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CHUGAI

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Chugai Announces 2022 Full Year Results and Forecasts for 2023

- Record-high Core revenues and Core operating profit for the sixth consecutive year at ¥1,168.0 billion (+16.8%) and ¥451.7 billion (+4.1%), respectively
- R&D activities progressed smoothly in both the early and late stages. For in-house projects, several antibody projects that applied Chugai's proprietary antibody engineering technologies initiated clinical studies
- Planned 2022 year-end dividends are ¥40 per share (annual dividends for the fiscal year: ¥78 per share)
- Core revenues and Core operating profit are expected to decrease in 2023 to ¥1,070.0 billion (△8.4%) and ¥415.0 billion (△8.1%), respectively. Revenues are expected to increase, excluding the temporary impact of COVID-19-related therapies

TOKYO, February 2, 2023 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced its consolidated financial results for the fiscal year ended December 31, 2022, and forecasts for the fiscal year ending December 31, 2023.

“In 2022, the second year of Chugai’s growth strategy TOP I 2030, Chugai’s revenue exceed ¥1 trillion for the first time, and we achieved record-high revenues and profits for the sixth consecutive year. Domestic sales were driven by steady market penetration of our new products, including Vabysmo®, which is our first full-scale entry into the ophthalmology field. In addition, the supply of Ronapreve® (an antibody cocktail for COVID-19) to the government also contributed. The mainstay product Hemlibra® continued to drive growth in overseas sales. In R&D, the new drug discovery research center ‘Chugai Life Science Park Yokohama’ was completed in October, which will serve as the foundation to maximize our drug discovery capabilities. In addition, clinical studies have begun for several in-house projects applying Chugai's proprietary antibody engineering technologies, which will further enhance our pipeline for medium to long-term growth. In 2023 we will enter a new phase in our financial performance, as we move away from the initial contribution of COVID-19-related drugs. However, excluding the temporary impact of those products, we expect revenue growth this fiscal year as our core business in Japan and overseas is solid, with a robust portfolio of products and projects that will support our future growth. ‘Chugai Life Science Park Yokohama’ will go into full-scale operation this April. From this new drug discovery research center, we will continue to pursue innovation in order to deliver innovative new drugs to patients as quickly as possible,” said Dr. Osamu Okuda, Chugai’s President and CEO.

<Full year Core results for 2022>

Chugai reported financial results for 2022 with revenues of ¥1,168.0 billion (+¥168.2 billion, +16.8), royalties and other operating income declined by approximately 30%, while sales increased by

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approximately 30%. Sales exceeded ¥1 trillion for the first time since Chugai's foundation, with record-high revenue and core operating profit for the sixth consecutive year.

Domestic sales were ¥654.7 billion (+¥135.8 billion, +26.2%). Sales in the oncology field decreased by approximately 2% as the impact of the NHI drug price revision and biosimilars in mature products, including Avastin® and Herceptin®, exceeded the sales growth from a new product Polivy®, and a mainstay product Kadcyla® as well as Foundation Medicine business. Sales in the specialty field increased by more than 50% due to the significant increase in sales from the supply of Ronapreve® to the government, as well as an approximately 20% increase in sales of the mainstay product Hemlibra, and the contributions from the steady market penetration of new products, including Evrysdi®, Enspryng® and Vabysmo. Overseas sales were ¥384.6 billion (+¥100.7 billion, +35.5%). Hemlibra increased significantly by approximately 70% owing to the full-scale export to Roche at regular shipping price, and Actemra® also showed solid growth. Royalties and other operating income decreased by approximately 30%, mainly due to a significant decrease in royalty income related to the initial shipments of Hemlibra.

The cost to sales ratio rose by 3.9% points year-on-year to 45.7%, mainly due to changes in the product mix. Operating expenses grew by approximately 5% as marketing and distribution expenses slightly increased and research and development expenses increased, while general and administration expenses decreased. Marketing and distribution expenses slightly increased mainly due to the impact of foreign exchange. Research and development expenses increased mainly due to the progress of development projects under development and the effects of foreign exchange. General and administration expenses decreased mainly due to decreases in various expenses and recognizing gains on sales of property, plant and equipment. As a result, Core operating profit totaled ¥451.7 billion (+¥17.6 billion, +4.1%).

Reflecting the favorable results and based on our dividend policy, Chugai plans to pay year-end dividends of ¥40 per share. As a result, the annual dividend will be ¥78 per share, and the Core dividend payout ratio is 42.0% on a five-year average basis (40.4% on a single fiscal year basis).

<R&D activities>

Regarding research and development, the Company made good progress in both early and late-stage development toward achieving TOP I 2030. For in-house projects, applying Chugai’s proprietary antibody engineering technologies, DONQ52, RAY121, and ALPS12 entered the clinical development stage for celiac disease, autoimmune disease, and solid tumors, respectively. For crovalimab, the world's first application for approval for the treatment of paroxysmal nocturnal hemoglobinuria (PNH), was filed in China and granted priority review designation. Also, Roche initiated overseas development for sickle cell disease. Simultaneous development for in-house products is also in progress, with new clinical studies initiated for Enspryng in myelin oligodendrocyte glycoprotein antibody-associated disease (MOGAD) and autoimmune encephalitis (AIE), and GYM329 in spinal muscular atrophy (SMA), in combination with Evrysdi. Furthermore, Maruho, the licensee of nemolizumab (product name: Mitchga®) in Japan, obtained approval and launched the new product in August to treat itching associated with atopic dermatitis. For NXT007, which is being developed as the next-generation project following Hemlibra, Chugai and Roche entered a license agreement. Among products in-licensed from Roche, Tecentriq® and Polivy received approval for additional indications for adjuvant treatment of non-small cell lung cancer and previously untreated diffuse large B-cell lymphoma, respectively. Several new projects mainly in the oncology area,

were added to the Company's pipeline. In addition, the company has entered into a license agreement with Noile-Immune Biotech for its PRIME CAR-T Technology, progressing steadily to achieve its multi-modality strategy.

<Full year forecast for 2023>

In 2023, Core revenues, Core operating profit, and Core net income are expected to be ¥1,070.0 billion (-¥97.8 billion, -8.4%), ¥415.0 billion (-¥36.7 billion, -8.1%), and ¥306.0 billion (-¥11.7 billion, -3.7%), all of which will be lower than those in the previous year respectively. Sales are expected to decrease both in Japan and overseas, totaling ¥920.0 billion (-¥119.2 billion, -11.5%). Domestic sales are expected to decrease due to the reduction in the supply of Ronapreve to the government and the effect of generics, while new products and mainstay products will grow in both oncology and specialty fields. The supply of Ronapreve to the government is expected to be ¥81.2 billion, and the domestic sales excluding Ronapreve are expected to increase steadily to ¥460.5 billion (+¥9.5 billion, +2.1%). Overseas sales are expected to decrease slightly to ¥378.3 billion (-¥6.3 billion, -1.6%) due to sales declines of Hemlibra and Actemra, while Alecensa will grow. Sales of Hemlibra are expected to decrease due to the effect of the optimization of inventory levels at Roche and the effects of lower export price. Actemra is expected to decrease mainly due to a decline in COVID-19 demand. Other revenue* is expected to increase to ¥150.0 billion (+¥21.4 billion, +16.6%), driven by an increase in royalty and profit-sharing income from Hemlibra and one-time income.

*The category "Royalties and other operating income" until the fiscal year ended December 31, 2022, has been renamed. In addition, income from disposal of product rights is excluded from this category.

For the fiscal year 2023, Chugai expects annual dividends per share of ¥80 with a Core dividend payout ratio of 41.8% on a five-year average basis (43.0% on a single fiscal year basis).

[2022 full year results]

Billion JPY	2022	2021	% Change
Core results			
Revenues	1,168.0	999.8	+16.8%
Sales	1,039.2	802.8	+29.4%
Royalties and other operating income	128.8	196.9	△34.6%
Operating profit	451.7	434.1	+4.1%
Net income	317.7	311.5	+2.0%
IFRS results*			
Revenues	1,259.9	999.8	+26.0%
Operating profit	533.3	421.9	+26.4%
Net income	374.4	303.0	+23.6%

*IFRS results include non-Core items, such as the income and other related items, which totaled ¥90.7 billion associated with the settlement agreement between Chugai and Alexion Pharmaceuticals, Inc., which are excluded from the Core results Chugai adopts to manage recurring business activities.

[2023 full year forecast]

Billion JPY	2023 Forecast	2022 Actual*	% Change
Core-basis			
Revenues	1,070.0	1,167.8	△8.4%
Operating profit	415.0	451.7	△8.1%
Net income	306.0	317.7	△3.7%

*The amounts shown are after the reclassification of actual results following a partial change in the method of presentation starting in 2023.

[Progress in R&D activities for Oct 25th, 2022-Feb 2nd, 2023]

As of February 2, 2023

Launched	Edirol tablet	Osteoporosis (Additional dosage form)	December 2022
Approved	Gazyva	CD20-positive CLL (including small lymphocytic lymphoma)	December 2022
	Actemra/RG1569	COVID-19 in hospitalized adult patients (US)	December 2022
	Hemlibra/RG6013	Moderate hemophilia A (EU)	January 2023
Filed	FoundationOne Liquid CDx cancer genomic profile	Capmatinib hydrochloride hydrate: NSCLC (*MET* exon14 skipping alterations)	December 2022
New to pipeline	Alecensa/RG7853	Stage III NSCLC (maintenance treatment after chemoradiotherapy)	P3(November 2022)
	tiragolumab	Non-squamous NSCLC (1L)	P3(November 2022)
	RAY121	Autoimmune disease	P1(October 2022)
	ALPS12/RG6524	Solid tumors	P1(January 2023)
	cevostamab	r/r MM	P1(November 2022)
Medical conference	crovalimab/RG6107	COMMODORE 3 study (PNH), efficacy and safety data: ASH	December 2022
	Hemlibra/RG6013	HAVEN 7 study (infant with hemophilia A), interim analysis: ASH	December 2022
	Polivy	POLARIX study (DLBCL), PFS and OS data at 3 years: ASH	December 2022
	AMY109	Non-clinical efficacy data including MOA: The 44th Annual Meeting of the Japanese Society of Endometriosis	January 2023
Others	OWL833/orforglipron	Announcment of P2 study results for obesity* and type 2 diabetes	December 2022
Development discontinued	Tecentriq	NSCLC (2L) (CONTACT-01 study in combination with cabozantinib)	
	Tecentriq	UC (1L) (IMvigor130 study)	
	gantenerumab	Alzheimer's disease (GRADUATE1/2 study)	

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

About Core results

Chugai discloses its results on a Core basis from 2013 in conjunction with its decision to apply IFRS. Core results are the results after adjusting non-Core items 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 underlying business performance both internally and externally, and as the basis for payment-by-results such as a return to shareholders.

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