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CHUGAI

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Chugai Announces 2022 1st Quarter Results

- Record-high core revenues and core operating profit for the first quarter at ¥268.6 billion (+59.1%) and ¥98.9 billion (+51.2%), respectively
- Vabysmo, the first bispecific antibody in ophthalmology in-licensed from Roche, and Mitchga, a Chugai antibody out-licensed to Maruho, newly obtained regulatory approval

TOKYO, April 25, 2022 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced its financial results for the first quarter of fiscal year 2022.

"The first quarter marked a strong start to 2022. Significant increases in both domestic and overseas sales resulted in record revenues and profits for the quarter. Domestic sales were driven by the supply of Ronapreve® to the government and good penetration of our new products Enspryng®, Polivy®, and Evrysdi®, while Hemlibra® posted a remarkable increase in overseas sales. These products are on track to become our next growth drivers. In R&D, Vabysmo®, a bispecific antibody in-licensed from Roche, obtained regulatory approval for two diseases that may potentially lead to vision loss. This unlocks Chugai's first full-scale entry into ophthalmology. For Mitchga®, the anti-IL-31 receptor A inhibitor created by Chugai, regulatory approval for itching associated with atopic dermatitis was obtained by Maruho, our partner for the Japanese market. Both of these products have novel modes of action, and I am very pleased that we can provide new treatment options based on innovation. We will continue to challenge ourselves to create innovative new drugs," said Dr. Osamu Okuda, Chugai's President and CEO.

[First quarter results for 2022]

Chugai reported a significant growth in revenues and operating profit, achieving record highs for the first quarter (Core-basis).

Revenues increased by approximately 60% over the same period last year. Sales increased sharply by almost 90%, while royalties and other operating income decreased by approximately 30%. Domestic sales increased by approximately 70%. In the oncology field, sales remained almost flat over the same period last year. The contribution of the new product Polivy offset declines in mature products, including Avastin® and Herceptin®, due to NHI drug price revisions last year and biosimilars. In the primary field, sales almost tripled year-on-year due to the supply of Ronapreve to the government and the contribution of new products, Enspryng and Evrysdi. Overseas sales more than doubled given a five-hold growth of Hemlibra owing to the full-scale export to Roche at regular shipping price, and a 50% increase in Actemra, which obtained emergency use authorization and regulatory approval for severe COVID-19 in the U.S. and Europe, respectively, since last June. On the other hand, royalties and other operating income decreased by approximately 30%, mainly due to a significant decrease in royalty income related to the initial shipments

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of Hemlibra. Revenues on IFRS basis including Non-Core items totaled ¥360.6 billion (+113.6%), including the lump-sum income of ¥91.9 billion from the settlement agreement with Alexion Pharmaceuticals, Inc.

Cost to sales ratio rose by 4.8% points year-on-year to 47.0%, mainly due to a change in the product mix. Marketing and distribution, research and development, and general and administration expenses have all increased, resulting in an overall increase in operating expenses by almost 15%. Marketing and distribution expenses increased due to an increase in activities at overseas group companies and the effects of foreign exchange. Research and development expenses increased due to the progress of projects. General and administration expenses increased due to the enterprise tax and various expenses. As a result, Core operating profit totaled ¥98.9 billion (+51.2%).

The Company also made good progress in research and development. Chugai obtained regulatory approval in March 2021 for Vabysmo for neovascular age-related macular degeneration (nAMD) and diabetic macular edema (DME). Vabysmo, in-licensed from Roche, is the first bispecific antibody in ophthalmology. Clinical development of RG6321, the port delivery system with ranibizumab in-licensed from Roche, was newly initiated also in the field of ophthalmology. In-house projects that will drive the company's mid-to-long-term growth also progressed well, including Mitchga and several projects applying Chugai's proprietary antibody engineering technologies. Maruho, the licensee of anti-IL-31 receptor A antibody Mitchga in Japan, obtained regulatory approval for the product in March for the treatment of pruritus associated with atopic dermatitis (only when existing treatment is insufficiently effective). As for the anti-C5 recycling antibody crovalimab, a phase III clinical trial conducted in China in paroxysmal nocturnal hemoglobinuria (PNH) met its primary endpoint. Application for regulatory approval will be filed in China ahead of other countries by the end of this year. Also, Roche started clinical development in sickle cell disease outside Japan.

Regarding development of treatments for COVID-19, WHO granted prequalification of Actemra for patients with severe or critical COVID-19 in February. Furthermore, in April, the U.S. Food and Drug Administration (FDA) accepted Genentech's supplemental Biologics License Application (sBLA) for Actemra for the treatment of COVID-19 in hospitalized adults, granting priority review. In the U.S., Actemra has been used under the Emergency Use Authorization (EUA) since June 2021.

[2022 first quarter results]

Billion JPY	2022 Jan - Mar	2021 Jan - Mar	% change
Core results			
Revenues	268.6	168.8	+59.1%
Sales	242.7	130.3	+86.3%
Royalties and other operating income	25.9	38.6	-32.9%
Operating profit	98.9	65.4	+51.2%
Net income	70.6	48.4	+45.9%
IFRS results			
Revenues	360.6	168.8	+113.6%
Operating profit	187.0	64.0	+192.2%
Net income	131.8	47.4	+178.1%

[Sales breakdown]

Billion JPY	2022 Jan - Mar	2021 Jan - Mar	% change
Sales	242.7	130.3	+86.3%
Domestic sales	161.7	94.9	+70.4%
Oncology	58.4	57.9	+0.9%
Primary	103.2	36.9	+179.7%
Overseas sales	81.0	35.4	+128.8%

[Progress in R&D activities from Feb 4th, 2022 to Apr 25th, 2022]

Letters in orange : in-house projects (global development) Letters in blue : in-licensed from Roche (development and distribution in Japan) As of April 25, 2022

Approved	Mitchga	pruritus associated with atopic dermatitis	March 2022
	Vabysmo	age-related macular degeneration associated with subfoveal choroidal neovascularization and diabetic macular edema (DME)	March 2022
	Perjeta/Herceptin	advanced or recurrent HER2-positive colon cancer or rectal cancer not amenable to curative resection that has progressed after cancer chemotherapy	March 2022
Filed	Actemra	COVID-19 in hospitalized adults - under Priority Review by the U.S. FDA	April 2022 (acceptance of filing)
	Gazyva	chronic lymphocytic leukemia (CLL) - combination with acalabrutinib	March 2022
Pipeline entry	SKY59/crovalimab	Sickle cell disease (US and EU)	P2 study (March 2022)
	RG6321/ranibizumab(PDS)	neovascular age-related macular degeneration (nAMD) and DME	P1/2 study (March 2022)
	RG7828/mosunetuzumab	follicular lymphoma (3rd Line)	P1 study (March 2022)
Development discontinued	RG7992	non-alcoholic steatohepatitis (NASH)	
Readout in pivotal study	SKY59/crovalimab	COMMODORE 3 (China) met co-primary endpoints in PNH	P3 study (Q1 2022)
	RG6058/tiragolumab	SKYSCRAPER-02 did not meet its co-primary endpoint of PFS in SCLC	P3 study (March 2022)
Medical conference	Vabysmo	YOSEMITE/RHINE studies (DME)	AED (February 2022)
	Evrysdi	SUNFISH/RAINBOWFISH studies (Spinal muscular atrophy)	MDA (March 2022)

Underlined are disclosed due to changes in pipeline entry rule

PDS: Port Delivery System with ranibizumab AED: Angiogenesis, Exudation and Degeneration MDA: Muscular Dystrophy Association

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 the basis for payment-by-results such as a return to shareholders.

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