

# Conference on FY2023.12 Q3 Financial Results

**CHUGAI PHARMACEUTICAL CO., LTD.**

24 October 2023



# Important Reminder

## Forward-Looking Statements

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

## Core Results

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

Note:

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

# Agenda

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**Dr. Osamu Okuda**

President & CEO

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**Tetsuya Yamaguchi**

Executive Vice President, Head of Project &  
Lifecycle Management Unit

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## FY2023 Q3 Consolidated Financial Overview (Core)

**Toshiaki Itagaki**

Director, Executive Vice President & CFO

# FY2023 Q3 Overview

**Dr. Osamu Okuda**

President & CEO

# Financial Overview

- Increases in revenue and profits were mainly driven by good penetration of new/mainstay products and steady growth of exports to Roche
- Due to steady growth of domestic and overseas sales, the company expects to achieve the initial full year target, with no changes to the initial forecast

Core (billions of JPY)	2022 Jan - Sep actual*	2023 Jan - Sep actual	Growth		2023 Jan - Dec forecast	Progress (%)
<b>Revenue</b>	<b>729.3</b>	<b>837.6</b>	<b>+108.3</b>	<b>+14.8%</b>	<b>1,070.0</b>	<b>78.3%</b>
Domestic sales	387.6	429.2	+41.6	+10.7%	541.7	79.2%
Overseas sales	257.1	312.9	+55.8	+21.7%	378.3	82.7%
Other revenue	84.6	95.5	+10.9	+12.9%	150.0	63.7%
<b>Operating profit</b>	<b>299.0</b>	<b>340.5</b>	<b>+41.5</b>	<b>+13.9%</b>	<b>415.0</b>	<b>82.0%</b>
Operating margin	41.0%	40.7%	-0.3%pts	-	38.8%	-
<b>Net income</b>	<b>213.0</b>	<b>250.3</b>	<b>+37.3</b>	<b>+17.5%</b>	<b>306.0</b>	<b>81.8%</b>
<b>EPS (yen)</b>	<b>129.48</b>	<b>152.11</b>	<b>+22.63</b>	<b>+17.5%</b>	<b>186.00</b>	<b>81.8%</b>

- Domestic sales grew due to the good market penetration of new/mainstay products and the supply of Ronapreve to the government despite the impact of NHI drug price revision and generics.
- Overseas sales significantly increased mainly due to Hemlibra and Alecensa exports to Roche.
- Other revenue increased mainly due to the increase of Hemlibra related income.

## Hemlibra: Patient Share in Hemophilia A in Japan

Q3 2022	Q4 2022	Q1 2023	Q2 2023	Q3 2023
28.5%	29.2%	30.0%	30.8%	31.7%

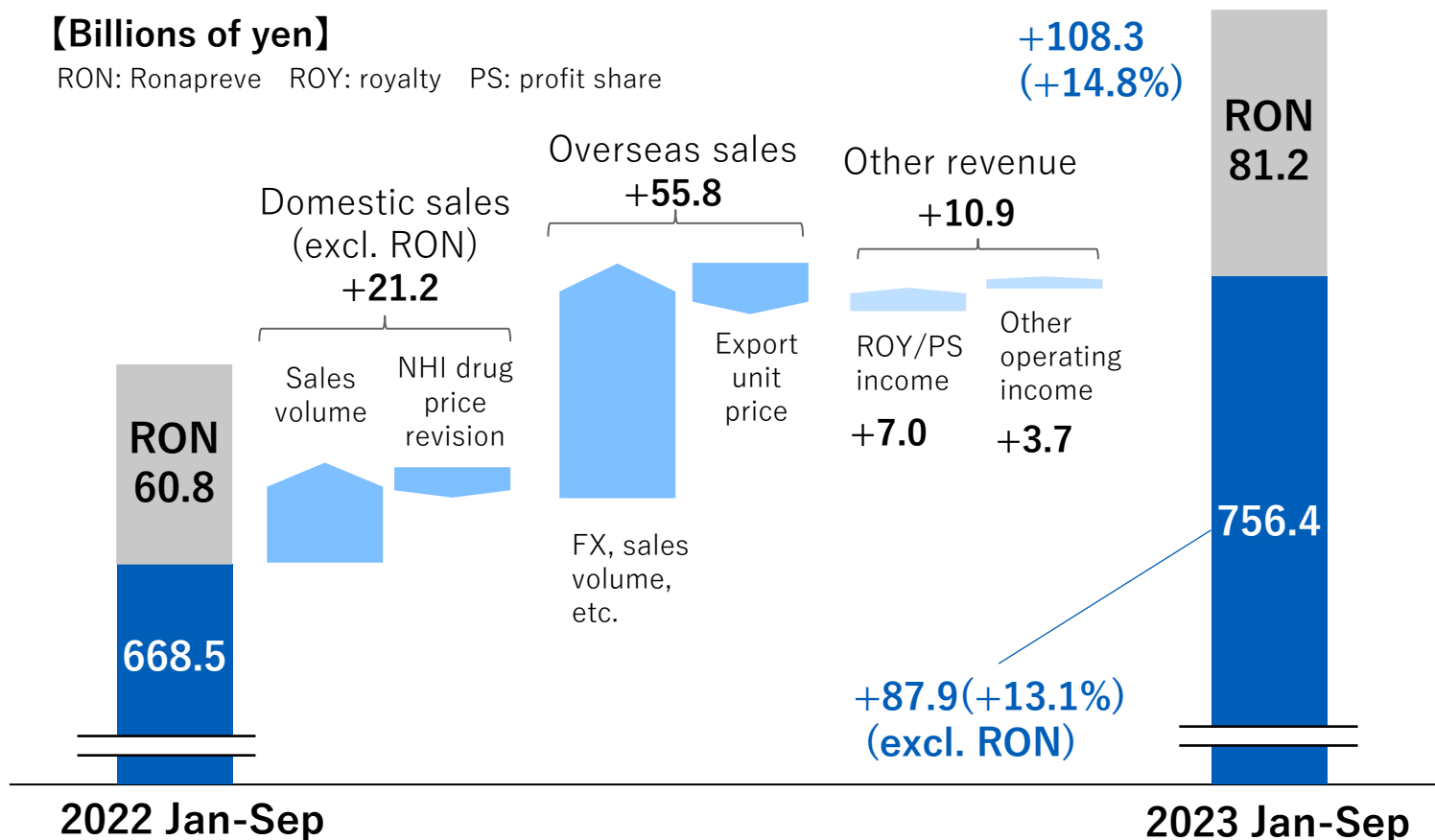
\* Starting from FY 2023, Chugai has excluded income from disposal of product rights from revenue. In conjunction with this change, the results for FY 2022 have been restated accordingly.

# Topline Overview

- Domestic sales (excl. Ronapreve) increased due to the steady penetration of new/mainstay products despite the negative impact from NHI drug price revision and others
- Overseas sales significantly increased driven by the impacts of foreign exchange rates and higher sales volume, which outweighed the decline in export unit price
- In other revenue, both royalty income and other operating income increased

【Billions of yen】

RON: Ronapreve ROY: royalty PS: profit share



- Domestic sales (excl. RON) increased due to growth of the new products such as Polivy and Vabysmo, as well as the favorable sales of the mainstay products including Enspryng, Hemlibra, and Tecentriq, absorbing the negative impacts of NHI drug price revision and the erosion caused by generic drugs. Progress was mostly in line with the initial forecast.
- Overseas sales increased significantly by FX impact and higher sales volume, surpassing the decline in export unit price. Export of Hemlibra significantly increased and export of Alecensa progressed well. Progress was more favorable than expected.
- Other revenue increased overall primarily due to the increase in royalties related to the intellectual property rights and profit-sharing income of Hemlibra. Progress was mostly in line with forecast.

# Progress in 2023 toward Sustainable Growth

- Steady progress in in-house drug projects contributing to sustainable growth, despite the negative impact expected from the competitive environment against Actemra and other factors

## Short to mid-term drivers



### Further growth of mainstay products

- **Hemlibra:** Obtained additional indication for Hemophilia A(moderate) in EU. Expansion of market share
- **Alecensa:** Met primary endpoints in ALK+ early NSCLC(P3). Sales growth in domestic and overseas market

### Continuous launch and market penetration of in-house products

- **crovalimab:** Filed in JP, U.S., EU (expected approval next year)
- **nemolizumab(overseas):** Met primary endpoints in AD/PN(overseas P3) \*
- **nemolizumab(domestic):** Filed for additional indication(pruritus with AD/PN)\*\*
- **Enspryng:** Simultaneous development progress in gMG/MOGAD/AIE/TED
- **orforglipron:** Started P3 for Diabetes/Obesity\*\*\*

### Stable revenues from Roche products

- **Tecentriq, Polivy, Evrysdi, etc.:** Steady market penetration
- **Vabysmo:** Steady growth, filed for additional indication for RVO, development started for AS
- **Phesgo:** Obtained approval (to be launched within 2023)
- **tiragolumab, etc.:** Initiation and progress of consecutive late-stage development projects

\*Out-licensed to Galderma overseas \*\*Out-licensed to Maruho in Japan \*\*\*Out-licensed to Eli Lilly and Company

## Mid to long-term drivers



### Initiating P1 for in-house products

- **ALPS12**
- **SAIL66**
- **ROSE12**

### Continuous development of next-generation products

- **NXT007:** Presentation on healthy volunteer part in medical conference
- **GYM329:** Simultaneous development in SMA/FSHD
- **LUNA18:** Confirmation of oral absorption
- **Mid-size molecule:** Progress in follow-on projects

### Accelerating innovation

- **Chugai LSP Yokohama:** Started full operation
- **CVF:** Preparing to start activities

## Factor of revenue decline (Risk)



### Competitive environment

- **Actemra:** Multiple biosimilars in approved/filed/development stages in EU and the U.S.
- **Avastin, Kadcyla, etc.:** Penetration of biosimilars and changes in competitive landscape

### End of upside effect on COVID-19 related therapies

- **Ronapreve:** Completion of supply to the government
- **Actemra:** Decrease in demand for COVID-19

### NHI drug price revision, etc.

- **Hemlibra, etc.:** Re-pricing for market expansion



# Overview of Development Pipeline

**Tetsuya Yamaguchi**

Executive Vice President, Head of Project & Lifecycle Management Unit



# Q3 Topics (1/2)

As of October 24, 2023

Launched	Enspryng	NMOSD (Taiwan)	October 2023
Approved	Actemra	CRS induced by cancer therapy	September 2023
	Phesgo	“HER2+ BC” and “advanced or recurrent HER2+ CC that has progressed following cancer chemotherapy and is not amenable to curative resection	September 2023
	Rituxan	Lupus nephritis that has not responded sufficiently to existing therapies	August 2023
Initiation of study	Enspryng	TED	P3 study (Q3 2023)
	tiragolumab + Tecentriq + Avastin	1L HCC	P3 study (October 2023)
	Gazyva	Extra renal lupus	P3 study (October 2023)
	RG6139 (tobemstomig)	Solid tumors	P1 study (August 2023)
Phase transition	RG6102 (trontinemab)	Alzheimer’s disease	P1 study → P1/2 study

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

# Q3 Topics (2/2)

As of October 24, 2023

Readout	<b>Alecensa</b>	ALINA study (adjuvant ALK+ NSCLC) met primary endpoint of DFS	September 2023
	<b>Tecentriq + Avastin</b>	BEAT-SC study (1L SCLC) met primary endpoint of PFS	October 2023
	<b>Tecentriq</b>	CONTACT-02 study (2L prostate cancer) met primary endpoint of PFS. Continuous assessment of OS.	August 2023
	<b>tiragolumab + Tecentriq</b>	SKYSCRAPER-01 (1L NSCLC): results from second interim analysis*	August 2023
Medical conference	<b>nemolizumab</b>	ARCADIA 1/2 studies** (AD), OLYMPIA 1 study** (PN): EADV	October 2023
	<b>Alecensa</b>	ALINA study (adjuvant ALK+ NSCLC): ESMO	October 2023
Withdrawal	<b>Actemra</b>	SSc-ILD (EU)	
Removed from pipeline	<b>RG7906 (ralmitaront)</b>	P2 study (schizophrenia): development discontinued	
	<b>RG7802 (cibisatamab)</b>	P1 study (solid tumors): temporary suspension of development	

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

\* The second interim analysis took place in February 2023 and was based on a data cut-off in November 2022.

\*\* Conducted by Galderma, an overseas licensee

# 2023: Key R&D Milestones

Underlined and bolded are new progress since July 27, 2023

	Product	Indication/Study name	Progress
Projects to be approved	<u>Actemra</u>	<u>Systemic sclerosis with interstitial lung disease (SSc-ILD) (EU)</u>	<u>withdrawal</u>
	Hemlibra	Moderate hemophilia A (EU)	approved
	crovalimab	PNH (China)	2024
	<u>RG6264 (PER/HER FDC)</u>	<u>HER2-positive Breast cancer/Colorectal cancer</u>	<u>approved</u>
P3/Pivotal readouts	<u>Alecensa</u>	<u>ALINA study: NSCLC [adjuvant]</u>	<u>met PE</u>
	crovalimab	COMMODORE 1/2 study: PNH	met PE/filed
	nemolizumab	ARCADIA 1/2 study <sup>1</sup> : Atopic dermatitis	met PE
	Tecentriq + Avastin	IMbrave050 study: HCC [adjuvant]	met PE <sup>2</sup>
	Tecentriq	IMpassion030: eBC [adjuvant]	Development discontinued
	Tecentriq	IMvoke010 study: HNC [adjuvant]	
	Tecentriq+ tiragolumab	SKYSCRAPER-01 study: NSCLC [1st line]	2024 Q1
	mosunetuzumab+Polivy	SUNMO study: r/r aNHL	2024
	delandistrogene moxeparvovec	EMBARK study: Duchenne muscular dystrophy (DMD)	

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

1. Conducted by Galderma, an overseas licensee

2. Changes in the expected filing year (2023 → 2024)

# Alecensa: Positive Phase 3 (ALINA) results at ESMO

Expect further patients to be cured by Alecensa as a treatment of adj ALK+ NSCLC

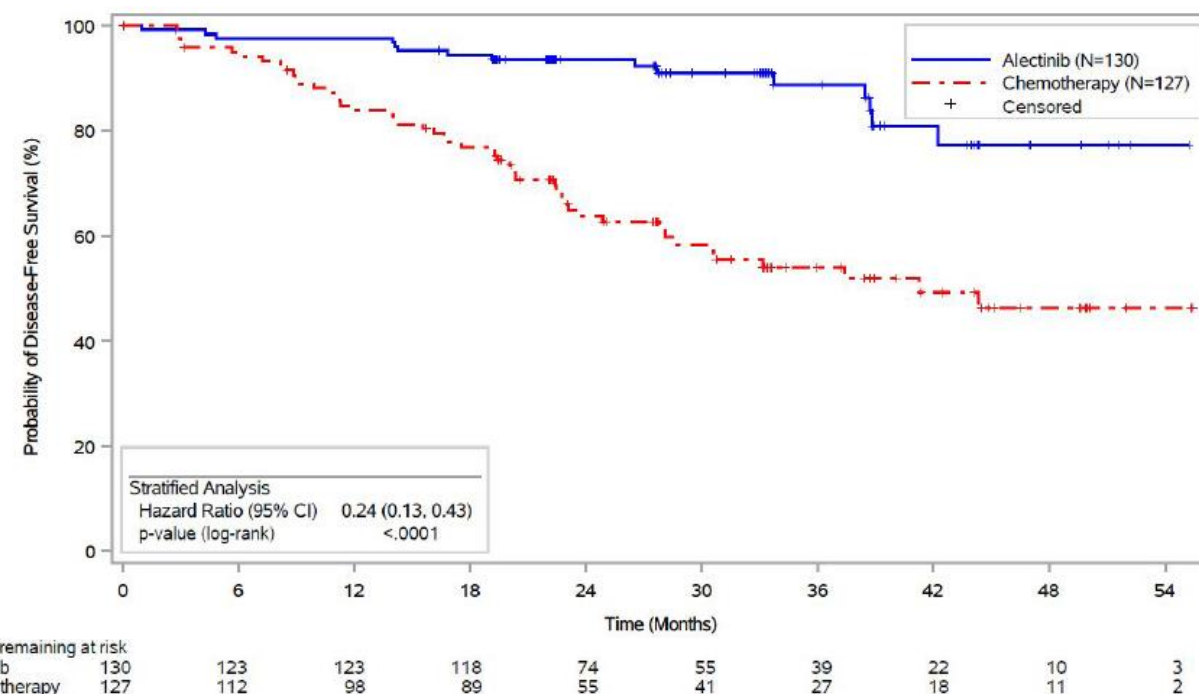
## ■ Efficacy

- Alecensa shows a statistically significant and clinically meaningful improvement compared to chemotherapy in disease-free survival (DFS; primary endpoint) in people with completely resected stage IB to IIIA ALK+ NSCLC
- Alecensa reduces the risk of disease recurrence or death by 76%
- Secondary endpoints of overall survival data were immature at the time of this analysis

## ■ Safety

- No unexpected safety findings were observed

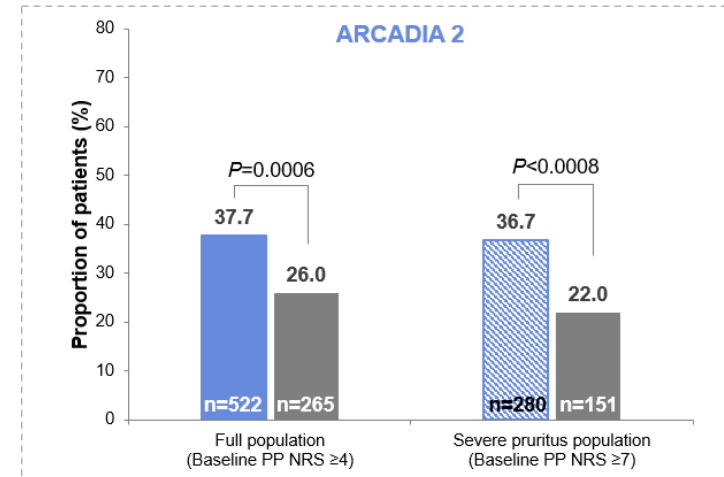
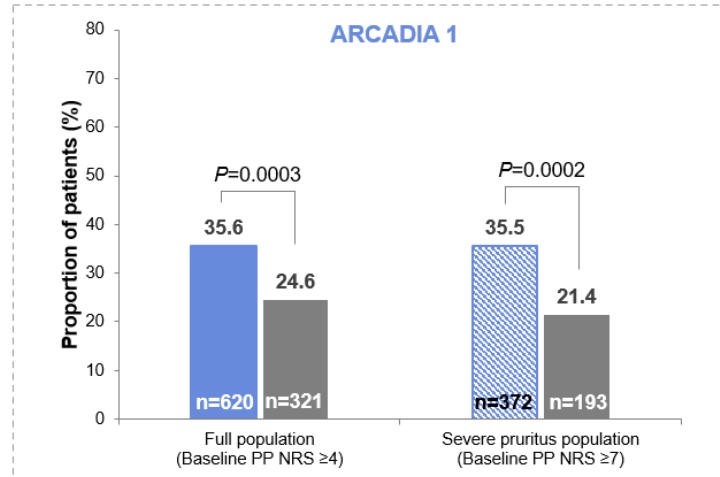
DFS Interim Analysis	ITT (Stage IB- IIIA)	
	Alectinib (N=130)	Chemotherapy (N=127)
# of events (%)	15(11.5%)	50 (39.4%)
Median(95% CI)	NE	41.3 (28.5, NE)
Stratified HR (95% CI)	0.24 (0.13, 0.43)	
p-value(2-sided)	<0.0001	
Median duration of survival follow-up	27.8 months	28.4 months



# Nemolizumab: Global P3 ARCADIA 1&2 (Atopic Dermatitis)

Achieved co-primary endpoints: improvement in skin lesions and eczema area & severity

Week 16  
IGA success <sup>a</sup>



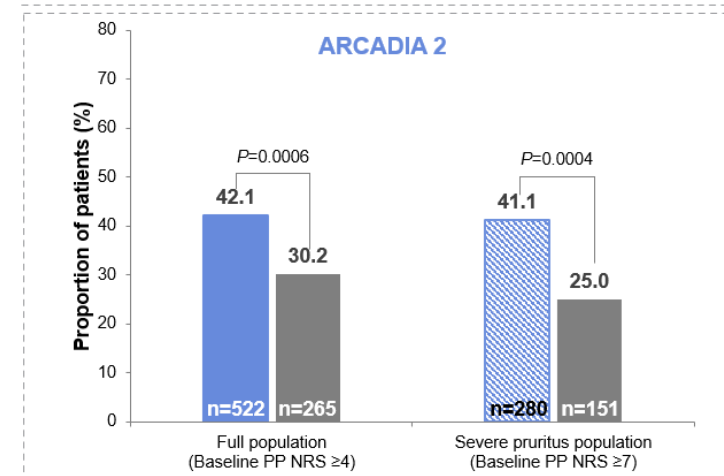
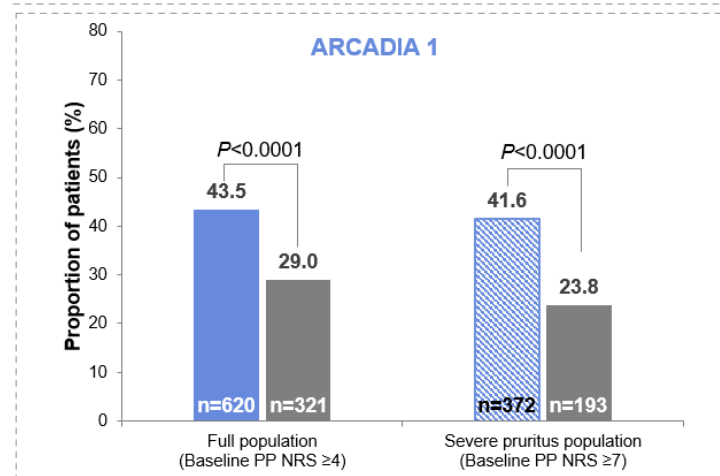
Full population (baseline PP NRS ≥4)

- Nemolizumab<sup>§</sup> + TCS/TCI
- Placebo + TCS/TCI

Severe pruritus population (baseline PP NRS ≥7)

- Nemolizumab<sup>§</sup> + TCS/TCI
- Placebo + TCS/TCI

Week 16  
EASI 75 <sup>b</sup>

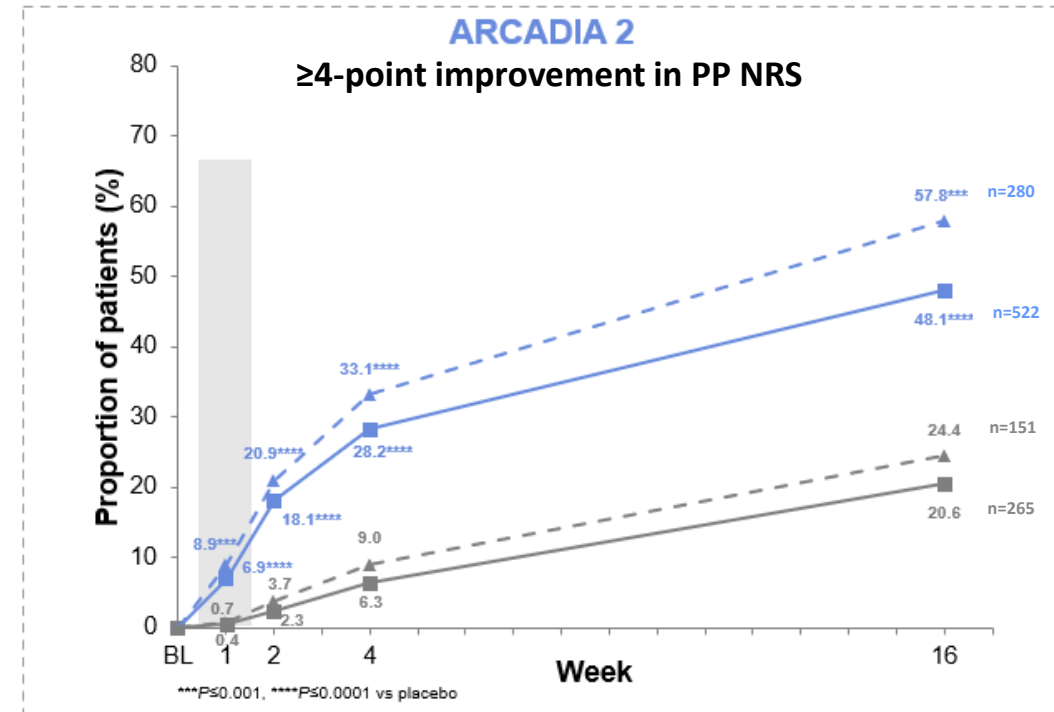
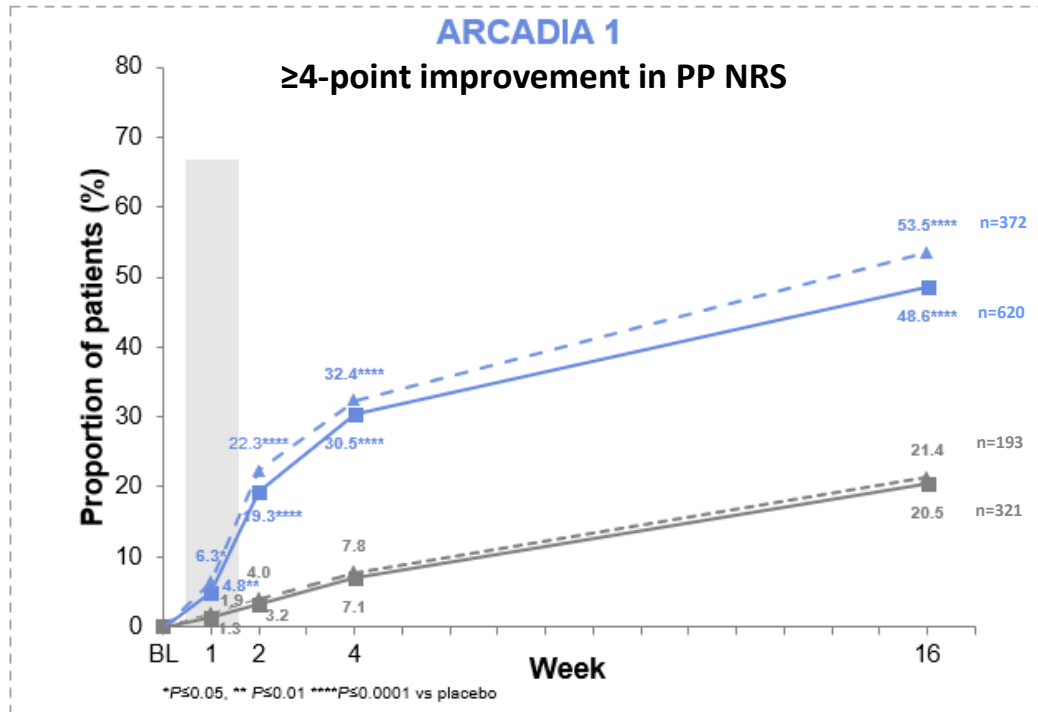


## ITT, NRI analysis

Source: Silverberg J et al. European Academy of Dermatology Venereology 2023  
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# Nemolizumab: Improvement of Pruritus in Atopic Dermatitis

Rapidly suppresses pruritus in ARCADIA 1&2 studies



Full population (baseline PP NRS ≥4) —■— Nemolizumab<sup>§</sup> + TCS/TCI —▲— Placebo + TCS/TCI  
Severe pruritus population (baseline PP NRS ≥7) —▲— Nemolizumab<sup>§</sup> + TCS/TCI —■— Placebo + TCS/TCI

ITT, MI MAR analysis

BL, baseline; ITT, intent-to-treat; MAR, missing at random; MI, multiple imputation; PP NRS, Peak Pruritus Numerical Rating Scale; TCI, topical calcineurin inhibitors; TCS, topical corticosteroids  
The baseline value was the weekly score derived using diary data of 7 consecutive days prior to the first injection of the initial treatment period.  
If a patient received any rescue therapy, the data after receipt of rescue therapy were considered treatment failure.  
The estimates are from 50 complete datasets by MI with MAR assumption.

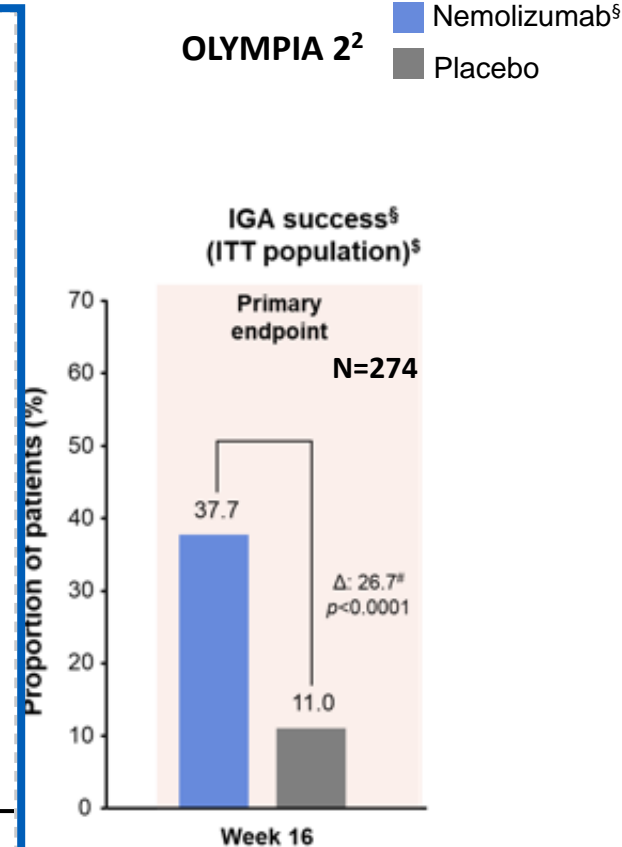
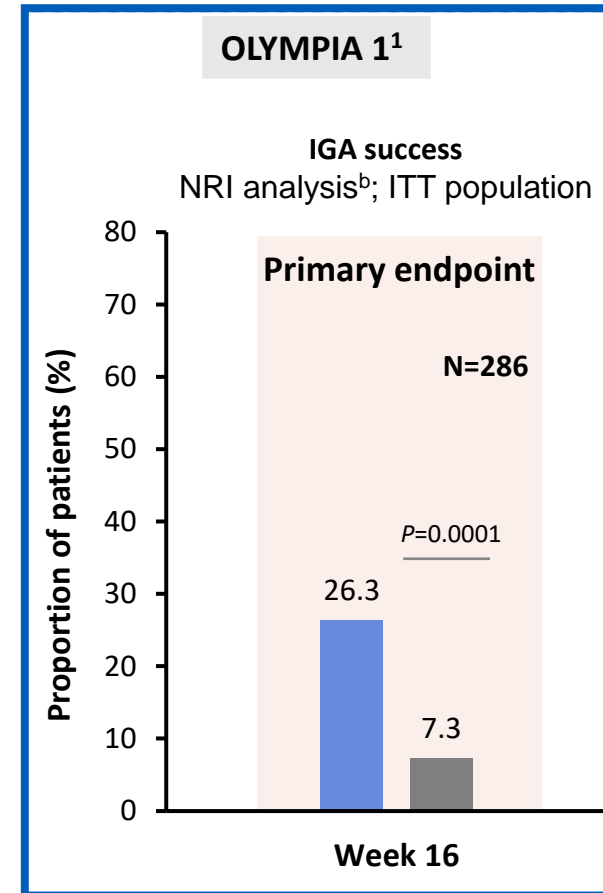
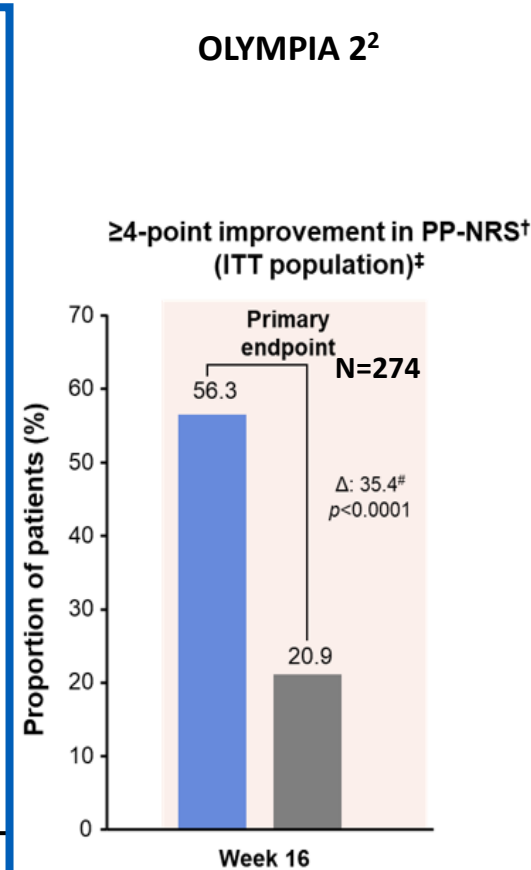
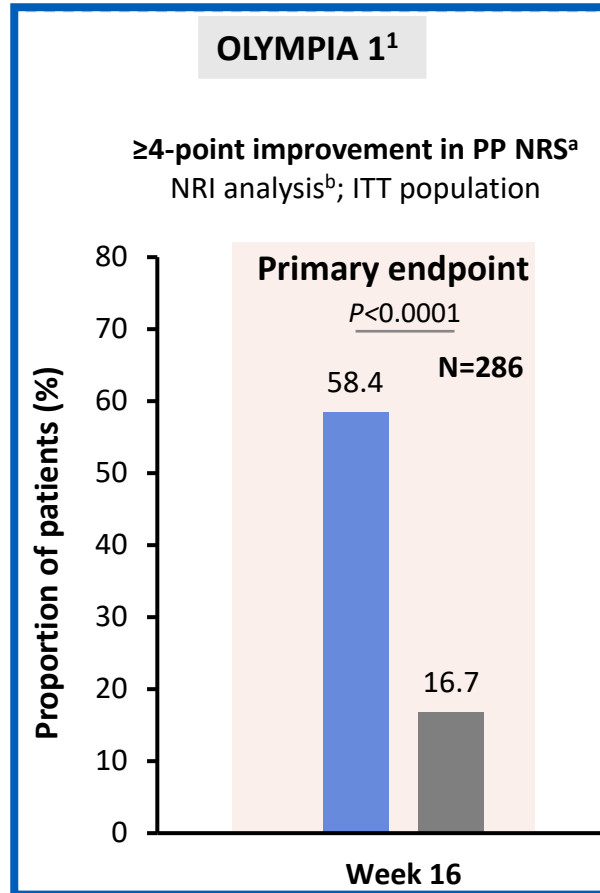
Strata-adjusted P-values are presented. These are derived from a Cochran-Mantel-Haenszel test adjusting for the randomised stratification variables (full population: IGA severity [3=moderate, 4=severe] and PP NRS [≥7, <7]; Baseline PP NRS ≥7 population: IGA severity only).

<sup>§</sup>Galderma is investigating the use of nemolizumab and has not received approval in any jurisdiction for any indication.

\*Weekly PP NRS score was calculated using diary data of 7 consecutive days and set to missing if data for less than 4 days were available.

# Nemolizumab: Global P3 OLYMPIA 1 (Prurigo Nodularis)

Following OLYMPIA 2, achieved co-primary endpoints: improvement in pruritus (PP NRS) and skin lesions (IGA)



OLYMPIA 1:  
BL, baseline; IGA, Investigator's Global Assessment; ITT, intent-to-treat; NRI, non-responder imputation; PP-NRS, Peak Pruritus Numerical Rating Scale. Unadjusted p-values are presented which were derived from Cochran-Mantel-Haenszel. <sup>§</sup>Galderma is investigating the use of nemolizumab and has not received approval in any jurisdiction for any indication. <sup>¶</sup>Weekly average PP-NRS score was considered, and the values were calculated as average of 7 consecutive days' data up to the target study day (excluding) and set to missing if <4 days' data are available. <sup>†</sup>If a patient received any rescue therapy, composite variable strategy is applied, the underlying data at/after receipt of rescue therapy is set as worst possible value, and the response is derived from underlying data value. Patients with missing values were considered as non-responders.

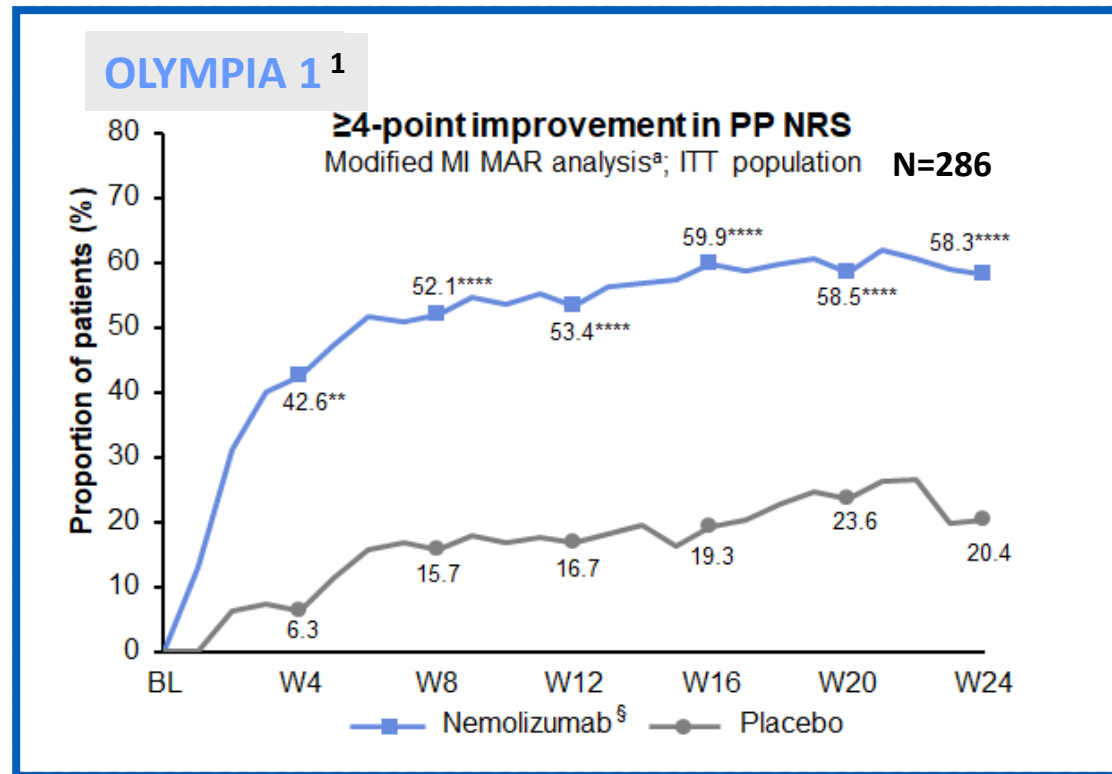
OLYMPIA 2:  
CMH, Cochran-Mantel-Haenszel  
Data presented here are of non-responder imputation (missing result at a visit was considered non-response).  
If a subject received any rescue therapy, the data at/after receipt of rescue therapy were considered as non-responders.  
<sup>\*</sup>Nemolizumab is an investigational drug and Galderma has not received approval for any indication in any country.  
<sup>†</sup>Weekly average PP-NRS score was considered, and the values were calculated as average of 7 consecutive days' data up to the target study day (excluding) and set to missing if <4 days data are available.  
<sup>‡</sup>Baseline was defined as the last non-missing weekly value before the first dose of the study drug.  
<sup>§</sup>Defined as an IGA response of 0 (clear) or 1 (almost clear) and a ≥2-point reduction from baseline.  
<sup>¶</sup>Baseline was defined as the last non-missing value before the first dose of the study drug.  
<sup>¶</sup>Unadjusted proportion differences are presented. Unadjusted p-values for between-group comparisons are from the CMH test.

Source: <sup>1</sup> Ständer S, et al. European Academy of Dermatology Venereology 2023,  
<sup>2</sup> Kwatra S, et al. American Academy of Dermatology Annual Meeting 2023



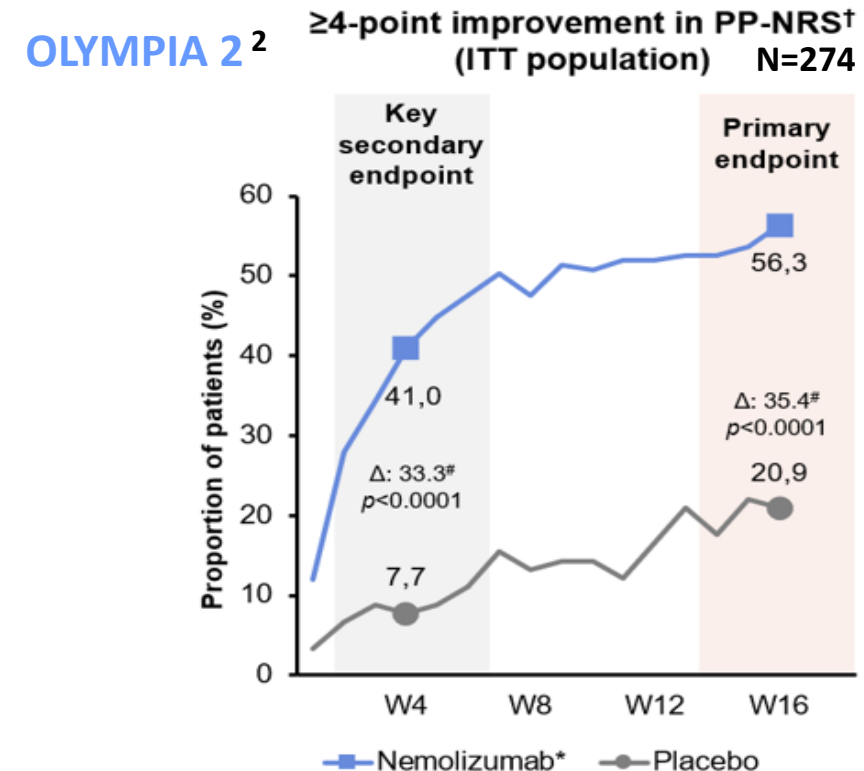
# Nemolizumab: Improvement of Pruritus in Prurigo Nodularis

Rapidly suppresses pruritus in OLYMPIA 1 study



\*\* $P \leq 0.01$ ; \*\*\*\* $P \leq 0.0001$  vs placebo

OLYMPIA 1:  
MI MAR, Multiple imputation under the assumption of Missing at Random; MMRM, mixed-effect model for repeated measures; NRI, non-responder imputation.  
Baseline was defined as the last non-missing weekly value before the first dose of the study drug. Weekly average PP NRS score was considered, and the values were calculated as average of 7 consecutive days' data up to the target study day (excluding) and set to missing if <4 days' data are available.  
<sup>§</sup> Galderma is investigating the use of nemolizumab and has not received approval in any jurisdiction for any indication.  
<sup>a</sup> If a patient received any rescue therapy, composite variable strategy is applied, the data at/after receipt of rescue therapy are set as worst possible value. The estimate is based on 50 complete datasets by multiple imputation with the assumption of MAR for patient who completed the study and missing as treatment failure after discontinuation for patients discontinued from the study. Strata-adjusted P-values for between-group comparisons are presented which were derived from the Cochran-Mantel-Haenszel test.



OLYMPIA 2:  
CMH, Cochran-Mantel-Haenszel; ITT, intention-to-treat; PP-NRS, peak pruritus Numerical Rating Scale; W, week  
Baseline was defined as the last non-missing weekly value before the first dose of the study drug.  
Data presented here are of non-responder imputation (missing result at a visit was considered non-response).  
If a subject received any rescue therapy, the data at/after receipt of rescue therapy were considered non-responders.  
\*Nemolizumab is an investigational drug and Galderma has not received approval for any indication in any country.  
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# AMY109: Anti-IL-8 Recycling Antibody for Endometriosis

Expecting improvement of endometriosis such as lesion reduction due to anti-inflammatory effects

## ■ Endometriosis

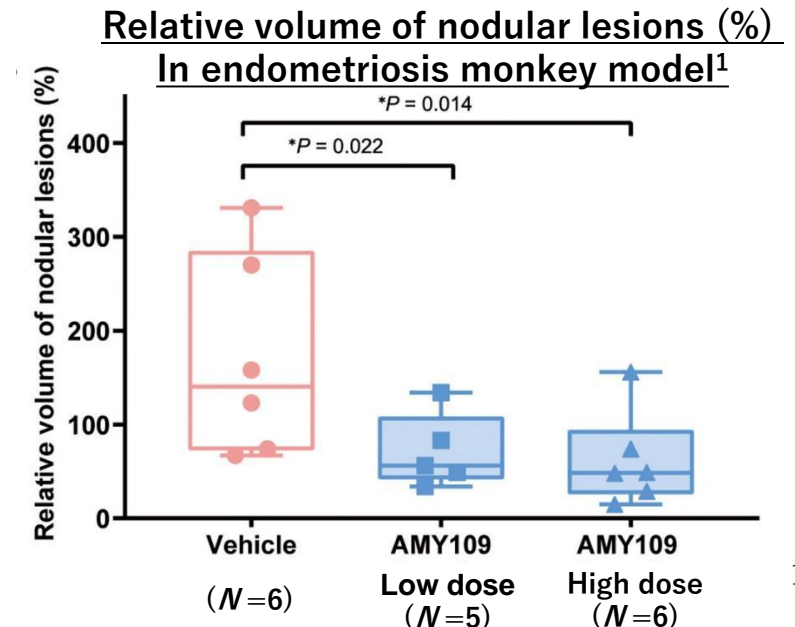
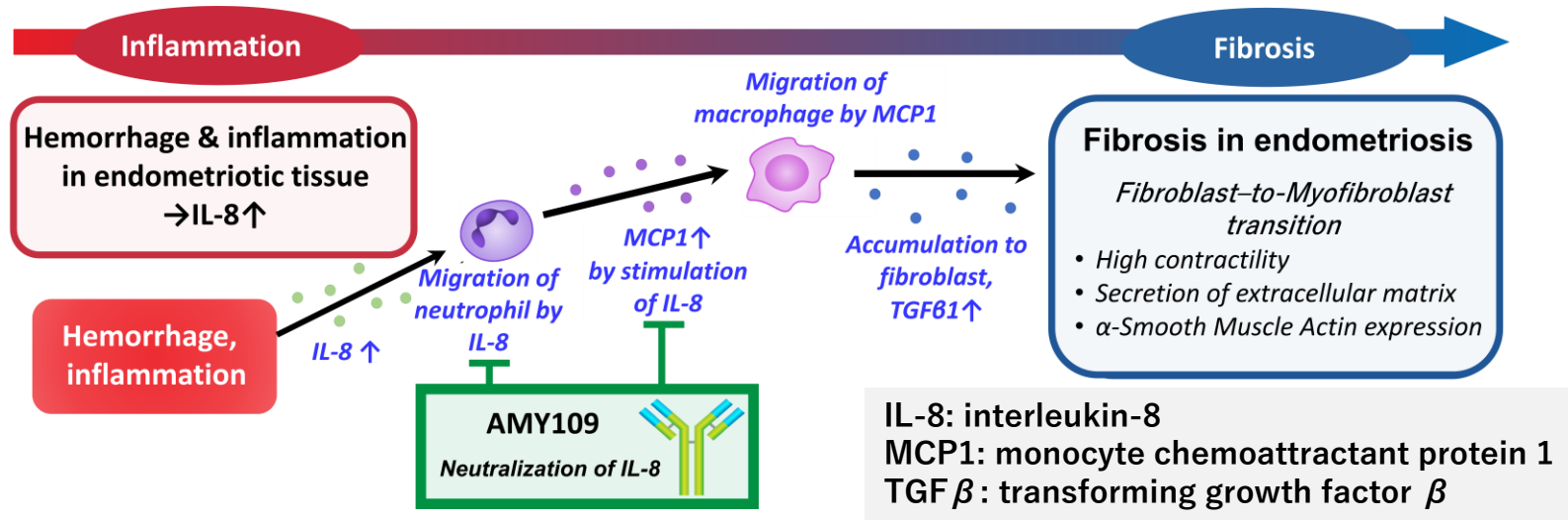
- Endometriosis occurs 1 in 10 women aged 20-49 years old\*
- Main symptoms are severe menstrual pain and chronic pelvic pain, and it can also cause infertility, potentially changing the lives of patients.

## ■ AMY109

- In endometriosis monkey models, it was confirmed that the inflammatory chemokine IL-8 is involved in the progression of inflammation and fibrosis of endometriosis, and that the treatment of anti-IL-8 antibodies improved severity of endometriosis such as lesion reduction<sup>1</sup>
- AMY109 is expected to deliver a new value to patients by anti-inflammation, with a different approach from standard hormone therapy.
- In Phase 1 study, the favorable safety, tolerability, and pharmacokinetics of single-dose administration in healthy volunteers and multiple-dose administration in endometriosis patients were confirmed. Phase 2 study aimed at evaluating efficacy and safety is in preparation.

\*No racial differences have been reported

<sup>1</sup> Nishimoto-Kakiuchi A et al, *Science Translational Medicine*. 2023 Feb 22;15(684)



# Enspryng: Thyroid Eye Disease (TED)

IL-6 blockade may improve ocular symptoms by inhibiting inflammation, adipogenesis and fibrosis. Global Phase 3 study has started.

- TED is an autoimmune inflammatory disease of the orbital tissues (eyelids, lacrimal glands, extraocular muscles, adipose tissue, etc.) associated with Graves' disease and rarely Hashimoto's disease. Various ocular symptoms appear, including diplopia and visual impairment in severe cases, severely impair QOL.<sup>1)</sup>
- According to a recent report using a claim database, the incidence in Japan is estimated to be approx. 7/100,000 person-years, and the number of patients is estimated to be approx. 35,000.<sup>1)</sup>
- High-dose steroids used for the treatment of moderate-to-severe active TED have been reported to have non-responders or relapsers. On the other hand, there is no established drug therapy for chronic inactive TED, and surgical intervention is still the mainstay of treatment. Moderate-to-severe TED is a disease with high UMN.<sup>2,3,4)</sup>

1) The Japan Thyroid Association and the Japan Endocrine Society: Diagnostic Criteria and Treatment Guideline for Graves' Malignant Exophthalmos (Thyroid Ophthalmopathy) 2023 (3rd Draft)

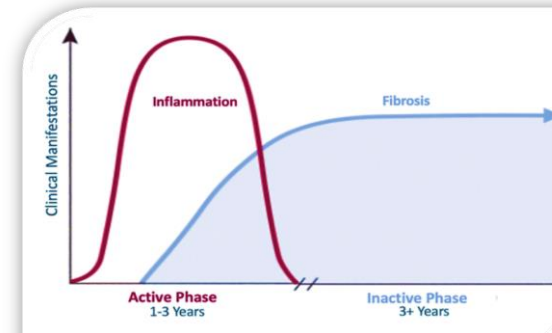
2) Zang S, et al. J Clin Endocrinol Metab. 2011;96(2):320-32.

3) Allen RC, et al. Ophthalmology. 2021;128(8):1125-8.

4) Bartalena L, et al. Eur Thyroid J. 2016;5(1):9-26.

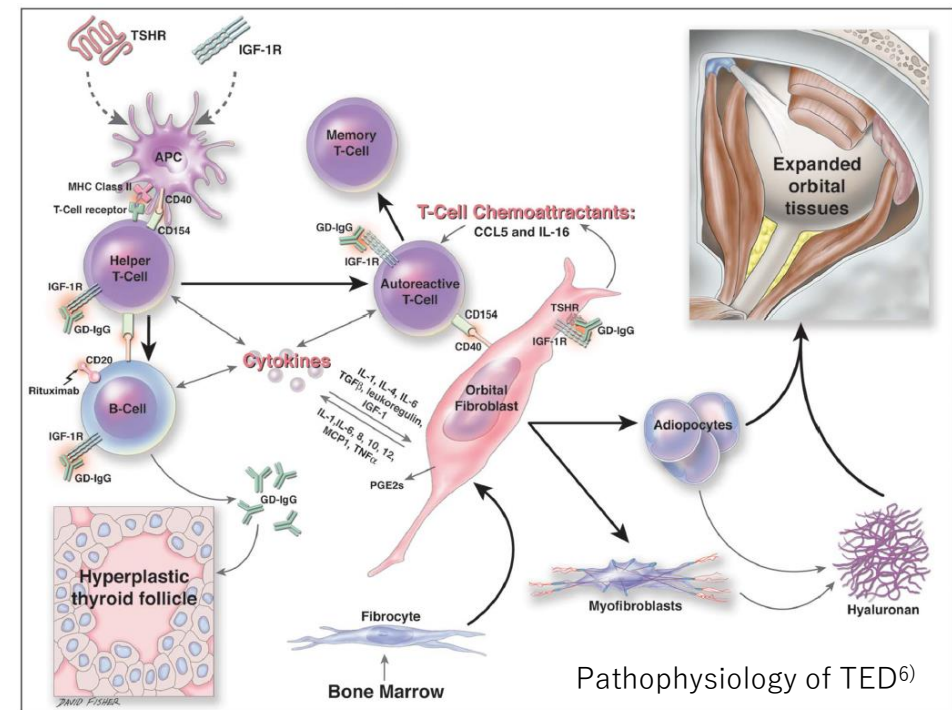
5) Rundle FF. Metabolism. 1957;6:36-48.

6) Shan SJC, et al. J Neuroophthalmol. 2014;34(2):177-85.



Natural course of TED<sup>5)</sup>

GD-IgG: Graves' disease-associated autoantibodies,  
IGF-1R: insulin-like growth factor 1 receptor,  
TSHR: thyroid-stimulating hormone receptor



Pathophysiology of TED<sup>6)</sup>

# Tobemstomig (PD1-LAG3)/RG6139

Bispecific checkpoint inhibitor that preferentially targets TILs. Japanese Phase 1 study in advanced solid tumors was initiated.

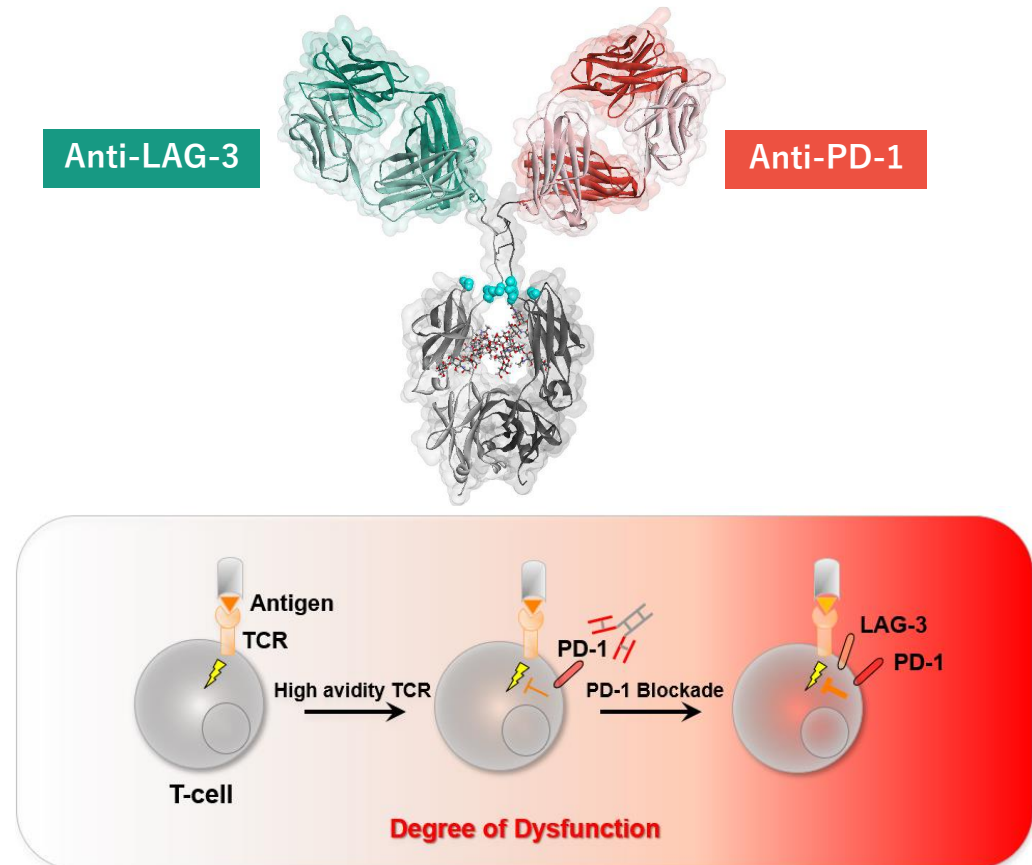
## About Tobemstomig

- Bispecific antibody binding to PD-1 and LAG-3, reinvigorates T-cells by blocking two co-inhibitory checkpoint receptors
- Preferential targeting of tumor-reactive TILs
- Avoids immunosuppressive effects by preferential binding to T effector cells vs Tregs

## Addressing alternative adaptive resistance mechanism

- Tumor-reactive T-cells with high avidity for tumor antigens upregulate PD-1
- Chronic T-cells activation, including the blockade of PD-1/PD-L1, induces expression of additional immune checkpoints (e.g. LAG-3) on TILs with non-redundant regulatory functions\*
- Blocking PD-1 and LAG-3 may better maintain T-cells functionality

## Tobemstomig structure and MoA



\* Scott Gettinger et al. Cancer Discov. 2017;7(12):1420-1435.

# Projected Submissions (Post PoC NMEs and Products)

as of October 24, 2023

## Filed

crovalimab (SKY59/RG6107) PNH (China)	crovalimab (SKY59/RG6107) PNH (US)	VABYSMO (RG7716) RVO
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crovalimab (SKY59/RG6107) PNH (Japan)	crovalimab (SKY59/RG6107) PNH (EU)	
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NME

Line extension

in-house



in-licensed (Roche)



mosunetuzumab+ POLIVY (RG7828+RG7596) r/r aNHL	Vabysmo (RG7716) Angioid streaks	ENSPRYNG (SA237/RG6168) MOGAD	giredestrant (RG6171) 1L BC	giredestrant (RG6171) BC (adjuvant)	GAZYVA (RG7159) Extra renal lupus
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SRP-9001 (RG6356) DMD	TECENTRIQ (RG7446) HNC (adjuvant)	giredestrant (RG6171) 1L - 3L BC	TECENTRIQ+AVASTIN (RG7446 + RG435) HCC (intermediate stage)	ALECENSA (AF802/RG7853) NSCLC (Stage III)	RG6179 UME	GAZYVA (RG7159) Pediatric nephrotic syndrome
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mosunetuzumab (RG7828) 3L FL	AVASTIN (RG435) 1L SCLC + TECENTRIQ	tiragolumab + TECENTRIQ (RG6058 + RG7446) NSCLC (Stage III)	TECENTRIQ (RG7446) MIBC (adjuvant)	crovalimab (SKY59/RG6107) SCD* (US/EU)	mosunetuzumab (RG7828) 2L FL	GAZYVA (RG7159) LN
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tiragolumab (RG6058) 1L NSCLC + TECENTRIQ	TECENTRIQ+AVASTIN (RG7446 + RG435) HCC(adjuvant)	ENSPRYNG (SA237/RG6168) AIE	ranibizumab(PDS) (RG6321) DME	GYM329/RG6237 FSHD*	tiragolumab(RG6058) 1L HCC TECENTRIQ + AVASTIN	TECENTRIQ (RG7446) 2L HCC
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ALECENSA (AF802/RG7853) NSCLC (adjuvant)	ENSPRYNG (SA237/RG6168) gMG	TECENTRIQ (RG7446) eBC (neoadjuvant)	crovalimab (SKY59/RG6107) aHUS	ranibizumab(PDS) (RG6321) nAMD	GYM329/RG6237 SMA* + EVRYSDI	tiragolumab + TECENTRIQ (RG6058 + RG7446) EC	TECENTRIQ (RG7446) NSCLC (neoadjuvant)
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2023

2024

2025

2026 and beyond

★ : new entry

★ : changes in submission year

\*Before obtaining PoC

# Appendix



# Projects under Development (1/2)

As of October 24, 2023

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

Letters in orange : in-house projects (development in global) Letters in blue : in-licensed from Roche (development and distribution in Japan) \* maintenance therapy after chemoradiation

In principle, completion of first dose is regarded as pipeline entry into each phase of clinical studies. ★: Projects with advances in stages since July 27, 2023



# Projects under Development (2/2)

As of October 24, 2023

	Phase I	Phase II	Phase III	Filed
Immunology	<b>DONQ52</b> - Celiac disease  <b>RAY121</b> - Autoimmune disease	<b>SKY59(RG6107)/crovalimab</b> - LN	<b>RG7159 / Gazyva</b> - LN - Pediatric nephrotic syndrome - Extra renal lupus ★	<b>MRA (RG1569) / Actemra (EU)</b> - SSc-ILD
Neurology	<b>RG7935 / prasinezumab</b> - Parkinson's disease  <b>RG6100 / semorinemab</b> - Alzheimer's disease  <b>RG6102 / trontinemab</b> - Alzheimer's disease (PI/II) ★	<b>GYM329 (RG6237) + RG7916/ Evrysdi</b> - SMA (PII/III) - FSHD  <b>RG6042 / tominersen</b> - Huntington's disease	<b>SA237 (RG6168) / Enspryng</b> - gMG - MOGAD - AIE  <b>SRP-9001(RG6356) / delandistrogene moxeparvovec</b> -DMD*	
Hematology	<b>NXT007 (RG6512)</b> - hemophilia A (PI/II)	<b>SKY59 (RG6107) / crovalimab (US/EU)</b> - SCD	<b>SKY59 (RG6107) / crovalimab</b> - aHUS	<b>SKY59 (RG6107) / crovalimab (Japan, US, EU)</b> - PNH <b>SKY59 (RG6107) / crovalimab (China)</b> - PNH
Ophthalmology	<b>RG6321 / PDS</b> - nAMD (PI/II) - DME (PI/II)		<b>RG7716 / Vabysmo</b> - Angioid streaks  <b>RG6179</b> - UME	<b>RG7716 / Vabysmo</b> - RVO
Other	<b>AMY109</b> - endometriosis			

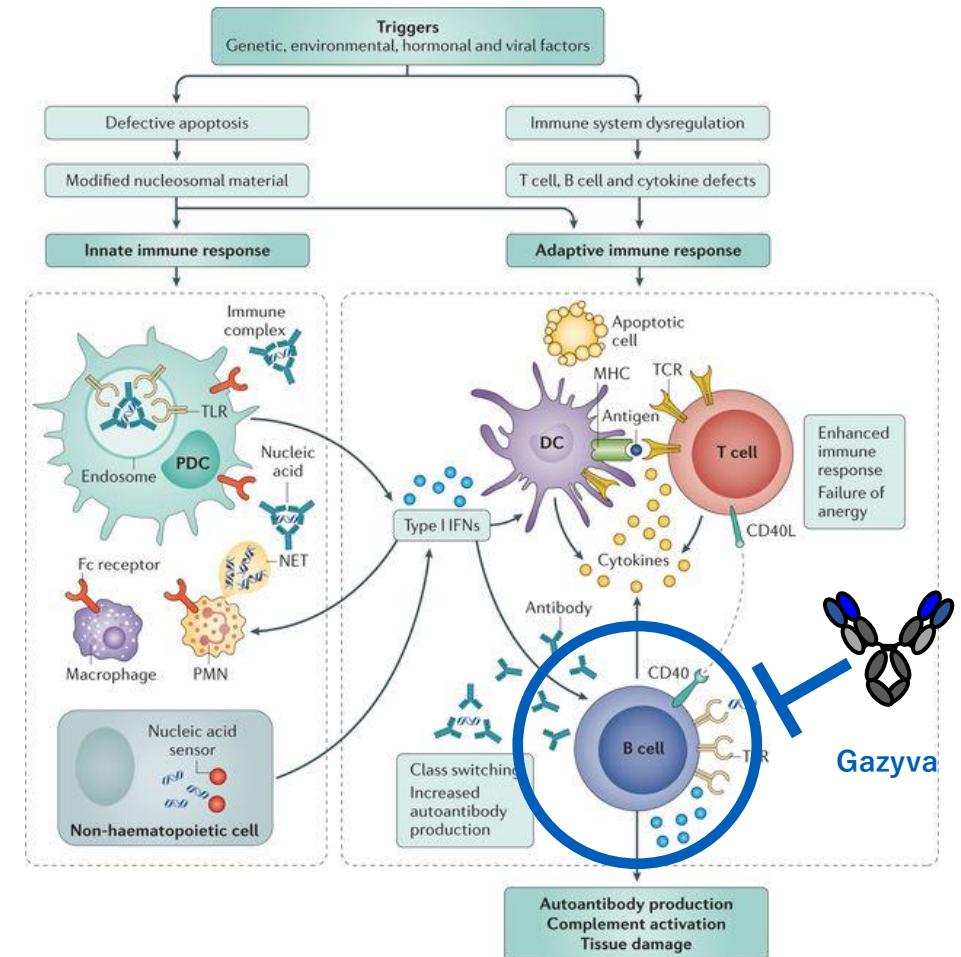
**Letters in orange** : in-house projects (development in global)    **Letters in blue** : in-licensed from Roche (development and distribution in Japan)    \* Sarepta manages the global study, including Japan

★: Projects with advances in stages since July 27, 2023    In principle, completion of first dose is regarded as pipeline entry into each phase of clinical studies.

# Gazyva (Obinutuzumab)

Gazyva provides enhanced B cell depletion which could bring benefit to Extra Renal Lupus patients, local Phase 3 ongoing

- Systemic Lupus Erythematosus (SLE): An autoimmune disease which activated self-reactive T cells and B cells cause widespread inflammation and attack its own organ by the tissue deposition of immune complexes formed by autoantibodies produced by B cells
- Approx. 60,000 patients in Japan, half of them are diagnosed Extra Renal Lupus and another half are Lupus Nephritis
- Humanized anti-CD20 monoclonal antibody that binds to the CD20 antigen on B cells, engineered to induce greater ADCC and direct cell death\*<sup>1</sup>
- Japanese Phase 3 study for Extra Renal Lupus is ongoing

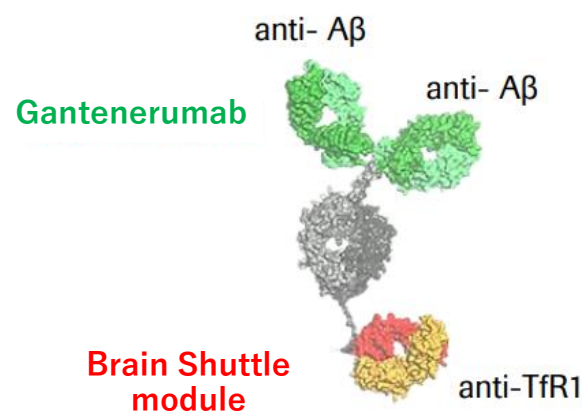


\*<sup>1</sup> Approved and launched for CD20-positive follicular lymphoma in 2018

# Trontinemab (Brain Shuttle Gantenerumab)/ RG6102

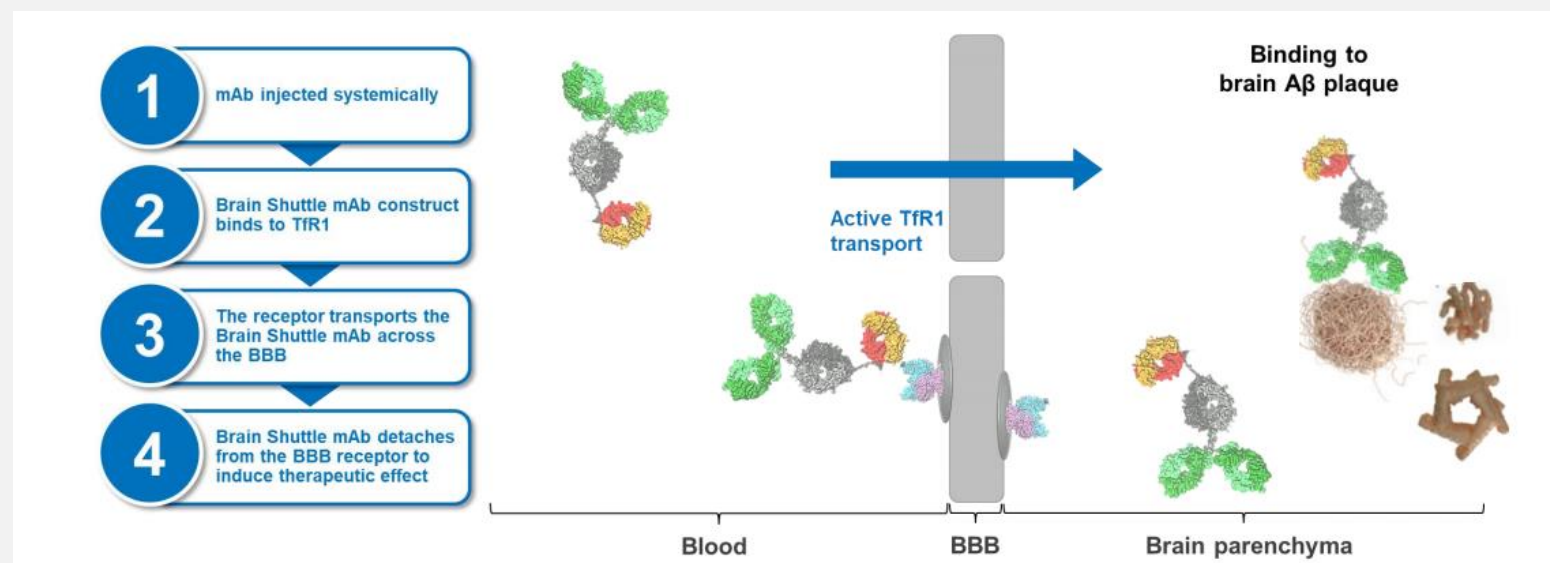
Potential for greater and more efficient A $\beta$  clearance in brain to delay progression of Alzheimer's disease

## Anti-A $\beta$ -TfR1 fusion protein



- Gantenerumab with a novel transferrin receptor (TfR1) binding Ab moiety to achieve efficient transport over the BBB and target A $\beta$  engagement in the brain
- Brain shuttle technology could also be applied to other CNS disorders

## Superior brain access through brain shuttle technology



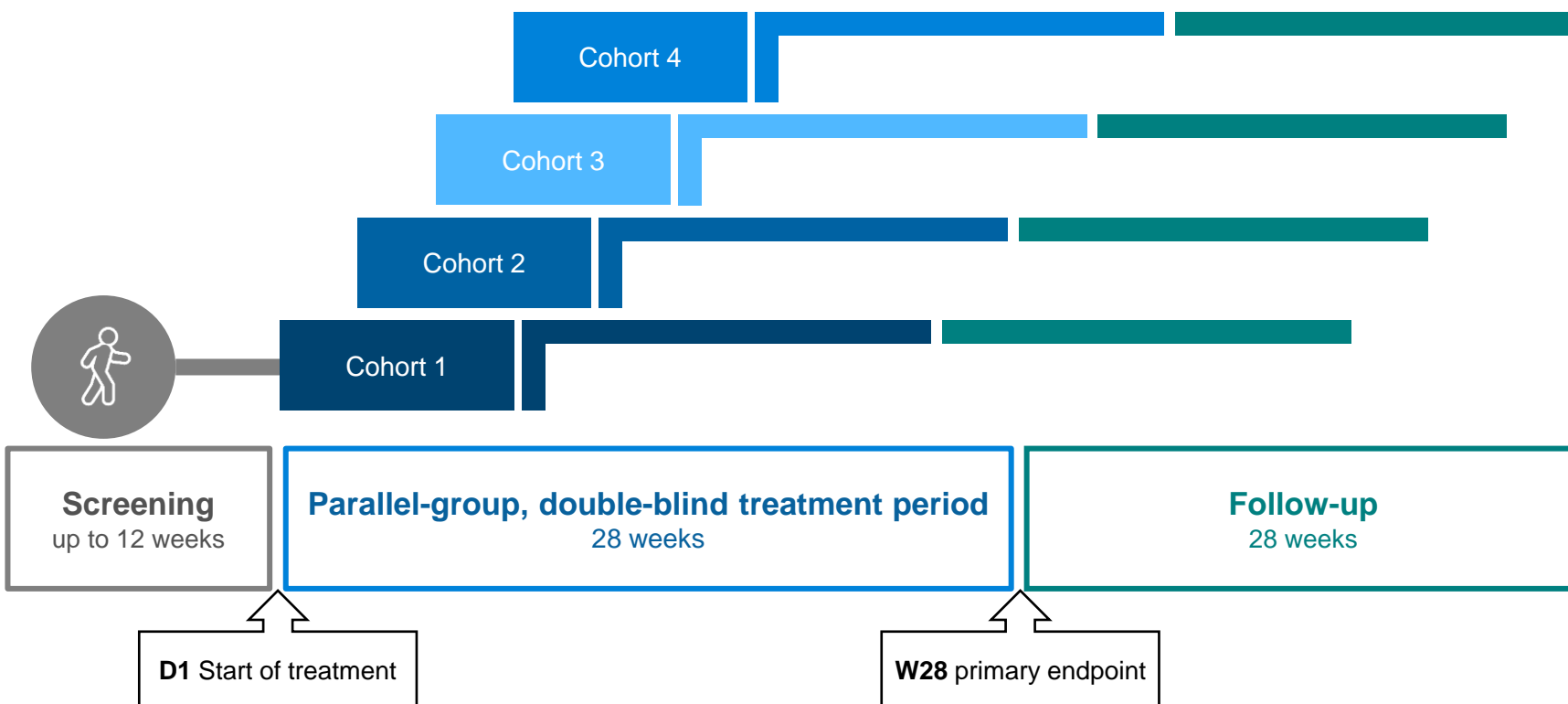
### Mechanism and evidences of Brain Shuttle Gantenerumab

- Microglia-mediated clearance of amyloid beta plaques in the brain
- Brain penetration is greatly enhanced through transferrin receptor-mediated transport across the BBB
- Preclinical work provides in vitro and in vivo evidence that binding to the TfR1 receptor facilitates transcellular transport across the BBB
- Phase 1 study in healthy subjects in overseas resulted in ~8-fold increase of CSF/plasma ratio compared with gantenerumab alone

# Trontinemab (Brain Shuttle Gantenerumab)/RG6102

Join the Global Phase I/II study from Japan

Randomized, Double Blind, Placebo-Controlled, Multiple Ascending Dose, Parallel-Group Study



- Ongoing Ph I/II study investigating four patient cohorts (10-15 patients per cohort) with **prodromal or mild-to-moderate AD** for 7 months and with an option to expand most promising cohorts
- Faster and more efficient plaque removal, could result in a more pronounced delay in disease progression compared to first generation anti-amyloid therapies
- Updated data from the ongoing Ph I/II study to be presented at CTAD 2023

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

As of October 24, 2023

Generic name/development code	Mode of Action	Licensee	Granted rights to licensee	Indication	Stage	Progress
avutometinib/ VS-6766	RAF/MEK inhibitor	Verastem Oncology	exclusive global license for the manufacturing, development and marketing	Ovarian cancer	global: P2	• US FDA BTB (recurrent LGSOC in combination with defactinib)
				NSCLC	global: P2	—
					global: P1/2	• RAMP 203 trial (in combination with KRAS G12C inhibitor sotorasib) initiated • RAMP 204 trial (in combination with KRAS G12C inhibitor, adagrasib) initiated
nemolizumab	Anti-IL-31 receptor A humanized monoclonal antibody	Global (Galderma) Japan (Maruho)	Galderma exclusive global license for the development and marketing excluding Japan and Taiwan Maruho rights for development and marketing in the skin disease area for the Japanese market	Atopic dermatitis	global: P3	• Two P3 studies met primary endpoints
					Japan: filed	• Filed for additional indication for pruritus associated with atopic dermatitis (pediatric)
				Prurigo nodularis	global: P3	• US FDA BTB
					Japan: filed	• Primary endpoint was met in the one of two P3 studies
				CKDaP	global: P2/3	—
orforglipron/ LY3502970	Oral non-peptidic GLP-1 receptor agonist	Eli Lilly and Company	worldwide development and commercialization rights	T2D	global: P3	• 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*
				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**

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

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

# FoundationOne CDx Cancer Genomic Profile -Companion diagnostic indications-

As of October 24, 2023

Alterations	Cancer type	Relevant drugs
Activated <i>EGFR</i> gene alterations	NSCLC	afatinib dimaleate, erlotinib hydrochloride, gefitinib, osimertinib mesylate, dacomitinib hydrate
<i>EGFR</i> exon 20 T790M alterations		osimertinib mesylate
<i>ALK</i> fusion genes		alectinib hydrochloride, crizotinib, ceritinib, brigatinib
<i>ROS1</i> fusion genes		entrectinib
<i>MET</i> exon 14 skipping alterations		capmatinib hydrochloride hydrate
<i>BRAF</i> V600E and V600K alterations	Malignant melanoma	dabrafenib mesylate, trametinib dimethyl sulfoxide, vemurafenib, encorafenib, binimetinib
<i>ERBB2</i> copy number alterations (HER2 gene amplification positive)	BC	trastuzumab (genetical recombination)
<i>KRAS/NRAS</i> wild-type	CRC	cetuximab (genetical recombination), panitumumab (genetical recombination)
Microsatellite Instability-High		nivolumab (genetical recombination)
Microsatellite Instability-High	Solid tumors	pembrolizumab (genetical recombination)
Tumor Mutational Burden-High		pembrolizumab (genetical recombination)
<i>NTRK1/2/3</i> fusion gene		entrectinib, larotrectinib sulfate
<i>BRCA1/2</i> alterations	Ovarian cancer	olaparib
<i>BRCA1/2</i> alterations	Prostate cancer	olaparib
<i>FGFR2</i> fusion genes	Biliary tract cancer	pemigatinib

# FoundationOne Liquid CDx Cancer Genomic Profile

## Companion diagnostic indications

As of October 24, 2023

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



# Public Clinical Trial Information regarding Chugai Originated Products to be Initiated

NOTE: No additional data other than public information are disclosed prior to initiation of trials

Development Code	Indication	Phase	CT information
REVN24	Acute disease	P1	<a href="#">jRCT2071230074</a> *

\* In Japanese only

## Upcoming events:

- Information Meeting on Phesgo® (November 30)
- R&D meeting (December 12, platform for mid-size molecule will be included in the topics)

# FY2023 Q3 Consolidated Financial Overview(Core)

**Toshiaki Itagaki**

Director, Executive Vice President & CFO

# P/L Jan – Sep (Non-core adjustment)

(Billions of JPY)	IFRS results	Non-core items		Core results
		Intangible assets	Others	
<b>Revenue</b>	<b>837.6</b>			<b>837.6</b>
Sales	742.1			742.1
Other revenue	95.5			95.5
Cost of sales	-321.2	+0.9	+0.1	-320.2
Research and development	-133.0	+5.4	+6.0	-121.7
Selling, general and administration	-81.8		+10.4	-71.4
Other operating income (expense)	16.1		+0.2	16.3
<b>Operating profit</b>	<b>317.6</b>	<b>+6.3</b>	<b>+16.7</b>	<b>340.5</b>
Financial account balance	3.5			3.5
Income taxes	-86.9	-1.9	-5.0	-93.8
<b>Net income</b>	<b>234.3</b>	<b>+4.4</b>	<b>+11.7</b>	<b>250.3</b>
<b>EPS (JPY)</b>	<b>142.37</b>			<b>152.11</b>

## Non-core items

(Billions of JPY)

### Intangible assets

Amortization	+1.2
Impairment	+5.1

### Others

Restructuring expenses, etc.	+6.3
Early retirement incentive program	+10.4

# P/L (2022 Jan – Sep) Renaming and Reclassification

(Billions of JPY)	2022 Actual
<b>Revenue</b>	<b>729.5</b>
Sales	644.7
Domestic	387.6
Overseas	257.1
Royalties and other operating income	84.9
Royalty and profit-sharing income	80.7
Other operating income	4.2
<b>Cost of sales</b>	<b>- 262.4</b>
(cost to sales ratio)	40.7%
<b>Operating expenses</b>	<b>- 168.1</b>
M&D and G&A	- 67.1
Research and development	- 101.0
<b>Operating profit</b>	<b>299.0</b>
(operating margin)	41.0%
<b>Net income</b>	<b>213.0</b>
<b>EPS (JPY)</b>	<b>129.48</b>

Blue text :renamed categories

0.2 billion JPY

Income from disposal of product rights is reclassified to the new category "Other operating income (expense)"

1.2 billion JPY

Income and expenses associated with operating activities that were previously included in "G&A" but could not be classified into functional expense categories such as gain (loss) on sale of land and buildings, etc., is reclassified to the new category "Other operating income (expense)"

(Billions of JPY)	2022 Actual
<b>Revenue</b>	<b>729.3</b>
Sales	644.7
Domestic	387.6
Overseas	257.1
Other revenue	84.6
Cost of sales	- 262.4
(cost to sales ratio)	40.7%
Research and development	- 101.0
Selling, general and administration	- 68.3
Other operating income (expense)	1.5
<b>Operating profit</b>	<b>299.0</b>
(operating margin)	41.0%
<b>Net income</b>	<b>213.0</b>
<b>EPS (JPY)</b>	<b>129.48</b>

For 2022 results in the following slides, categories are shown after renaming and reclassification.

# P/L Jan – Sep (Year on Year)

(Billions of JPY)	2022	2023	Growth	
<b>Revenue</b>	<b>729.3</b>	<b>837.6</b>	<b>+ 108.3</b>	<b>+ 14.8%</b>
Sales	644.7	742.1	+ 97.4	+ 15.1%
Domestic	387.6	429.2	+ 41.6	+ 10.7%
Overseas	257.1	312.9	+ 55.8	+ 21.7%
Other revenue	84.6	95.5	+ 10.9	+ 12.9%
Cost of sales	-262.4	-320.2	- 57.8	+ 22.0%
(cost to sales ratio)	40.7%	43.1%	+2.4%pts	-
Research and development	-101.0	-121.7	- 20.7	+ 20.5%
Selling, general and administration	-68.3	-71.4	- 3.1	+ 4.5%
Other operating income (expense)	1.5	16.3	+ 14.8	+ 986.7%
<b>Operating profit</b>	<b>299.0</b>	<b>340.5</b>	<b>+ 41.5</b>	<b>+ 13.9%</b>
(operating margin)	41.0%	40.7%	-0.3%pts	-
Financial account balance	-1.9	3.5	+ 5.4	-
Income taxes	-84.1	-93.8	- 9.7	+ 11.5%
<b>Net income</b>	<b>213.0</b>	<b>250.3</b>	<b>+ 37.3</b>	<b>+ 17.5%</b>
<b>EPS (JPY)</b>	<b>129.48</b>	<b>152.11</b>	<b>+22.63</b>	<b>+ 17.5%</b>

## Domestic sales

Increase due to growth of new and mainstay products

## Overseas sales

Increase in sales of Hemlibra and Alecensa

## Other revenue

Increase in royalty income of Hemlibra, etc.

## Cost of sales

Cost to sales ratio higher due to foreign exchange rate, etc.

## Research and development expenses

Increase due to investments in research and early development, including start of operations at Chugai Life Science Park Yokohama and progress of development projects

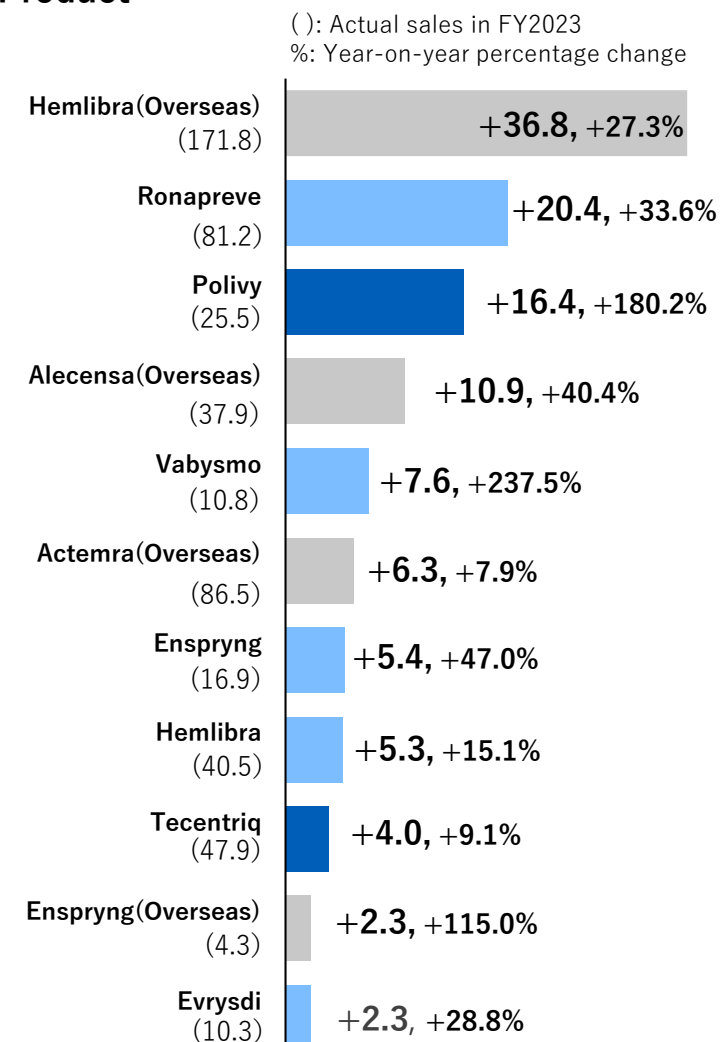
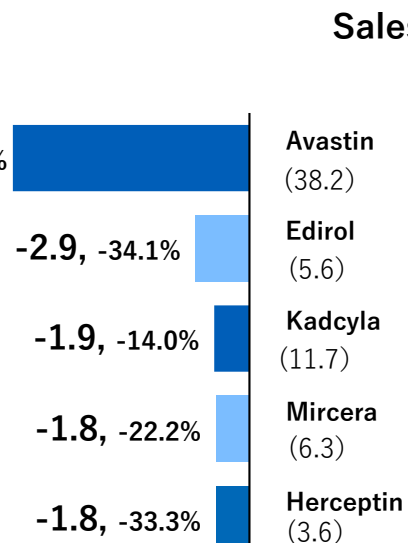
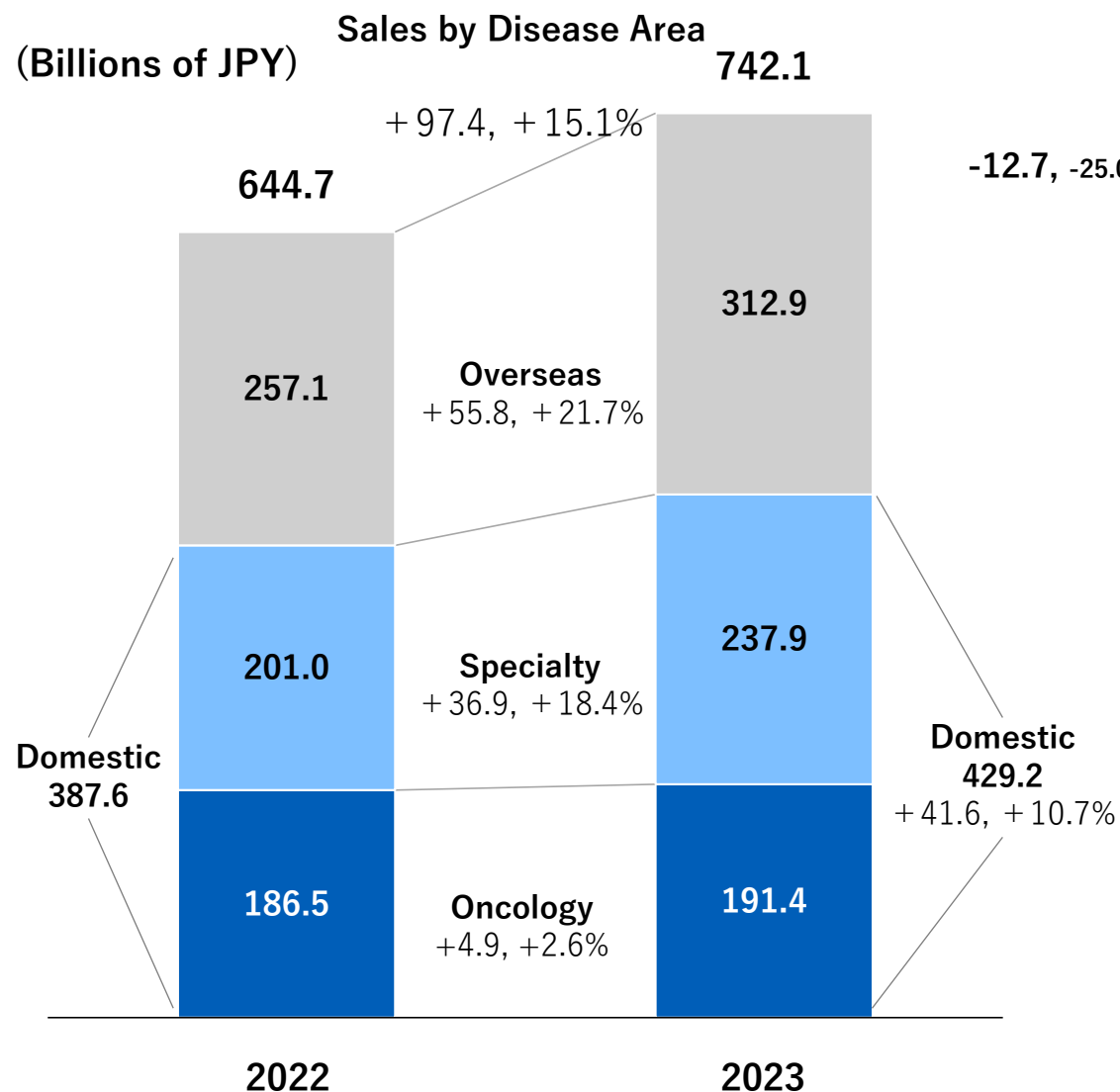
## Selling, general and administration expenses

Increase in various expenses

## Other operating income (expense)

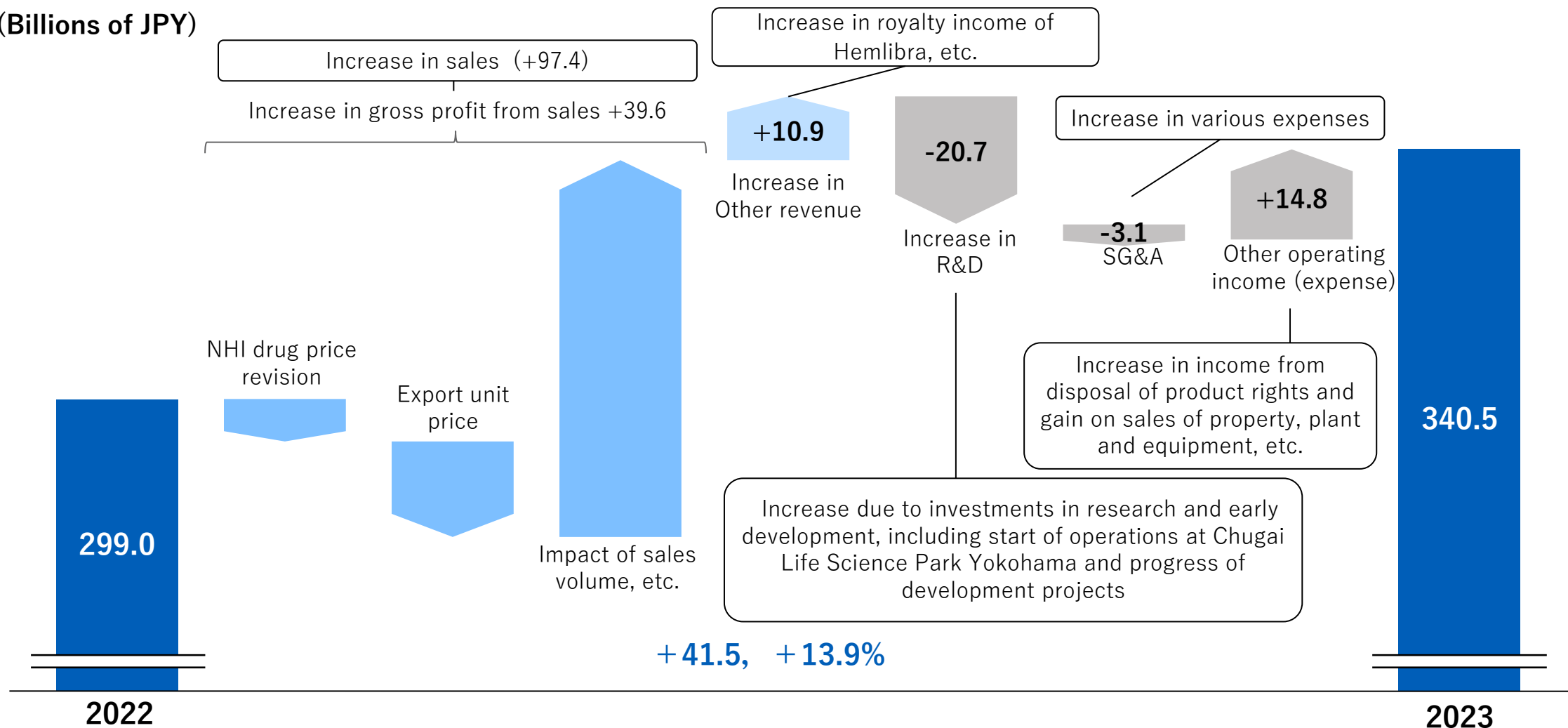
Increase in income from disposal of product rights and gain on sales of property, plant and equipment, etc.

# Sales Jan – Sep (Year on Year)



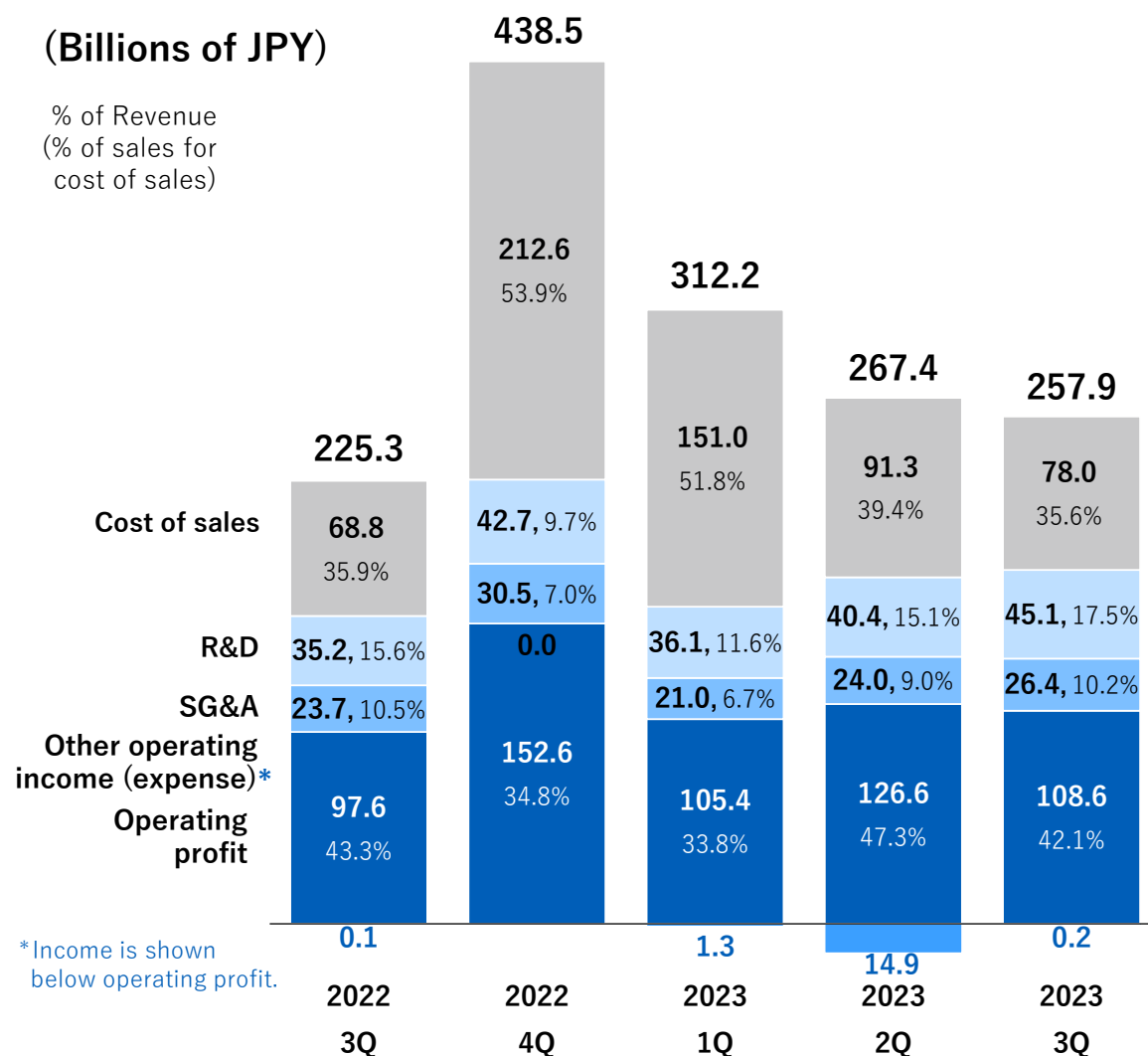
# Operating Profit Jan – Sep (Year on Year)

(Billions of JPY)





# Structure of Costs and Profit by Quarter



## Year on Year (vs. 2022 Q3)

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

**R&D:** increase due to investments in research and early development, including start of operations at Chugai Life Science Park Yokohama and progress of development projects

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

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

**Operating profit:** +11.0 billion JPY, +11.3%

## Quarter on Quarter (vs. 2023 Q2)

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

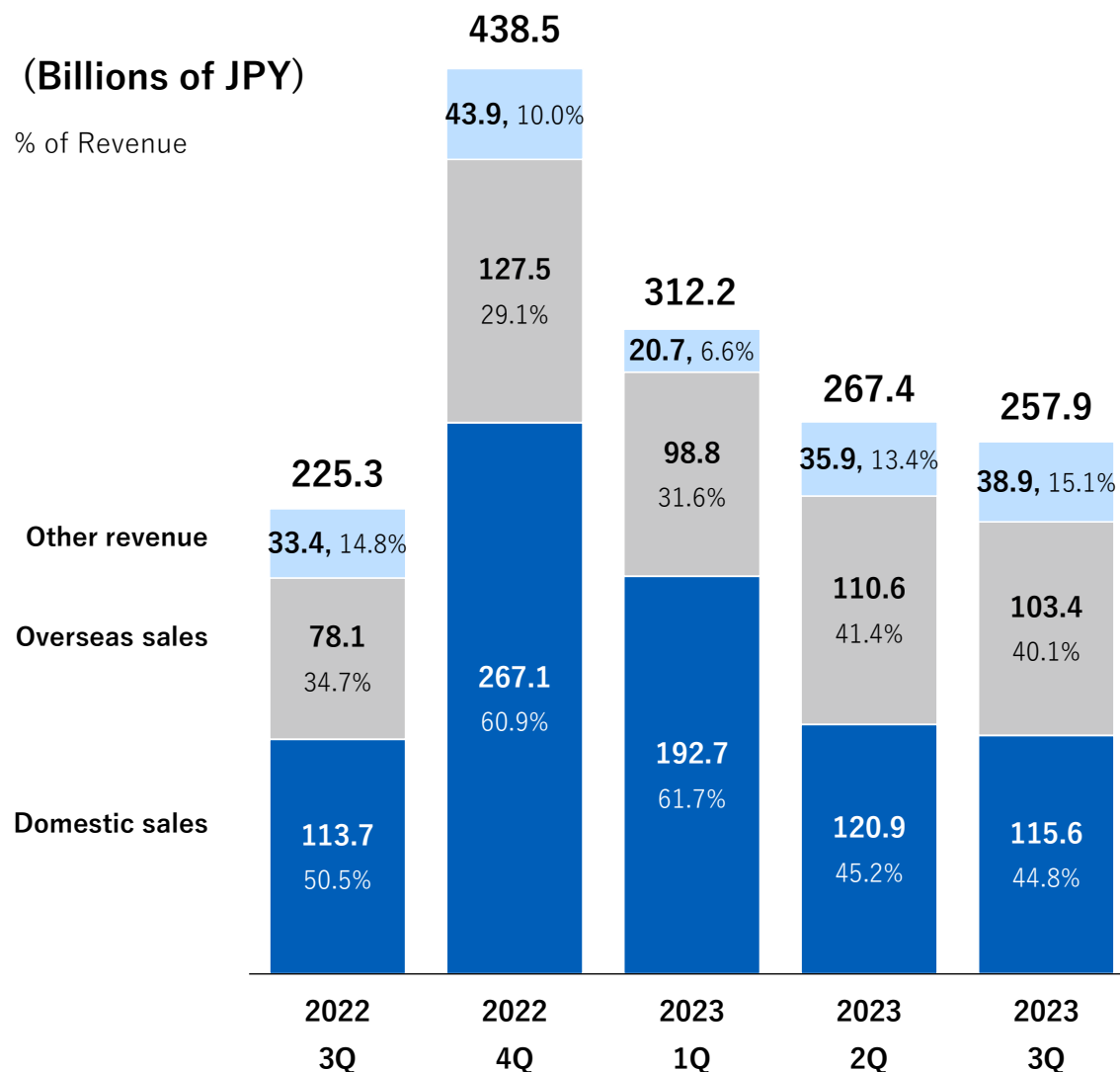
**R&D:** increase due to progress of development projects, etc.

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

**Other operating income (expense):** decrease due to income from disposal of product rights in Q2

**Operating profit:** -18.0 billion JPY, -14.2%

# Structure of Revenue by Quarter



## Year on Year (vs. 2022 Q3)

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

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

**Other revenue:** increase in royalty income of Hemlibra

## Quarter on Quarter (vs. 2023 Q2)

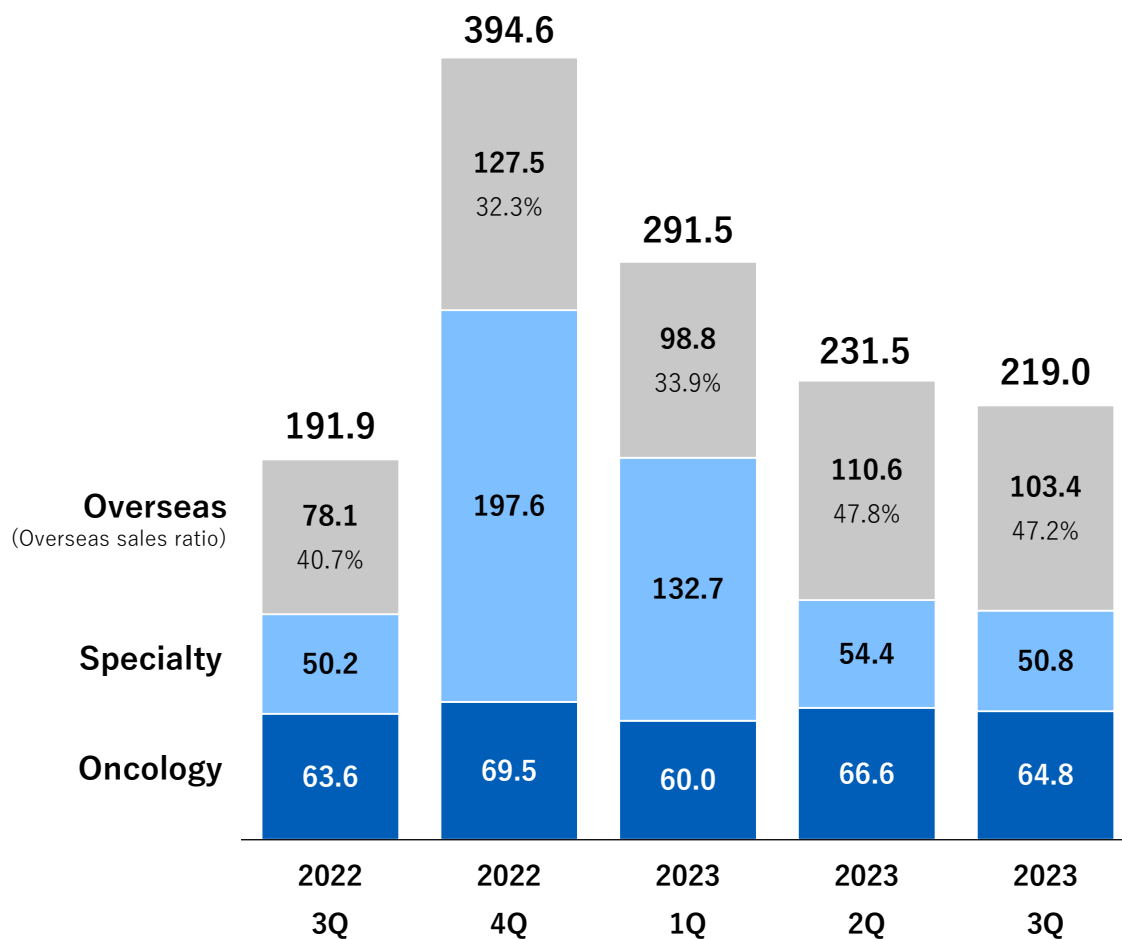
**Domestic sales:** decrease in sales of transferred product

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

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

# Structure of Sales by Quarter

(Billions of JPY)



Year on Year (vs. 2022 Q3)

Oncology	Polivy:	+6.1	Avastin:	-4.6
Specialty	Vabysmo:	+1.7	Enspryng:	+1.6
	Decrease in sales of transferred product			
Overseas	Hemlibra:	+23.9	Actemra:	+4.7
	Enspryng:	+2.9	Alecensa:	-5.9

Quarter on Quarter (vs. 2023 Q2)

<b>Oncology</b>	Avastin:	-1.1		
<b>Specialty</b>	Decrease in sales of transferred product			
<b>Overseas</b>	Actemra:	-11.8	Alecensa:	-8.2
	Hemlibra:	+9.9	Enspryng:	+2.9

# P/L Jan – Sep (vs. Forecast)

(Billions of JPY)	Actual	Forecast		2022
	2023 Jan - Sep	2023 Jan - Dec	Progress	Progress*
<b>Revenue</b>	<b>837.6</b>	<b>1,070.0</b>	<b>78.3%</b>	<b>62.5%</b>
Sales	742.1	920.0	80.7%	62.0%
Domestic	429.2	541.7	79.2%	59.2%
Overseas	312.9	378.3	82.7%	66.8%
Other revenue	95.5	150.0	63.7%	65.8%
Cost of sales	- 320.2	- 405.0	79.1%	55.2%
(cost to sales ratio)	43.1%	44.0%	-	-
Research and development	- 121.7	- 165.0	73.8%	70.3%
Selling, general and administration	- 71.4	- 100.0	71.4%	69.1%
Other operating income (expense)	16.3	15.0	108.7%	107.1%
<b>Operating profit</b>	<b>340.5</b>	<b>415.0</b>	<b>82.0%</b>	<b>66.2%</b>
(operating margin)	40.7%	38.8%	-	-
<b>Net income</b>	<b>250.3</b>	<b>306.0</b>	<b>81.8%</b>	<b>67.0%</b>
<b>EPS (JPY)</b>	<b>152.11</b>	<b>186.00</b>	<b>81.8%</b>	<b>67.0%</b>

## Domestic sales

Overall progress mostly in line with forecast  
(2023 progress excluding Ronapreve: 75.6%  
2022 progress excluding Ronapreve: 72.5%)

## Overseas sales

Sales of Hemlibra to Roche exceeding forecast

## Other revenue

Progress mostly in line with forecast

## Cost of sales

Cost to sales ratio for Jan-Sep slightly lower than forecast

## Research and development expenses

Progress mostly in line with forecast

## Selling, general and administration expenses

Progress mostly in line with forecast

## Other operating income (expense)

Progress mostly in line with forecast

\* Jan - Sep progress versus Jan – Dec actual

# Sales Jan – Sep (vs. Forecast)

(Billions of JPY)	Actual	Forecast		2022 Progress *
	2023 Jan - Sep	2023 Jan - Dec	Progress	
<b>Sales</b>	<b>742.1</b>	<b>920.0</b>	<b>80.7%</b>	<b>62.0%</b>
<b>Domestic</b>	<b>429.2</b>	<b>541.7</b>	<b>79.2%</b>	<b>59.2%</b>
<b>Oncology</b>	<b>191.4</b>	<b>253.3</b>	<b>75.6%</b>	<b>72.9%</b>
↓ Tecentriq	47.9	67.7	70.8%	72.1%
↑ Avastin	38.2	48.1	79.4%	75.4%
↑ Polivy	25.5	31.6	80.7%	58.7%
↑ Perjeta	24.6	31.0	79.4%	72.8%
↑ Alecensa	22.0	28.2	78.0%	72.3%
↑ Kadcyla	11.7	14.1	83.0%	75.1%
Herceptin	3.6	4.9	73.5%	76.1%
↓ Gazyva	2.6	4.5	57.8%	77.5%
Rituxan	2.9	3.7	78.4%	75.0%
↓ Foundation Medicine	5.6	8.3	67.5%	74.6%
↓ Other	6.6	11.2	58.9%	74.8%

(Billions of JPY)	Actual	Forecast		2022 Progress *
	2023 Jan - Sep	2023 Jan - Dec	Progress	
<b>Specialty</b>	<b>237.9</b>	<b>288.4</b>	<b>82.5%</b>	<b>50.4%</b>
Ronapreve	81.2	81.2	100.0%	29.8%
Hemlibra	40.5	53.7	75.4%	71.4%
Actemra	32.2	44.3	72.7%	72.9%
↑ Enspryng	16.9	21.6	78.2%	68.9%
↓ Vabysmo	10.8	17.4	62.1%	50.0%
Evrysdi	10.3	14.1	73.0%	69.6%
↑ Mircera	6.3	7.6	82.9%	75.0%
CellCept	5.2	6.7	77.6%	73.4%
↑ Edirol	5.6	5.2	107.7%	75.9%
Other	29.0	36.7	79.0%	75.1%
<b>Overseas</b>	<b>312.9</b>	<b>378.3</b>	<b>82.7%</b>	<b>66.8%</b>
↑ Hemlibra	171.8	185.2	92.8%	69.7%
↓ Actemra	86.5	121.4	71.3%	61.5%
↑ Alecensa	37.9	50.4	75.2%	66.7%
↑ Enspryng	4.3	3.8	113.2%	71.4%
↑ Neutrogin	6.0	7.3	82.2%	77.0%
↓ Edirol	0.1	0.5	20.0%	0.0%
Other	6.2	9.7	63.9%	74.7%

↑ exceed forecast

↓ below forecast

\* Jan - Sep progress versus Jan - Dec actual

# Impact from Foreign Exchange Jan – Sep

(Billions of JPY)	vs. 2022 Actual rate	vs. 2023 Forecast rate <sup>*1</sup>
<b>Revenue</b>	<b>+41.1</b>	<b>+4.9</b>
Sales	+31.2	+3.1
Other revenue	+9.9	+1.8
<b>Cost of sales</b>	<b>-28.0</b>	<b>-0.3</b>
<b>Other than above<sup>*2</sup></b>	<b>-3.2</b>	<b>-1.5</b>
<b>Operating profit</b>	<b>+9.8</b>	<b>+3.1</b>

Exchange rate (JPY)	2022 Jan - Sep Actual rate <sup>*3</sup>	2023 Jan - Sep Actual rate <sup>*3</sup>
1CHF	123.87	138.62
1EUR	135.92	149.03
1USD	115.14	133.42

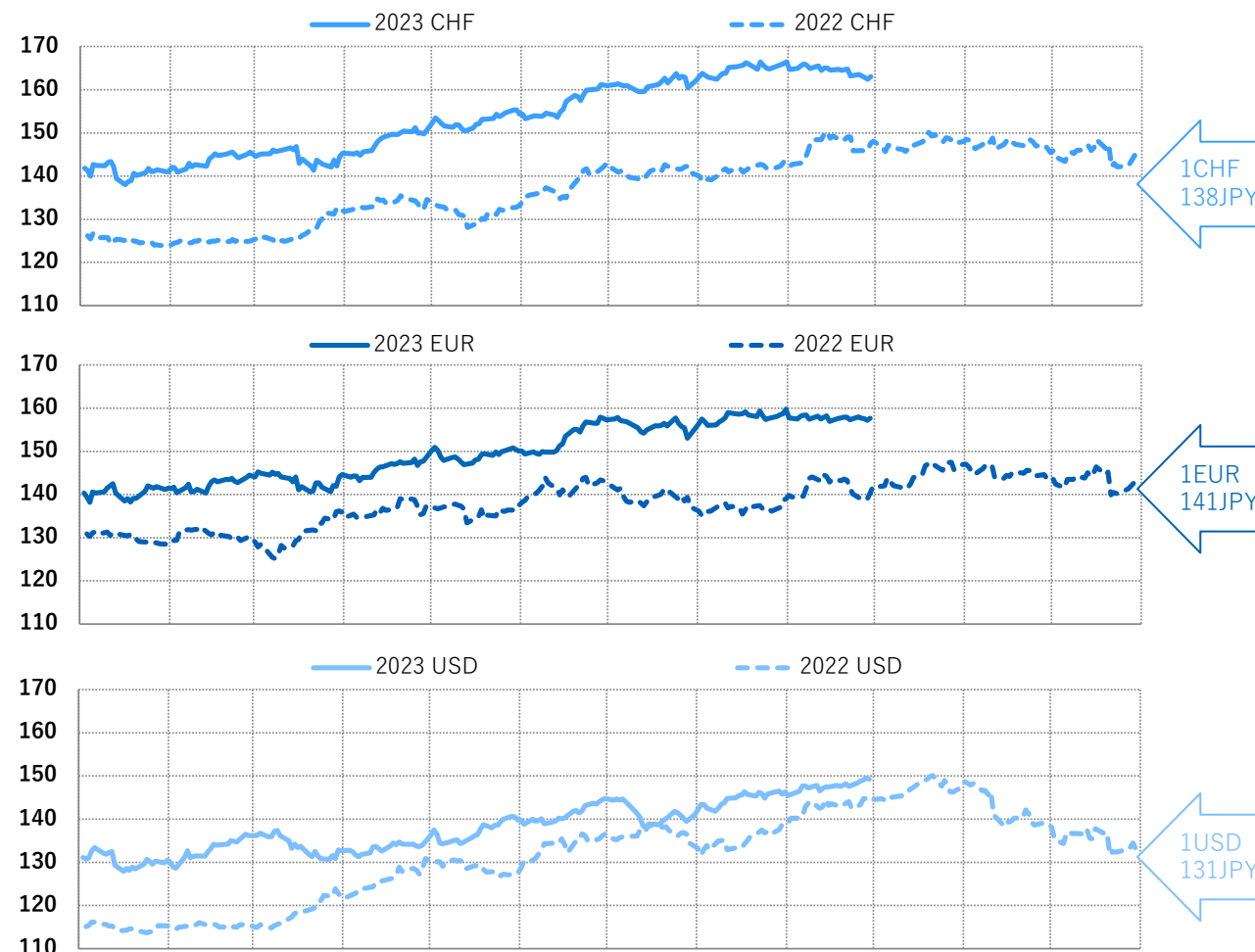
<sup>\*1</sup> Foreign Exchange effect from Jan-Sep Forecast rate(2023)

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

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

## Historical exchange rate to the JPY

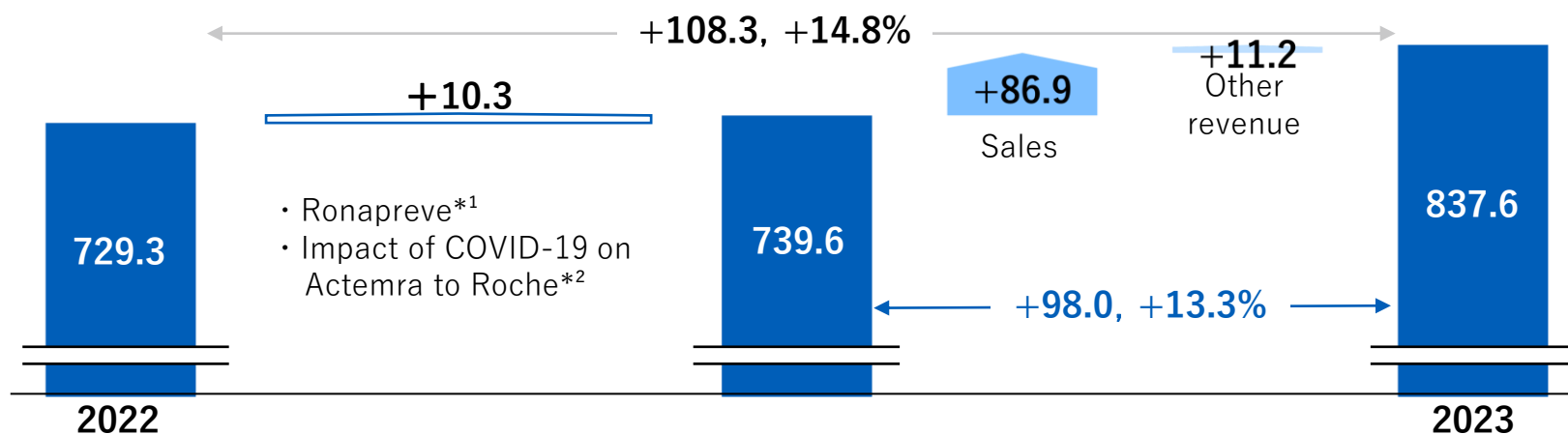
◀ : Full-year Forecast rate(2023)



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

(Billions of JPY)

## &lt; Revenue &gt;

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

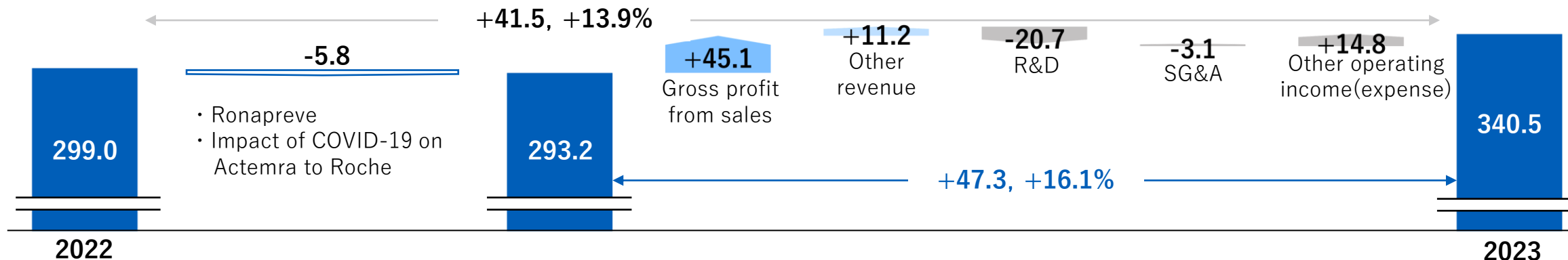
2022 Jan-Sep	60.8
2023 Jan-Sep	81.2
Year on Year	+20.4

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

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

2022 Jan-Sep	37.0
2023 Jan-Sep	26.8
Year on Year	-10.2

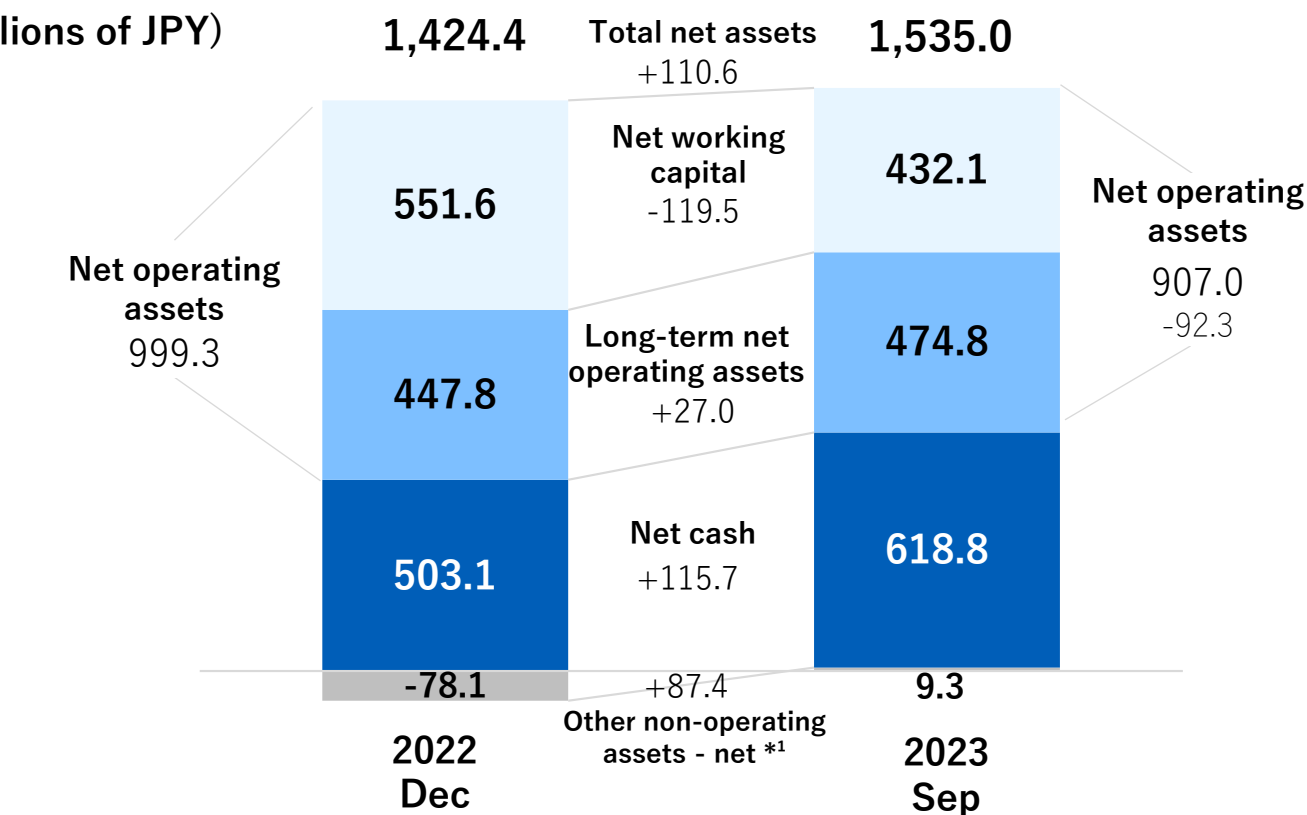
## &lt; Operating profit &gt;





# Financial Position (vs. 2022 Year End)

(Billions of JPY)



## Decrease in net working capital

Decrease in trade accounts receivable including Ronapreve

## Increase in long-term net operating assets

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

## Increase in net cash

(See next slide)

## Increase in other non-operating assets – net

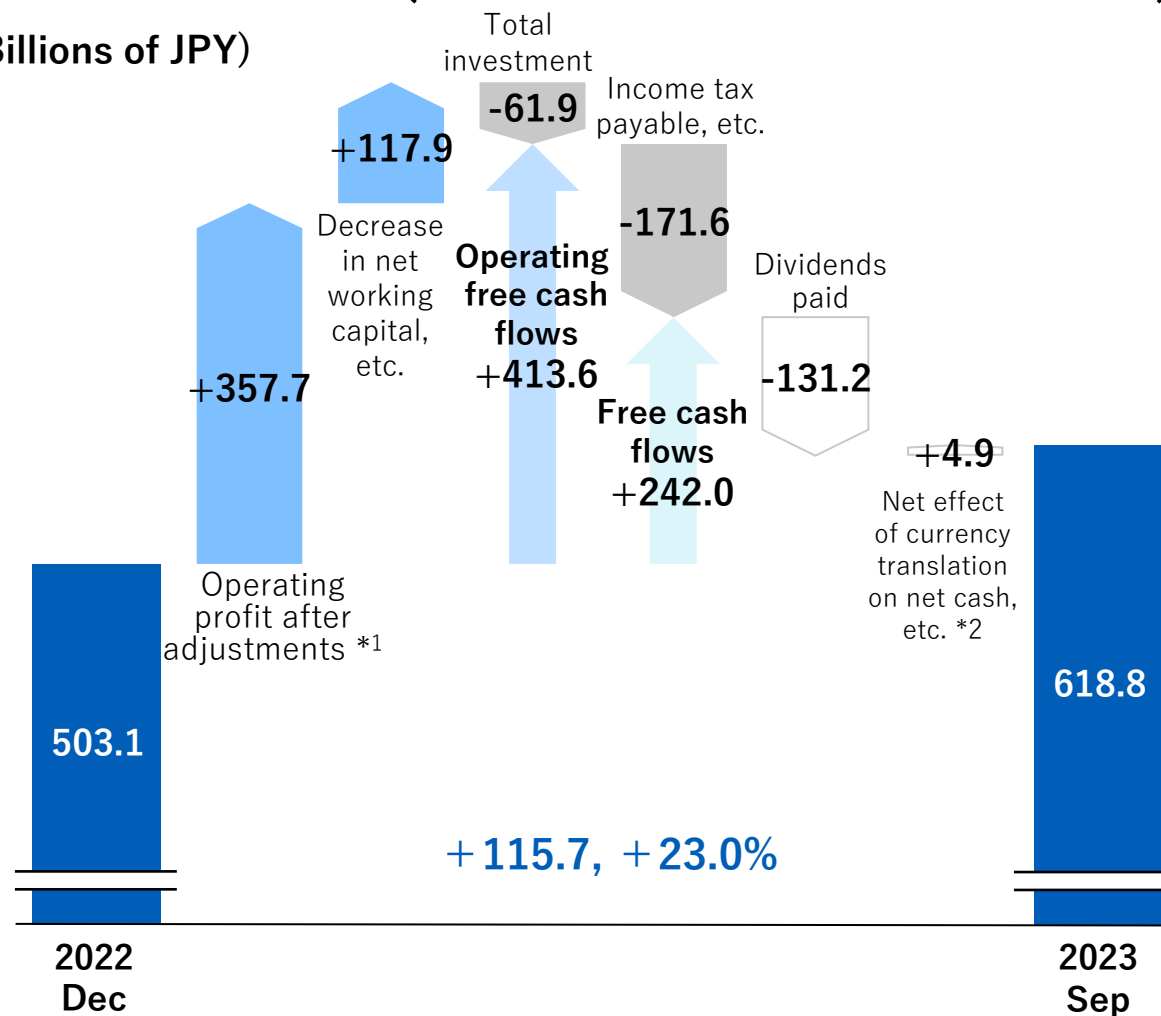
Increase mainly due to a decrease in accrued corporate tax

Total assets	1,869.8	-52.2	1,817.6
Total liabilities	-445.4	+162.7	-282.7
Total net assets	1,424.4	+110.6	1,535.0
Ratio of equity attributable to Chugai shareholders	76.2%	+8.3%pts	84.4%

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

# Net Cash (vs. 2022 Year End)

(Billions of JPY)



Operating profit after adjustment <sup>*1</sup>	+357.7
Operating profit <sup>*1</sup>	+317.6
Depreciation, amortization and impairment <sup>*1</sup>	+30.2
Decrease in net working capital, etc.	+117.9
Trade accounts receivable, accounts payable and inventory of Ronapreve	+107.3
Total investment	-61.9
Property, plant and equipment	-54.1
Payment for lease liabilities	-5.9
Intangible assets	-1.9
Operating free cash flows	+413.6
Income tax payable, etc.	-171.6
Income tax payable	-175.8
Free cash flows	+242.0
Dividends paid	-131.2
Net effect of currency transaction on net cash, etc. <sup>*2</sup>	+4.9

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

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

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

# Current Status / Plan for Major Investments

		~2022	2023	2024	2025	2026	2027	2028~	Planned investment			Start of investment	Planned completion
									Total amount	Investment to-date	Unit		
Manufacturing	Fujieda plant	FJ3: Manufacture APIs of small and mid-size molecule drugs for late-stage clinical development and early commercial use							55.5	41.9	billion JPY	2021	2024
	Ukima site	UK4: Manufacture bio-APIs for early-stage clinical development							12.1	10.7	billion JPY	2021	2023
	Utsunomiya plant	UT3: Manufacture bio-APIs for middle to later- stage clinical development and early commercial use							37.4	5.5	billion JPY	2023	2026
	Utsunomiya plant	UTA: Manufacture sterile injectables for early commercial use							19.0	2.5	billion JPY	2023	2025
Research and development	CPR	Accelerate creation of clinical candidates utilizing proprietary antibody technologies							758	541	million SGD	2012	2026
									of which, capital investment: 82	76	million SGD		
	Chugai LSP Yokohama	Building of state-of-the-art R&D site to create innovative new drug candidates							128.8	124.5	billion JPY	2019	2022
									- Land of 43.0 billion JPY excluded			- Start of operation: Apr. 2023	
	IFReC	Funding to IFReC per comprehensive collaboration agreement							10.0	6.5	billion JPY	2017	2027
Environment	Environmental investment	Equipment upgrade to achieve Mid-Term Environmental Goals 2030							107.2 estimated total amount		billion JPY	2022	2032

# Abbreviations

<b>AD</b>	atopic dermatitis	<b>MIBC</b>	muscle-invasive bladder cancer
<b>adj</b>	adjuvant	<b>MM</b>	multiple myeloma
<b>AS</b>	angioid streaks	<b>MOGAD</b>	myelin oligodendrocyte glycoprotein antibody-associated disease
<b>aHUS</b>	atypical hemolytic uremic syndrome	<b>nAMD</b>	neovascular age-related macular degeneration
<b>AIE</b>	autoimmune encephalitis	<b>NHI</b>	national health insurance
<b>aNHL</b>	aggressive B-cell non-Hodgkin lymphoma	<b>NME</b>	new molecular entity
<b>BC</b>	breast cancer	<b>NMOSD</b>	Neuromyelitis Optica Spectrum Disorder
<b>CRC</b>	colorectal cancer	<b>NSCLC</b>	non-small cell lung cancer
<b>CRS</b>	cytokine release syndrome	<b>NSQ</b>	non-squamous
<b>DCT</b>	Decentralized Clinical Trial	<b>OS</b>	Overall Survival
<b>DFS</b>	Disease-Free Survival	<b>PER</b>	Perjeta
<b>DMD</b>	duchenne muscular dystrophy	<b>PFS</b>	Progression-Free Survival
<b>DME</b>	diabetic macular edema	<b>PDS</b>	port delivery system with ranibizumab
<b>EADV</b>	European Academy of Dermatology and Venereology	<b>PN</b>	prurigo nodularis
<b>eBC</b>	early breast cancer	<b>PNH</b>	paroxysmal nocturnal hemoglobinuria
<b>EC</b>	esophageal cancer	<b>PS</b>	profit share
<b>ESMO</b>	European Society for Medical Oncology	<b>QOL</b>	quality of life
<b>ePoC</b>	early proof of concept	<b>r/r</b>	relapsed or refractory
<b>FDC</b>	fixed-dose combination	<b>RON</b>	Ronapreve
<b>FL</b>	follicular lymphoma	<b>ROY</b>	royalty
<b>FSHD</b>	facioscapulohumeral muscular dystrophy	<b>RVO</b>	retinal vein occlusion
<b>gMG</b>	generalized myasthenia gravis	<b>sc</b>	subcutaneous
<b>HCC</b>	hepatocellular carcinoma	<b>SCD</b>	sickle cell disease
<b>HER</b>	Herceptin	<b>SCLC</b>	small cell lung cancer
<b>HNC</b>	head and neck carcinoma	<b>SMA</b>	spinal muscular atrophy
<b>IFReC</b>	Immunology Frontier Research Center	<b>SSc-ILD</b>	systemic sclerosis with interstitial lung disease
<b>IV</b>	intravenous	<b>TED</b>	thyroid eye disease
<b>LGSOC</b>	low-grade serous ovarian cancer	<b>ULN</b>	upper limit of normal
<b>LN</b>	lupus nephritis	<b>UME</b>	uveitic macular edema
<b>LSP</b>	Life Science Park	<b>T2D</b>	type 2 diabetes

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INNOVATION BEYOND IMAGINATION