Innovation all for the patients CHUGAI PHARMACEUTICAL CO., LTD. (Rochy: A member of the Roche group

## CHUGAI PHARMACEUTICAL CO., LTD.

Conference on FY2023.12 Q3 Financial Results

October 24, 2023

# **Event Summary**

[Company Name]	CHUGAI PHARMACEUTICAL CO	D., LTD.
[Company ID]	4519-QCODE	
[Event Language]	JPN	
[Event Type]	Earnings Announcement	
[Event Name]	Conference on FY2023.12 Q3	Financial Results
[Fiscal Period]	FY2023 Q3	
[Date]	October 24, 2023	
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[Time]	18:00 – 19:12 (Total: 72 minutes, Presentati	on: 34 minutes, Q&A: 38 minutes)
[Venue]	Webcast	
[Venue Size]		
[Participants]		
[Number of Speakers]	5 Dr. Osamu Okuda Toshiaki Itagaki Tetsuya Yamaguchi Shinji Hidaka Kae Miyata	President & CEO Director, Executive Vice President & CFO Executive Vice President, Head of Project & Lifecycle Management Unit Vice President, Head of Marketing & Sales Div. Head of Corporate Communications Dept.
[Analyst Names]*	Seiji Wakao Shinichiro Muraoka Hidemaru Yamaguchi Kazuaki Hashiguchi Hiroyuki Matsubara Miki Sogi Fumiyoshi Sakai	JPMorgan Securities Morgan Stanley MUFG Securities Citigroup Global Markets Daiwa Securities Nomura Securities AllianceBernstein Japan Ltd. UBS Securities

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\*Analysts that SCRIPTS Asia was able to identify from the audio who spoke during Q&A or whose questions were read by moderator/company representatives.

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## Presentation

**Miyata**: Thank you very much for attending today's financial results briefing for Q3 of the fiscal year ending December 31, 2023. I am Miyata from Corporate Communications, and I will be facilitating today's session. Thank you.

Today's session will be conducted via Zoom webinar. Please turn to the agenda shown on page three of the slides. Questions will be taken in batches after all presentations have been completed. The Q&A session is expected to last 30 minutes. Please note that your audio will be muted during the presentation.

Now, Dr. Okuda will present an overview of Q3 of FY2023.

FY2023 Q3 Overview Financial Overview



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- 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	Grow	rth	2023 Jan - Dec forecast	Progress (%)
Revenue	729.3	837.6	+108.3	+14.8%	1,070.0	78.3%
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%
Operating profit	299.0	340.5	+41.5	+13.9%	415.0	82.0%
Operating margin	41.0%	40.7%	-0.3%pts	-	38.8%	-
Net income	213.0	250.3	+37.3	+17.5%	306.0	81.8%
EPS (yen)	129.48	152.11	+22.63	+17.5%	186.00	81.8%

- 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.

Okuda: Thank you. Okuda here. I will now provide a summary of Q3 of FY2023.

Please see page five of the slides. Revenue increased 14.8% YoY, operating profit increased 13.9%, and net income increased 17.5%. Domestic sale of new products and mainstay products and exports to Roche of inhouse products continue to grow steadily. There is no change in the forecast for FY2023, and we expect to achieve our initial forecast.

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#### FY2023 Q3 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



Page six. This graph shows the change in revenue compared to the same period last year, from January to September. Excluding Ronapreve, revenue grew steadily during this period, up JPY87.9 billion, or 13.1%.

I will present this from left to right. Regarding domestic sales, sales volume increased due to steady penetration of new products and mainstay products. These effects absorbed the impact of negative factors such as NHI price revisions, resulting in an increase of JPY21.2 billion.

Next, in overseas sales, FX impact and growth of sales volume significantly outweighed the impact of lower export unit prices, resulting in an increase of JPY55.8 billion. Export sales of Hemlibra and Alecensa were particularly strong.

Other revenue increased primarily due to the increase in royalties on Hemlibra's intellectual property and profit-sharing income.

As a result, the core business, excluding Ronapreve sales, grew steadily, resulting in an increase in revenues. For the full year, related to core business, revenues and profits are expected to increase in line with our initial forecast.

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FY2023 Q3 Overview

# 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	Mid to long-term drivers	Factor of revenue decline (Risk)
<ul> <li>Hemlibra: Obtained additional indication for Hemophilia A(moderate) in EU. Expansion of market share</li> <li>Alecensa: Met primary endpoints in ALK+ early NSCLC(P3). Sales growth in domestic and overseas market</li> <li>Continuous launch and market penetration of in-house products</li> <li>crovalimab: Filed in JP, U.S., EU (expected approval next year)</li> </ul>	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	Competitive environment <ul> <li>Actemra: Multiple biosimilars in approved/filed/development stages in EU and the U.S.</li> <li>Avastin, Kadcyla, etc.: Penetration of biosimilars and changes in competitive landscape</li> <li>End of upside effect on COVID-19 related therapies</li> <li>Ronapreve: Completion of supply the government</li> <li>Actemra: Decrease in demand for</li> </ul>
Stable revenues from Roche products	<ul> <li>Mid-size molecule: Progress in follow- on projects</li> </ul>	COVID-19
Average and the started for AS     Phesgo: Obtained approval (to be launched within 2023)     tiragolumab, etc.: Initiation and progress of consecutive late-stage     development projects	Accelerating innovation Chugai LSP Yokohama: Started full operation CVF: Preparing to start activities dto Maruho In Jacon ***Out-licensed to Eli Lilly and Company	<ul> <li>HHI drug price revision, etc</li> <li>Hemlibra, etc.: Re-pricing for market expansion</li> </ul>

Page seven. I will continue with an overview of the progress made during the first nine months of the current fiscal year with regard to pipeline and core products that could affect growth in the short, medium, and long term.

Although Actemra is expected to be affected by maturation and other factors, the Company is making steady progress, mainly in in-house projects, with the aim of achieving sustainable growth. Both Hemlibra and Alecensa, the current mainstay products, are seeing further market share gains and sales growth. Hemlibra obtained an additional indication of Hemophilia A (moderate) in Europe. Alecensa met its primary endpoint in a Phase III study, and we are preparing to expand its indications in early-stage NSCLC.

We anticipate that crovalimab, nemolizumab, Enspryng, and orforglipron will drive growth in the short to medium term. We have successfully completed pivotal studies, developed simultaneously for multiple diseases, and initiated Phase III studies, and are making good progress toward global market launch, market penetration and revenue growth.

In the mid to long term, three new in-house antibody projects started this year. Also, in LUNA18, we have confirmed the oral absorption of mid-size molecules. Subsequent projects are also showing solid results in terms of both quality and quantity.

Progress is also being made in laying the groundwork for accelerated innovation, including the full operation of the Chugai Life Science Park Yokohama. We will continue our activities to become a top innovator in the healthcare industry as stated in TOP I 2030.

Mr. Yamaguchi will explain specific R&D progress in Q3 later in this presentation. That is all from me.

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## Overview of Development Pipeline Q3 Topics (1/2)



As of October 24, 2023

Launched	Enspryng	NMOSD (Taiwan)	October 2023
	Actemra	CRS induced by cancer therapy	September 2023
Approved	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
	Enspryng	TED	P3 study (Q3 2023)
nitiation of	tiragolumab + Tecentriq + Avastin	1L HCC	P3 study (October 2023)
study	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)

Tetsuya Yamaguchi: Thank you. Yamaguchi here. See slide nine. This slide covers Q3 topics.

Information about launch and approval has already been announced. Of these, Phesgo is a subcutaneous formulation of Perjeta and Herceptin combined with vorhyaluronidase, which is administered subcutaneously for five to eight minutes, compared to the conventional 60- to 150-minute intravenous infusion. Medication adjustments are also no longer necessary, reducing the burden on patients and medical facilities.

Four trials have started. I will talk about Enspryng in more detail later.

We participated in the Phase III study of tiragolumab in hepatocellular carcinoma. We have initiated a domestic Phase III study for Gazyva for extra renal lupus.

RG6139, which entered Phase I, will be explained later.

In phase transition, we began participating in a global Phase I/II study for Alzheimer's disease with trontinemab. The brain shuttle technology, which enhances the transport of the blood-brain barrier, is expected to have high clinical efficacy due to the removal of strong amyloid- $\beta$ .

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## **Overview of Development Pipeline Q3** Topics (2/2)



As of October 24, 2023

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

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

\* 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

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Please proceed to the next slide. Both trial readouts and conference presentations have already been announced.

The results of ALINA study for Alecensa in adjuvant therapy will be discussed later. BEAT-SC, a Phase III study for Tecentrig and Avastin in small cell lung cancer, led by the Company and Roche China, met its primary endpoints of progression-free survival.

The CONTACT-02 trial for Tecentriq and cabozantinib in a second-line prostate cancer, co-developed with Takeda, has met one of its primary endpoints, PFS.

I will mention the conference presentation of the three pivotal trials of nemolizumab later.

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# 2023: Key R&D Milestones



Underlined and bolded are new progress since July 27, 2023

	Product	Indication/Study name	Progress
	Actemra	Systemic sclerosis with interstitial lung disease (SSc-ILD) (EU)	withdrawal
Projects to be	Hemlibra	Moderate hemophilia A (EU)	approved
approved	crovalimab	PNH (China)	2024
	RG6264 (PER/HER FDC)	HER2-positive Breast cancer/Colorectal cancer	approved
	Alecensa	ALINA study: NSCLC [adjuvant]	met PE
	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>
P3/Pivotal readouts	Tecentriq	IMpassion030: eBC [adjuvant]	Developmen 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  $\rightarrow$  2024)

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Please proceed to the next slide. Here is the progress of this year's major R&D events. I have already indicated this, but the underlined portion here is the progress this time.



Please proceed to the next slide. Here are the results of the Alecensa in non-small cell lung cancer adjuvant therapy trial presented at ESMO.

About half of the patients with NSCLC with completely resected who are eligible for this study have experienced recurrence of the disease and have high unmet medical needs. As shown in the graph, which

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represents disease-free survival, Alecensa reduces the risk of disease recurrence or death by 76%, compared with the chemotherapy group.

Also, although not shown on the slide, the incidence of intracerebral recurrence, which is a major clinical problem, was reduced by 78%. No new safety findings have been identified. As the first adjuvant therapy with an ALK inhibitor, we will submit this data to authorities around the world.



Please proceed to the next slide. Next, I will discuss the results of the global Phase III study of nemolizumab in atopic dermatitis and prurigo nodularis presented at EADV, the European Academy of Dermatology & Venereology.

The first slide shows the results of ARCADIA, global Phase III studies for atopic dermatitis. The percentage of patients who improved IGA (Investigator's Global Assessment) 2 points or more is shown in the upper panel and the percentage of patients who achieved more than 75% improvement in eczema area & severity index is shown in the lower panel. In both studies, there was a statistically significant increase in the percentage of patients who improved in the nemolizumab group, both in overall cases and in severe cases of pruritus. In addition, all secondary endpoints were met and improvement in sleep disturbances was confirmed. The drug was well tolerated, and the safety profile was consistent in both studies.

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Nemolizumab: Improvement of Pruritus in Atopic Dermatitis

Rapidly suppresses pruritus in ARCADIA 1&2 studies



Please proceed to the next slide. Next, we show the percentage of patients whose PP NRS, a measure of pruritus, improved by 4 points or more through 16 weeks.

In both studies, the nemolizumab group, blue line, showed more sustained improvement in pruritus than the placebo group, gray line, both in the solid line, all patients, and in the dotted line, severe cases of pruritus.

In particular, statistically significant improvement in pruritus was observed even after the initial one, two, and four weeks of treatment, confirming the rapid suppression of pruritus that is characteristic of nemolizumab.

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## Nemolizumab: Global P3 OLYMPIA 1 (Prurigo Nodularis)

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



Please proceed to the next slide. Next are the results of OLYMPIA 1, a global Phase III study for prurigo nodularis.

The left half shows the percentage of patients who improved at least 4 points over 16 weeks on the PP NRS, a measure of pruritus, and the right half shows the percentage of patients who improved significantly on the IGA.

Both showed statistically significant improvement in the nemolizumab group. All secondary endpoints were also met with nemolizumab, and improvement in sleep was also observed. Nemolizumab was well tolerated. These results are consistent with another global Phase III study, OLYMPIA 2, which was announced earlier.

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## Nemolizumab: Improvement of Pruritus in Prurigo Nodularis Rapidly suppresses pruritus in OLYMPIA 1 study



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Please proceed to the next slide. Next, I will show you the change in pruritis symptoms from prurigo nodularis up to 24 weeks.

The nemolizumab group, indicated by the blue line, showed statistically significant improvement in pruritus after four weeks of treatment. Here, too, nemolizumab has been shown to rapidly suppress pruritus.

Common symptoms in patients with atopic dermatitis and prurigo nodularis are poor sleep and reduced quality of life due to pruritus. We expect that nemolizumab, which targets IL-31 signaling involved in pruritus and inflammation, will be an effective and safe treatment for patients worldwide with these diseases.

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(N=5)

(N = 6)

# AMY109: Anti-IL-8 Recycling Antibody for Endometriosis

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

#### Endometriosis

#### AMY109

Endometriosis occurs 1 in 10 In endometriosis monkey models, it was confirmed that the inflammatory chemokine IL-8 is involved in the women aged 20-49 years old\* progression of inflammation and fibrosis of endometriosis, and that the treatment of anti-IL-8 antibodies improved severity of endometriosis such as lesion reduction Main symptoms are severe menstrual pain and chronic pelvic AMY109 is expected to deliver a new value to patients by anti-inflammation, with a different approach from pain, and it can also cause standard hormone therapy In Phase 1 study, the favorable safety, tolerability, and pharmacokinetics of single-dose administration in healthy infertility, potentially changing the lives of patients. 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 oto-Kakiuchi A et al, Science Translational Medicine. 2023 Feb 22:15(684) Relative volume of nodular lesions (%) In endometriosis monkey model<sup>1</sup> (%) Inflammation Fibrosis Migration of crophage by MCP1 \*P = 0.022 Hemorrhage & inflammatic Fibrosis in endometriosis in endometriotic tissue 300 . Fibroblast-to-Myofibroblast . →IL-8↑ transi MCP11 High contractility 200 fibroblast, Secretion of extracellular matrix of IL-8 TGF811 nhil h α-Smooth Muscle Actin expressio 11-8 1 100 IL-8: interleukin-8 AMY109 Relati MCP1: monocyte chemoattractant protein 1 Vahi AMY109 TGF  $\beta$ : transforming growth factor  $\beta$ 17 High dose (N=6)

Now, please proceed to the next slide. We have the slide of the paper and conference presentation related to AMY109 organized here.

First, in a monkey model of endometriosis, we have confirmed that IL-8 contributes to the development of inflammation and fibrosis in endometriosis. If anti-IL-8 antibodies are administered, there is a reduction of pathological changes associated with endometriosis. The results are shown in the lower right graph.

In the Phase I study of AMY109, we have confirmed good tolerability and blood dynamics in single dosing in healthy adults and multiple dosing in patients with endometriosis, and we are now preparing for the Phase II study. With AMY109, we aim to provide an antibody drug that provides new value through its antiinflammatory and anti-fibrotic effects, which are different from those of conventional hormone therapy.

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# 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>)

 The Japan Thyroid Association and the Japan Endocrine Society: Diagnostic Criteria and Treatment Guideline for Graves' Malignant Exophthalmos (Thyroid Ophthalmopathy) 2023 (3rd Draft)
 Zang S, et al. J Olin Endocrinol Metab. 2011;96(2):320-32.
 Allen RC, et al. Ophthalmology. 2021;128(8):1125-8.
 Bratleina L, et al. Eur Thyroid J. 2016;5(1):9-26.
 Rundle FF. Metabolism. 1957;6:32-48.
 Shan SJC, et al. J Neuroophthalmol. 2014;34(2):177-85.



Please proceed to the next slide. I will then discuss the global Phase III study of Enspryng in thyroid eye disease.

Thyroid eye disease is an autoimmune inflammatory disease of the orbital tissues, as seen in Graves' disease and other conditions. The lower right corner of the slide depicts the orbital tissue as seen from the inside of the eye. Thickening of the orbital tissues can cause a variety of eye symptoms, impairing vision and significantly affecting quality of life.

In thyroid eye disease, elevated IL-6 levels and a correlation between inflammatory symptoms of the eye and IL-6 levels have been reported. Inhibition of IL-6 signaling by Enspryng is expected to reduce inflammatory responses and fibrosis and improve eye symptoms.

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# Tobemstomig (PD1-LAG3)/RG6139



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

Anti-I AG

#### **About Tobemstomig**

- Bispecific antibody binding to PD-1 and LAG-3, reinvigorates Tcells 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

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

Tobemstomig structure and MoA



DP-1=programmed death-1; LG-3=lymphocyte activation gene-3; TILs=tumor-infiltrating lymphocytes; Tregs=regulatory T-cells; MoA=mode of action; TCR=T-cell receptor

Please proceed to the next slide. Tobemstomig is a bispecific antibody that binds to two immunosuppressive checkpoint molecules, PD-1 and LAG-3. It also preferentially binds to tumor-infiltrating cells, blocking their signals and activating T cells.

In addition, the drug binds preferentially to effector T cells rather than regulatory T cells, which is expected to avoid immunosuppressive effects. A phase I study has been initiated in Japan for the treatment of solid tumors.

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	of Development P ected Si	•	ons (Pos	t PoC NI	MEs and I	Products	CHUGAI
	Filed			NME	Line extension	as of C	october 24, 2023
crovalimab (SKY59/RG6107) PNH (China)		VABYSMO (RG7716) RVO	in-house in-license	d (Roche)			
crovalimab (SKY59/RG6107) PNH (Japan)	crovalimab (SKY59/RG6107) PNH (EU)				tiragolumab + TECENTRIQ (RG6058 + RG7446) 1L NSQ NSCLC ☆	giredestrant (RG6171) 1L BC	
			mosunetuzumab+ POLIVY (RG7828+RG7596) r/r aNHL	Vabysmo (RG7716) Angioid streaks	ENSPRYNG (SA237/RG6168) MOGAD	giredestrant (RG6171) BC (adjuvant)	GAZYVA (RG7159) ★ Extra renal lupus
	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
	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
	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
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)
2023 ★ : new entry	2( ★ : changes in submiss	)24 ion year *Before obta	20 ining PoC	25	2	2026 and beyon	<b>d</b> 20

Next slide, please. Finally, the schedule for future applications is shown. Those with red stars are new additions, and green stars are projects whose year of application has changed. Based on the progress of trials, we have changed the year of application for some items.

The following few pages are for reference only, please refer to them as appropriate. That is all from me.

## FY2023 Q3 Consolidated Financial Overview (Core) P/L Jan – Sep (Non-core adjustment)

	IFRS	Non-core	e items	Core
(Billions of JPY)	results	Intangible assets	Others	results
Revenue	837.6			837.6
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
Operating profit	317.6	+6.3	+16.7	340.5
Financial account balance	3.5			3.5
Income taxes	-86.9	-1.9	-5.0	-93.8
Net income	234.3	+4.4	+11.7	250.3
EPS (JPY)	142.37			152.11



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Miyata: Finally, Mr. Itagaki will give an overview of the consolidated financial results and core results for Q3.

Itagaki: I will explain the details of the financial figures. See page 32.



Adjustments from full IFRS-based results to core results are shown at right. The four items are the same as in Q2, and the total increase over the past three months is JPY1.9 billion, all of which are within the expected adjustment range.

Early retirement incentives, including additional retirement benefits and outplacement costs, totaled JPY10.4 billion. This has not changed since Q2. These adjustments will add back JPY23 billion in the operating profit stage, resulting in an operating profit of JPY340.5 billion on a core basis.

The following explanation is based on this core base.

(Billions of JPY)	2022 Actual	)Renaming and	(Billions of JPY)	2022 Actual
Revenue	729.5		Revenue	729.3
Sales	644.7		Sales	644.7
Domestic	387.6	Planta de la constante de la const	Domestic	387.6
Overseas	257.1	Blue text :renamed categories	Overseas	257.1
Royalties and other operating income	84.9	0.2 billion JPY	Other revenue	84.6
Royalty and profit-sharing income	80.7	0.2 Billion JP f	Cost of sales	- 262.4
Other operating income	4.2	Income from disposal of	(cost to sales ratio)	40.7%
Cost of sales	- 262.4	product rights is reclassified	Research and development	- 101.0
(cost to sales ratio)	40.7%	to the new category "Other operating income (expense)"	Selling, general and administration	- 68.3
Operating expenses	- 168.1		Other operating income (expense)	1.5
M&D and G&A	- 67.1	1.2 billion JPY	Operating profit	299.0
Research and development	- 101.0	Income and expenses associated with	(operating margin)	41.0%
Operating profit	299.0	operating activities that were	Net income	213.0
(operating margin)	41.0%	previously included in "G&A" but could	EPS (JPY)	129.48
Net income	213.0	not be classified into functional expense categories such as gain (loss)		
EPS (JPY)	129.48	on sale of land and buildings, etc., is		

See page 33. For comparison purposes, this chart shows what would happen if the presentation changes and reclassifications made this year were applied to last year's results.

Revenues are shown JPY200 million lower, but operating profit and quarterly income remain the same. The following slides are also based on the previous year's core results, after reclassification.

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#### FY2023 Q3 Consolidated Financial Overview (Core)

# P/L Jan – Sep (Year on Year)

(Billions of JPY)	2022	2023	Growth		
Revenue	729.3	837.6	+ 108.3	+ 14.8%	
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	117	
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%	
Operating profit	299.0	340.5	+ 41.5	+ 13.9%	
(operating margin)	41.0%	40.7%	-0.3%pts	27	
Financial account balance	-1.9	3.5	+ 5.4	-	
Income taxes	-84.1	-93.8	- 9.7	+ 11.5%	
Net income	213.0	250.3	+ 37.3	+ 17.5%	
EPS (JPY)	129.48	152.11	+22.63	+ 17.5%	



#### 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.

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See page 34. The table shows the YoY profit/loss results for Q3.

Revenue was JPY837.6 billion, up 14.8%. Domestic sales increased 10.7% thanks to growth of new products, including Ronapreve, and mainstay products. Overseas sales also grew by 21.7% with increases in sales of Hemlibra and Alecensa. Other sales revenue grew 12.9%, mainly due to higher royalty income of Hemlibra.

The cost to sales ratio increased by 2.4% points to 43.1%, mainly due to foreign exchange rates.

R&D expenses increased 20.5% due to investments in research and early development, including the start of operations at Chugai Life Science Park Yokohama, and progress of development projects. On the other hand, SG&A expenses increased only 4.5%.

Other operating profit totaled JPY16.3 billion, including income from the disposal of product right of Bonviva, and gains on sales of property, plant, and equipment.

As a result, operating profit increased by JPY340.5 billion, or 13.9%. Operating margin was 40.7%.

The net financial income of JPY3.5 billion, which included gains on foreign exchange derivatives, brought quarterly income to JPY250.3 billion, an increase of 17.5%.

Sales, operating profit, and net income all reached record highs in Q3.

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Next, page 35. This is a breakdown of change in sales of manufactured goods.

The dark blue block in the lower left, the domestic oncology area, saw a 2.6% increase in sales. Looking at the individual products in dark blue on the right, sales of Avastin, Kadcyla, and Herceptin were down due to price revisions, biosimilars, or competitive products. Growth of Polivy and Tecentriq exceeded these negative factors.

The next block in light blue, the specialty area, showed an 18.4% increase in sales, the largest of which was a JPY20.4 billion increase for Ronapreve. Even excluding Ronapreve, domestic sales in the specialty field increased by JPY16.5 billion, or 11.8%, or 10% range growth. Looking at individual products, Vabysmo, Enspryng, Hemlibra, and Evrysdi are growing.

The gray block, the overseas area, also continued to perform well with a 21.7% increase in sales. The four products we export to Roche, including Hemlibra, Alecensa, and Actemra, are all growing.

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Please proceed to page 36. This is a breakdown of the increase in operating profit.

The second to fourth bars on the left show a factor breakdown of the increase in gross profit. The negative effects of the price revision and export unit prices were absorbed by the increase in volume and the effect of yen depreciation, resulting in a JPY39.6 billion increase in gross profit.

Next, other sales revenue increased by JPY10.9 billion. This includes a negative JPY10.9 billion impact from the Royalty 2 on the initial shipment of Hemlibra, which expired last year. Excluding the impact of Royalty 2, other sales revenue increased by JPY21.8 billion.

The JPY21.8 billion increase includes a JPY17.9 billion increase in regular royalty and profit-sharing income and a JPY3.8 billion increase in milestone income. The increase in R&D expenses and SG&A expenses and other operating revenues has already been explained.

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#### FY2023 Q3 Consolidated Financial Overview (Core)





#### Year on Year (vs. 2022 Q3)

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

 ${\bf R\&D};$  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  $\ensuremath{\mathsf{Q2}}$ 

Operating profit: -18.0 billion JPY, -14.2%

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#### FY2023 Q3 Consolidated Financial Overview (Core)

# 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

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#### FY2023 Q3 Consolidated Financial Overview (Core)



## Structure of Sales by Quarter



Next, from page 37, there are three more slides showing quarterly changes.

The quarterly transition has been variable, depending on whether or not there have been government supply of Ronapreve. Ronapreve sales totaled JPY142.8 billion in Q4 last year, and JPY81.2 billion in Q1 of this year. We are not particularly concerned about this variability. Therefore, since time is limited, I would like to skip the explanation of this slide of quarterly trends, and jump ahead a little.

### FY2023 Q3 Consolidated Financial Overview (Core)

# P/L Jan – Sep (vs. Forecast)

	Actual	Fore	cast	2022	
(Billions of JPY)	2023	2023	Brogroop	Progress*	
	Jan - Sep	Jan - Dec	Frogress		
Revenue	837.6	1,070.0	78.3%	62.5%	
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%	
Operating profit	340.5	415.0	82.0%	66.2%	
(operating margin)	40.7%	38.8%	-	-	
Net income	250.3	306.0	81.8%	67.0%	
EPS (JPY)	152.11	186.00	81.8%	67.0%	



#### 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  $% \left( {{{\rm{S}}_{{\rm{s}}}}} \right)$ 

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

### Page 40. This is the progress against the full-year forecast.

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The progress rate of revenue is 78.3%, 15.8 percentage points higher than last year. The rate of progress has also been affected by Ronapreve. Looking at the progress rate of sales in the domestic market, the figure is 79.2% this year, 20 percentage points higher than last year's 59.2%.

Excluding Ronapreve, the progress rate this year would be 75.6% and the difference from last year would be about 3.1 percentage points.

Progress toward the full-year forecast for overseas sales is also up from last year, at 82.7%. That is 15.9% points above last year's figure. Since overseas sales inevitably change with the timing of shipments, it is difficult to say whether the progress rate alone is favorable or unfavorable, but sales of Hemlibra at Roche are stronger than we had expected, and this has led to strong exports.

In terms of costs, I think it is safe to say that cost of sales, R&D expenses, and SG&A expenses are generally in line with expectations. Other operating revenues have already met the full-year forecast.

Overall, the government supply of Ronapreve and the timing of other operating income, in addition to strong exports, have resulted in fast progress in terms of profits. Now that we are on track to achieve our full-year forecast, we just have to see how much further we can go. With less than two months to go, that means we are almost there. We will continue to do our best.

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## FY2023 Q3 Consolidated Financial Overview (Core) Sales Jan – Sep (vs. Forecast)

	Actual	Forecast		2022		Actual	Forecast		2022	
(Billions of JPY)	2023 Jan - Sep	2023 Jan - Dec	Progress	Progress *	(Billions of JPY)	2023 Jan - Sep	2023 Jan - Dec	Progress	Progress *	
Sales	742.1	920.0	80.7%	62.0%	Specialty	237.9	288.4	82.5%	50.4%	
Domestic	429.2	541.7	79.2%	59.2%	Ronapreve	81.2	81.2	100.0%	29.89	
Oncology	191.4	253.3	75.6%	72.9%	Hemlibra	40.5	53.7	75.4%	71.49	
Tecentriq	47.9	67.7	70.8%	72.1%	Actemra	32.2	44.3	72.7%	72.99	
🕇 Avastin	38.2	48.1	79.4%	75.4%	1 Enspryng	16.9	21.6	78.2%	68.99	
🔷 Polivy	25.5	31.6	80.7%	58.7%	🚚 Vabysmo	10.8	17.4	62.1%	50.09	
🔷 Perjeta	24.6	31.0	79.4%	72.8%	Evrysdi	10.3	14.1	73.0%	69.69	
🔷 Alecensa	22.0	28.2	78.0%	72.3%	1 Mircera	6.3	7.6	82.9%	75.09	
👚 Kadcyla	11.7	14.1	83.0%	75.1%	CellCept	5.2	6.7	77.6%	73.49	
Herceptin	3.6	4.9	73.5%	76.1%	1 Edirol	5.6	5.2	107.7%	75.99	
🞩 Gazyva	2.6	4.5	57.8%	77.5%	Other	29.0	36.7	79.0%	75.15	
Rituxan	2.9	3.7	78.4%	75.0%	Overseas	312.9	378.3	82.7%	66.89	
Foundation Medicine	5.6	8.3	67.5%	74.6%	👚 Hemlibra	171.8	185.2	92.8%	69.79	
- Other	6.6	11.2	58.9%	74.8%	- Actemra	86.5	121.4	71.3%	61.5	
					1 Alecensa	37.9	50.4	75.2%	66.75	
					The Enspryng	4.3	3.8	113.2%	71.49	
					1 Neutrogin	6.0	7.3	82.2%	77.09	
exceed forecast					- Edirol	0.1	0.5	20.0%	0.05	
below forecast					Other	6.2	9.7	63.9%	74.79	

Now, I would like to turn to page 41, which is the sales progress of individual items.

In overseas sales, oncology and specialty sales are generally in line with expectations. However, when looking at individual products, there is some variability in progress, which is indicated by the arrows as good or bad.

Among them, in the oncology area we can see that Polivy, Perjeta, and Alecensa are performing particularly well. In the specialty area, Enspryng and Edirol are also performing well. Also, the forecasts for Tecentriq and Vabysmo were quite bullish, and it appears at present that these may be a little tough to achieve.

Overseas sales are strong, and although there are some bumps in the road for individual products, exports of Hemlibra are particularly strong. Overall overseas sales are on track to exceed the full-year forecast.





Now turn to page 42. This slide covers foreign exchange impacts.

As shown in the graph on the right, the trend of yen depreciation has been continuing since last year, but it seems to have reached a plateau.

However, in our case, we use the rate we hedged against in the previous year for actual settlement, so as shown in the table below left, the actual settlement rate is about 10% to 16% lower than the rate for the same period last year.

As a result, as shown in the table above, the depreciation of the yen compared to the previous year had a favorable effect on earnings and a disadvantageous effect on costs, resulting in a net increase in operating profit of JPY9.8 billion. In addition, some transactions were not hedged against the assumed and planned exchange rates, and the weakening trend of the yen in the market also had a favorable impact of JPY3.1 billion on the operating profit level.

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Now let's move on to page 43. This slide shows the profit/loss of the so-called base business, excluding the impact of COVID-19.

This fiscal year, Ronapreve's government supply totaled JPY81.2 billion, a JPY20.4 billion increase in revenue compared to last year. In addition, the export of Actemra IV formulations has been affected by the decline in COVID-19-related demand. Comparing like-for-like, we can see a negative of JPY10.2 billion. The net effect of this was JPY10.3 billion, which is the effect of the increase in sales of COVID-19 treatment. You can see from the graph how this relates to the 13.3% increase in revenue of the base business. This is shown in the top graph.

Similarly, in terms of operating profit, COVID-19 therapeutic profits are down JPY5.8 billion.

The reason for the negative effect of JPY5.8 billion in profit despite the positive effect of JPY10.3 billion in revenue is that Ronapreve's profit margin this year is considerably lower than last year. This is because of the higher purchase price of Ronapreve because of the weaker yen. Therefore, excluding the negative impact of JPY5.8 billion, the graph below shows a 16.1% increase in operating profit for the base business.

This means that sales and profits in the base business are experiencing double-digit growth. We can confirm here that the business continues to be strong.

This concludes the explanation of the profit and loss slides.

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### Page 44 shows the balance sheet.

If you look at the second line from the bottom on the left, total net assets increased by JPY110.6 billion from the end of last year to JPY1.535 trillion. Below that, the ratio of shareholder equity is 84.4%, a very robust financial position.

Net cash, shown in the middle of the chart, increased by JPY115.7 billion from the end of last year to a balance of JPY618.8 billion.

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The breakdown of this change in net cash is explained on page 45.

The first factor is cash flows from operating activities. There was JPY357.7 billion in adjusted operating profit, the second from the left. The decrease in net working capital of JPY117.9 billion is due to the cash collection of JPY142.8 billion in Ronapreve sales supplied at the end of last year.

After deducting JPY61.9 billion for capital investment, operating free cash flow was positive at JPY413.6 billion.

The cash outflows include JPY171.6 billion in income taxes and JPY131.2 billion in dividends, resulting in a net cash increase of JPY115.7 billion over the nine-month period to JPY618.8 billion at the end of September.

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#### FY2023 Q3 Consolidated Financial Overview (Core)

# Current Status / Plan for Major Investments



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									Planned investment			Start of	Planned
		~2022	2023	2024	2025	2026	2027	2028~	Total amount	Investment to-date		investment	completion
	Fujieda plant		F33: 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- 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	CPR	Accelerate cre	ation of clinical (	candidates utilizi	ng proprietary a	intibody technolog	ties		758 of which, capital im 82		million SGD million SGD	2012	2026
and Chugai LSP development Yokohama		Building of sta	te-of-the-art R&	D site to create	innovative new	drug candidates			128.8 - Land of 43.0 billion		billion JPY	2019 - Start of operati	2022 on: Apr. 2023
	IFReC	Funding to IFF	eC per compreh	ensive collabora	tion agreement				10.0	6.5	billion JPY	2017	2027
Environment	Environmental investment	E	quipment upgrad	le to achieve Mic	I-Term Environr	nental Goals 2030			107.2 estimated total a	amount	billion JPY	2022	2032

Page 46, this is the last slide. This is the status of the main investments. There are no additional projects from Q2. As for the update on the results of investment activities, all activities are progressing as planned.

This concludes my presentation. Thank you very much.

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## **Question & Answer**

**Miyata** [M]: We will now move to the question-and-answer session. Please be advised that Mr. Hidaka, Executive Vice President, Head of Marketing & Sales Division, is also present for the Q&A session.

**Wakao [Q]**: This is Wakao from JPMorgan, thank you very much. I would like to ask about Q3, and the outlook for the next fiscal year.

I deeply understand that the key point for the current fiscal year is how much the full-year forecast can be exceeded due to strong exports of Hemlibra. So, can we extrapolate this trend and expect profit growth in the next fiscal year as well?

On page seven, you listed risk factors and other information. In looking at the next fiscal year, how do you anticipate that growth of your current growth driver, Hemlibra, will change? Also, how do you anticipate that the risk factors you have listed will change? Thank you.

**Okuda [A]**: Thank you for your question, Mr. Wakao. Okuda here. Regarding your question about the outlook for the next fiscal year, I would like to refrain from making any specific comments at this time.

This year, revenue and operating profit both grew steadily, as I explained in my presentation as the core business, excluding COVID-19 related effects. However, you are aware that this will not be the case in the next fiscal year, since we had sales of JPY81.2 billion this fiscal year by government deliveries of Ronapreve. This is right.

Hemlibra's global sales have been quite strong. If you look at our market share, we are now at 40%. Accordingly, exports from Chugai have been higher than expected. That's one point.

Looking overseas, for example in the UK or France, the market share has increased considerably. Roche's explanation is that there are some countries where the patient share is over 60%, so I think it is safe to say that this is expected to continue to be steady growth.

Another factor is Actemra. As I have explained, several companies are developing Actemra biosimilars. Fresenius Kabi announced the approval of both SC and IV formulations in Europe in September of this year. However, as we have already announced, we have entered into a settlement agreement.

There is also Biogen and Bio-Thera, the IV formulation of which was approved in China in January 2023. It was announced that an IV formulation was approved in the U.S. in September of this year. As we announced at 15:00 today, we have entered into settlement agreements with both Biogen and Bio-Thera worldwide.

As is the case with both Fresenius Kabi and Biogen, please note that the details of the contract are not disclosed, in accordance with the contract.

However, in 2023, we expect the impact of the biosimilars this year to be very limited. In 2024, we expect some degree of competition to enter the market. We will explain next year's earnings forecast when we announce our full financial results next year, and I would like to explain at that time about our sales forecast for Actemra. That is all from me.

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**Wakao [Q]**: Thank you very much. As for the next fiscal year, there is some degree of competition for Actemra, and next fiscal year it will be due to biosimilars.

I thought that the fact that it was only a little bit was not a factor that would cause a significant downward swing in the earnings forecast, or a downward swing compared to the current term, but I guess it is difficult to forecast Actemra's total net sales for the next term? How do you rate the likelihood of Actemra contributing to increases in earnings in future years?

**Okuda [A]**: I used the phrase "some degree of," because it has been confirmed that the launch has not yet started at this point. Therefore, it is difficult to predict the competition and the speed of penetration of biosimilars.

We will discuss this in more detail at our financial briefing next February. Of course, such forecasts are based on our figures, which take a little time to put together. I hope you can appreciate that.

**Wakao [Q]**: Of course, thank you very much. Secondly, for nemolizumab, based on the data you have obtained this time, could you comment on the market penetration that you originally envisioned, or whether you will be able to gain market share against Dupixent?

In terms of suppressing pruritus, which is one of its strengths, I have the impression that it is not as capable as Dupixent, so I would like to know what your company thinks about it based on this data.

**Tetsuya Yamaguchi [A]**: Thank you. As to the degree of efficacy, including itch suppression, compared to Dupixent, I am of course aware that it is very difficult to make comparisons between trials. In addition, a single-agent study and our study, which was a combination study, are two quite different things, which further complicates comparison. We understand that the figures are in the context of combination therapy, with a bottom-up increase.

Therefore, we feel that nemolizumab is competitive enough to enter the market, especially in the area of pruritus, as we had expected. Given that there is a subgroup of patients for whom suppression of pruritus is a major priority, these results would support our expectations of sales for this product.

Wakao [Q]: Thank you very much. By the way, the placebo is a bit high, is there any background to this?

**Tetsuya Yamaguchi [A]**: Since it is inevitably a combination therapy, we have not compared it with other trials, so I think that improvement may have been observed in the area of such combination therapy. I do not have any further explanation. I'm sorry I don't have more to say on that.

Wakao [M]: Okay, thank you very much. That is all.

Muraoka [Q]: Hello. Morgan Stanley, Muraoka. Thank you very much.

This is a continuation of Mr. Wakao's question about positives and negatives for the next fiscal year. I would like to ask you about Actemra and the inventory adjustment of other products as well. I know you talked about the inventory adjustment of Hemlibra a year ago at this time. Is there any possibility of further adjustments or other elements like this in the near future? This type of event is difficult for us to appreciate as outside observers.

Regarding the Company's thinking about Actemra, is it based on the idea that it is better to make a conservative forecast and get better results, or is it more likely to be based on the assumption that the lawsuit

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settlements mean that there is likely to be less of an effect? It would be helpful if you could guide us in this area to the extent possible.

**Okuda [A]**: Thank you for your question, Mr. Muraoka. Okuda here. I will give you my response, and CFO Itagaki will respond to you regarding the prospects for inventory adjustments.

The situation with Actemra is as I explained earlier. We will make what we believe to be the most appropriate projections to the extent possible, and then, including local sales and inventory adjustments, we will consider our export projections for next year's announcement of the full financial results. Therefore, for us, we will not be conservative, but will make the best forecast.

As for Hemlibra, local sales growth has been quite strong, and we expect this momentum to continue, as explained earlier.

I will hand over to Mr. Itagaki.

**Itagaki [A]**: Regarding inventory adjustment, this is all about Roche-side inventory adjustment affecting our exports. First of all, regarding Actemra, if we look at the current results, this year's Actemra exports have grown by 8.1% YoY, but as I mentioned earlier, there has been a considerable impact from the depreciation of the yen. Therefore, if we do it on a volume basis, it would be rather negative.

On the other hand, if you look at Roche's Q3 sales, you see a 1.9% increase. However, since a considerable amount of time has passed since the COVID-19 pandemic settled down, I don't anticipate that an inventory adjustment would happen next year.

I would also like to say a few words about Hemlibra. From the beginning, we predicted Hemlibra exports this year would be affected by the adjustment of Roche safety stock, which would have an impact of about JPY20 billion on our exports. In conclusion, we believe that inventory adjustments have occurred.

Similarly, exports of Hemlibra have increased by 27.5% over the same period. Naturally, there is also the positive effect of the yen's depreciation. On a volume basis, I think it is probably a little more than 10%, but on the other hand, Roche's external and third-party sales grew 19.8% compared to the previous year, so our volume of exports is still a little lower than the Roche assumption. We can verify that inventory adjustments are still occurring.

As we have said since the beginning, we expect inventory adjustment to be almost completed by the end of this year. Although inventory adjustments were made as initially planned, the progress rate is already 93.3% toward the full-year forecast of JPY181.5 billion in exports, and exports are also doing well, pulled by Roche's external sales.

We had forecasted that the full-year forecast would be JPY9.6 billion less than the JPY191.1 billion last year, but at this point, I think we will exceed the full-year forecast or even last year's results, so there will be no impact from inventory adjustments next year. We are now hopeful that the momentum is very strong and that it will continue next year.

I would like to explain the specific figures at the time of the next financial results briefing.

Muraoka [Q]: Thank you very much. Thank you for your detailed explanation.

One more thing, about the orforglipron royalties, there was a lot of talk in the market at the end of September, and I think Roche is saying that it is a tiered, at most in the teens. but can you just tell me if I am wrong about this comment that came out from Roche? Thank you.

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**Itagaki [A]**: We have a confidentiality agreement with Lilly, so I can't say anything about the details of the contract. Therefore, please be aware that I cannot comment on whether it is or not, or even whether that is accurate or not.

Muraoka [M]: I understand. Thank you, that's all.

Miyata [M]: Next, Mr. Yamaguchi, Citigroup Global Markets. Please go ahead.

**Hidemaru Yamaguchi [Q]**: Thank you very much. I would also like to ask about orforglipron. I believe they said, "high teens."

I understand that you and Lilly have an agreement that you can't say anything about this, but at the risk of sounding strange, if the confidentiality agreement is lifted to some degree in the future, including with Lilly, could you say something about this?

**Itagaki [A]**: Itagaki here. Since the contract does not provide for the termination of the confidentiality obligation, I think that from the outside, when royalties are paid in the future, as is the case now, we do not disclose how much is paid for each individual item, but you can only guess by looking at the picture of the overall rise and fall of the royalty rate.

**Hidemaru Yamaguchi [Q]**: Thank you very much. My second question is about GYM329, which is now being clinically tested, including in combination. I understand that Roche mentioned at their presentation that they are focusing on the muscle-enhancing aspect of this drug and using it to treat diabetes and obesity in areas where muscle mass is lost. What opportunities do you see in this compound?

**Tetsuya Yamaguchi [A]**: Yamaguchi here. We are currently in the process of investigating the possibility of GYM329 in the area of rare diseases such as neuromuscular deterioration.

Naturally, we have been discussing with Roche about the possibilities and future development of this area, and the possibility of increasing muscle mass and addressing the calorie consumption associated with obesity, which you have mentioned, cannot be denied. I think this is a very interesting area, with a great deal of potential. We are currently discussing whether or not this should be pursued in light of the total product profile, including the efficacy of the drug.

Of course, there is a very large market potential for enhancing muscle mass and muscle strength in addition to obesity, so we will discuss how to proceed with the development of this product and will provide an appropriate explanation when the trials are started.

### Hidemaru Yamaguchi [M]: Thank you. That is all.

**Hashiguchi [Q]**: Hashiguchi here. Thank you. The first is about the pace of impact on sales based on the results of the ALINA trial of Alecensa.

As for whether this treatment is really necessary compared to the advanced or recurrent stage, I think OS data tend to be much more important in the perioperative period. I understand that even at the time of osimertinib for EGFR, despite the overwhelming difference in DFS from the beginning, doctors were cautious when the OS benefit was not yet available, and in fact, the guidelines stated as such. Acceptance of the drug increased after the OS benefit data became available.

I understand that it will take some time for data showing the OS benefits to emerge, since only six OS events have been reported in this presentation. I wonder if you could tell us when we can expect to see data showing the benefits of OS in the future.

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**Tetsuya Yamaguchi [A]**: Yamaguchi here. As you pointed out, I think you are aware that it is quite a while before we can see OS results with this adjuvant.

We believe that the market has changed considerably, as you mentioned with osimertinib. From the very overwhelming DFS extension this time around, I think one can expect considerable penetration.

However, on the other hand, considering the fact that adjuvant therapy is different from advanced or recurrent disease, or considering the changes in adjuvant therapy in the perioperative period of lung cancer, it is true that we have not yet painted a picture in which sales of adjuvant therapy will account for a large majority of the total sales of Alecensa. In fact, we do not have such a picture in mind.

**Hashiguchi [Q]**: Thank you. My second point is about orforglipron's royalty rate, and communication with the market.

When I ask Roche, they explain that it is the analyst's interpretation that the figure that it is in the teens or high teens. It means there is no such communication. Therefore, I fully understand your position, but I would like to ask for your comments on whether or not Roche has said.

If Roche did, I understand the confidentiality obligation, but I think there should be a change in the method of communication, as in the case of the recent disclosure of the tiragolumab data because it had already been released.

**Okuda [A]**: Okuda here. Thank you, Mr. Hashiguchi. Please understand that we cannot comment on whether it was said or not. As I have explained earlier, there is a contract between Eli Lilly and CHUGAI, and due to confidentiality obligations, I will not disclose the economic terms of orforglipron. I apologize. I hope you can appreciate our position.

Hashiguchi [M]: Thank you very much. That is all.

Matsubara [Q]: My name is Matsubara, Nomura Securities. Thank you very much. I also have two questions.

First of all, I would like to start with Vabysmo. In your explanation, you mentioned that it would be difficult to achieve the forecast for this fiscal year. Could you please explain the current sales situation, including whether new patients are continuing to increase and what the switching is?

Hidaka [A]: Thank you for your question. Hidaka here.

Vabysmo was initially a highly anticipated drug for patients who were not responding well to previous treatment, or for patients who wanted to extend the interval between treatments but were unable to do so. In some cases, the drug is used for such patients, and it has been difficult to obtain a sense of its effectiveness, but in such cases, data from Japanese patients have recently been published at medical meetings.

In this context, including overseas Phase III trials, we have obtained equivalent, close to equivalent, or even better results, and we would like to promote the uptake of the drug, especially for naïve patients, while monitoring the data. That is all from me.

**Matsubara [Q]**: Thank you very much. Next, I would like to ask about tobemstomig. but I believe that Opdualag is a competitor that is approved for this. Can you tell us about the potential of this drug in your Company at this time, such as its superiority over the competitor, or whether you believe it has efficacy in non-small cell lung cancer and breast cancer, where LAG-3 expression is high?

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**Tetsuya Yamaguchi [A]**: Thank you for your question. This is a bispecific antibody, which is expected to have a stronger anti-LAG-3 effect on T cells that infiltrate tumors expressing PD-1.

Although it may not be a well-established concept yet, there are data showing that when LAG-3 is blocked, the inhibitory function of regulatory T cells is enhanced. In the sense that the degree of PD-1 and LAG-3 suppression is a key factor, our current view is that the profile of tobemstomig may be superior to the competitor.

Please understand that the target cancer types are still undecided at this stage.

Matsubara [M]: Understood. Thank you very much.

Miyata [M]: Thank you very much. Next, Ms. Sogi, AllianceBernstein. Thank you.

**Sogi [Q]**: Thank you very much. Please tell us about the Avastin and Tecentriq for small cell lung cancer trial that was announced today.

This is a clinical trial in Japan and China, and the PFS has been achieved, but the OS has not yet been achieved. Can you tell us the reason behind Japan and China have been involved in the trial? Is the plan to go ahead with filing for approval in Japan and then China regardless of global trial plans?

Also, I think that PFS is the only primary endpoint and OS is secondary, but can you tell me if this means that if OS is not achieved, the study itself is still positive?

**Tetsuya Yamaguchi [A]**: Thank you for your question. Yamaguchi here. Before answering, I'd like to address the question of why this trial was conducted in Japan and China. It was actually originally planned for Japan only, and we had a lot of demand from China to expand. Incidentally, 37 facilities participated in the program in Japan, while 17 facilities participated in the program in China.

The trial results are positive. However, we do not have the OS results yet, and we are following up on that.

On the other hand, we are still in the process of obtaining the data for our application strategy, so we will be looking at the data carefully to see if this will allow us to make an application. We are still in the process of considering the best way to proceed in the context of the situation in China and Japan, so we are unable to give an answer at this stage. Thank you.

**Sogi [Q]**: Thank you very much. I understand that China wanted to do this, but Roche did not do it globally in the first place, so can you tell us the background behind this project?

**Hidaka [A]**: Hidaka here. Originally, Avastin itself was not approved for small-cell lung cancer, but very good data were available. And as for Roche, there were some things related to tiragolumab that made it difficult for them to go through with this study. There was a strong desire from clinicians to try it in Japan, and that is how we decided to start.

As mentioned earlier, China wanted to enter the trial, so both countries decided to work together to promote the project, and here we are today. That is all.

Sogi [M]: Understood. Thank you very much.

**Miyata** [M]: Thank you very much. We apologize, but we have reached the scheduled end of the session. The next question will be our last. Now, UBS Securities, Mr. Sakai. Thank you.

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**Sakai [Q]**: Just one question. I know there have been a few questions about orforglipron today. I don't intend to ask about the royalty rate, but I would like to review or rather refresh my memory about the position of this drug in the GLP-1 agonist market.

Recently, opinions of GLP-1 agonists have been going up and down a bit, and the impact on the stock prices of other sub-sectors, such as medical equipment and food products, has become so large that it is affecting the stock prices of other sectors. Is this just about obesity or are we also looking at things like further development of GLP-1? Or is this a correction to a very sudden increase in interest?

I think there are many ways to look at this, but I think it would be better to ask Mr. Yamaguchi about this, but from your perspective, what is the current situation of the GLP-1 market and how do you think orforglipron should be positioned within this market in the future? What would be the best choice for CHUGAI? If you have any thoughts, please let me know. Thank you.

**Tetsuya Yamaguchi [A]**: Thank you, Mr. Sakai. This is only my perception, but I believe that the effect of GLP-1 agonists on obesity is strongly recognized, and that obesity has become a major health issue on a global scale.

GLP-1 agonists have been very strong in reducing blood sugar and obesity, but Novo's formulations have penetrated the market to a greater extent, and I believe that the market has recognized the necessity of this product.

In addition, Eli Lilly has released a GLP-1 injectable that has shown very good data as well, and there are now products that have both GIP and GLP-1 agonist activity, or even triple. I think we are in a situation where the recognition of needs and the recognition of effectiveness are advancing in tandem.

On the one hand, of course, we are fully aware of the development of such injectable formulations in our relationship with Eli Lilly, but on the other hand, orforglipron's oral profile is overwhelmingly ahead at the moment. In that sense, there is a great deal of expectation and attention being paid to this drug right now. That is how I perceive it.

**Sakai [Q]**: At this stage, would you say there is no need to be concerned about the side effects or adverse events that some people are talking about?

**Tetsuya Yamaguchi [A]**: If the side effects you mentioned are the on-target effects of GLP-1 agonists such as nausea and vomiting, the pharmacokinetic profile of orforglipron seems to be very stable, and I think it is relatively manageable or not at a level that would cause problems. I do not see this as a problem. Of course, we would like to confirm the results of the Phase III trials.

Sakai [M]: I understand. Thank you very much.

**Miyata [M]**: This concludes the presentation of the financial results for Q3 of the fiscal year ending December 31, 2023. For questions that could not be answered due to time constraints, please contact IR separately.

Thank you very much for taking time out of your busy schedule to join us today. Thank you.

[END]

### **Document Notes**

1. Portions of the document where the audio is obscured by technical difficulty are marked with [TD].

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- 2. Speaker speech is classified based on whether it [Q] asks a question to the Company, [A] provides an answer from the Company, or [M] neither asks nor answers a question.
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