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CHUGAI

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Chugai Announces 2023 Half Year Results

- Core revenue and core operating profit in the first half at ¥579.7 billion (+15.0%) and ¥232.0 billion (+15.2%), respectively
- The application for approval of crovalimab, created by Chugai, for the treatment of paroxysmal nocturnal hemoglobinuria filed in Japan, the U.S., and Europe. Similarly, Maruho, the licensee of nemolizumab filed an application for approval of nemolizumab for the treatment of prurigo nodularis and pruritus associated with atopic dermatitis (pediatric) in Japan
- Announcement of the establishment of corporate venture capital, aiming at accelerating the drug discovery engine by combining its strengths and external technologies

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

“In the second quarter of this year, we saw a continuation of the increase in both revenue and profits on a Core-basis from the first quarter. Domestic and overseas sales as well as other revenue increased. Domestic sales were driven by new products Polivy®, Vabysmo®, and Evrysdi®, mainstay products Hemlibra®, Enspryng® and Tecentriq®, and the supply of Ronapreve® to the government in the first quarter. Overseas sales increased from the growth of mainstay products Alecensa® and Hemlibra. In R&D, Chugai’s crovalimab was filed for approval in Japan, the U.S., and Europe. In addition, our in-house project ROSE12 entered the discovery pipeline, and we announced the decision to establish a corporate venture capital to further accelerate our discovery engine. Although contributions of COVID-19-related drugs have run their course, our core business remains solid, and we will continue to strive to create innovation,” said Dr. Osamu Okuda, Chugai’s President and CEO.

< Half Year Financial Results (Core results, January to June 2023)>

Chugai reported increased revenue and operating profit for the first half year (Core-basis) consistent with first-quarter results, compared to the same period of the previous fiscal year.

Revenue increased in 15% overall, with growth in both domestic and overseas sales and other revenue. Domestic sales increased by approximately 15%. In the oncology field, the growth was approximately 3% year-on-year due to the contribution of steady market penetration of new product Polivy, and the mainstay product Tecentriq 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 24%, driven by the penetration of new products Vabysmo and Evrysdi, as well as the contribution of mainstay products Hemlibra and Enspryng, and the supply of Ronapreve to the government in the first quarter. Overseas sales increased by 17%. Sales

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of Alecensa doubled year-on-year, and sales of Hemlibra were also solid. Other revenue increased by approximately 11%, mainly due to the increase in milestone revenues. Revenue on IFRS basis, including Non-Core 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 3.5% points year-on-year to 46.3%, mainly due to the impact of foreign exchange. Research and development expenses increased mainly due to investments into drug discovery and early development, including the start of operation of Chugai Life Science Park Yokohama, and increases associated with the progress of development projects. Selling, general and administration expenses were comparable to the same period of last year. Other operating income (expense) was an income of ¥16.2 billion, mainly due to the recognition of income from disposal of product rights and gain on sale of property, plant and equipment. As a result, Core operating profit totaled ¥232.0 billion (+15.2%).

<R&D activities>

The company also made good progress in research and development. Among our in-house projects, anti-complement C5 recycling antibody crovalimab was filed in Japan, the U.S., and Europe in addition to filing in China, for paroxysmal nocturnal hemoglobinuria (PNH). Anti-IL-31 receptor A antibody nemolizumab was also filed for approval in Japan for additional indication of prurigo nodularis, and pruritus associated with atopic dermatitis (pediatric), by Maruho, the licensee of the drug in Japan. Furthermore, ROSE12 entered the clinical development phase for solid tumors, as the second Switch Antibody ™ project applying Chugai's proprietary antibody engineering technology. Overall, in-house projects which will contribute to the company's mid to long term growth, is progressing steadily. As for projects in-licensed from Roche, anti-IL -6 antibody RG6179 newly entered the company's pipeline, as an ophthalmology project for noninfectious uveitic macular edema.

In June, Chugai announced its decision to establish a corporate venture capital (CVC) "Chugai Venture Fund, LLC," which will make investments in drug discovery targets, drug discovery technologies and digital technologies that will lead to the creation of innovative new drugs. Primarily targeting drug discovery start-ups, it will invest an overall US $200 million, as well as providing technical advisory support and promoting partnership with Chugai. Through co-creation with investment partners, this CVC aims to combine Chugai's strengths with external technologies, and to further accelerate our drug discovery engine.

[2023 half year results]

Billion JPY	2023 Jan - Jun	2022 Jan - Jun	% Change
Core results			
Revenue	579.7	504.0	+15.0%
Sales	523.0	452.8	+15.5%
Other revenue	56.6	51.2	+10.5%
Operating profit	232.0	201.4	+15.2%
Net income	171.4	144.7	+18.5%
IFRS results*			
Revenue	579.7	595.9	-2.7%
Operating profit	210.9	286.9	-26.5%
Net income	156.7	204.2	-23.3%

*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 - Jun	2022 Jan - Jun	% change
Sales	523.0	452.8	+15.5%
Domestic sales	313.6	273.8	+14.5%
Oncology	126.5	123.0	+2.8%
Specialty	187.1	150.9	+24.0%
Overseas sales	209.4	179.0	+17.0%

[Progress in R&D activities for Apr 28th, 2023-Jul 27th, 2023]

As of July 27, 2023

Launched	Hemlibra	Hemophilia A without inhibitors (Taiwan)	July 2023
Approved	FoundationOne Liquid CDx	Capmatinib hydrochloride hydrate: *MET* exon 14 skipping mutation-positive advanced and/or recurrent unresectable NSCLC	May 2023
Filed	crovalimab/RG6107	PNH (Japan, EU, U.S.)	June 2023
	Mitchga®	Prurigo nodularis, pruritus associated with atopic dermatitis (pediatric) (Japan)	Q2 2023*
Pipeline entry	ROSE12	Solid tumors	P1 study (June 2023)
	RG6179 (anti-IL-6 antibody)	UME	P3 study (June 2023)
Medical conference	crovalimab/RG6107	COMMODORE 1/2 studies (PNH): EHA	June 2023
	orforglipron /LY3502970**	Phase 2 study in adults with obesity or overweight: ADA Phase 2 study in adults with type 2 diabetes: ADA	June 2023
	NXT007/RG6512	NXTAGE study (healthy adults, hemophilia A): ISTH	June 2023
Development discontinued	Tecentriq	Early breast cancer (adjuvant) / P3 study (IMpassion030 study)	
Other	Chugai Venture Fund, LLC	Investment activities for drug discovery targets, drug discovery technologies, and digital technologies that lead to the creation of innovative new drugs (location: Boston area)	To be established by the end of 2023

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

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

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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