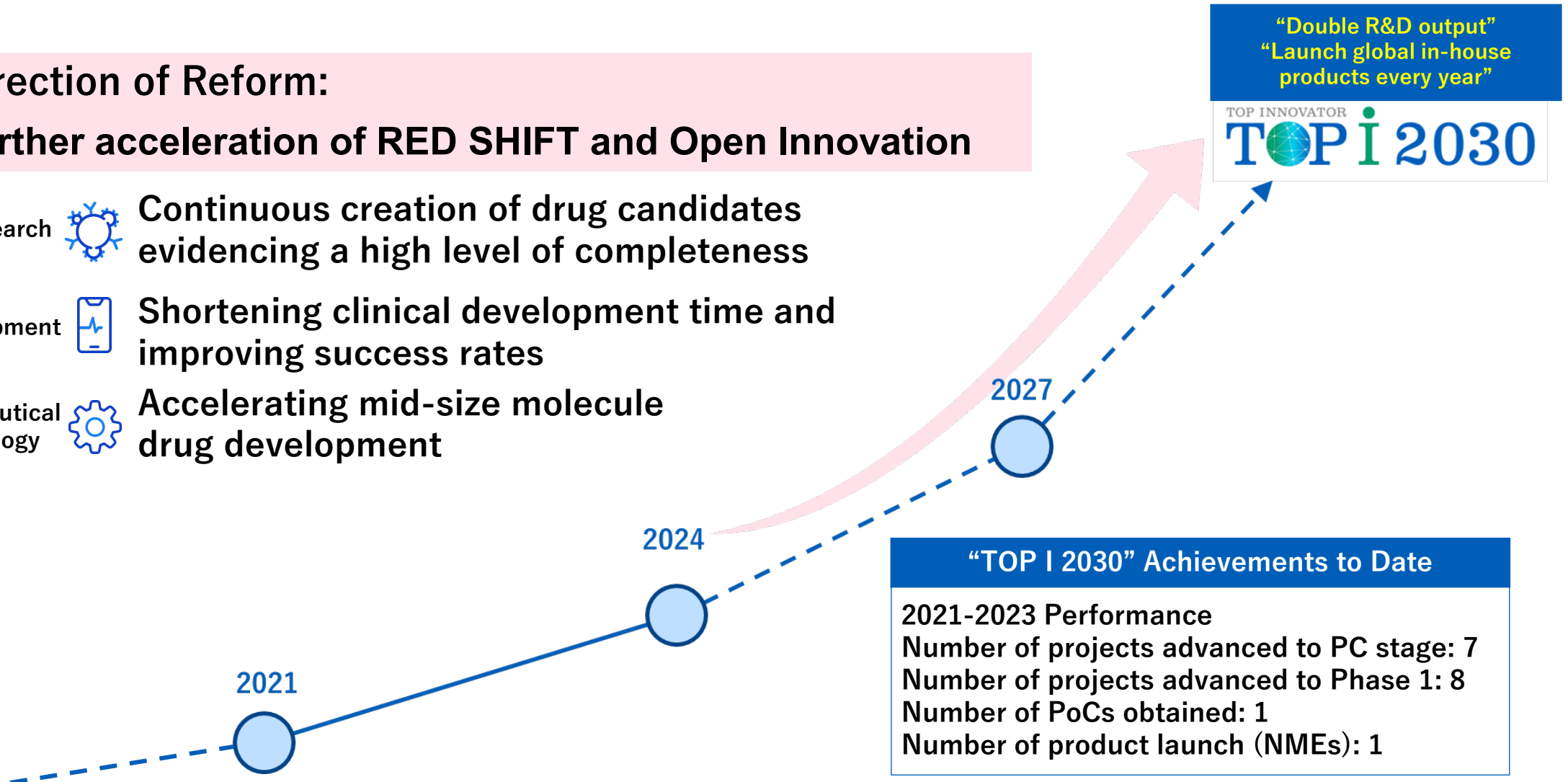
## Direction of Reform:

### Further acceleration of RED SHIFT and Open Innovation

Research  Continuous creation of drug candidates evidencing a high level of completeness

Development  Shortening clinical development time and improving success rates

Pharmaceutical Technology  Accelerating mid-size molecule drug development



### “TOP I 2030” Achievements to Date

#### 2021-2023 Performance

Number of projects advanced to PC stage: 7

Number of projects advanced to Phase 1: 8

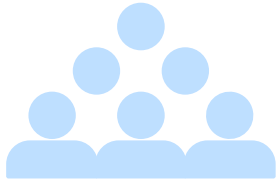
Number of PoCs obtained: 1

Number of product launch (NMEs): 1



# Vision for Top Innovator 2030 (**Revised**)

- ✓ **Role model for the world: Replaced the word “ESG” with “sustainability” to include even broader implications**



## Expectation from patients all over the world

With world-class drug discovery capabilities, patients around the world expect that “Chugai will surely create new treatments.”



## Attracting talent and players from around the world

Attract passionate talent from all over the world, and inspire players globally to think they can create something new by partnering with Chugai



## Role model for the world

With sustainability at the heart of its business activities, Chugai will become a global role model as a leader in resolving social issues

### Our definition of “Top Innovator in the healthcare industry”

In collaboration with Roche, we will continue to place “innovative new drugs” at the core of our business, while aiming to become a leading innovator in the global healthcare field, where a diverse range of players, not limited to pharmaceutical companies, are taking on the challenge of innovation.

# Five Reforms (Progress and Challenges) VD, Foundation for Growth

## Progress

## Challenges



- » Achieved industry-leading MR productivity
- » Acquired high customer satisfaction
- » Progress in building evidence generation foundation utilizing RWD

- » **Early creation of useful data for treatment selection after product launch**
- » **Building an efficient information provision system that addresses changing customer needs**

Foundation for Growth	People and organization	» Successfully introduced new HR system and transitioned to new work styles
	Digital	» Created value through promotion of CHUGAI DIGITAL VISION 2030, received external recognition such as DX Grand Prix and DX Platinum Enterprise
	Sustainability and Environment	» Continued selection for DJSI. Steady progress on Mid-Term Environmental Goals
	Quality	» Formulated QUALITY VISION 2030, setting more specific quality goals
	PHC Solution	» Newly established "PHC Solution Unit" to demonstrate and maximize the value of pharmaceuticals

## » Strengthening foundations for sustainable growth

- Promoting proactive career development and securing specialized talent, promoting diversity
- Co-creation with business divisions and accumulation of in-house know-how
- Various initiatives to achieve goals
- Permeation of quality culture
- Establishing solution promotion system and business development capabilities in and outside Japan

# Five Reforms ④ Value Delivery

Pursue rapid evidence generation that contributes to optimal patient-centric treatment selection, and provide advanced value with high productivity through the establishment of a customer engagement model

## Direction of Reform

### Achieving Personalized Medical & Safety Care

- Generation of evidence to offer the best treatment option for each patient

### Establishing a new customer engagement model

- Quick and accurate information provision through optimized use of in-person, remote, and digital means
- Evolution of new customer database and information platforms

### Resource shift/digital utilization

- Priority allocation of resources to strategic areas
- Field force optimization
- Back-office function reform
- Continuous optimization of distribution functions

## Goal

Early generation of high-value evidence after product launch

Risk prediction and prevention of aggravation in actual clinical practice

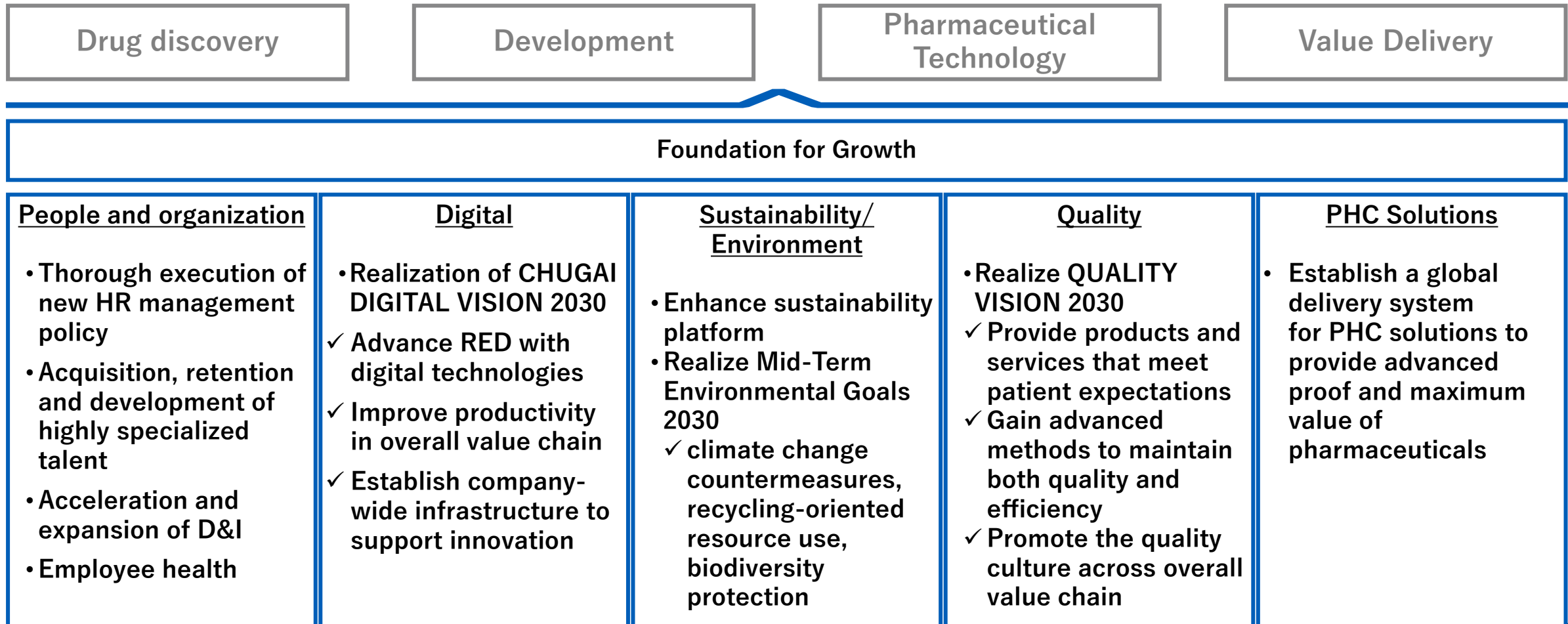
Highest global market share\* for the strategic products

Industry-leading activities for patient-centric information provision

Maintaining and improving industry-leading productivity

# Five Reforms ⑤ Foundation for Growth

New Challenges for PHC Solutions and building a foundation worthy of a Top Innovator



# List of Mid-Term Milestones (1/3)



## Drug discovery

### Research

1. **Expansion of output and maximize project value through biological research**
  - Number of projects to transfer to PC/P1 stages between 2025 and 2027 <2027>
2. **Development of existing and new modality technologies with competitive advantages <2027>**
3. **Project creation through Open Innovation**
  - Acquire technologies that expand the scope and value of in-house drug discovery <2027>
4. **Pursuit of productivity to realize sustainable drug discovery**
  - Save labor and time through utilizing digital technology <2027>
  - Increase efficiency through developing a platform of drug discovery process <2027>



## Development

### Early Development

1. **Appropriate and rapid Go/No-Go decisions by integrating clinical development and human predictive capabilities**
  - Efforts to maximize the speed of clinical trials from the perspectives of both science and operation <2026>
  - Establish clinical development plans and clinical trials according to project characteristics based on benchmarking activities and internal non-clinical data <2026>
  - Implement human prediction technology through Modelling and Simulation, use of digital biomarkers, etc. <2027>
2. **Value maximization of early-stage projects**
  - Realize a master protocol that allows studies for multiple drugs to be conducted under a single protocol <2026>
  - Establish true endpoint hypotheses primarily using digital utilization <2028>
3. **Establishment of new technology**
  - Assess the possibility that human PK prediction can replace animal in vivo PK tests by utilizing organoids <2026>
  - Practical application of technology to predict human hepatotoxicity of small and mid-size molecules <2028>

### Late-stage Development

1. **Realization of a clinical development platform utilizing new technologies**
  - Start using Direct Data Capture System <2027>

# List of Mid-Term Milestones (2/3)



Pharmaceutical Technology	Pharmaceutical technology	<ol style="list-style-type: none"> <li><b>Establishment of competitive pharmaceutical technologies</b> <ul style="list-style-type: none"> <li>Start application of mid-size molecules platform technology to development projects &lt;2027&gt;</li> <li>Establishment of production technology and production infrastructure for mid-size molecule drug substances/formulations &lt;2027&gt;</li> <li>Start of application of next-generation antibody platform technology to a development project &lt;2027&gt;</li> </ul> </li> <li><b>World-class development speed</b> <ul style="list-style-type: none"> <li>Shorten development period of mid-size molecules and antibodies through technology development &lt;2027&gt;</li> </ul> </li> </ol>
	Manufacturing	<ol style="list-style-type: none"> <li><b>Establishment of a supply system that ensures both stable supply and high quality</b> <ul style="list-style-type: none"> <li>Engage contract manufacturing partners for a robust and flexible antibody production system &lt;2027&gt;</li> </ul> </li> </ol>



Value Delivery	Medical affairs /Safety	<ol style="list-style-type: none"> <li><b>Early generation of high-value evidence after product launch</b> <ul style="list-style-type: none"> <li>Start of clinical research with new efficacy evaluation indices as endpoint &lt;2027&gt;</li> </ul> </li> <li><b>Risk prediction and prevention of aggravation in actual clinical practice</b> <ul style="list-style-type: none"> <li>Establish research infrastructure for risk prediction in clinical practice &lt;2027&gt;</li> <li>*Safety biomarker exploratory studies etc.                             <ul style="list-style-type: none"> <li>Conducted risk study from Roche/academia collaboration</li> </ul> </li> </ul> </li> </ol>
	Sales & Marketing	<ol style="list-style-type: none"> <li><b>Industry-leading activities for patient-centric information provision</b> <ul style="list-style-type: none"> <li>No. 1 in customer satisfaction in priority areas (oncology and hemophilia) &lt;2027&gt;</li> <li>Top 3 in customer satisfaction in strategic areas (Ophthalmology, PNH, NMOSD, SMA, etc.) &lt;2027&gt;</li> </ul> </li> <li><b>Maintaining industry-leading productivity</b> <ul style="list-style-type: none"> <li>MR Productivity &lt;2027&gt;</li> </ul> </li> </ol>

# List of Mid-Term Milestones (3/3)



## Foundation for Growth

### People and organization

1. **Employee enablement and engagement**
  - Employee enablement: 71% positive response <2026>, Employee engagement: 79% positive response <2026>
2. **Acquisition, retention, and development of highly specialized talent**
  - Fulfillment rate of highly specialized human resources: 85% <2027>
3. **Acceleration and expansion of D&I**
  - Ratio of female managers: 25% <2026>
4. **Employee health**
  - Cancer retest rate 88% <2027>, Percentage of smokers <2027>, Interview request rate for high-stress individuals <2026>

### Digital

1. **Accelerate company-wide RED shift through IT/digital utilization: double the number of DX implementation in RED area**
  - Double the number of DX PoC in RED area <2026>

### Sustainability and Environment

1. **Strengthening world-class sustainability platform**
  - Continued inclusion in the Dow Jones Sustainability World Index <2027>
2. **Achievement of Mid-Term Environmental Goal 2030 (Climate change countermeasures/recycling-oriented resource use/biodiversity protection)**
  - Scope 1+2 CO<sub>2</sub> emissions (compared to 2019): 50% reduction <2027>
  - CFC use (compared to 2020): 35% reduction <2027>
  - Obtaining supplier's commitment to achieve Scope 3 CO<sub>2</sub> emissions reduction targets <2027>
  - Execution of plan to introduce natural refrigerant heat pumps to achieve both CO<sub>2</sub> reduction and energy reduction <2027>
  - Establish various waste reduction methods <2027>

### Quality

1. **Promotion of the quality culture across overall value chain**
  - Affirmation rate of “Quality and Customer Orientation” in the Employee awareness survey (at the level of global high-performing companies) <2026>

### PHC Solutions

1. **Establishment of promotion structure and capability; start of clinical implementation**
  - Establish the development process and project management system; promote projects end-to-end from technology exploration and alliance building to development and launch <2026>
  - Start use of PHC solutions in clinical trials for in-house project/product <2027>



# Overview of Development Pipeline

**Tsukasa Kusano**

Executive Vice President, Head of Project & Lifecycle Management Unit

# Q2 Topics (1/2)



As of July 25, 2024

Launched	PiaSky	Paroxysmal nocturnal hemoglobinuria (PNH)	May 2024 (Japan)
	Mitchga	Pruritus associated with atopic dermatitis (children aged $\geq 6$ and $<13$ years), Prurigo nodularis* <sup>1</sup>	June 2024 (Japan)
Approved	Sigmart Injection	Unstable angina	April 2024 (China)
	Alecensa	ALK-positive early-stage NSCLC (adjuvant)	June 2024 (EU/China)
	PiaSky	PNH	June 2024 (U.S.)
	FoundationOne Liquid CDx Cancer Genomic Profile	Copy number alterations of cancer-related genes, and blood tumor mutational burden (bTMB) score	May 2024
	CellCept	Systemic sclerosis-associated interstitial lung disease (public knowledge-based application)	June 2024
Filed	avutometinib	Recurrent KRAS mutant low-grade serous ovarian cancer in combination with defactinib, who received at least one prior systemic therapy* <sup>2</sup>	May 2024 (U.S.: initiation of rolling NDA submission)
Initiation of Study	GYM329	Obesity	P1 study (May 2024)
	DONQ52	Celiac disease (evaluation of safety, PK/PD)	P1c study (July 2024)
	RG6299(ASO Factor B)	IgA nephropathy	P3 study (May 2024)
	zilebesiran	Hypertension	P1/2 study (June 2024)

\*<sup>1</sup> Conducted by Maruho, a domestic licensee, \*<sup>2</sup> Conducted by Verastem, a global licensee

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

NSCLC: non-small cell lung cancer

# Q2 Topics (2/2)



As of July 25, 2024

Removed from Pipeline	PiaSky	Lupus nephritis: development discontinued	
	tiragolumab+Tecentriq +chemotherapy	Non-squamous NSCLC (1st Line, SKYSCRAPER-06 study): development discontinued	
	Tecentriq + Avastin	Hepatocellular carcinoma (adjuvant, IMbrave050 study): development discontinued	
	migoprotafib (SHP2 inhibitor)	Solid tumors: development discontinued	
	pralsetinib	NSCLC, solid tumors: development discontinued	
Medical Conference	Evrysdi	FIREFISH study (five-year data for Type I SMA): Cure SMA Research & Clinical Care Meeting	June 2024
	Vabysmo	RHONE-X extension study (four-year data for diabetic macular edema): American Society of Retina Specialists Annual Meeting	July 2024
China Breakthrough Therapy Designation	AP306 (EOS789)	Hyperphosphatemia in patients with chronic kidney disease*	June 2024
Business Transfer	Monilac Syrup	Transfer of the business in Japan: Maruishi Pharmaceutical Co., Ltd.	July 2024

\*Conducted by Alebund, a global licensee

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

NSCLC: non-small cell lung cancer, SMA: spinal muscular atrophy

# 2024: Key R&D Milestones

Underlined and bolded are new progress since April 24, 2024

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

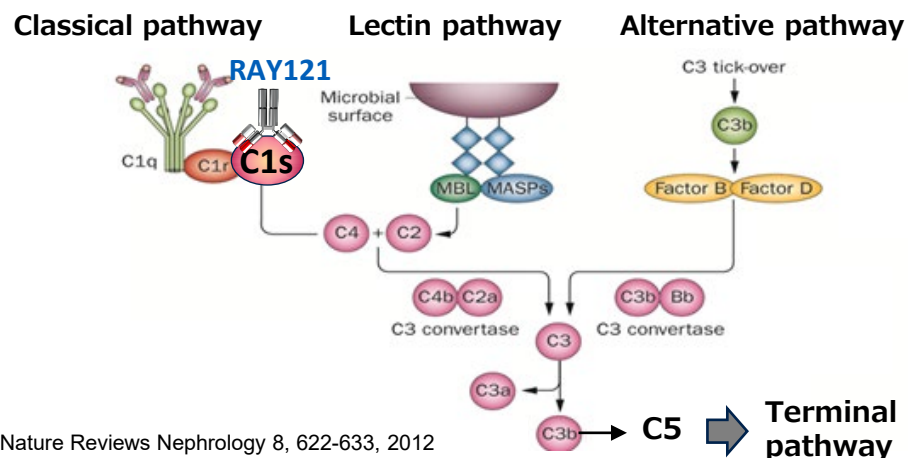
PE: primary endpoint, r/r: relapsed or refractory

# RAY121: Anti-Complement C1s Recycling Antibody

Maximize value through simultaneous development for multiple indications

## RAY121

- Selectively bind to complement C1s and suppress classical complement pathway (CP)
- Expected superior efficacy and safety to C3/C5 inhibitors in diseases which CP mainly contributes
- Provide convenience (i.e. lower dosing volume and frequency) by recycling antibody technology
- Sustained CP suppression and favorable safety profile demonstrated in Ph1a healthy volunteer study



Source: Nature Reviews Nephrology 8, 622-633, 2012

## Project Concept

Deliver the best medical solution (superior efficacy, safety and convenience) to every patient with CP dependent disorders where UMN remains, as early as possible by front-loaded development for multiple indications

[Global Ph1b basket study (RAINBOW trial)]

- A flagship study in six autoimmune diseases
- Evaluate safety & efficacy of RAY121
- Preparing for initiation in JP/EU/US

 A RAY121 CLINICAL TRIAL  
**RAINBOW “Basket” Trial** ([NCT06371417](https://clinicaltrials.gov/ct2/show/study/NCT06371417))

Anti-phospholipid syndrome  
Bullous pemphigoid  
Behcet's syndrome  
Dermatomyositis  
Immune-mediated necrotizing myopathy  
Immune thrombocytopenia

# DONQ52: Patient Enrollment for Ph1a/b Completed, Ph1c Initiated

## Ph1c: Evaluation of inhibitory effects by DONQ52 on wheat induced immune responses

### DONQ52

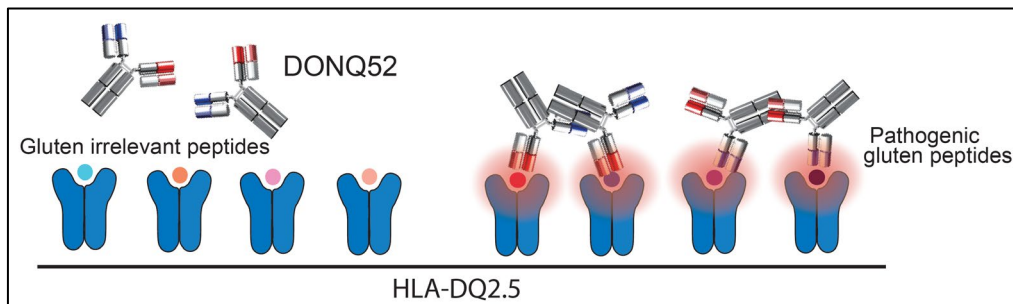
- Specific binding to complexes of HLA-DQ2.5 /gluten peptides
- No binding to HLA molecule itself or complexes of HLA-DQ 2.5/irrelevant peptides
- Bispecific technology enables binding to more than 25 complexes of HLA-DQ 2.5/gluten peptides, including all dominant peptides responsible for celiac disease

### Ph1a/b studies (NCT05425446)

- Consisting of SAD/MAD part
- Evaluating safety/PK
- Patient enrollment completed (May 2024)

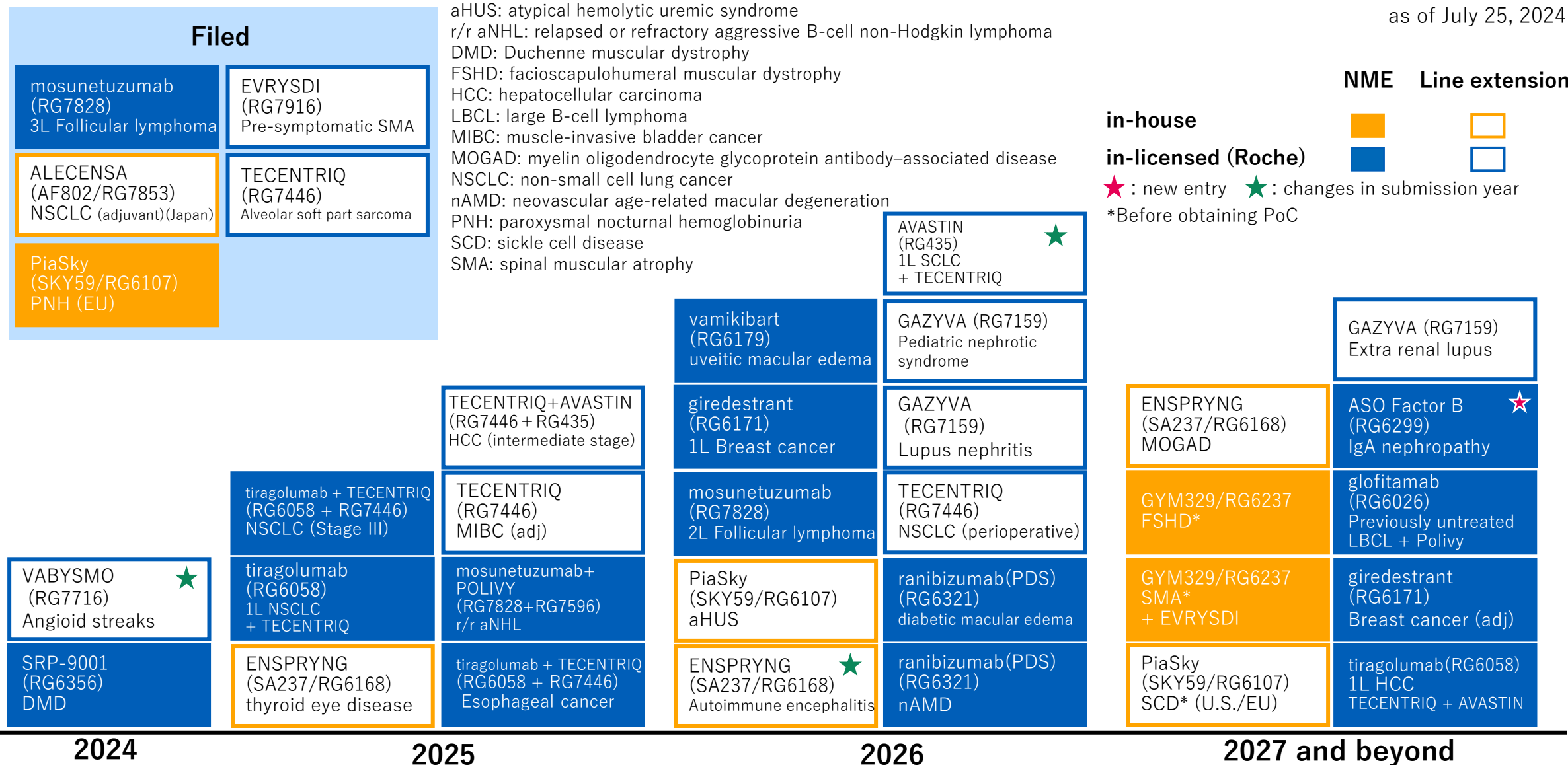
### Ph1c study (ACTRN12624000316505)

- Three-day gluten challenge study to induce gluten-dependent immune response
- Evaluating safety/PK/pharmacological effects (Inhibition of T cell activation/IL-2 secretion)
- First Patient dosed (July 2024)



# Projected Submissions (Post PoC NMEs and Products)

as of July 25, 2024





# Projects under Development (1/2)

As of July 25, 2024

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

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

In principle, completion of first dose is regarded as pipeline entry into each phase of clinical studies.

aNHL: aggressive B-cell non-Hodgkin lymphoma, BC: breast cancer, HCC: hepatocellular carcinoma, MIBC: muscle-invasive bladder cancer, NSCLC: non-small cell lung cancer, r/r: relapsed or refractory, SCLC: small cell lung cancer

# Projects under Development (2/2)

	Phase I	Phase II	Phase III	Filed
<b>Immunology</b>	<b>DONQ52</b> - Celiac disease <b>RAY121</b> - Autoimmune disease		<b>RG7159 / Gazyva</b> - Lupus nephritis - Pediatric nephrotic syndrome - Extra renal lupus <b>ASO factor B (RG6299)</b> - IgA nephropathy ★	
<b>Neurology</b>	<b>RG7935 / prasinezumab</b> - Parkinson's disease <b>RG6102 / trontinemab</b> - Alzheimer's disease (PI/II)	<b>GYM329 (RG6237)</b> + <b>Evrysdi</b> - SMA (PII/III) - FSHD <b>RG6042 / tominersen</b> - Huntington's disease	<b>SA237 (RG6168) / Enspryng</b> - MOGAD - AIE <b>SRP-9001(RG6356) / delandistrogene moxeparvovec</b> - DMD*	<b>RG7916 / Evrysdi</b> - Pre-symptomatic SMA
<b>Hematology</b>	<b>NXT007 (RG6512)</b> - Hemophilia A (PI/II)	<b>SKY59 (RG6107) / PiaSky (U.S./EU)</b> - SCD	<b>SKY59 (RG6107) / PiaSky</b> - aHUS	<b>SKY59 (RG6107) / PiaSky (EU)</b> - PNH
<b>Ophthalmology</b>	<b>RG6321 / PDS</b> - nAMD (PI/II) - DME (PI/II)		<b>SA237 (RG6168) / Enspryng</b> - TED <b>RG7716 / Vabysmo</b> - Angioid streaks <b>RG6179/ vamikibart</b> - UME	
<b>Other</b>	<b>REVN24</b> - Acute diseases <b>GYM329 (RG6237)</b> - Obesity ★ <b>RG6615 / zilebesiran</b> - Hypertension (PI/II) ★	<b>AMY109</b> - Endometriosis		

In principle, completion of first dose is regarded as pipeline entry into each phase of clinical studies.

**Letters in orange** : in-house projects (development in global) **Letters in blue** : in-licensed from Roche (development and distribution in Japan) ★: Projects with advances in stages since April 24, 2024

\* Sarepta manages the global study, including Japan

aHUS: atypical hemolytic uremic syndrome, AIE: autoimmune encephalitis, DMD: Duchenne muscular dystrophy, DME: diabetic macular edema, FSHD: facioscapulohumeral muscular dystrophy, MOGAD: myelin oligodendrocyte glycoprotein antibody-associated disease, nAMD: neovascular age-related macular degeneration, PNH: paroxysmal nocturnal hemoglobinuria, SCD: sickle cell disease, TED: thyroid eye disease, UME: uveitic macular edema

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

As of July 25, 2024

Generic name/development code	Mode of Action	Licensee	Granted rights to licensee	Indication	Stage	Progress
<b>avutometinib /VS-6766</b>	RAF/MEK clamp	Verastem Oncology	exclusive global license for the manufacturing, development and marketing	Recurrent low-grade serous ovarian cancer (LGSOC)	global: P3  US: initiation of ongoing rolling NDA submission	<ul style="list-style-type: none"> <li>US FDA BTB (recurrent LGSOC in combination with defactinib)</li> <li>US orphan drug designation (avutometinib alone or in combination with defactinib in recurrent LGSOC)</li> <li>RAMP301 trial (P3) initiated</li> <li>Initiation of ongoing rolling NDA submission to the U.S. FDA seeking accelerated approval for the combination of avutometinib and defactinib for adult patients with recurrent KRAS mutant low-grade serous ovarian cancer, who received at least one prior systemic therapy★</li> </ul>
				Non-small cell lung cancer (NSCLC)	global/U.S. : P1/2	<ul style="list-style-type: none"> <li>RAMP 203 trial (P1/2 in combination with KRAS G12C inhibitor sotorasib with or without defactinib) ongoing globally</li> <li>U.S. FDA fast track designation of avutometinib in combination with sotorasib</li> <li>U.S. FDA fast track designation for the combination of avutometinib plus defactinib with sotorasib★</li> <li>RAMP 204 trial (P1/2 in combination with KRAS G12C inhibitor, adagrasib) ongoing in the U.S.</li> <li>U.S. FDA fast track designation of avutometinib in combination with adagrasib★</li> </ul>
				First-line metastatic pancreatic ductal adenocarcinoma (mPDAC)	US: Phase 1/2	<ul style="list-style-type: none"> <li>RAMP 205 trial (P1/2 evaluating avutometinib and defactinib in combination with gemcitabine and nab-paclitaxel) ongoing</li> </ul>

★ Changes from the last announcement on April 24, 2024

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

As of July 25, 2024

Generic name/development code	Mode of Action	Licensee	Granted rights to licensee	Indication	Stage	Progress
<b>nemolizumab</b>	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	• FDA BLA / EMA MAA accepted in Feb 2024 + consortium countries accepted in May 2024★
				Prurigo nodularis	FDA BLA / EMA MAA review	• FDA BLA / EMA MAA accepted in Feb 2024 (FDA priority review designation for prurigo nodularis) + consortium countries accepted in May 2024★
				Chronic kidney disease associated pruritus (CKDaP)	global: P2/3	• Ongoing
<b>orforglipron/ LY3502970</b>	Oral non-peptidic GLP-1 receptor agonist	Eli Lilly and Company	worldwide development and commercialization rights	Type 2 diabetes	global: P3	• 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* <sup>1</sup>
				Obesity	global: P3	• 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* <sup>2</sup>
<b>-/AP306 (EOS789)</b>	Oral inhibitor of phosphate transporters	Alebund	exclusive global license for the manufacturing, development and marketing	Hyperphosphatemia	China: P2	<ul style="list-style-type: none"> <li>• In a phase 2 study, AP306 showed a clinically significant reduction in serum phosphorus levels at the end of treatment compared to baseline</li> <li>• AP306 is granted China Breakthrough Therapy Designation for the treatment of hyperphosphatemia in patients with chronic kidney disease★</li> </ul>

\*<sup>1</sup> 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.

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

★ Changes from the last announcement on April 24, 2024

# FoundationOne CDx Cancer Genomic Profile -Companion diagnostic indications-

As of July 25, 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		capivasertib
<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 July 25, 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

# FY2024 Q2 Interim Consolidated Financial Overview (Core)

**Iwaaki Taniguchi**

Executive Vice President & CFO



# P/L Jan – Jun (Year on Year)

(Billions of JPY)	2023	2024	Growth	
<b>Revenue</b>	<b>579.7</b>	<b>552.9</b>	<b>- 26.8</b>	<b>- 4.6%</b>
Sales	523.0	485.5	- 37.5	- 7.2%
Domestic	313.6	217.2	- 96.4	- 30.7%
Overseas	209.4	268.4	+ 59.0	+ 28.2%
Other revenue	56.6	67.3	+ 10.7	+ 18.9%
Cost of sales	-242.3	-160.2	+ 82.1	- 33.9%
(cost to sales ratio)	46.3%	33.0%	-13.3%p	-
Research and development	-76.5	-84.0	- 7.5	+ 9.8%
Selling, general and administration	-45.0	-46.6	- 1.6	+ 3.6%
Other operating income (expense)	16.2	0.8	- 15.4	- 95.1%
<b>Operating profit</b>	<b>232.0</b>	<b>262.8</b>	<b>+ 30.8</b>	<b>+ 13.3%</b>
(operating margin)	40.0%	47.5%	+7.5%p	-
Financial account balance	2.7	0.5	- 2.2	- 81.5%
Income taxes	-63.3	-73.8	- 10.5	+ 16.6%
<b>Net income</b>	<b>171.4</b>	<b>189.5</b>	<b>+ 18.1</b>	<b>+ 10.6%</b>
<b>EPS (JPY)</b>	<b>104.19</b>	<b>115.15</b>	<b>+10.96</b>	<b>+ 10.5%</b>

## Domestic sales

Decrease due to the absence of supply of Ronapreve (81.2 billion JPY) to the government recorded in the same period of the previous year, the NHI drug price revisions and the market penetration of generic drugs

## Overseas sales

Significant increase in sales of Hemlibra to Roche

## Other revenue

Increase in income of Hemlibra and in one-time income

## Cost of sales

Cost to sales ratio improved due to a change in 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

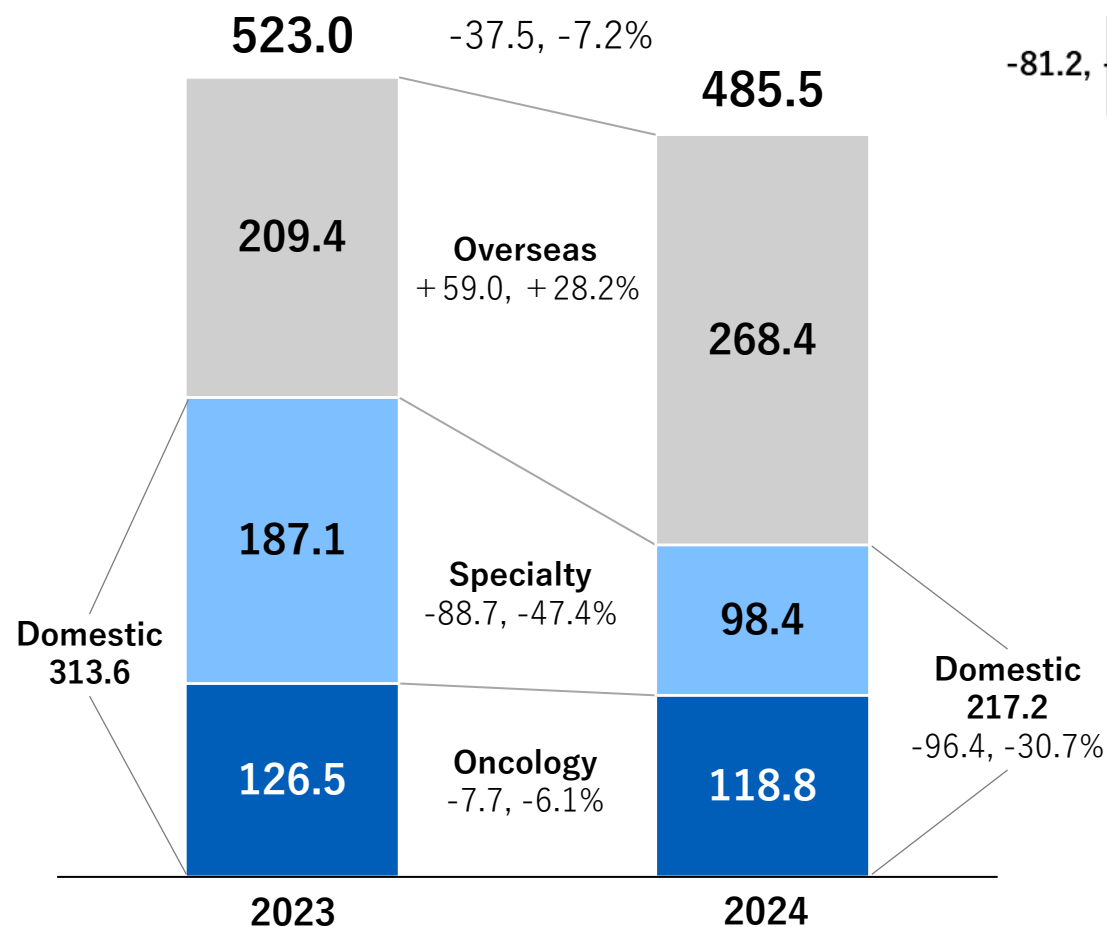
Increase due to impact from foreign exchange and increase in enterprise tax, etc.

## Other operating income (expense)

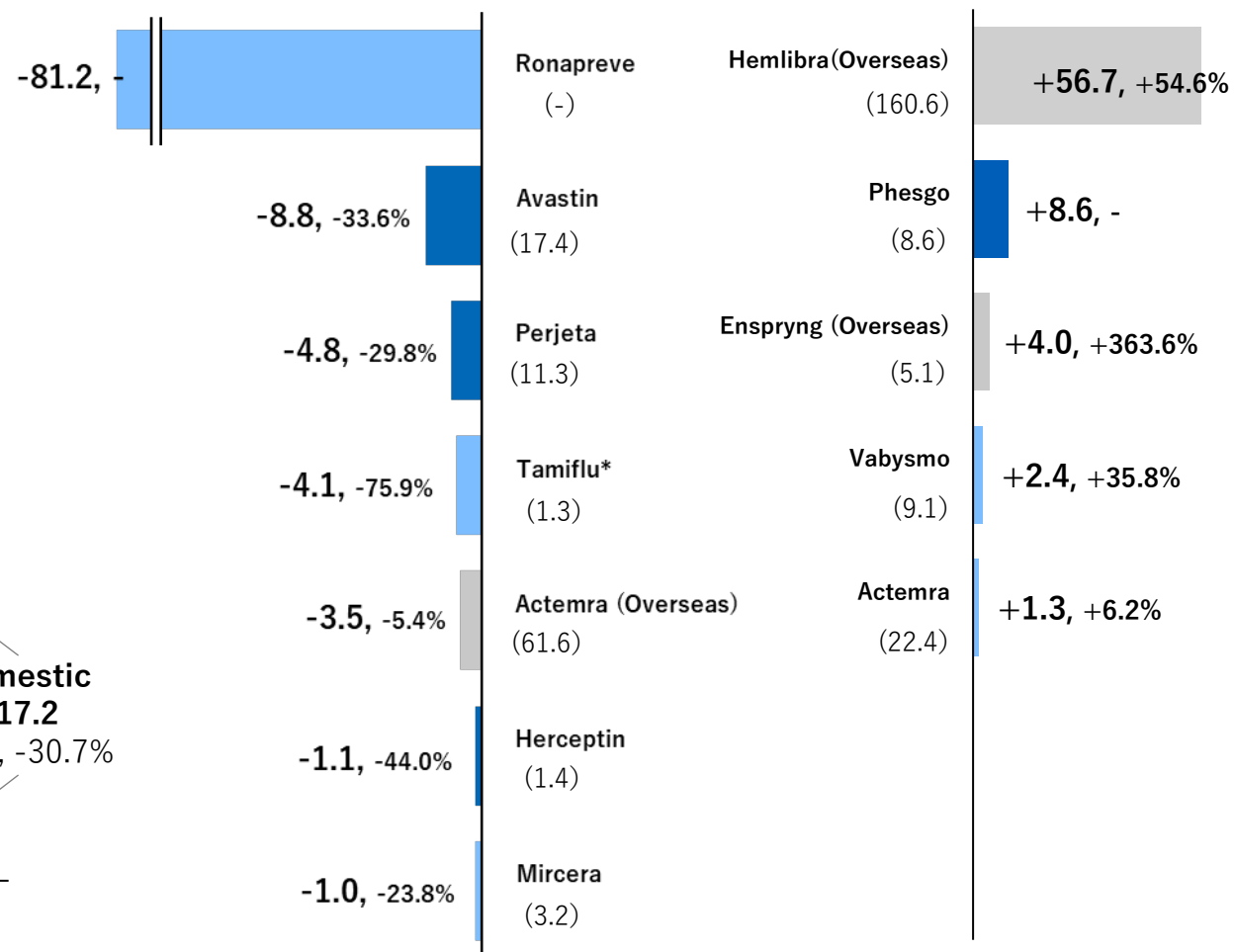
Absence of income from disposal of product rights and gain on sales of property, plant and equipment, etc. recorded in the same period of the previous year

# Sales Jan – Jun (Year on Year)

(Billions of JPY)

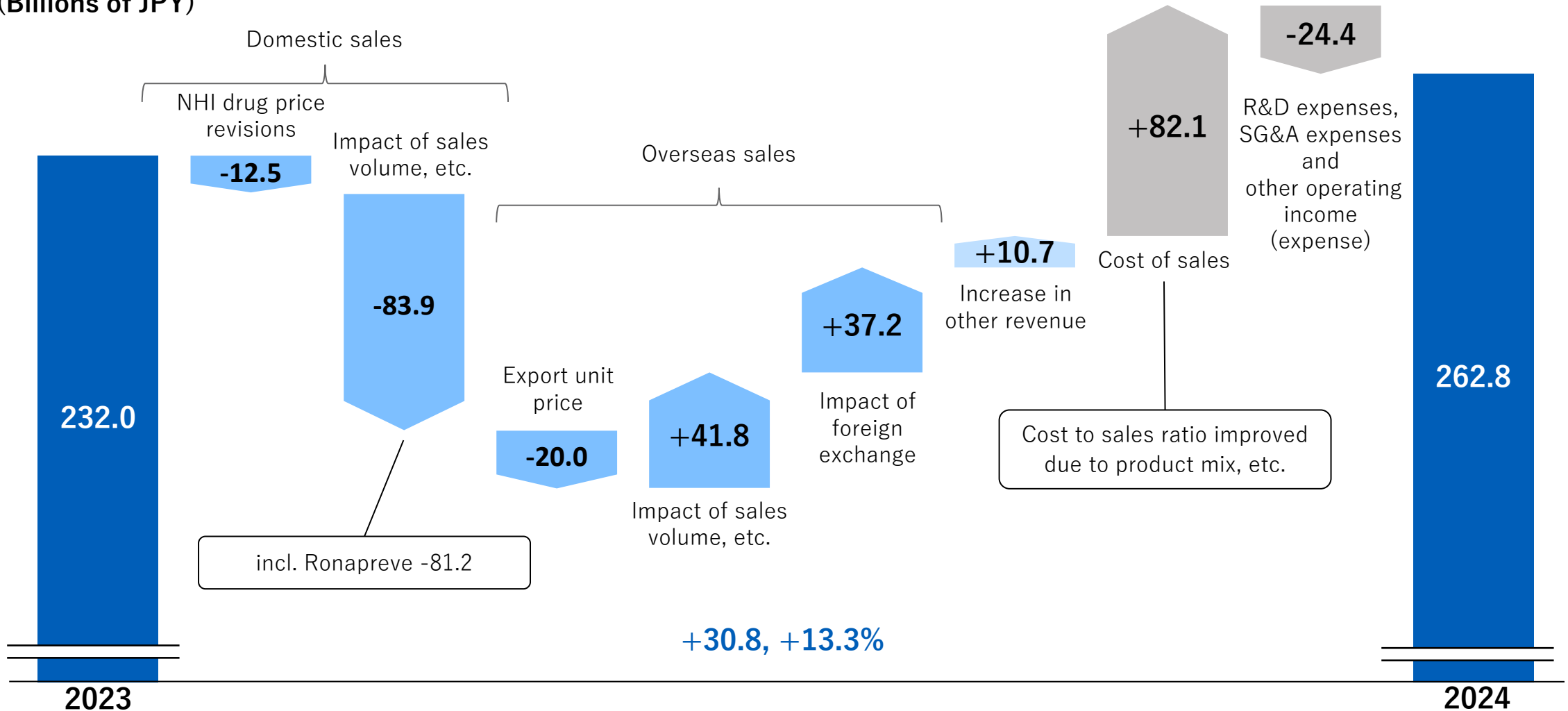
Sales by Disease Area,  
Year on YearSales by Product,  
Year on Year

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



# Operating Profit Jan – Jun (Year on Year)

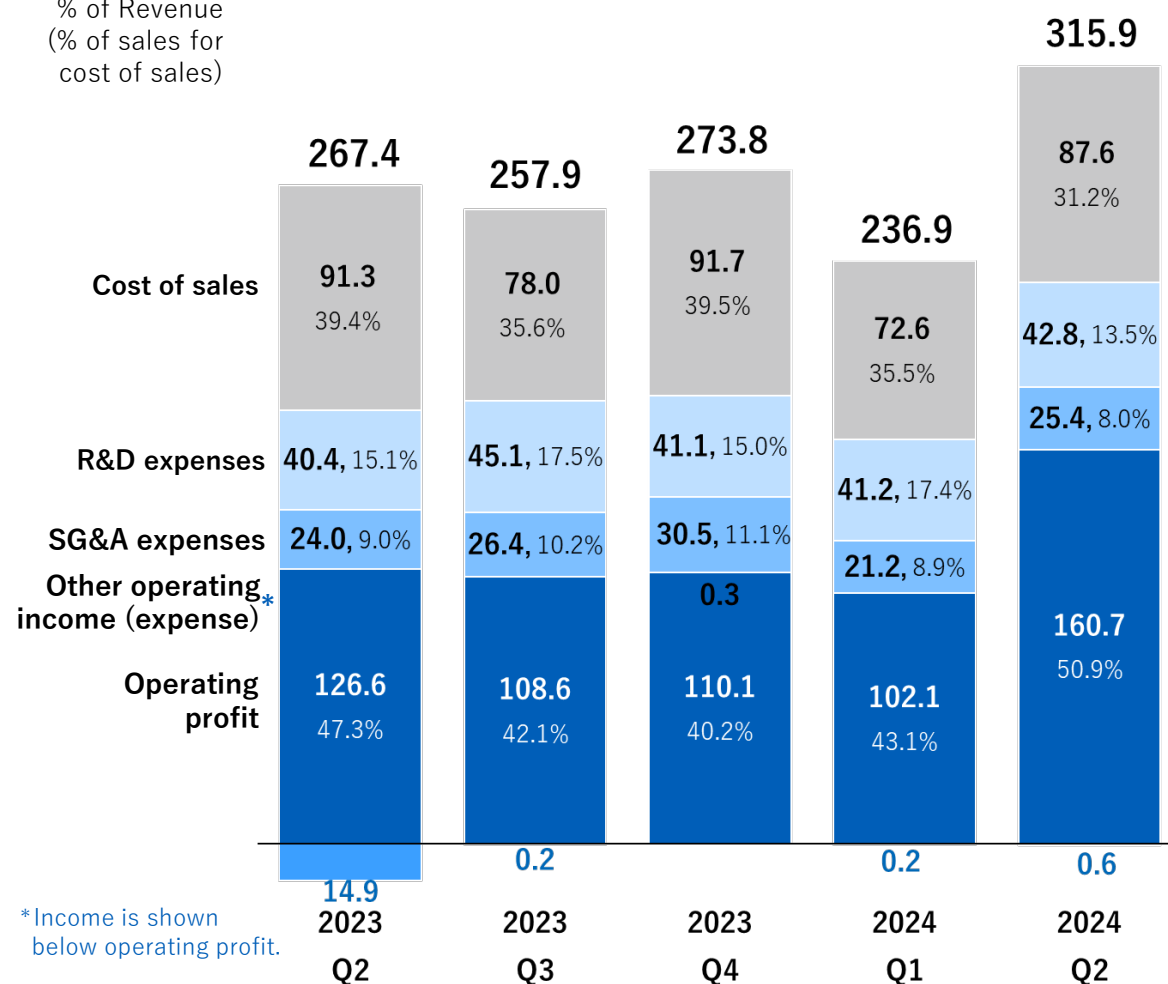
(Billions of JPY)



# Structure of Costs and Profit by Quarter

(Billions of JPY)

% of Revenue  
(% of sales for  
cost of sales)



\* Income is shown  
below operating profit.

Year on Year (vs. 2023 Q2)

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

**R&D:** increase due to investments in research and early development, and progress of development projects

**SG&A:** increase in various expenses

**Other operating income (expense):** absence of income from disposal of product rights recorded in the same period of the previous year

**Operating profit:** +34.1 billion JPY, +26.9%

Quarter on Quarter (vs. 2024 Q1)

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

**R&D:** increase due to progress of development projects

**SG&A:** increase due to various sales activities and in various expenses

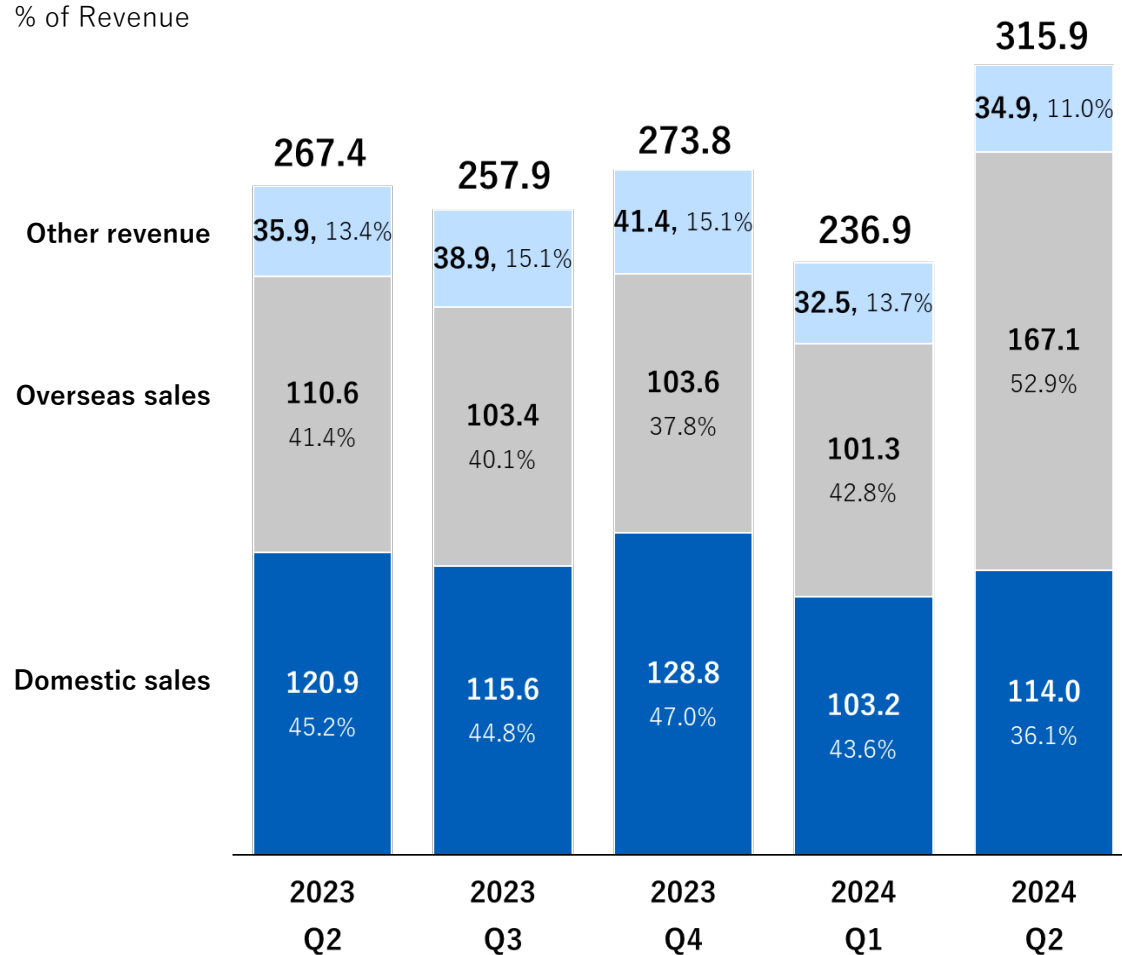
**Other operating income (expense):** same level as the previous quarter

**Operating profit:** +58.6 billion JPY, +57.4%

# Structure of Revenue by Quarter

(Billions of JPY)

% of Revenue



## Year on Year (vs. 2023 Q2)

**Domestic sales:** decrease due to market penetration of generic drugs and impact of disposal of product rights, etc.

**Overseas sales:** significant increase in sales of Hemlibra

**Other revenue:** decrease in milestone income, despite increase in royalty income of Hemlibra

## Quarter on Quarter (vs. 2024 Q1)

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

**Overseas sales:** significant increase in sales of Hemlibra and Actemra

**Other revenue:** increase in royalty income of Hemlibra, despite decrease in milestone income

# P/L Jan – Jun (vs. Forecast)

(Billions of JPY)	Actual	Forecast		2023
	2024 Jan - Jun	2024 Jan - Dec	Progress	Progress*
<b>Revenue</b>	<b>552.9</b>	<b>1,070.0</b>	<b>51.7%</b>	<b>52.2%</b>
Sales	485.5	922.0	52.7%	53.7%
Domestic	217.2	454.9	47.7%	56.2%
Overseas	268.4	467.1	57.5%	50.3%
Other revenue	67.3	148.0	45.5%	41.3%
Cost of sales	- 160.2	- 337.5	47.5%	58.8%
(cost to sales ratio)	33.0%	36.6%	-	-
Research and development	- 84.0	- 171.0	49.1%	47.0%
Selling, general and administration	- 46.6	- 102.0	45.7%	44.1%
Other operating income (expense)	0.8	0.5	160.0%	100.6%
<b>Operating profit</b>	<b>262.8</b>	<b>460.0</b>	<b>57.1%</b>	<b>51.5%</b>
(operating margin)	47.5%	43.0%	-	-
<b>Net Income</b>	<b>189.5</b>	<b>335.5</b>	<b>56.5%</b>	<b>51.4%</b>
<b>EPS (JPY)</b>	<b>115.15</b>	<b>204.00</b>	<b>56.4%</b>	<b>51.4%</b>

## Domestic sales

Progress in line with forecast of domestic sales  
(2023 progress excluding Ronapreve: 50.5%)

## Overseas sales

Sales of Actemra and Hemlibra to Roche  
exceeding forecast

## Other revenue

Progress nearly in line with forecast

## Cost of sales

Cost to sales ratio nearly in line with Jan-Jun  
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 – Jun 2023 progress versus Jan – Dec 2023 actual

# Sales Jan – Jun (vs. Forecast)

(Billions of JPY)	Actual	Forecast		2023
	2024 Jan - Jun	2024 Jan - Dec	Progress	Progress *
<b>Sales</b>	<b>485.5</b>	<b>922.0</b>	<b>52.7%</b>	<b>53.7%</b>
<b>Domestic</b>	<b>217.2</b>	<b>454.9</b>	<b>47.7%</b>	<b>56.2%</b>
<b>Oncology</b>	<b>118.8</b>	<b>246.5</b>	<b>48.2%</b>	<b>48.6%</b>
Tecentriq	31.1	66.2	47.0%	48.2%
Polivy	15.7	37.3	42.1%	44.8%
Avastin	17.4	33.9	51.3%	52.6%
Alecensa	14.9	31.3	47.6%	47.9%
Perjeta	11.3	22.0	51.4%	47.9%
Kadcyla	7.9	16.2	48.8%	48.1%
Phesgo	8.6	15.5	55.5%	0.0%
Herceptin	1.4	2.2	63.6%	52.1%
Foundation Medicine	3.6	7.1	50.7%	50.0%
Other	7.0	14.8	47.3%	49.4%

(Billions of JPY)	Actual	Forecast		2023
	2024 Jan - Jun	2024 Jan - Dec	Progress	Progress *
<b>Specialty</b>	<b>98.4</b>	<b>208.4</b>	<b>47.2%</b>	<b>62.8%</b>
Hemlibra	27.4	56.5	48.5%	48.7%
Actemra	22.4	45.9	48.8%	47.6%
Vabysmo	9.1	22.8	39.9%	43.8%
Enspryng	11.6	22.4	51.8%	45.6%
Evrysdi	7.5	16.5	45.5%	45.5%
Mircera	3.2	6.8	47.1%	50.0%
CellCept	3.1	6.3	49.2%	50.0%
Edirol	2.9	5.6	51.8%	50.7%
PiaSky	0.4	1.8	22.2%	-
Ronapreve	-	-	-	100.0%
Other	10.7	23.9	44.8%	54.8%
<b>Overseas</b>	<b>268.4</b>	<b>467.1</b>	<b>57.5%</b>	<b>50.3%</b>
Hemlibra	160.6	267.3	60.1%	48.9%
Actemra	61.6	109.8	56.1%	51.1%
Alecensa	30.5	58.9	51.8%	56.4%
Enspryng	5.1	6.4	79.7%	26.2%
Neutrogen	4.6	6.8	67.6%	48.1%
Edirol	0.2	1.8	11.1%	0.0%
Other	5.7	16.1	35.4%	45.9%

\* Jan – Jun 2023 progress versus Jan – Dec 2023 actual

# Impact from Foreign Exchange Jan – Jun

(Billions of JPY)	vs.2023 Actual rate 【C】 vs. 【A】	vs.2024 Forecast rate 【C】 vs. 【B】
<b>Revenue</b>	+45.3	+4.0
Sales	+37.2	+3.4
Other revenue	+8.1	-0.6
<b>Cost of sales</b>	-3.0	-0.1
<b>Other than above<sup>*1</sup></b>	-2.6	-0.8
<b>Operating profit</b>	+39.7	+3.1

Exchange Rate (JPY)	2023 Actual rate <sup>*2</sup> Jan - Jun 【A】	2024 Forecast rate Jan - Jun 【B】	2024 Actual rate <sup>*2</sup> Jan -Jun 【C】	2024 Forecast rate Jan - Dec
<b>1CHF</b>	138.30	158.77	160.90	159.00
<b>1EUR</b>	141.96	157.00	164.63	157.00
<b>1USD</b>	133.45	137.58	135.45	136.00

<sup>\*1</sup> Total of R&D, SG&A and other operating income (expense)

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

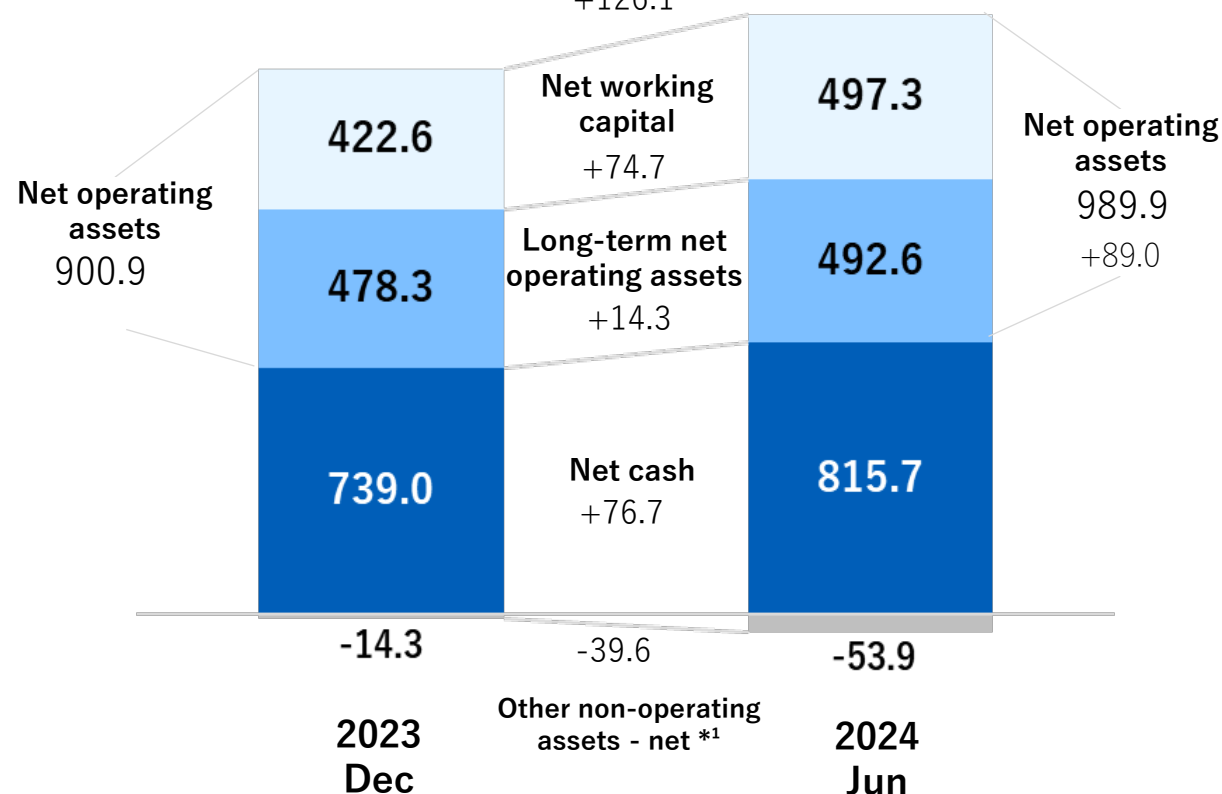


# Financial Position (vs. 2023 Year End)

(Billions of JPY)

Total assets	1,932.5	+127.7	2,060.2
Total liabilities	-307.0	-1.5	-308.5

1,625.6	Total net assets +126.1	1,751.7
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Ratio of equity attributable to Chugai shareholders

84.1%

+0.9%p

85.0%

## Increase in net working capital

Increase mainly due to an increase 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 active pharmaceutical ingredients (FJ3) at Fujieda Plant
- the manufacturing building for bio drug substance (UT3) at Utsunomiya Plant

## Increase in net cash

(See next page)

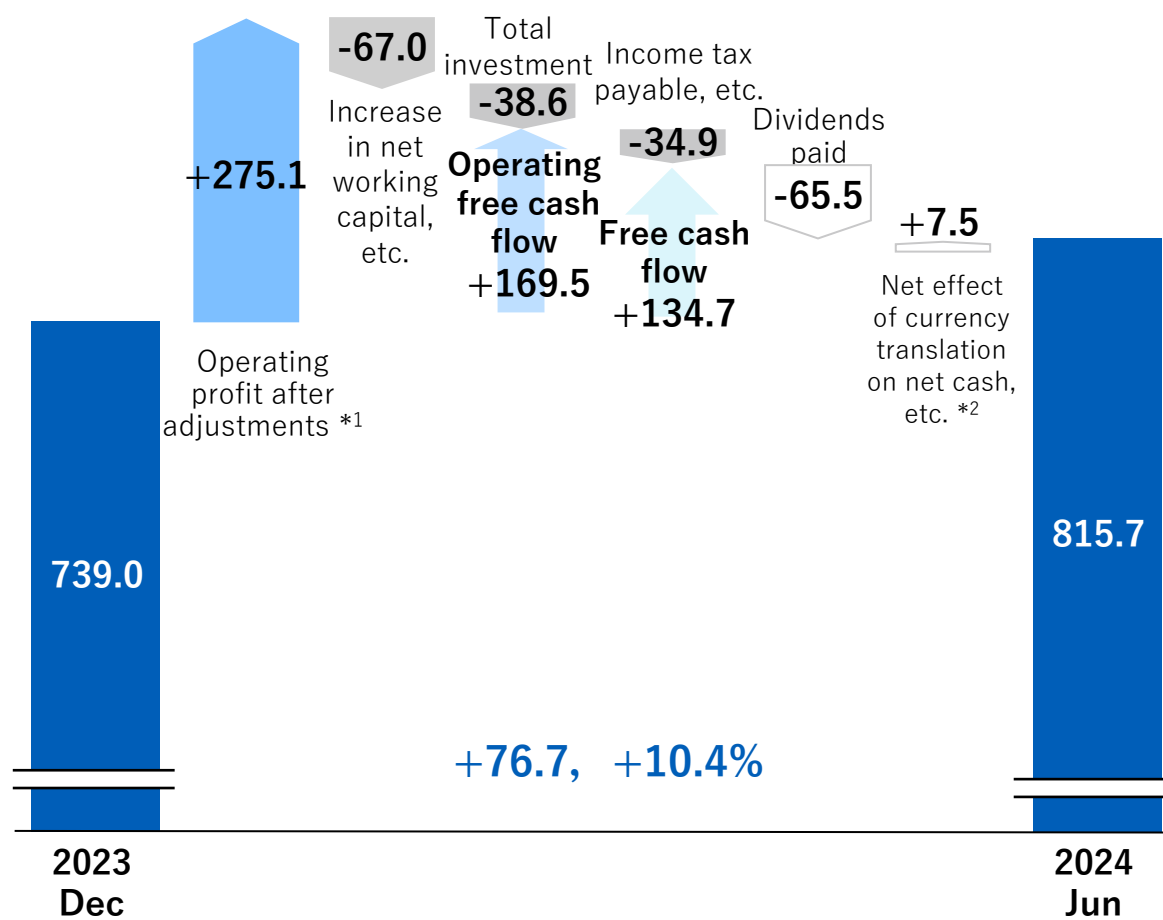
## Decrease in other non-operating assets – net

Increase 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 <sup>*1</sup>	+275.1
Operating profit <sup>*1</sup>	+258.2
Depreciation, amortization and impairment <sup>*1</sup>	+15.7
Increase in net working capital, etc.	-67.0
Total investment	-38.6
Property, plant and equipment	-32.9
Payment for lease liabilities	-4.0
Intangible assets	-1.7
<b>Operating free cash flows</b>	<b>+169.5</b>
Income tax payable, etc.	-34.9
Income tax payable	-40.0
<b>Free cash flows</b>	<b>+134.7</b>
Dividends paid	-65.5
Net effect of currency transaction on net cash, etc. <sup>*2</sup>	+7.5

<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(\*3)

<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 International Accounting Standard (IAS) 7 and IAS 21)

# P/L Jan – Jun (Non-core adjustment)

(Billions of JPY)	IFRS results	Non-core items		Core results
		Intangible assets	Others	
<b>Revenue</b>	<b>552.9</b>			<b>552.9</b>
Sales	485.5			485.5
Other revenue	67.3			67.3
Cost of sales	-160.9	+0.7		-160.2
Research and development	-84.3	+0.2	+0.1	-84.0
Selling, general and administration	-49.9		+3.3	-46.6
Other operating income (expense)	0.4		+0.4	0.8
<b>Operating profit</b>	<b>258.2</b>	<b>+0.9</b>	<b>+3.8</b>	<b>262.8</b>
Financial account balance	0.5			0.5
Income taxes	-72.4	-0.3	-1.1	-73.8
<b>Net income</b>	<b>186.3</b>	<b>+0.6</b>	<b>+2.6</b>	<b>189.5</b>
<b>EPS (JPY)</b>	<b>113.19</b>			<b>115.15</b>

## Non-core items

(Billions of JPY)

## Factors affected operating profit

### Intangible assets

Amortization	+0.8
Impairment	+0.1

### Others

Business rebuilding expenses	+3.3
Restructuring expenses	+0.5

# Summary of Chugai Originated Global Products

Product (Billions of JPY)	FY2024 Q2 Results	Year on Year	Full Year Forecast	Comments
<b>Hemlibra<sup>®</sup></b>	Domestic: <b>27.4</b> Export: <b>160.6</b> Overseas local: <b>1,972</b> mCHF	+2.6% +54.6% +8%	<b>56.5</b> <b>267.3</b>	<ul style="list-style-type: none"> <li>• Japan: Sales slightly increased YoY despite last year's drug price revision <sup>*1</sup>, Domestic market share steadily increased</li> <li>• Overseas: Sales increased especially in International and EU. Exports are progressing better than expectations</li> <li>- • We provide value to patients worldwide through convenience and accumulated clinical evidence</li> </ul>
<b>Actemra<sup>®</sup></b>	Domestic: <b>22.4</b> Export: <b>61.6</b> Overseas local: <b>1,130</b> mCHF	+6.2% -5.4% +3%	<b>45.9</b> <b>109.8</b>	<ul style="list-style-type: none"> <li>• Japan: Continued to obtain new prescriptions for rheumatoid arthritis. Other indications also penetrated</li> <li>• Overseas: Impact of BS is minimal, with slight increase in local sales. Exports are progressing better than expectations</li> <li>- • We provide value to patients through the established evidence as an originator of IL-6 inhibitors</li> </ul>
<b>Alecensa<sup>®</sup></b>	Domestic: <b>14.9</b> Export: <b>30.5</b> Overseas local: <b>670</b> mCHF	+2.8% -2.9% +8%	<b>31.3</b> <b>58.9</b>	<ul style="list-style-type: none"> <li>• Japan: Competitors entered first-line therapy since 2021, but maintained a high market share</li> <li>• Overseas: Continued market penetration in all regions. Exports are generally in line with expectations</li> <li>- • We anticipate that the expanded indication for NSCLC adj. will further contribute to the treatment of patients</li> </ul>
<b>Enspryng<sup>®</sup></b>	Domestic: <b>11.6</b> Export: <b>5.1</b> Overseas local: <b>74</b> mCHF	+6.4% +363.6% +67%	<b>22.4</b> <b>6.4</b>	<ul style="list-style-type: none"> <li>• Japan: Sales increased YoY despite this year's April drug price revision <sup>*2</sup></li> <li>• Overseas: Sales increased in international and the US. Exports are progressing better than expectations</li> <li>- • We provide a convenient treatment option for patients who wish to avoid steroids</li> </ul>

\* "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.  
BS: biosimilar, NSCLC: non-small cell lung cancer

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

\*2 Market expansion re-pricing in April 2024 (-25.0%)

[Hemlibra] Domestic Hemophilia A Patient Share Trends

Q2 2023	Q3 2023	Q4 2023	Q1 2024	Q2 2024
30.8%	31.7%	32.5%	33.2%	33.8%

# Outline of Arrangements for Sales, Royalties, and Expenses of Five Products Out-licensed to Roche

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

\*1 PiaSky is manufactured by Roche

\*2 Trading schemes of Actemra was changed from co-promotion to royalty in 2023, co-promotion countries of Hemlibra are UK, Germany, France and China

\*3 Chugai provides promotion services in UK and Germany

# 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	53.0	billion JPY	2021	2024
	Utsunomiya plant	UT3: Manufacture bio drug substance for middle to later- stage clinical development and early commercial use							37.4	10.4	billion JPY	2023	2026
	Utsunomiya plant	UTA: Manufacture sterile injectables for early commercial use							19.0	5.9	billion JPY	2023	2025
	Ukima plant	UK3(modification): Manufacture bio drug substance							20.3	0.1	billion JPY	2024	2027
Research and development	CPR	Move and renovate facilities to enhance research functions							60	0	million SGD	2024	2026
	IFReC	Funding to IFReC per comprehensive collaboration agreement							10.0	7.3	billion JPY	2017	2027
Environment	Environmental investment*	Equipment upgrade to achieve Mid-Term Environmental Goals 2030							109.5 estimated total amount	3.1	billion JPY	2022	2033

\* incl. part of investments described in the schedule above

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