Innovation all for the patients

CHUGAI

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Chugai Announces 2021 1st Quarter Results

- Revenues and core operating profit for the first quarter at ¥168.8 billion (-5.9%) and ¥65.4 billion (-11.7%), respectively
- Maintaining full-year forecasts for growth in revenues and profits
- Regulatory approval granted for the anti-CD79b antibody-drug conjugate (ADC) Polivy and the blood-based comprehensive genomic profiling test FoundationOne Liquid CDx Cancer Genomic Profile
- Start a domestic phase I clinical trial of antibody cocktail therapy for COVID-19

TOKYO, April 22, 2021 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced its financial results for the first quarter of fiscal year 2021.

“In the first quarter of 2021, despite growth in royalties and other operating income, both revenues and profits declined due to a decline in domestic and overseas sales. Still, there is no change to the full-year forecast for growth in revenues and profits as sales of mainstay products Tecentriq® and Kadcyla® are progressing significantly higher than expected at the beginning of the fiscal year, and we are also anticipating increases in exports to Roche and in royalty and profit-sharing income from the overseas growth of in-house products such as Hemlibra®. In terms of R&D, we have received regulatory approval for our new anti-cancer drug Polivy® and the liquid biopsy test FoundationOne® Liquid CDx Cancer Genomic Profile, and we have begun a domestic Phase I clinical trial for the antibody cocktail casirivimab and imdevimab for COVID-19. We will continue striving to deliver innovation to patients as quickly as possible,” said Dr. Osamu Okuda, Chugai’s President and CEO.

[First quarter results for 2021]

Chugai reported declines in revenues and operating profit for the first quarter (Core-basis) by approximately 6% and 12% year-on-year, respectively.

Revenues decreased as a whole due to a decrease in domestic and overseas sales, despite an increase in royalties and other operating income. Domestic sales declined by approximately 7% overall. Despite the sales increase in Oncology field driven by the double-digit growths of Tecentriq and Kadcyla, sales in the Primary field decreased by 20%, significantly impacted by the NHI drug price revision in April 2020 as well as generic competition. Overseas sales decreased by less than 20%, due to a decrease in exports of Actemra® and other products to Roche. On the other hand, royalties and other operating income increased by double digits mainly due to an increase in royalty and profit-sharing income of Hemlibra, despite a decrease in other operating income from one-time income.

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Cost to sales ratio remained at the same level as the same period last year. Operating expenses increased by approximately 9% as research and development expenses increased approximately by 15% due to steady progress in development projects while marketing and distribution expenses and general and administration expenses were almost flat year-on-year. As a result, operating profit declined by double digits.

The Company also made good progress in research and development. Chugai obtained regulatory approval in March 2021 for Polivy in relapsed or refractory diffuse large B-cell lymphoma, and FoundationOne Liquid CDx Cancer Genomic Profile as the first blood-based comprehensive genomic profiling test for solid tumors in Japan. A Phase III clinical trial evaluating Tecentriq in early-stage lung cancer achieved its primary endpoint, making a steady progress toward the regulatory application for line extension in 2021.

Regarding the clinical development of Actemra for COVID-19 pneumonia, Chugai announced in March 2021 that the Phase III REMDACTA study in combination with remdesivir did not meet its primary endpoint. Chugai is continuing further evaluation of overall risk-benefit profile based on the results of J-COVACTA, REMDACTA, COVACTA, EMPACTA trials and other studies of Actemra for COVID-19 pneumonia. In addition, a Phase I clinical trial in Japan was initiated in March 2021 for the investigational antibody cocktail casirivimab and imdevimab for COVID-19 in-licensed from Roche.

[2021 first quarter results]

Billion JPY	2021 Jan - Mar	2020 Jan - Mar	% change
Core results			
Revenues	168.8	179.4	-5.9%
Sales	130.3	144.5	-9.8%
Royalties and other operating income	38.6	34.9	+10.6%
Operating profit	65.4	74.1	-11.7%
Net income	48.4	52.7	-8.2%
IFRS results			
Revenues	168.8	179.4	-5.9%
Operating profit	64.0	72.4	-11.6%
Net income	47.4	51.5	-8.0%

[Sales breakdown]

Billion JPY	2021 Jan - Mar	2020 Jan - Mar	% change
Sales	130.3	144.5	-9.8%
Domestic sales	94.9	101.9	-6.9%
Oncology	57.9	55.3	+4.7%
Primary	36.9	46.6	-20.8%
Overseas sales	35.4	42.6	-16.9%

[Progress in R&D activities from Feb 5th, 2021 to Apr 22nd, 2021]

Approved	Actemra	Adult patients with SSc-ILD	March, 2021 (US)
	Polivy	Relapsed or refractory diffuse large B-cell lymphoma	March, 2021
	FoundationOne Liquid CDx[1]	Blood-based comprehensive genomic profiling test for solid tumors	March, 2021
	FoundationOne CDx[2]	Pemigatinib: biliary tract cancer (*FGFR2* fusion genes)	February, 2021
New to pipeline	Tecentriq＋Avastin	Hepatocellular carcinoma (intermediate stage: combination with TACE)	P3 study (TALENTACE)
	faricimab	Retinal vein occlusion (CRVO / BRVO)	P3 study
	casirivimab/imdevimab[3]	COVID-19	P1 study
Development Discontinued	Tecentriq	Early breast cancer (HER2+, neoadjuvant)	P3 study (IMpassion050)
Late-stage Readout	Actemra	COVID-19 pneumonia: primary endpoint not met	P3 study (REMDACTA)
	Tecentriq	Non small cell lung cancer (adjuvant): primary endpoint met	P3 study (IMpower010)
	casirivimab/imdevimab[3]	COVID-19: primary endpoint met	P3 study (2067, 2069)
Medical Conference	risdiplam	P2/3 SUNFISH study (2-year data)	March, 2021(MDA)
		P2/3 FIREFISH study (2-year data)	April, 2021(AAN)
	faricimab	Results of P3 studies (YOSEMITE, RINE / TENAYA, LUCERNE)	February, 2021(AED)
Others	AT-527	New oral treatment against COVID-19 in-licensed from Roche	February, 2021

Letters in orange: in-house projects
Letters in blue : in-licensed (Roche)

1: FoundationOne Liquid CDx Cancer Genomic Profile
2: FoundationOne CDx Cancer Genomic Profile
3: antibody cocktail

SSc-ILD: Systemic Sclerosis-associated Interstitial Lung Disease
TACE: Transarterial chemoembolization
CRVO: Central Retinal Vein Occlusion
BRVO: Branch Retinal Vein Occlusion

MDA: Muscular Dystrophy Association
AAN: American Academy of Neurology
AED: Angiogenesis, Exudation, and Degeneration

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, and are consistent with the Core concept disclosed by Roche. 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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