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Chugai Announces 2023 1st Quarter Results

- Core revenue and core operating profit for the first quarter at ¥312.2 billion (+16.3%) and ¥105.4 billion (+6.6%), respectively
- Both in-house projects crovalimab and nemolizumab, achieved the primary endpoint of the phase III clinical study. Steady progress in early in-house projects

TOKYO, April 27, 2023 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced its financial results for the first quarter of fiscal year 2023.

"In the first quarter we saw an increase in both revenue and profits on a Core-basis due to steady growth of new and mainstay products. Sales increased both in Japan and overseas. Domestic sales were driven by new products Polivy® and Vabysmo®, mainstay products Hemlibra® and Tecentriq®, and the supply of Ronapreve® to the government under the fiscal 2022 contract. Overseas sales increased from the growth of mainstay products. In R&D, Chugai's crovalimab achieved the primary endpoint in its phase III clinical study and is scheduled to be filed for approval in Japan, the U.S., and Europe during the first half of this year. In addition, the foundation of future growth is steadily progressing, as evidenced by Chugai's early-stage project SAIL66 entering the development pipeline, and the start of the full-scale operation of 'Chugai Life Science Park Yokohama' in April, which will serve as a center for innovation. Although contributions of COVID-19-related drugs will cease in the second quarter and beyond, sales of our global products and new/mainstay domestic products are strong, and projects that will contribute to mid-to long-term growth are progressing steadily. We will continue to strive to become a top innovator in the healthcare industry and deliver innovative new drugs to patients," said Dr. Osamu Okuda, Chugai's President and CEO.

< First quarter results for 2023>

Chugai reported increased revenue and operating profit for the first quarter (Core-basis).

Revenue increased by 16.3% over the same period last year. Sales increased by approximately 20%, while other revenue decreased by approximately 20%. Domestic sales increased by approximately 20%. In the oncology field, the new product Polivy showed significant growth, and the mainstay product Tecentriq also contributed to the year-on-year increase despite the impact of biosimilars and NHI drug price revisions on mature products such as Avastin® and Herceptin®. In the specialty field, sales increased by approximately 30%, driven by the penetration of new products Vabysmo and Evrysdi®, the supply of Ronapreve to the government, and the contribution of mainstay products Hemlibra and Enspryng®. Overseas sales increased by approximately 20%. Sales of Alecensa® increased significantly, more than tripling, and sales of Actemra® remained strong. Other revenue decreased by approximately 20%, mainly due to the termination of royalty income from initial shipments of Hemlibra, despite the increase in royalties and profit-sharing income related to the intellectual property rights of Hemlibra. Revenue on IFRS basis, including Non-Core

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items, decreased due to the one-time impact of the lump-sum income from the settlement agreement with Alexion Pharmaceuticals, Inc in the previous year.

Cost to sales ratio rose by 4.8% points year-on-year to 51.8%, mainly due to a change in the product mix and the impact of foreign exchange. Research and development expenses increased mainly due to investments into drug discovery and early development, including the operation of Chugai Life Science Park Yokohama, and increases associated with the progress of development projects. Selling, general and administration expenses decreased mainly due to declines in various expenses. Other operating income (expense) was an income of ¥1.3 billion, mainly due to the recognition of gain on the sale of property, plant and equipment. As a result, Core operating profit totaled ¥105.4 billion (+6.6%).

<R&D activities>

The company also made good progress in research and development. Among our in-house projects that will contribute to mid to long-term profit growth, anti-C5 recycling anti-complement C5 recycling antibody crovalimab met the co-primary endpoints in the global Phase III clinical study in patients with paroxysmal nocturnal hemoglobinuria (PNH). Filing of applications for PNH is planned in Japan, the U.S., and Europe during the first half of this year. In addition, another phase I clinical study for crovalimab in lupus nephritis has newly started overseas. Furthermore, for GYM329, which is currently under development for several indications, a phase II study has started in facioscapulohumeral muscular dystrophy (FSHD), showing that simultaneous development of Chugai-originated projects is steadily progressing. Additionally, SAIL66, a novel antibody project which adopts Chugai's proprietary antibody engineering technologies, entered the clinical development phase for solid tumors. For anti-IL-31 receptor A antibody nemolizumab, Galderma, the overseas licensee of the drug, announced that it achieved the primary endpoints in two phase III clinical studies for moderate to severe atopic dermatitis. Regarding projects in-licensed from Roche, late-stage clinical studies have started for the ophthalmic product Vabysmo and anti-CD20 antibody Gazyva® for angioid streaks and pediatric nephrotic syndrome, respectively.

In April, Chugai Life Science Park Yokohama, a new research center combining the previous Fuji Gotemba Research Center and Kamakura Research Center, went into full operation, which will further advance drug discovery research to create innovation.

[2023 first quarter results]

Billion JPY	2023 Jan - Mar	2022 Jan - Mar	% Change
Core results			
Revenue	312.2	268.4	+16.3%
Sales	291.5	242.7	+20.1%
Other revenue*	20.7	25.7	-19.5%
Operating profit	105.4	98.9	+6.6%
Net income	78.4	70.6	+11.0%
IFRS results**			
Revenue	312.2	360.3	-13.3%
Operating profit	98.3	187.0	-47.4%
Net income	73.5	131.8	-44.2%

*Changed the title from “Royalties and other operating income” to “Other revenue”.

**IFRS results in 2022 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.

[Sales breakdown]

Billion JPY	2023 Jan - Mar	2022 Jan - Mar	% change
Sales	291.5	242.7	+20.1%
Domestic sales	192.7	161.7	+19.2%
Oncology	60.0	58.4	+2.7%
Specialty	132.7	103.2	+28.6%
Overseas sales	98.8	81.0	+22.0%

[Progress in R&D activities for Feb 3rd, 2023-Apr 27th, 2023]

As of April 27, 2023

Approved	Actemra/RG1569	COVID-19 in hospitalized adult patients (Taiwan, Import drug license)	April 2023
Filed	Actemra/RG1569	Cytokine release syndrome induced by cancer treatment	February 2023
	Vabysmo	Macular Edema Associated with Retinal Vein Occlusion (RVO)	April 2023
New to pipeline	Gazyva	Pediatric nephrotic syndrome	P3(March 2023)
	Vabysmo	Angioid streaks	P3(March 2023)
	giredestrant	Breast cancer [1L-3L] (in combination with everolimus)	P3(April 2023)
	GYM329/RG6237	Facioscapulohumeral muscular dystrophy (FSHD)	P2(March 2023)
	SAIL66	CLDN6 positive solid tumors	P1(April 2023)
	crovalimab/RG6107	Lupus nephritis (LN)	P1(February 2023)
Readout in pivotal study	crovalimab/RG6107	Paroxysmal nocturnal hemoglobinuria (PNH) / COMMODORE1, COMMODORE2	February 2023
	nemolizumab	Atopic dermatitis / ARCADIA1, ARCADIA2	March 2023

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

As of April 27, 2023

Medical conference	Vabysmo	BALATON / COMINO (RVO): Angiogenesis, Exudation, and Degeneration 2023	February 2023
	nemolizumab	OLYMPIA 2 (PN): American Academy of Dermatology (AAD) 2023	March 2023
	Tecentriq	IMbrave050 (HCC adjuvant): American Association for Cancer Research (AACR) 2023	April 2023
Literature publication	AMY109	Non-clinical efficacy data: Science Translational Medicine	February 2023
Others	Enspryng/RG6168	Forerunner Designation / AIE, MOGAD	March 2023
	Vabysmo	Orphan drug designation / Angioid streaks with neovascularization	March 2023
	gMSC®1	Termination of license agreement with TWOCELLS	April 2023
Development discontinued	ipatasertib	Prostate cancer (1L) (IPATential150 study in combination with abiraterone)	
	Tecentriq	Renal cell carcinoma (2L) (CONTACT-03 study in combination with cabozantinib)	

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

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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