



TOP INNOVATOR  
**TOPi 2030**

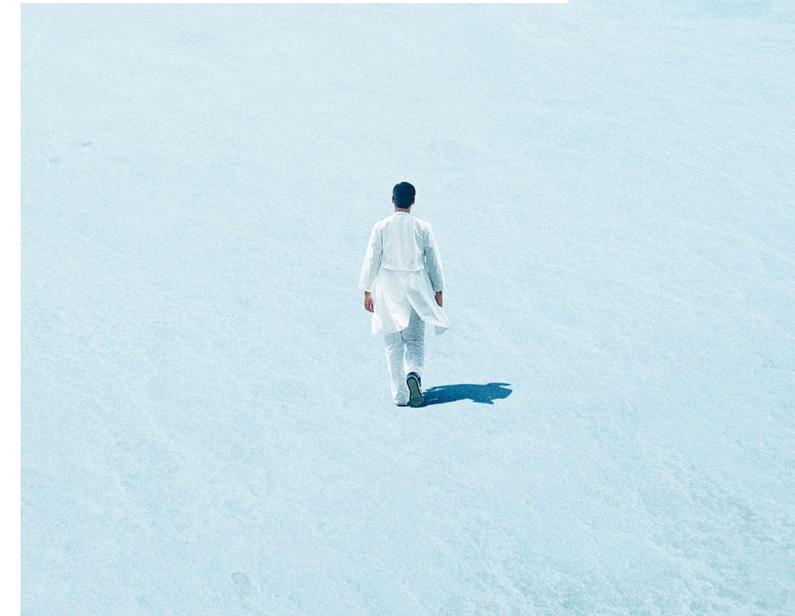
# Conference on FY2024.12 Q3 Financial Results

## CHUGAI PHARMACEUTICAL CO., LTD.

25 October 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



01

**FY2024 Q3 Overview**

**Dr. Osamu Okuda**

President & CEO

02

**Overview of Development Pipeline**

**Tsukasa Kusano**

Executive Vice President  
Head of Project & Lifecycle Management Unit

03

**FY2024 Q3 Consolidated Financial Overview (Core)**

**Iwaaki Taniguchi**

Director, Executive Vice President & CFO



# FY2024 Q3 Overview

**Dr. Osamu Okuda**

President & CEO

# Financial Overview

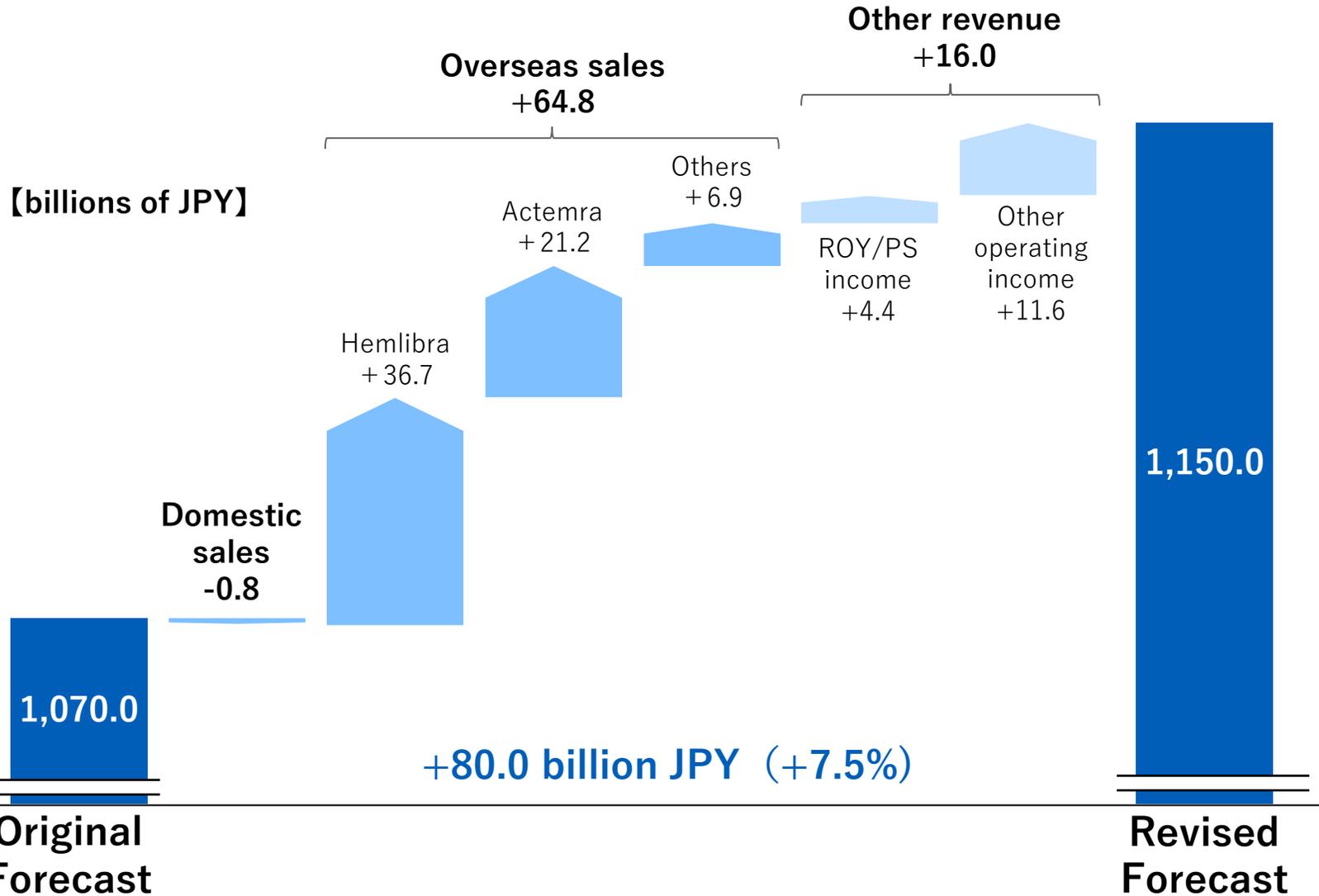
- Revenue increased, as the increase of overseas sales and other revenue overwhelmed the decrease of domestic sales, and exceeded the original forecast
- Operating profit and net income significantly increased YoY, and exceeded the original forecast
- Full-year forecast revised upwards by 1,150.0 billion yen in revenue and 540.0 billion yen in operating profit

Core (billions of JPY)	2023	2024	Growth (year on year)		Original Forecast		Revised Forecast	
	Jan - Sep actual	Jan - Sep actual			Jan - Dec	Progress	Jan - Dec	Vs. 2023 actual
<b>Revenue</b>	<b>837.6</b>	<b>868.5</b>	<b>+30.9</b>	<b>+3.7%</b>	<b>1,070.0</b>	<b>81.2%</b>	<b>1,150.0</b>	<b>+3.5%</b>
Domestic sales*	429.2	331.7	-97.5	-22.7%	454.9	72.9%	454.1	-18.6%
Overseas sales	312.9	418.7	+105.8	+33.8%	467.1	89.6%	531.9	+27.7%
Other revenue	95.5	118.2	+22.7	+23.8%	148.0	79.9%	164.0	+19.8%
<b>Operating profit</b>	<b>340.5</b>	<b>426.6</b>	<b>+86.1</b>	<b>+25.3%</b>	<b>460.0</b>	<b>92.7%</b>	<b>540.0</b>	<b>+19.8%</b>
Operating margin	40.7%	49.1%	+8.4%pts	-	43.0%	-	47.0%	+6.4%pts
<b>Net income</b>	<b>250.3</b>	<b>301.3</b>	<b>+51.0</b>	<b>+20.4%</b>	<b>335.5</b>	<b>89.8%</b>	<b>388.0</b>	<b>+16.3%</b>
<b>EPS (yen)</b>	<b>152.11</b>	<b>183.09</b>	<b>+30.98</b>	<b>+20.4%</b>	<b>204.00</b>	<b>89.8%</b>	<b>236.00</b>	<b>+16.4%</b>

- Domestic sales declined due to completion of Ronapreve supply to the government\*, the NHI drug price revisions, and the market penetration of generic drugs, despite the growth of new and mainstay products
- Overseas sales significantly increased mainly due to Hemlibra exports to Roche. Progress was better than original expectation
- Other revenue increased mainly due to increase in one-time incomes and Hemlibra related revenue. Progress was better than original expectation
- Revised upward by 80.0 billion yen (+7.5%) in revenue and 80.0 billion yen (+17.4%) in operating profit

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

# Topline Overview



- **Domestic sales:**  
Reflecting progress and revised projections for each product, including Phesgo, Polivy, Vabysmo, and Perjeta
- **Overseas sales:**  
Hemlibra and Actemra expected to exceed original forecasts
- **Other revenue:**  
Primarily updated for one-time income and royalty forecasts

ROY: Royalty, PS: Profit Share

# Progress of Chugai Originated Products Supporting Short- to Mid-term Growth

- Steady development including global approval of PiaSky and NEMLUVIO®, and expanded indication of ALECENSA



<p><b>PiaSky™</b> (crovalimab-akkz) 340 mg/2 mL injection for subcutaneous use</p> <ul style="list-style-type: none"> <li>Second Recycling antibody drug</li> <li>First Q4W subcutaneous treatment in PNH</li> <li>Expected reduce of burden on patients</li> </ul>	<p><b>nemluvio™</b> (nemolizumab-ilto) for injection 30 mg</p> <ul style="list-style-type: none"> <li>Antibody inhibiting IL-31, a cause of itching</li> <li>Approved in the U.S. under priority review for prurigo nodularis</li> <li>Filed in prurigo nodularis in EU, and atopic dermatitis in the U.S. and EU</li> <li>Expected early itch relief and inflammation improvement</li> </ul>	<p><b>ALECENSA™</b> alectinib 150 mg capsules</p> <ul style="list-style-type: none"> <li>Only ALK inhibitor for early-stage lung cancer</li> <li>Offers new treatment opportunity potentially leading to cure</li> </ul>
---	---	--

**Overseas sales potential:** Enspryng (MOGAD, AIE, TED: 1-2bn CHF), PiaSky (paroxysmal nocturnal hemoglobinuria (PNH), aHUS, SCD: 1-2bn CHF), GYM329 (SMA, FSHD: 0.5-1bn CHF); based on the forecast by Roche

Indications under development: orforglipron (diabetes, obesity), GYM329 (spinal muscular atrophy (SMA), facioscapulohumeral muscular dystrophy (FSHD), obesity), avutometinib (low-grade serous ovarian cancer, non-small cell lung cancer, pancreatic ductal adenocarcinoma), NEMLUVIO (atopic dermatitis, prurigo nodularis), Enspryng (myelin oligodendrocyte glycoprotein antibody-associated disease (MOGAD), autoimmune encephalitis (AIE), thyroid eye disease (TED)), PiaSky (atypical hemolytic uremic syndrome (aHUS), sickle cell disease (SCD))

3<sup>rd</sup> party licensees: NEMLUVIO (Galderma), avutometinib (Verastem Oncology), orforglipron (Eli Lilly and Company)

# Overview of Development Pipeline

**Tsukasa Kusano**

Executive Vice President, Head of Project & Lifecycle Management Unit

# Q3 Topics (1/2)



As of October 25, 2024

Approved	<b>PiaSky</b>	Adults and adolescents (12 years of age or older with a weight of 40 kg and above) with paroxysmal nocturnal hemoglobinuria (PNH) who are either new to, or have been previously treated with C5 inhibitors	August 2024 (EU)
	<b>Alecensa</b>	Adjuvant therapy for <i>ALK</i> fusion gene-positive non-small cell lung cancer (NSCLC) (additional indication)	August 2024 (Japan) August 2024 (Taiwan)
	<b>NEMLUVIO (nemolizumab)*</b>	Prurigo nodularis (PN)	August 2024 (U.S.)
	<b>Evrysdi</b>	Pre-symptomatic spinal muscular atrophy (SMA) predicted by genetic testing (additional indication), patients under 2 months of age (additional dosage)	September 2024 (Japan)
	<b>Rituxan</b>	Refractory steroid-resistant nephrotic syndrome (additional indication)	September 2024 (Japan)
Filed	<b>RG6356/SRP-9001</b>	Duchenne muscular dystrophy (DMD)	August 2024 (Japan)
	<b>Vabysmo</b>	Angioid streaks associated with neovascularization (additional indication)	September 2024 (Japan)
Initiation of Study	<b>RAY121</b>	Six autoimmune diseases (basket study (RAINBOW trial))	P1b study (August 2024)
	<b>BRY10</b>	Chronic diseases	P1 study (September 2024)
	<b>RG6330/divarasib</b>	NSCLC [2 <sup>nd</sup> line]	P3 study (October 2024)

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

\*Conducted by Galderma, a global licensee

# Q3 Topics (2/2)



As of October 25, 2024

Removed from Pipeline	<b>SPYK04 (RAF-MEK molecular glue)</b>	Solid tumors: initiation of out-licensing activities	
	<b>RG6139/tobemstomig</b>	Solid tumors: development discontinued	
Medical Conference	<b>NEMLUVIO (nemolizumab)*</b>	EADV**: Long-term efficacy and safety in atopic dermatitis and early onset in prurigo nodularis	September 2024
	<b>avutometinib***</b>	International Society of Gynecologic Cancer (IGCS): RAMP 201 study data in recurrent low-grade serous ovarian cancer	October 2024
	<b>Evryssi</b>	World Muscle Society (WMS) Congress: Two-year data from RAINBOWFISH study	October 2024
Literature Publication	<b>SAIL66</b>	Journal for ImmunoTherapy of Cancer	October 2024
License-in Agreement	<b>RG6114/inavolisib</b>	PI3K inhibitor for breast cancer with a <i>PIK3CA</i> mutation	July 2024
	<b>RG6631</b>	Anti-TL1A antibody for ulcerative colitis and Crohn's disease	August 2024
Orphan Drug Designation	<b>Enspryng</b>	Thyroid eye disease (TED)	August 2024
Business Transfer	<b>Oxarol for Injection</b>	Transfer of the business in Japan: LTL Pharma Co., Ltd.	August 2024

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

\*Conducted by Galderma, a global licensee    \*\*EADV: European Academy of Dermatology and Venereology    \*\*\*Conducted by Verastem Oncology, a global licensee

# 2024: Key R&D Milestones

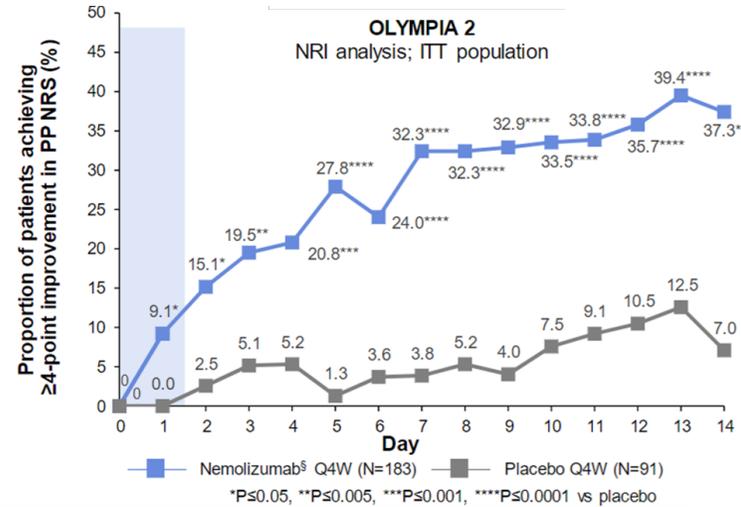
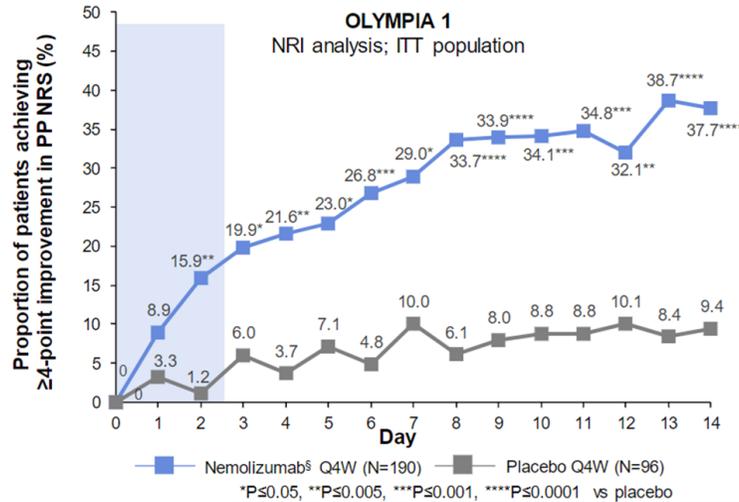
Underlined and bolded are new progress since July 25, 2024

	Product	Indication/Study name	Progress
<b>Projects to be Approved</b>	<b>PiaSky</b>	Paroxysmal nocturnal hemoglobinuria (Japan/EU/U.S.)	Approved (Japan/U.S./ <u>EU</u> )
	<b>Alecensa</b>	Non-small cell lung cancer (NSCLC) (adjuvant) (U.S./EU/Japan)	Approved (U.S./EU/ <u>Japan</u> )
	<b>Vabysmo</b>	Retinal vein occlusion	Approved
<b>P3/Pivotal Readouts</b>	<b>Enspryng</b>	Luminesce study: generalized myasthenia gravis	Achieved PE (the results did not reach our expectations on the degree of clinical benefit) /Development discontinued
	<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><u>Expected in 2025</u></b>
	<b>Vabysmo</b>	NIHONBASHI study: Angioid streaks	Achieved PE
<b>P2 Readouts</b>	<b>GYM329 + Evrysdi</b>	MANATEE study: Spinal muscular atrophy (SMA)	<b><u>Expected in 2025</u></b>

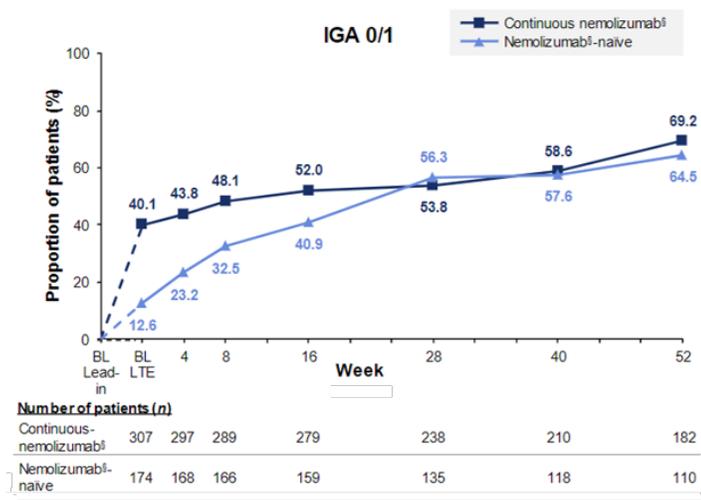
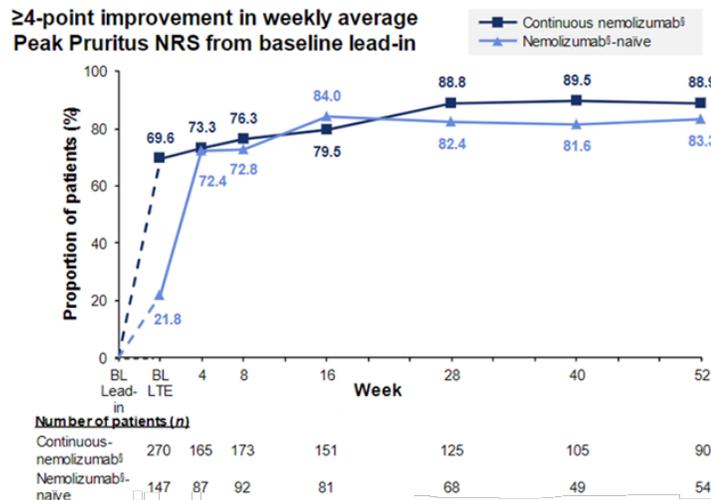
Letters in orange : in-house projects (development in global) Letters in blue : in-licensed from Roche (development and distribution in Japan) PE: primary endpoint, r/r: relapsed or refractory

# NEMLUVIO: Prurigo Nodularis Early Onset and Long-term Efficacy

- Nemolizumab exhibited significant pruritus improvement as early as day 2 or 1 in OLYMPIA programs (top) and continuous improvement in pruritus and IGA0/1 up to 52 weeks in OLYMPIA LTE study (bottom)



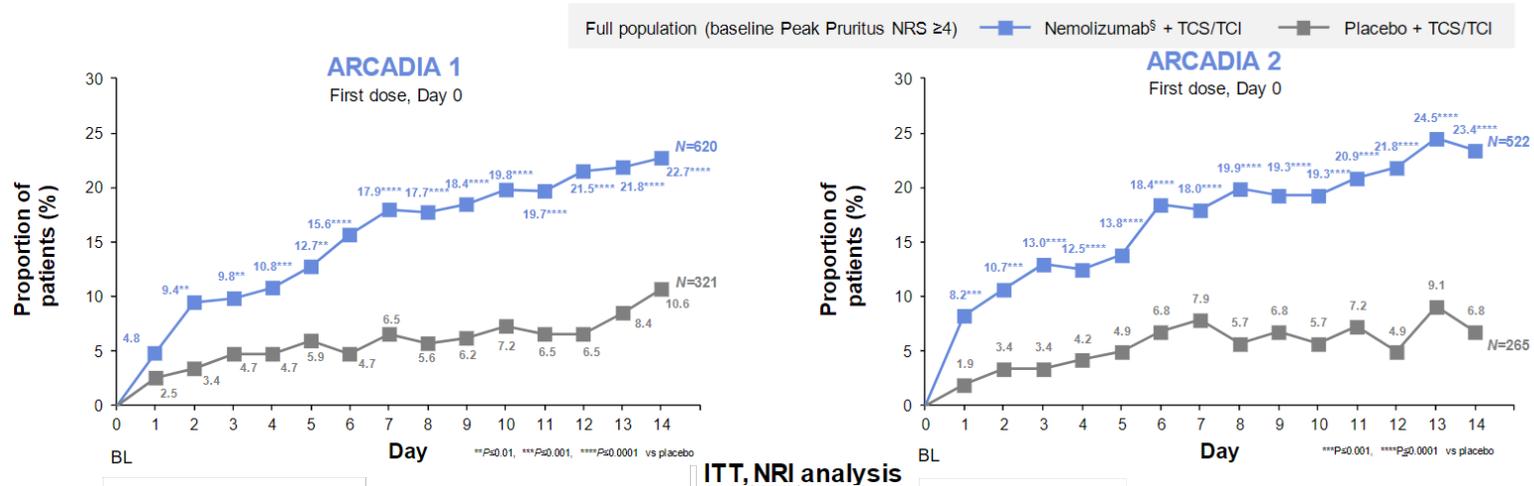
Source: Ständer S et al. European Academy of Dermatology and Venereology Annual Meeting 2024



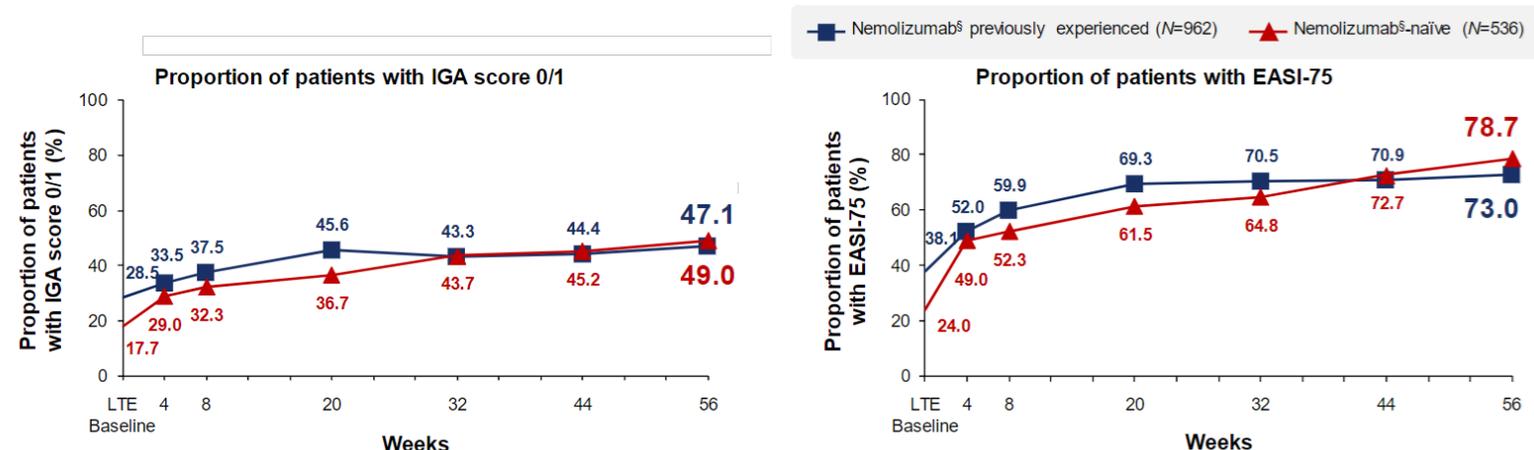
Source: Kwatra S et al. American Academy of Dermatology Annual Meeting 2024

# NEMLUVIO: Atopic Dermatitis Early Onset and Long-term Efficacy

- Nemolizumab exhibited significant pruritus improvement as early as day 2 or 1 in ARCADIA programs (top) and continuous improvement in IGA0/1 and EASI-75 up to 56 weeks in ARCADIA LTE study (bottom)



Source: Silverberg J et al. Revolutionizing Atopic Dermatitis Annual Meeting 2024



Source: Thaği D et al. European Academy of Dermatology and Venereology Annual Meeting 2024

n	Baseline	4	8	20	32	44	56
Nemolizumab <sup>s</sup> previously experienced	961	939	928	859	702	550	433
Nemolizumab <sup>s</sup> -naïve	536	524	514	471	389	321	253

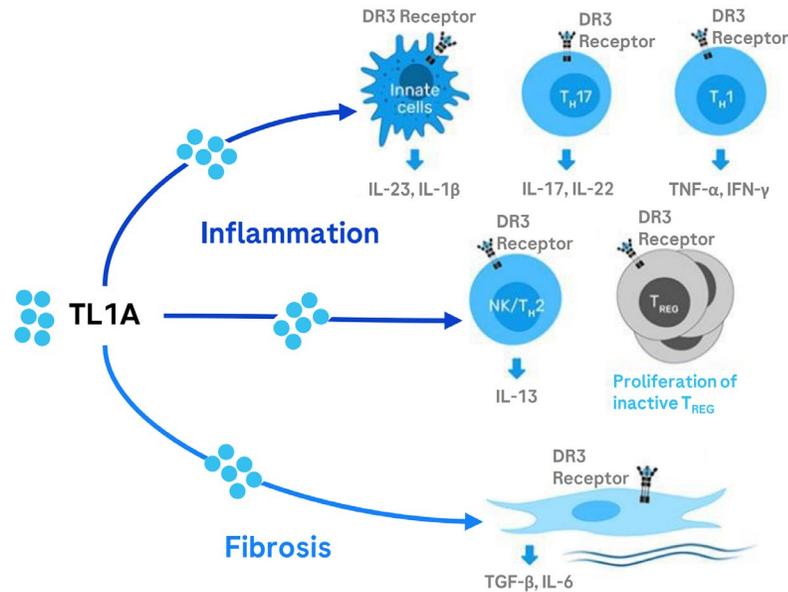
Observed Cases

n	Baseline	4	8	20	32	44	56
Nemolizumab <sup>s</sup> previously experienced	938	918	907	838	681	529	415
Nemolizumab <sup>s</sup> -naïve	495	484	474	434	361	300	239

# RG6631 (Anti-TL1A Antibody)

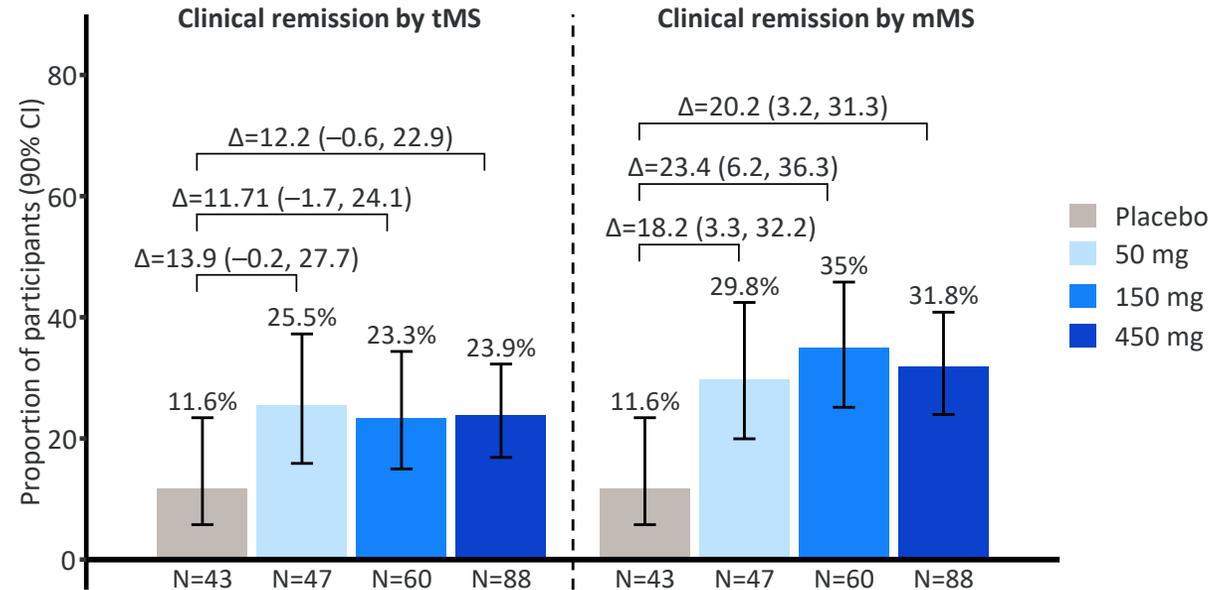
- With its novel mode of action, targeting suppression of inflammation and fibrosis by inhibiting TL1A, RG6631 has the potential to be a first-in-class and best-in-disease agent in inflammatory bowel disease\*<sup>1</sup> and to be applied in multiple other diseases.
- Given the promising results from the Phase 2b study in ulcerative colitis, Global Phase 3 studies are ongoing.

## In vivo effects of TL1A\*<sup>2, 3</sup>



TL1A binds to DR3 receptor on immune cells such as Th1, Th2, Th17, fibroblast, stimulating downstream inflammation and fibrosis\*<sup>4</sup> processes, and plays an important role in gut immunity.

## Results of Phase 2b study (TUSCANY-2) in patients with ulcerative colitis\*<sup>5</sup>

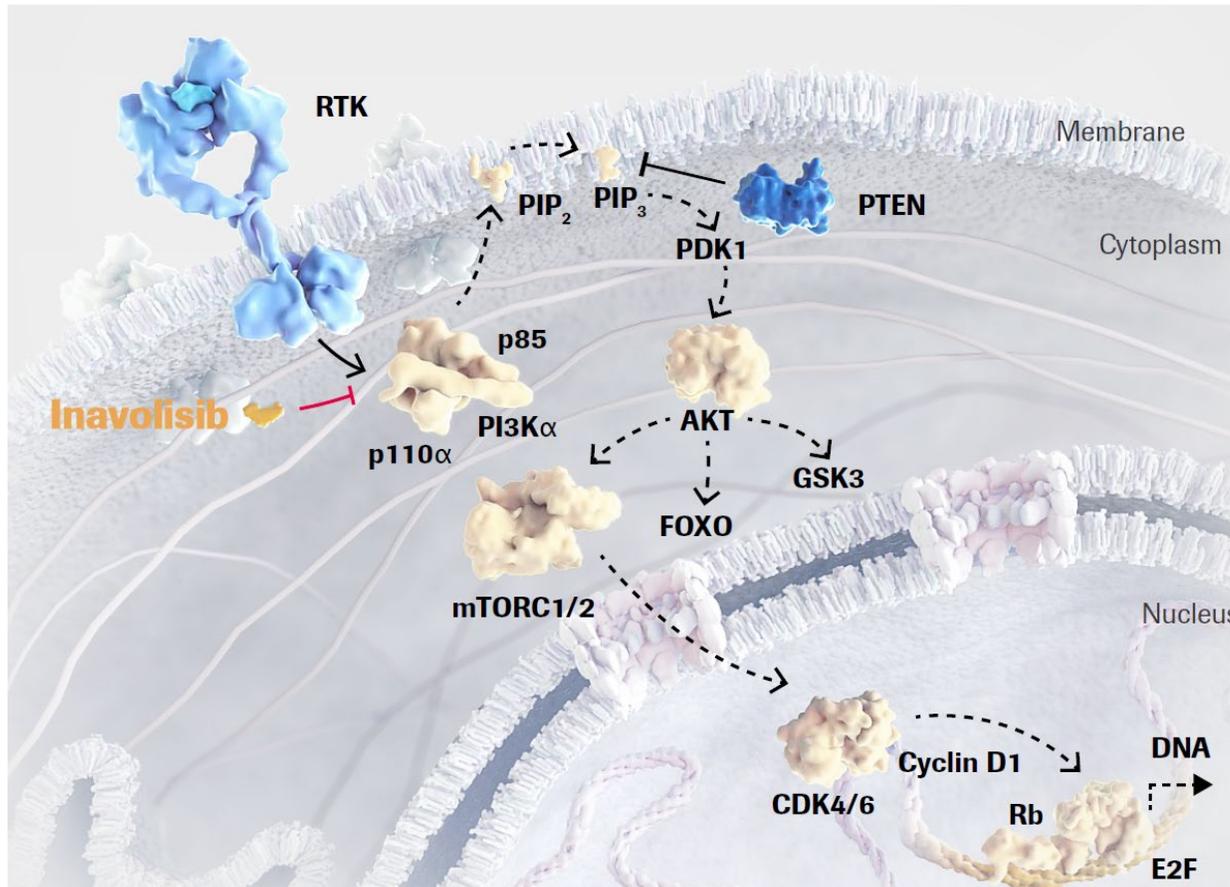


- Higher proportions of patients across all RG6631 doses experienced clinical remission vs placebo at week 14.
- RG6631 was well tolerated, with a favourable safety profile

TL1A = Tumor necrosis factor(TNF)-like ligand 1A; DR3 = Death receptor 3; tMS = total Mayo Score; mMS = modified Mayo Score; CI = confidence interval; \*1: The two main types of IBD are ulcerative colitis (mainly affecting the colon and rectum) and Crohn's disease (affecting the entire gastrointestinal tract). \*2 Hassan-Zahraee et al, Inflammatory Bowel Disease (2022), \*3 Roche 2023 results. 1Feb2024 \*4 Studies have shown that direct signaling of TL1A-DR3 on fibroblasts induces intestinal fibrosis in vivo (Refs: Shih DQ, et al. Mucosal Immunol 2014; Jacob N, et al. Sci Rep 2020; Li H, et al. Pathol Res Pract 2018) \*5 Silvio Danese, et al., uegw 2024. Clinical remission by tMS defined as tMS ≤2, with no individual subscore >1. Clinical remission by mMS defined as endoscopic subscore =0 or 1, ≥1-point decrease from baseline achieve a stool frequency subscore =0 or 1, and rectal bleeding subscore =0.

# Inavolisib (PI3K Inhibitor): Mode of Action

- Inavolisib is a highly potent, selective inhibitor of p110 $\alpha$ , the catalytic subunit of PI3K $\alpha$ . In addition, inavolisib promotes the degradation of mutated p110 $\alpha$  (mutant degrader)



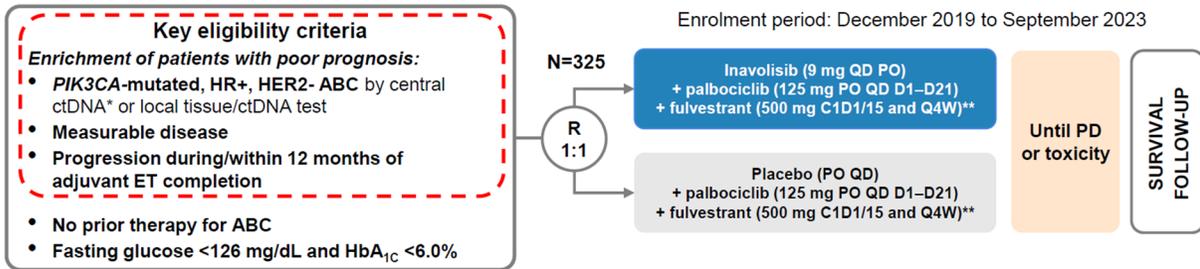
- Inavolisib is a new targeted molecular agent that specifically inhibits PI3K $\alpha$ <sup>1)</sup>, a key molecule involved in oncogenesis and tumor progression.
- PI3K $\alpha$  is composed of 2 subunits, p110 $\alpha$  and p85, and p110 $\alpha$ , called the catalytic subunit, is responsible for the main function of PI3K $\alpha$ . On the other hand, p85 is called a regulatory subunit and plays a role in controlling the activity of p110 $\alpha$ .
- A key feature of inavolisib is that it acts on both of these two subunits, thereby dual inhibiting PI3K $\alpha$  function. The effect on p110 $\alpha$  inhibits PI3K $\alpha$  and promotes the degradation of mutated p110 $\alpha$  (mutant degrader). These effects result in potent and sustained blockade of the PI3K $\alpha$  pathway.
- In addition, inavolisib selectively inhibits PI3K $\alpha$ , resulting in less impact on other PI3K molecules and a reduced risk of side effects.

1) Multiple PI3K isoforms ( $\alpha$ ,  $\beta$ ,  $\gamma$ ,  $\delta$ ) exist, with the PI3K $\alpha$  isoform playing a pivotal role in cellular proliferation and survival, exerting its oncogenic effects from the earliest stages of tumorigenesis. In contrast, the other PI3K isoforms are implicated in distinct physiological processes such as immune function and metabolic regulation, distinct from their roles in oncogenesis. Consequently, it is hypothesized that selective inhibition of the PI3K $\alpha$  isoform could suppress tumor cell proliferation while minimizing disruption of normal physiological functions mediated by the other PI3K isoforms.

# Global Phase 3 Study (INAVO120) of Inavolisib

- Expected to become a new standard molecular-targeted drug by combining CDK4/6 inhibitors and anti-estrogen drugs in advanced hormone receptor-positive, HER2-negative breast cancer with a *PIK3CA* mutation

## 【Study design】



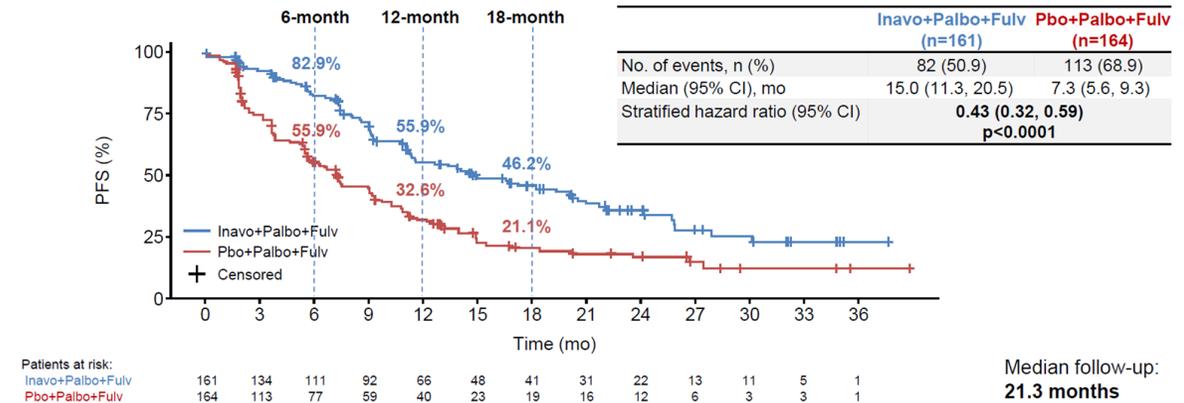
- Stratification factors:**
- Visceral Disease (Yes vs. No)
  - Endocrine Resistance (Primary vs. Secondary)<sup>†</sup>
  - Region (North America/Western Europe; Asia; Other)

- Endpoints**
- Primary: PFS by Investigator
  - Secondary: OS<sup>‡</sup>, ORR, BOR, CBR, DOR, PROs

\* Central testing for *PIK3CA* mutations was done on ctDNA using FoundationOne®Liquid (Foundation Medicine). In China, the central ctDNA test was the PredicineCARE NGS assay (Huidu). † Defined per 4th European School of Oncology (ESO)–European Society for Medical Oncology (ESMO) International Consensus Guidelines for Advanced Breast Cancer. ‡ Primary: relapse while on the first 2 years of adjuvant ET; Secondary: relapse while on adjuvant ET after at least 2 years or relapse within 12 months of completing adjuvant ET. † OS testing only if PFS is positive; interim OS analysis at primary PFS analysis; \*\* Pre-menopausal women received ovarian suppression. ctDNA, circulating tumor DNA; R, randomized. 1. Cardoso F, et al. *Ann Oncol* 2018;29:1634–1657.

## 【Results】

Primary endpoint: PFS (investigator-assessed)



CCOD: 29th September 2023  
CI, confidence interval; Fulv, fulvestrant; Inavo, inavolisib; mo, months; Palbo, palbociclib; Pbo, placebo; PFS, progression-free survival.

Jhaveri et al. SABCS 2023

- Patients with *PIK3CA*-mutated, hormone receptor-positive, HER2-negative locally advanced/metastatic breast cancer
  - ✓ relapsed during/within 12 months of adjuvant endocrine therapy completion in 1<sup>st</sup> line
- Palbociclib + fulvestrant (one of the standard of care) with inavolisib/placebo on the above segment

- INAVO120 met its primary endpoint, with a statistically significant and clinically meaningful improvement in PFS (15.0 months versus 7.3 months; hazard ratio, 0.43 [95% CI = 0.32, 0.59]; p<0.0001)
- Overall survival was immature, but with clear positive trend (HR=0.64, [95% CI=0.43, 0.97]; p=0.0338)
- Inavolisib discontinuations due to AEs were low: 6.2%, confirming the manageable safety and tolerability profile of inavolisib + palbociclib + fulvestrant

# Projected Submissions (Post PoC NMEs and Products)

as of October 25, 2024

**Filed**

<b>mosunetuzumab (RG7828)</b> 3L Follicular lymphoma	<b>TECENTRIQ (RG7446)</b> Alveolar soft part sarcoma	<b>SRP-9001 (RG6356)</b> ★ DMD	<b>VABYSMO (RG7716)</b> ★ Angioid streaks
---	---	-----------------------------------	--

■ in-house      ■ NME       Line extension  
■ in-licensed (Roche)     

★ : new entry    ☆ : changes in submission year  
\*Before obtaining PoC

aHUS: atypical hemolytic uremic syndrome  
r/r aNHL: relapsed or refractory aggressive B-cell non-Hodgkin lymphoma  
DMD: Duchenne muscular dystrophy  
FSHD: facioscapulohumeral muscular dystrophy  
HCC: hepatocellular carcinoma  
LBCL: large B-cell lymphoma  
MIBC: muscle-invasive bladder cancer  
MOGAD: myelin oligodendrocyte glycoprotein antibody-associated disease  
NSCLC: non-small cell lung cancer  
nAMD: neovascular age-related macular degeneration  
PNH: paroxysmal nocturnal hemoglobinuria  
SCD: sickle cell disease  
SMA: spinal muscular atrophy

<b>vamikibart (RG6179)</b> Uveitic macular edema	<b>GAZYVA (RG7159)</b> Pediatric nephrotic syndrome	<b>tiragolumab (RG6058)</b> 1L HCC TECENTRIQ + AVASTIN
<b>giredestrant (RG6171)</b> 1L Breast cancer	<b>GAZYVA (RG7159)</b> Lupus nephritis	<b>PiaSky (SKY59/RG6107)</b> SCD* (U.S./EU)
<b>mosunetuzumab (RG7828)</b> 2L Follicular lymphoma	<b>AVASTIN (RG435)</b> 1L SCLC + TECENTRIQ	<b>ENSPRYNG (SA237/RG6168)</b> MOGAD
<b>ENSPRYNG (SA237/RG6168)</b> ☆ Thyroid eye disease	<b>TECENTRIQ (RG7446)</b> NSCLC (perioperative)	<b>NXT007/RG6512</b> ★ Hemophilia A*
<b>PiaSky (SKY59/RG6107)</b> aHUS	<b>ranibizumab (PDS) (RG6321)</b> Diabetic macular edema	<b>GYM329/RG6237</b> FSHD*
<b>ENSPRYNG (SA237/RG6168)</b> Autoimmune encephalitis	<b>ranibizumab (PDS) (RG6321)</b> nAMD	<b>GYM329/RG6237</b> SMA* + EVRYSDI
<b>tiragolumab + TECENTRIQ (RG6058 + RG7446)</b> Esophageal cancer	<b>TECENTRIQ + AVASTIN (RG7446 + RG435)</b> HCC (intermediate stage)	<b>divarasib (RG6330)</b> ★ 2L NSCLC
<b>tiragolumab + TECENTRIQ (RG6058 + RG7446)</b> NSCLC (Stage III)	<b>TECENTRIQ (RG7446)</b> MIBC (adj)	<b>glofitamab (RG6026)</b> Previously untreated LBCL + Polivy
<b>tiragolumab (RG6058)</b> 1L NSCLC + TECENTRIQ	<b>mosunetuzumab + POLIVY (RG7828 + RG7596)</b> r/r aNHL	<b>giredestrant (RG6171)</b> Breast cancer (adj)

2025

2026

2027 and beyond

# Projects under Development (1/2)



As of October 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>RG6171 / giredestrant</b> - BC (adjuvant) - BC (1L) - BC (1L-3L)	<b>RG7446 / Tecentriq</b> - Alveolar soft part sarcoma
	<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>RG7828 / mosunetuzumab</b> - Follicular lymphoma (2L)	<b>RG7828 / mosunetuzumab</b> - Follicular lymphoma (3L)
	<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 + RG7596 / Polivy</b> - r/r aNHL	
	<b>STA551</b> - Solid tumors	<b>RG6160 / cevostamab</b> - r/r multiple myeloma	<b>RG6058 / tiragolumab + RG7446 / Tecentriq</b> - NSCLC (1L) - NSCLC (stage III) - Esophageal cancer	<b>RG6026 / glofitamab + RG7596 / Polivy</b> - Previously untreated large B-cell lymphoma	
	<b>SOF10 (RG6440)</b> - Solid tumors		<b>RG6058 / tiragolumab + RG7446 / Tecentriq + RG435 / Avastin</b> - HCC (1L)	<b>RG6330 / divarasib</b> - NSCLC (2L) ★	
	<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) ★: Projects with advances in stages since July 25, 2024

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)

As of October 25, 2024

	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> - SMA (PII/III) ( <b>Combination with Evrysdi</b> ) - FSHD <b>RG6042 / tominersen</b> - Huntington's disease	<b>SA237 (RG6168) / Enspryng</b> - MOGAD - AIE	<b>SRP-9001(RG6356) / delandistrogene moxeparovec</b> - DMD* ★
<b>Hematology</b>		<b>SKY59 (RG6107) / PiaSky (U.S./EU)</b> - SCD <b>NXT007 (RG6512)</b> - Hemophilia A (PI/II) ★	<b>SKY59 (RG6107) / PiaSky</b> - aHUS	
<b>Ophthalmology</b>	<b>RG6321 / PDS</b> - nAMD (PI/II) - DME (PI/II)		<b>SA237 (RG6168) / Enspryng</b> - TED <b>RG6179/ vamikibart</b> - UME	<b>RG7716 / Vabysmo</b> - Angioid streaks ★
<b>Other</b>	<b>REVN24</b> - Acute diseases <b>GYM329 (RG6237)</b> - Obesity <b>BRY10</b> - Chronic diseases ★	<b>RG6615 / zilebesiran</b> - Hypertension (PI/II)	<b>AMY109</b> - Endometriosis	<p><b>Letters in orange</b> : in-house projects (development in global)  <b>Letters in blue</b> : 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.                      * Sarepta manages the global study, including Japan.                      ★: Projects with advances in stages since July 25, 2024</p>

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 October 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>U.S. FDA BTB (recurrent LGSOC in combination with defactinib)</li> <li>U.S. 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 July 25, 2024

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

As of October 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	<ul style="list-style-type: none"> <li>FDA BLA / EMA MAA accepted in Feb 2024 + consortium countries accepted in May 2024</li> </ul>
				Prurigo nodularis	EMA MAA review	<ul style="list-style-type: none"> <li>FDA BLA / EMA MAA accepted in Feb 2024 (FDA priority review designation for prurigo nodularis) + consortium countries accepted in May 2024</li> <li>Obtained U.S. FDA approval in Aug 2024★</li> </ul>
<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	<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 <i>The Lancet</i>*<sup>1</sup></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 <i>New England Journal of Medicine</i>*<sup>2</sup></li> </ul>
<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 July 25, 2024

# FoundationOne CDx Cancer Genomic Profile -Companion diagnostic indications-

As of October 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 October 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

**Upcoming events:**  
**R&D Meeting December 17, 1:00-3:00 p.m. (JST)**

# **FY2024 Q3 Consolidated Financial Overview(Core)**

**Iwaaki Taniguchi**

Executive Vice President & CFO

# P/L Jan – Sep (Year on Year)

(Billions of JPY)	2023	2024	Growth	
<b>Revenue</b>	<b>837.6</b>	<b>868.5</b>	+ 30.9	+ 3.7%
Sales	742.1	750.3	+ 8.2	+ 1.1%
Domestic	429.2	331.7	- 97.5	- 22.7%
Overseas	312.9	418.7	+ 105.8	+ 33.8%
Other revenue	95.5	118.2	+ 22.7	+ 23.8%
Cost of sales	-320.2	-244.1	+ 76.1	- 23.8%
(cost to sales ratio)	43.1%	32.5%	-10.6%p	-
Research and development	-121.7	-127.9	- 6.2	+ 5.1%
Selling, general and administration	-71.4	-72.5	- 1.1	+ 1.5%
Other operating income (expense)	16.3	2.4	- 13.9	- 85.3%
<b>Operating profit</b>	<b>340.5</b>	<b>426.6</b>	+ 86.1	+ 25.3%
(operating margin)	40.7%	49.1%	+8.4%p	-
Financial account balance	3.5	-1.1	- 4.6	-
Income taxes	-93.8	-124.2	- 30.4	+ 32.4%
<b>Net income</b>	<b>250.3</b>	<b>301.3</b>	+ 51.0	+ 20.4%
<b>EPS (JPY)</b>	<b>152.11</b>	<b>183.09</b>	+30.98	+ 20.4%

## 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 one-time income and income related to Hemlibra

## Cost of sales

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

## Research and development expenses

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

## Selling, general and administration expenses

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

## Other operating income (expense)

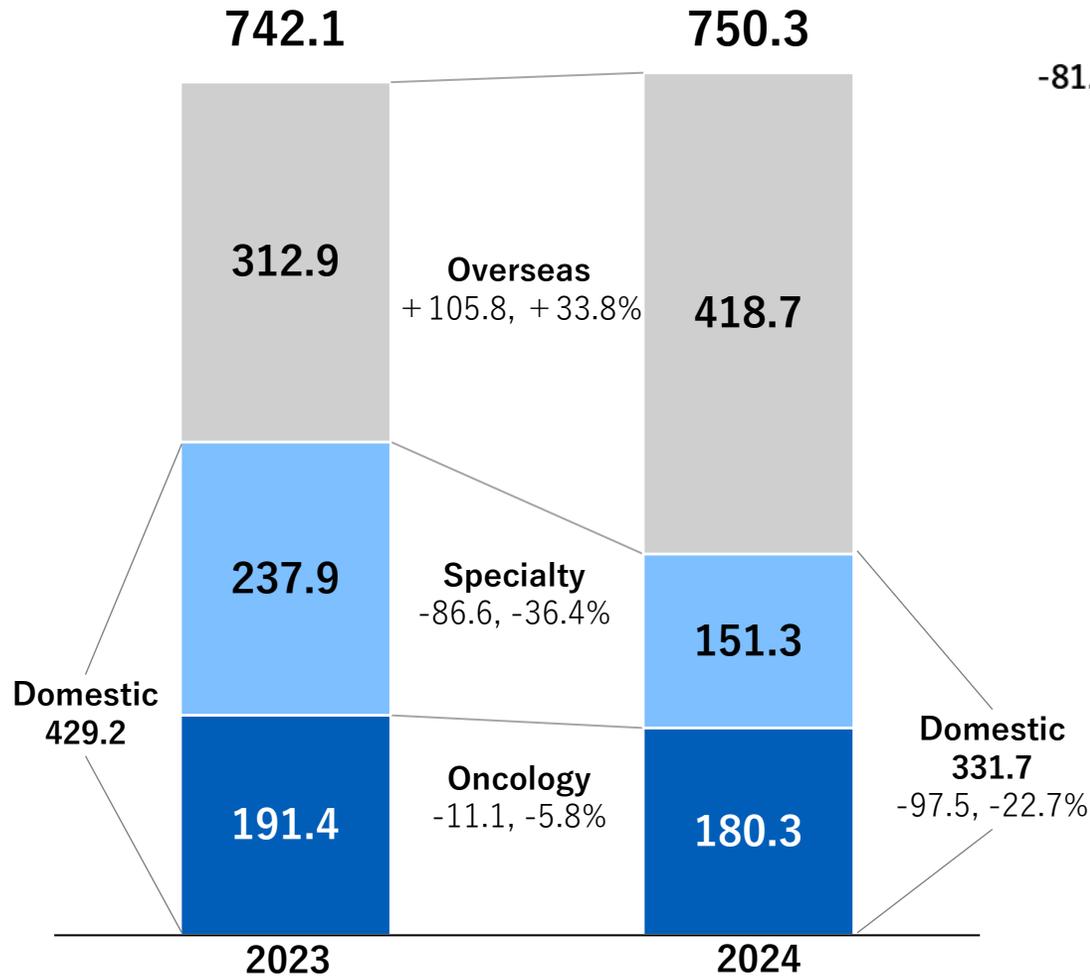
2.4 billion JPY of income from disposal of product rights, etc. was recorded

(Income from disposal of product rights and gain on sales of property, plant and equipment, etc. were recorded, resulted in 16.3 billion JPY of income in the same period of the previous year)

# Sales Jan – Sep (Year on Year)

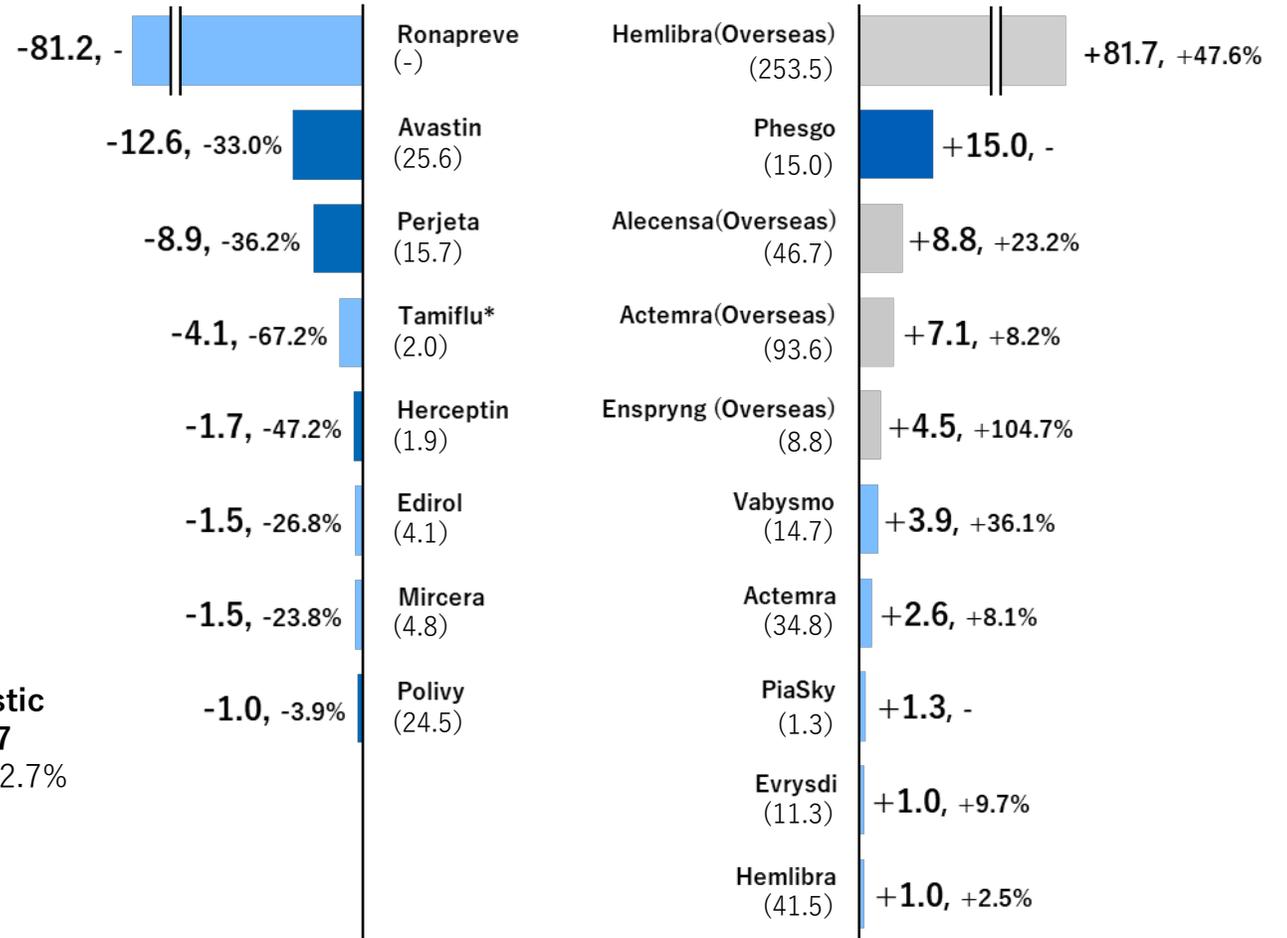
(Billions of JPY)

Sales by Disease Area,  
Year on Year  
+8.2, +1.1%



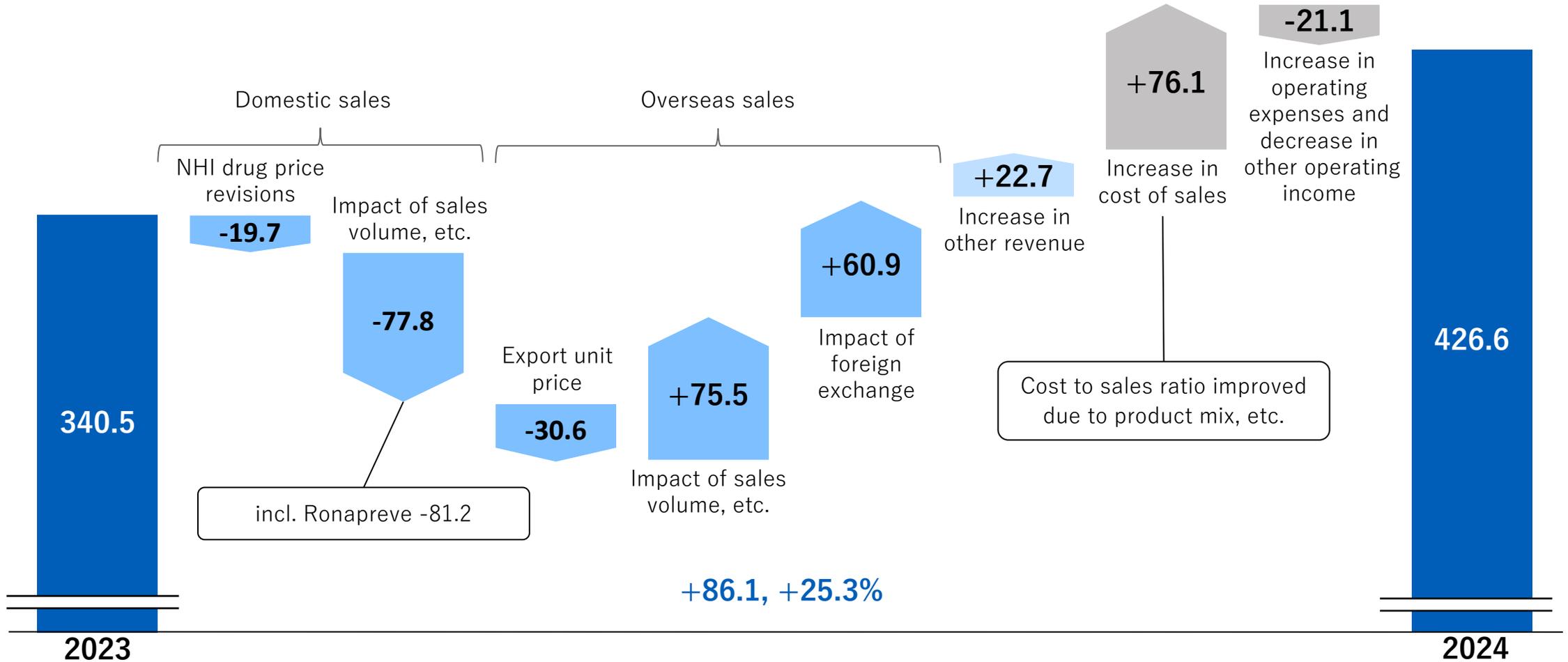
Sales by Product,  
Year on Year

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



# Operating Profit Jan – Sep (Year on Year)

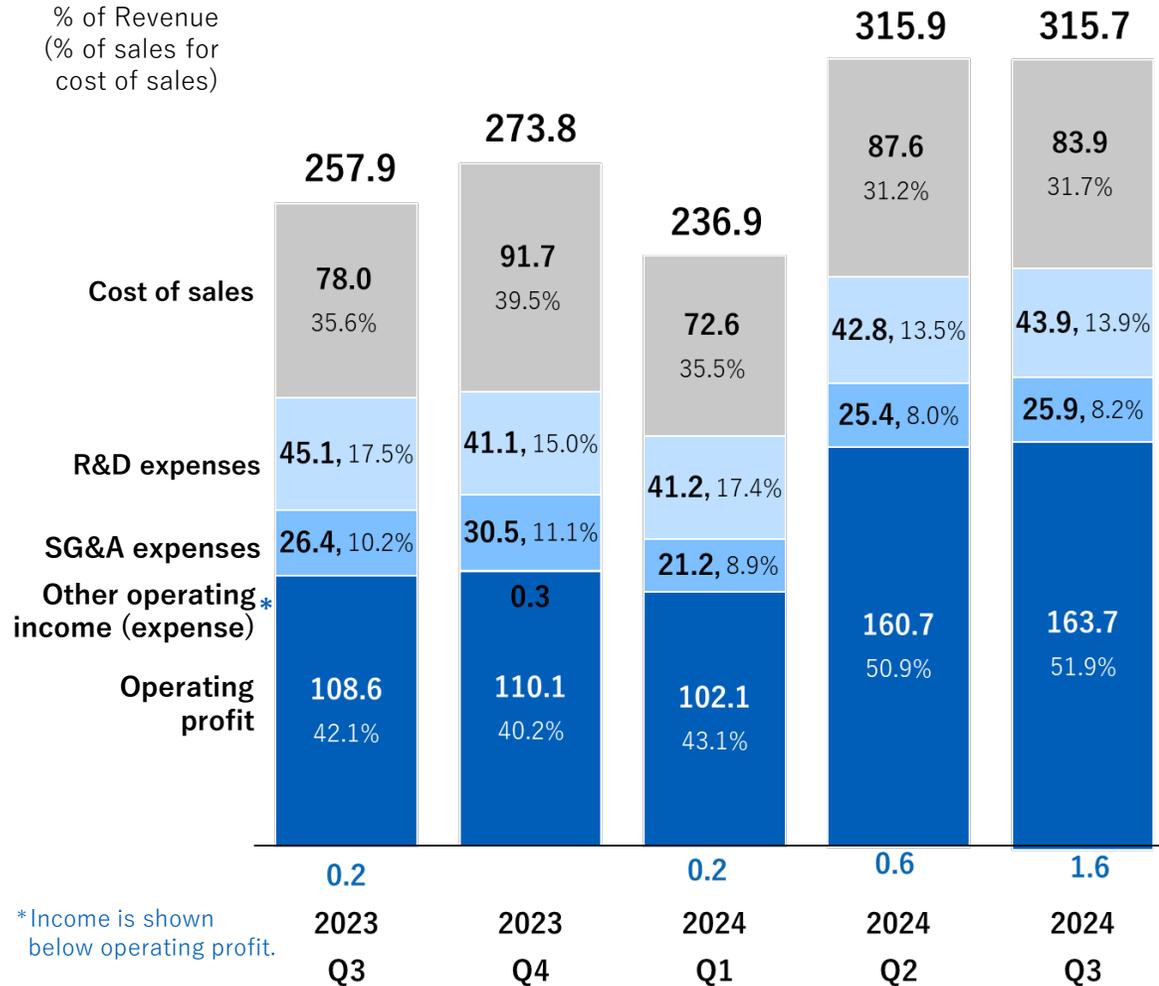
(Billions of JPY)



# 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 Q3)

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

**R&D:** same level as the same period of the previous year

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

**Other operating income (expense):** increase in income from disposal of product rights, etc.

**Operating profit:** +55.1 billion JPY, +50.7%

## Quarter on Quarter (vs. 2024 Q2)

**Cost of sales ratio:** same level as the previous quarter

**R&D:** same level as the previous quarter

**SG&A:** same level as the previous quarter

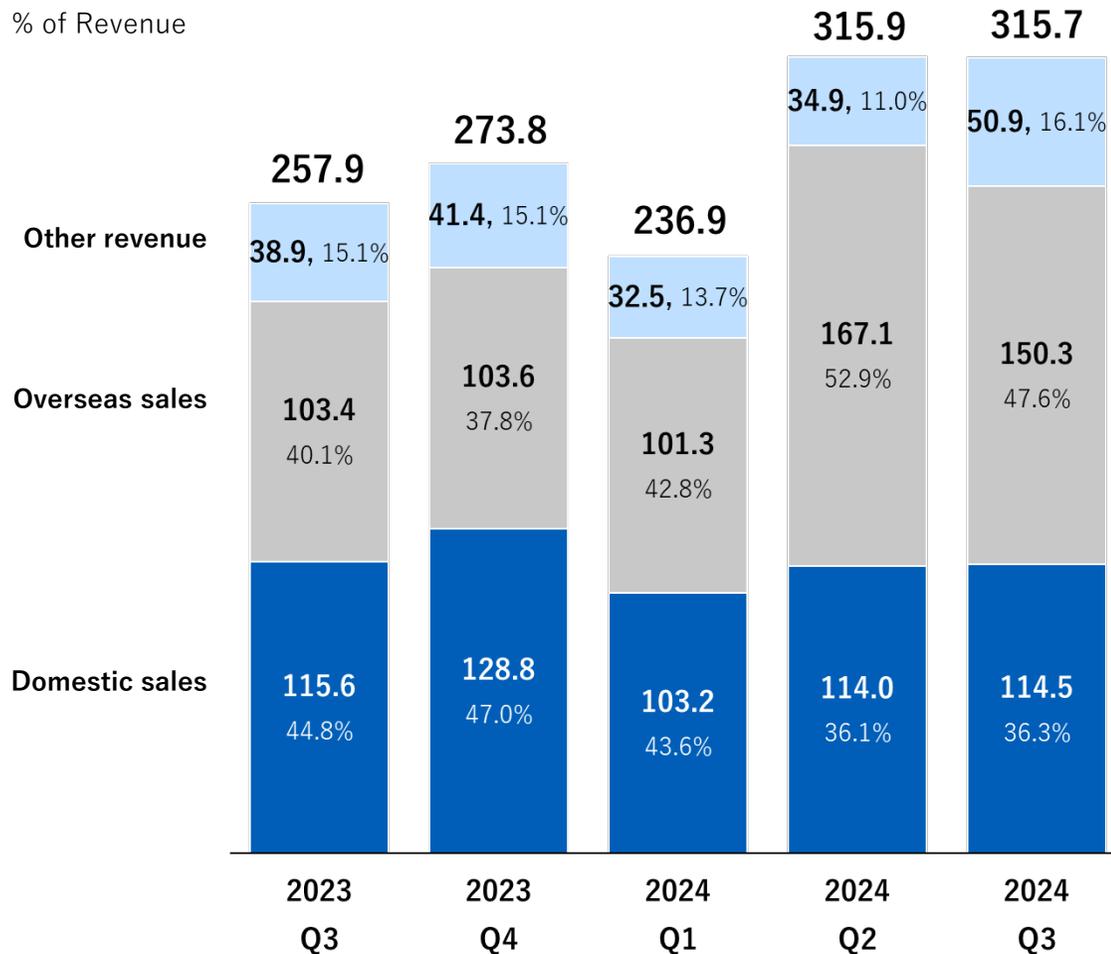
**Other operating income (expense):** increase due to income from disposal of product rights, etc.

**Operating profit:** +3.0 billion JPY, +1.9%

# Structure of Revenue by Quarter

(Billions of JPY)

% of Revenue



## Year on Year (vs. 2023 Q3)

**Domestic sales:** decrease due to the market penetration of generic drugs and the NHI drug price revisions, etc.

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

**Other revenue:** increase mainly due to an increase in milestone income

## Quarter on Quarter (vs. 2024 Q2)

**Domestic sales:** same level as the previous quarter

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

**Other revenue:** increase in royalty income of Hemlibra in addition to the increase mainly due to an increase in milestone income

# P/L Jan – Dec (Revision of Forecast)

(Billions of JPY)	Original	Revised	Revision		Year-on-Year	
	Forecast	Forecast				
	2024 Jan - Dec	2024 Jan - Dec				
<b>Revenue</b>	<b>1,070.0</b>	<b>1,150.0</b>	<b>+80.0</b>	<b>+7.5%</b>	<b>+38.6</b>	<b>+3.5%</b>
Sales	922.0	986.0	+64.0	+6.9%	+11.5	+1.2%
Domestic	454.9	454.1	- 0.8	-0.2%	- 103.9	-18.6%
Overseas	467.1	531.9	+64.8	+13.9%	+115.4	+27.7%
Other revenue	148.0	164.0	+16.0	+10.8%	+27.1	+19.8%
Cost of sales	- 337.5	- 335.0	+2.5	-0.7%	+77.0	-18.7%
(cost to sales ratio)	36.6%	34.0%	-2.6%p	-	-8.3%p	-
Research and development	- 171.0	- 175.0	- 4.0	+2.3%	- 12.2	+7.5%
Selling, general and administration	- 102.0	- 103.0	- 1.0	+1.0%	- 1.0	+1.0%
Other operating income (expense)	0.5	3.0	2.5	+500.0%	- 13.1	-81.4%
<b>Operating profit</b>	<b>460.0</b>	<b>540.0</b>	<b>+80.0</b>	<b>+17.4%</b>	<b>+89.3</b>	<b>+19.8%</b>
(operating margin)	43.0%	47.0%	+4.0%p	-	+6.4%p	-
<b>Net income</b>	<b>335.5</b>	<b>388.0</b>	<b>+52.5</b>	<b>+15.6%</b>	<b>+54.4</b>	<b>+16.3%</b>
<b>EPS (JPY)</b>	<b>204.00</b>	<b>236.00</b>	<b>+32.00</b>	<b>+15.7%</b>	<b>+33.29</b>	<b>+16.4%</b>
<b>Annual Dividend (JPY)</b>	<b>82.00</b>	<b>Undecided</b>	-	-	-	-

## Main reasons for revision:

### Domestic sales

Reflects the progress and revised assumptions for each product

### Overseas sales

Mainly exports of Hemlibra and Actemra to Roche will exceed the original forecast

### Other revenue

One-time income and royalty income, etc. will exceed the original forecast

### Cost of sales

Reflects the improvement in cost to sales ratio due to the change in product mix from the original forecast and to other factors

## vs. Year on Year:

Expects increases in revenues and profits by revenues+3.5%, operating profit+19.8%

# Sales Jan – Dec (Revision of Forecast)

(Billions of JPY)	Original Forecast	Revised Forecast	Revision		Year-on-Year	
	2024 Jan - Dec	2024 Jan - Dec				
<b>Sales</b>	<b>922.0</b>	<b>986.0</b>	<b>+64.0</b>	<b>+6.9%</b>	<b>+11.5</b>	<b>+1.2%</b>
<b>Domestic</b>	<b>454.9</b>	<b>454.1</b>	<b>- 0.8</b>	<b>-0.2%</b>	<b>- 103.9</b>	<b>-18.6%</b>
<b>Oncology</b>	<b>246.5</b>	<b>246.0</b>	<b>- 0.5</b>	<b>-0.2%</b>	<b>- 14.2</b>	<b>-5.5%</b>
<b>Specialty</b>	<b>208.4</b>	<b>208.1</b>	<b>- 0.3</b>	<b>-0.1%</b>	<b>- 89.7</b>	<b>-30.1%</b>
<b>Overseas</b>	<b>467.1</b>	<b>531.9</b>	<b>+64.8</b>	<b>+13.9%</b>	<b>+115.4</b>	<b>+27.7%</b>
Hemlibra	267.3	304.0	+36.7	+13.7%	+91.7	+43.2%
Actemra	109.8	131.0	+21.2	+19.3%	+3.5	+2.7%
Alecensa	58.9	63.3	+4.4	+7.5%	+7.6	+13.6%
Enspryng	6.4	13.8	+7.4	+115.6%	+9.6	+228.6%
Neutrogin	6.8	8.2	+1.4	+20.6%	+0.1	+1.2%
Edirol	1.8	0.4	- 1.4	-77.8%	+0.3	+300.0%
Other	16.1	11.1	- 5.0	-31.1%	+2.6	+30.6%

## Main reasons for revision: (Billions of JPY)

<b>Oncology</b>	<b>-0.5</b>
Polivy	-3.4
Perjeta	-2.1
Tecentriq	-1.3
Phesgo	+7.0
<b>Specialty</b>	<b>-0.3</b>
Vabysmo	-2.2
Evrysdi	-0.8
Actemra	+1.9
Enspryng	+1.9
<b>Overseas</b>	<b>+64.8</b>
Hemlibra	+36.7
Actemra	+21.2
Enspryng	+7.4

# Impact from Foreign Exchange Jan – Sep

(Billions of JPY)	vs.2023 Actual rate	vs.2024 Original Forecast rate	Exchange Rate (JPY)	2023 Actual rate* <sup>2</sup>	2024 Original Forecast rate	2024 Actual rate* <sup>2</sup>	2024 Original Forecast rate	2024 Revised Forecast rate
	【C】 vs. 【A】	【C】 vs. 【B】		Jan - Sep 【A】	Jan - Sep 【B】	Jan -Sep 【C】	Jan – Dec	Jan-Dec
<b>Revenue</b>	<b>+74.0</b>	<b>+14.7</b>						
Sales	+60.9	+8.2	<b>1CHF</b>	138.62	157.62	160.43	159.00	161.00
Other revenue	+13.1	+6.5						
<b>Cost of sales</b>	<b>-6.3</b>	<b>-0.7</b>	<b>1EUR</b>	149.03	157.00	163.89	157.00	163.00
<b>Other than above*<sup>1</sup></b>	<b>-3.8</b>	<b>-1.3</b>						
<b>Operating profit</b>	<b>+64.0</b>	<b>+13.4</b>	<b>1USD</b>	133.42	137.41	136.39	136.00	138.00

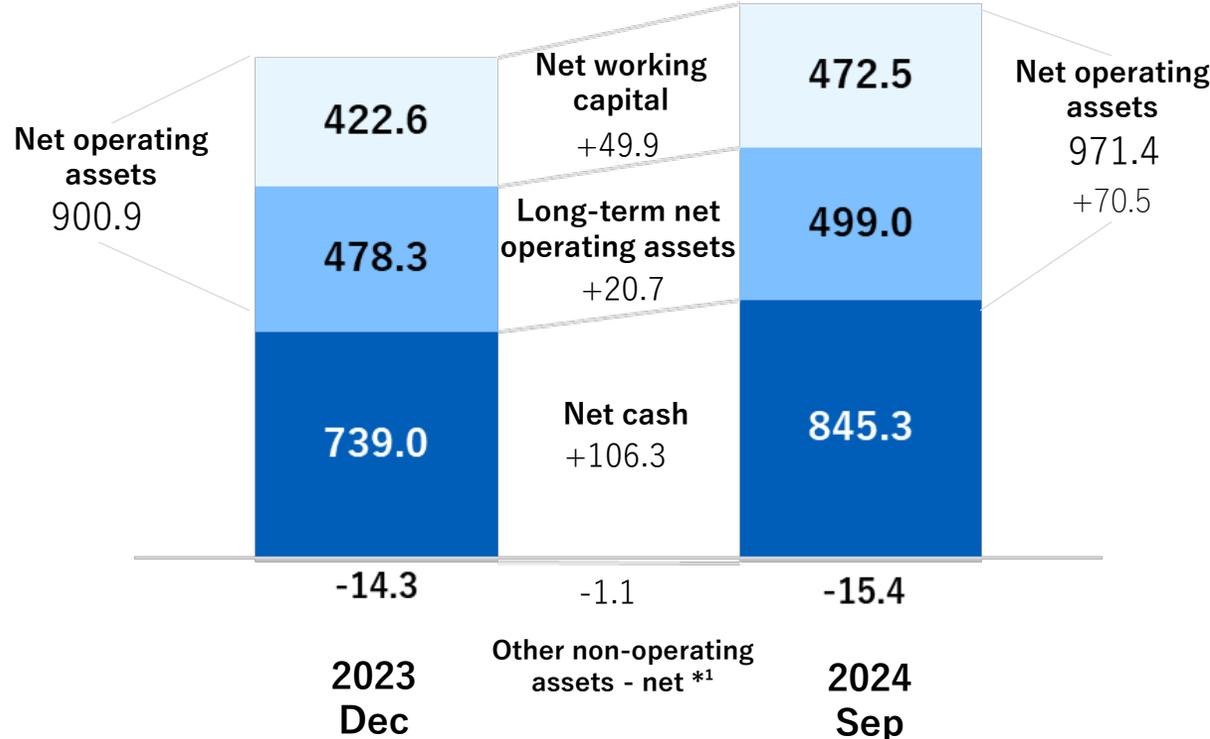
\*1 Total of R&D, SG&A and other operating income (expense)

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

# Financial Position (vs. 2023 Year End)

(Billions of JPY)

Total assets	1,932.5	+137.2	2,069.7
Total liabilities	-307.0	+38.6	-268.4
	<b>1,625.6</b>	<b>Total net assets +175.8</b>	<b>1,801.4</b>



	-14.3	-1.1	-15.4
	<b>2023 Dec</b>	<b>Other non-operating assets - net *1</b>	<b>2024 Sep</b>

Ratio of equity attributable to Chugai shareholders

84.1%	+2.9%p	87.0%
-------	--------	-------

## Increase in net working capital

Increase due to an increase in accounts receivable and a decrease in accounts payable purchase of property, plant and equipment, etc.

## Increase in long-term net operating assets

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

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

## Increase in net cash

(See next page)

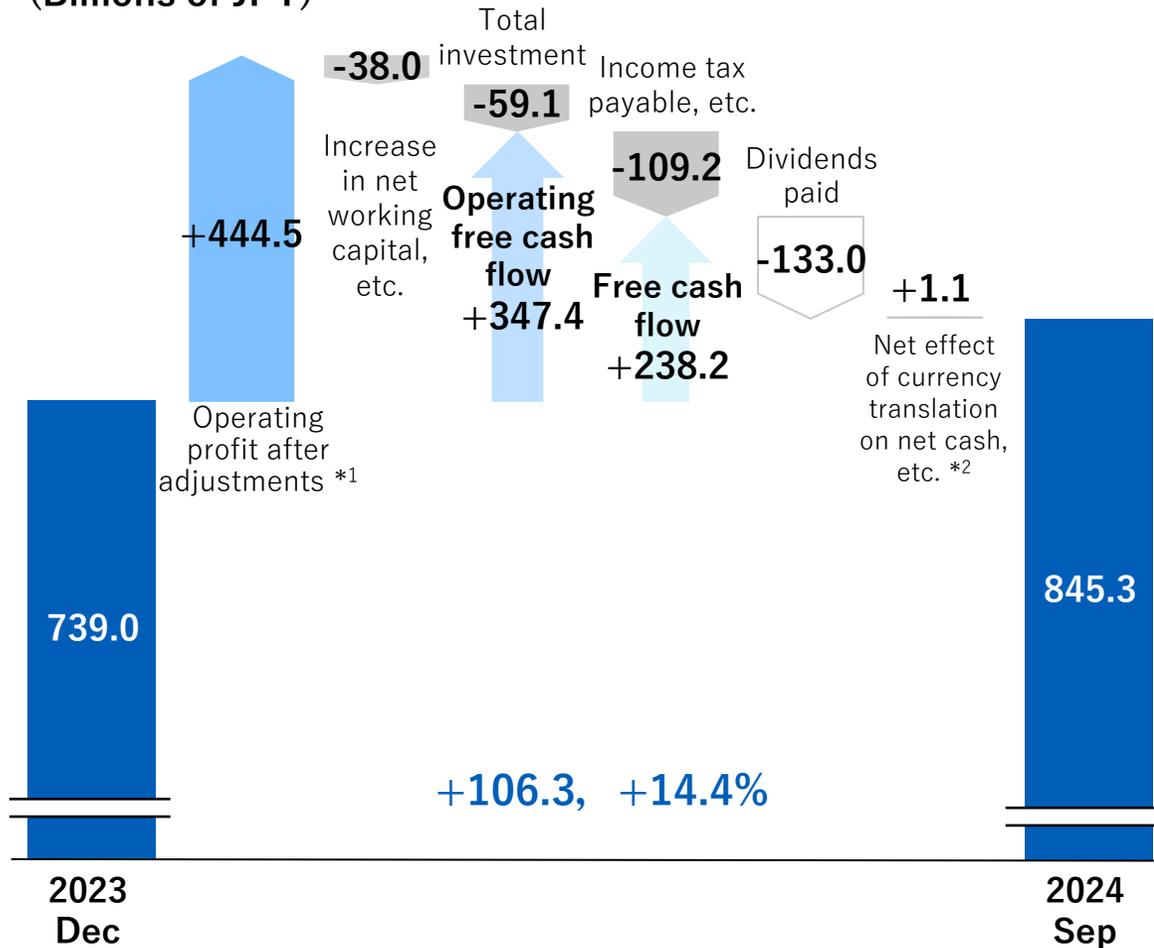
## Decrease in other non-operating assets – net

Decrease mainly due to increase in current income tax liabilities

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

# Net Cash (vs. 2023 Year End)

(Billions of JPY)



<b>Operating profit after adjustment *1</b>	<b>+444.5</b>
Operating profit *1	+418.6
Depreciation, amortization and impairment *1	+24.7
<b>Increase in net working capital, etc.</b>	<b>-38.0</b>
<b>Total investment</b>	<b>-59.1</b>
Property, plant and equipment	-50.2
Payment for lease liabilities	-6.1
Intangible assets	-2.9
<b>Operating free cash flows</b>	<b>+347.4</b>
<b>Income tax payable, etc.</b>	<b>-109.2</b>
Income tax payable	-100.4
<b>Free cash flows</b>	<b>+238.2</b>
<b>Dividends paid</b>	<b>-133.0</b>
<b>Net effect of currency transaction on net cash, etc. *2</b>	<b>+1.1</b>

\*1 Including Non-Core (IFRS results)

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

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

# P/L Jan – Sep (Non-core adjustment)

(Billions of JPY)	IFRS results	Non-core items		Core results
		Intangible assets	Others	
<b>Revenue</b>	<b>868.5</b>			<b>868.5</b>
Sales	750.3			750.3
Other revenue	118.2			118.2
Cost of sales	-245.1	+1.0		-244.1
Research and development	-129.2	+1.3	+0.1	-127.9
Selling, general and administration	-77.7		+5.2	-72.5
Other operating income (expense)	2.1		+0.4	2.4
<b>Operating profit</b>	<b>418.6</b>	<b>+2.3</b>	<b>+5.7</b>	<b>426.6</b>
Financial account balance	-1.1			-1.1
Income taxes	-121.8	-0.7	-1.7	-124.2
<b>Net income</b>	<b>295.8</b>	<b>+1.6</b>	<b>+4.0</b>	<b>301.3</b>
<b>EPS (JPY)</b>	<b>179.72</b>			<b>183.09</b>

## Non-core items

(Billions of JPY)

### Factors affected operating profit

#### Intangible assets

Amortization	+1.2
Impairment	+1.0

#### Others

Business rebuilding expenses	+5.2
Restructuring expenses	+0.5

# P/L Jan – Sep (vs. Forecast)

(Billions of JPY)	Actual	Original Forecast	Revised Forecast	2023 Progress*	
	2024 Jan -	2024 Jan - Dec	2024 Jan - Dec Progress		
<b>Revenue</b>	<b>868.5</b>	<b>1,070.0</b>	<b>1,150.0</b>	<b>75.5%</b>	<b>75.4%</b>
Sales	750.3	922.0	986.0	76.1%	76.2%
Domestic	331.7	454.9	454.1	73.0%	76.9%
Overseas	418.7	467.1	531.9	78.7%	75.1%
Other revenue	118.2	148.0	164.0	72.1%	69.8%
Cost of sales	- 244.1	- 337.5	- 335.0	72.9%	77.7%
(cost to sales ratio)	32.5%	36.6%	34.0%	-	-
Research and development	- 127.9	- 171.0	- 175.0	73.1%	74.8%
Selling, general and administration	- 72.5	- 102.0	- 103.0	70.4%	70.0%
Other operating income (expense)	2.4	0.5	3.0	80.0%	101.2%
<b>Operating profit</b>	<b>426.6</b>	<b>460.0</b>	<b>540.0</b>	<b>79.0%</b>	<b>75.5%</b>
(operating margin)	49.1%	43.0%	47.0%	-	-
<b>Net Income</b>	<b>301.3</b>	<b>335.5</b>	<b>388.0</b>	<b>77.7%</b>	<b>75.0%</b>
<b>EPS (JPY)</b>	<b>183.09</b>	<b>204.00</b>	<b>236.00</b>	<b>77.6%</b>	<b>75.0%</b>

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

# Sales Jan – Dec (Revision of Forecast)

(Billions of JPY)	Actual 2024 Jan - Sep	Original		2023 Progress *	
		Forecast 2024 Jan - Dec	Revised Forecast 2024 Jan - Dec		Progress
<b>Sales</b>	<b>750.3</b>	<b>922.0</b>	<b>986.0</b>	<b>76.1%</b>	<b>76.2%</b>
<b>Domestic</b>	<b>331.7</b>	<b>454.9</b>	<b>454.1</b>	<b>73.0%</b>	<b>76.9%</b>
<b>Oncology</b>	<b>180.3</b>	<b>246.5</b>	<b>246.0</b>	<b>73.3%</b>	<b>73.6%</b>
Tecentriq	47.4	66.2	64.9	73.0%	73.1%
Avastin	25.6	33.9	33.9	75.5%	76.7%
Polivy	24.5	37.3	33.9	72.3%	71.8%
Alecensa	22.4	31.3	31.3	71.6%	72.6%
Phesgo	15.0	15.5	22.5	66.7%	0.0%
Perjeta	15.7	22.0	19.9	78.9%	73.2%
Kadcyla	12.2	16.2	16.6	73.5%	73.1%
Herceptin	1.9	2.2	2.2	86.4%	75.0%
Foundation Medicine	5.8	7.1	7.7	75.3%	75.7%
Other	9.9	14.8	13.1	75.6%	72.9%

(Billions of JPY)	Actual 2024 Jan - Sep	Original		2023 Progress *	
		Forecast 2024 Jan - Dec	Revised Forecast 2024 Jan - Dec		Progress
<b>Specialty</b>	<b>151.3</b>	<b>208.4</b>	<b>208.1</b>	<b>72.7%</b>	<b>79.9%</b>
Hemlibra	41.5	56.5	56.8	73.1%	73.9%
Actemra	34.8	45.9	47.8	72.8%	72.7%
Enspryng	17.8	22.4	24.3	73.3%	70.7%
Vabysmo	14.7	22.8	20.6	71.4%	70.6%
Evrysdi	11.3	16.5	15.7	72.0%	71.0%
Mircera	4.8	6.8	6.8	70.6%	75.0%
CellCept	4.7	6.3	6.3	74.6%	74.3%
Edirol	4.1	5.6	5.2	78.8%	74.7%
PiaSky	1.3	1.8	2.3	56.5%	-
Ronapreve	-	-	-	-	100.0%
Other	16.2	23.9	22.4	72.3%	70.9%
<b>Overseas</b>	<b>418.7</b>	<b>467.1</b>	<b>531.9</b>	<b>78.7%</b>	<b>75.1%</b>
Hemlibra	253.5	267.3	304.0	83.4%	80.9%
Actemra	93.6	109.8	131.0	71.5%	67.8%
Alecensa	46.7	58.9	63.3	73.8%	68.0%
Enspryng	8.8	6.4	13.8	63.8%	102.4%
Neutrogin	6.7	6.8	8.2	81.7%	74.1%
Edirol	0.3	1.8	0.4	75.0%	100.0%
Other	9.0	16.1	11.1	81.1%	72.9%

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

# Summary of Chugai Originated Global Products

Product (Billions of JPY)	FY2024 Q3 Results	Year on Year	Revised Forecast	Comments
<b>Hemlibra</b> <sup>®</sup>	Domestic: <b>41.5</b>	+2.5%	<b>56.8</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 the initial expectation</li> <li>- · We provide value to patients worldwide through convenience and accumulated clinical evidence</li> </ul>
	Export: <b>253.5</b>	+47.6%	<b>304.0</b>	
	Overseas local: <b>3,021</b> mCHF	+10%	-	
<b>Actemra</b> <sup>®</sup>	Domestic: <b>34.8</b>	+8.1%	<b>47.8</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 below the initial expectation, with steady progress in local sales. Exports are progressing well</li> <li>- · We provide value to patients through the established evidence as an originator of IL-6 inhibitors</li> </ul>
	Export: <b>93.6</b>	+8.2%	<b>131.0</b>	
	Overseas local: <b>1,723</b> mCHF	+4%	-	
<b>Alecensa</b> <sup>®</sup>	Domestic: <b>22.4</b>	+1.8%	<b>31.3</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 the initial expectation</li> <li>- · Expanded indication for NSCLC adj. will further contribute to the treatment of patients</li> </ul>
	Export: <b>46.7</b>	+23.2%	<b>63.3</b>	
	Overseas local: <b>1,007</b> mCHF	+8%	-	
<b>Enspryng</b> <sup>®</sup>	Domestic: <b>17.8</b>	+5.3%	<b>24.3</b>	<ul style="list-style-type: none"> <li>· Japan: Sales increased YoY despite this year's drug price revision<sup>*2</sup> in April</li> <li>· Overseas: Sales increased in all regions. Exports are progressing better than the initial expectation</li> <li>- · We provide a convenient treatment option for patients who wish to avoid steroids</li> </ul>
	Export: <b>8.8</b>	+104.7%	<b>13.8</b>	
	Overseas local: <b>117</b> mCHF	+62%	-	

\* "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

Q3 2023	Q4 2023	Q1 2024	Q2 2024	Q3 2024
31.7%	32.5%	33.2%	33.8%	34.9%

# 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	53.8	billion JPY	2021	2024	
	Utsunomiya plant	UT3: Manufacture bio drug substance for middle to later-stage clinical development and early commercial use						37.4	12.3	billion JPY	2023	2026	
	Utsunomiya plant	UTA: Manufacture sterile injectables for early commercial use						19.0	6.2	billion JPY	2023	2025	
	Ukima plant	UK3(modification): Manufacture bio drug substance						20.3	0.2	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	7.5	billion JPY	2017	2027	
Environment	Environmental investment*	Equipment upgrade to achieve Mid-Term Environmental Goals 2030						109.5 estimated total amount	3.7	billion JPY	2022	2033	

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

# Contacts

## Corporate Communications Dept.

### For Media: Media Relations Group

**Tel :** +81 (0)3-3273-0881

**E-mail :** [pr@chugai-pharm.co.jp](mailto:pr@chugai-pharm.co.jp)

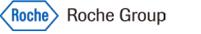
**Person in charge :** Hideki Sato, Shumpei Yokoyama, Naoki Kouzai, Ikue Miyazawa, Mari Otsuka

### For Investors: Investor Relations Group

**Tel :** +81 (0)3-3273-0554

**E-mail :** [ir@chugai-pharm.co.jp](mailto:ir@chugai-pharm.co.jp)

**Person in charge :** Takayuki Sakurai, Tomoyuki Shimamura, Shumpei Yokoyama, Sachiyo Yoshimura, Yayoi Yamada, Yuri Ikegaya



# INNOVATION BEYOND IMAGINATION