Innovation all for the patients

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Chugai Announces 2021 Half Year Results

- Record-high revenues and core operating profit for the first half at ¥390.2 billion (+6.0%) and ¥165.8 billion (+15.4%), respectively
- Both revenues and profits increased mainly due to growth in royalties and other operating income
- For COVID-19, Actemra received Emergency Use Authorization from the U.S. FDA and Ronapreve received Special Approval in Japan
- Steady progress in both early- and late-stage development, including the new product launch and approval, and the initiation of clinical development for an in-house project SOF10

TOKYO, July 26, 2021 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced its financial results for the first half of fiscal year 2021.

“We had a very good second quarter with strong earnings and steady progress in R&D activities. Revenues and profits grew significantly due to increases in domestic and overseas sales as well as Hemlibra® royalties. As a result, both revenues and profits for the first half turned to growth, despite declines in the first quarter. As for new products, in-house product Enspryng® received regulatory approval in Europe and is now being rolled out in Japan, the U.S. and Europe. In Japan, we launched Polivy® and received approval for Evrysdi®, two products we expect will drive future growth. Progress has also been made in the development of COVID-19 treatments. Actemra® received Emergency Use Authorization from the U.S. FDA, and Ronapreve® received Special Approval in Japan. In addition, I am pleased that we are able to report progress in many other projects in both our early- and late-stage pipelines. We will continue focusing on the creation of innovation to achieve our mission of contributing to the medical community and human health around the world.” said Dr. Osamu Okuda, Chugai’s President and CEO.

[Half year results for 2021]

Revenues increased by 6% and Core operating profit increased by approximately 15% for the half year (Core-basis), mainly due to a significant, roughly 40% increase in royalties and other operating income.

Revenues, which declined by 10% year-on-year in the first quarter, were almost flat compared to the same period of the previous year, while royalties and other operating income increased significantly, resulting in an overall increase in revenues. Sales, both domestic and overseas, remained at the same level as the first half of last year. Domestic sales in the oncology field increased by a little less than 10%, with the continued sales growth in Tecentriq® and Kadcyla®. On the other hand, domestic sales in the primary field decreased by double digits, despite the contribution of the new product Enspryng, due to the significant impact of the NHI drug price revision and generic competition. In total, domestic sales were almost flat

CHUGAI PHARMACEUTICAL CO., LTD. Corporate Communications Dept.
1-1, Nihonbashi-Muromachi 2-chome, Chuo-ku Tokyo, 103-8324 Japan
Media Relations Group TEL:+81-(0)3-3273-0881 E-mail:pr@chugai-pharm.co.jp
Investor Relations Group TEL:+81-(0)3-3273-0554 E-mail:ir@chugai-pharm.co.jp

compared with the same period of the previous year. As for overseas sales, increases in the sales of Hemlibra, which nearly doubled year-on-year, and other products offset the decrease in the sales of Actemra. Royalties and other operating income increased by approximately 40% mainly due to an increase in royalties and profit-sharing income relating to Hemlibra.

Cost to sales ratio improved by 2.8 % points year-on-year to 40.1%, mainly due to an increase in the proportion of in-house products including Hemlibra. Operating expenses increased by 10% due to the double-digit increase in research and development expenses associated with the progress of development projects. Marketing and distribution, and general and administration expenses also increased as these expenses decreased last year due to lower business activities caused by the spread of COVID-19. As a result, core operating profit increased by approximately 15%.

The Company also made good progress in research and development. Among the next growth drivers, Enspryng, a recycling antibody created by Chugai, obtained regulatory approval in Europe following Japan and the U.S. for the treatment of neuromyelitis optica spectrum disorder. Evrysdi, an SMN2 splicing modifier, obtained regulatory approval in Japan in June as the first oral drug for spinal muscular atrophy. A regulatory application was filed for faricimab, the first bispecific antibody in ophthalmology, for two indications, diabetic macular edema and neovascular age-related macular degeneration. An application was also filed for the line extension of Tecentriq as adjuvant therapy for non-small cell lung cancer. In addition, both early- and late-stage development products are steadily progressing. Phase III global clinical trials for several projects started in order to examine new indications. Phase I clinical trials for an in-house project SOF10 and other projects also started in Japan.

In the efforts to develop a treatment for COVID-19, the anti-IL-6 receptor antibody Actemra, created by Chugai, received Emergency Use Authorization from the U.S. FDA in June for hospitalized adults and children. A regulatory filing in Japan is planned by the end of this year. The antibody cocktail Ronapreve, in-licensed from Roche, obtained Special Approval in Japan in July following the filing of application in June. For AT-527, an oral antiviral agent also in-licensed from Roche, Chugai participated in a Phase III global clinical trial for the treatment of mild to moderate COVID-19 in outpatient setting and advances the development. Chugai ended the antibody research collaboration with A*STAR for COVID-19 with the completion of preclinical assessment studies for the lead antibody candidates against SARS CoV2. The collaboration was announced in May 2020.

[2021 half year results]

Billion JPY	2021 Jan - Jun	2020 Jan - Jun	% change
Core results			
Revenues	390.2	368.1	+6.0%
Sales	304.1	305.7	-0.5%
Royalties and other operating income	86.1	62.5	+37.8%
Operating profit	165.8	143.7	+15.4%
Net income	121.7	104.5	+16.5%
IFRS results			
Revenues	390.2	368.1	+6.0%
Operating profit	160.7	140.6	+14.3%
Net income	118.1	102.3	+15.4%

[Sales breakdown]

Billion JPY	2021 Jan - Jun	2020 Jan - Jun	% change
Sales	304.1	305.7	-0.5%
Domestic sales	203.4	204.6	-0.6%
Oncology	124.1	113.4	+9.4%
Primary	79.3	91.2	-13.0%
Overseas sales	100.7	101.0	-0.3%

[Progress in R&D activities from Apr 23rd, 2021 to Jul 26th, 2021]

launch	Polivy	r/ r DLBCL	May
	Ronapreve （Antibody Cocktail)	COVID-19	July
approved	Enspryng	NMOSD (EU)	June
	Evrysdi	SMA	June
	Cellcept	GVHD in hematopoietic stem-cell transplantation	June
	FoundationOne Liquid CDx [1]	olaparib: prostate cancer (*BRCA1/2* alterations)	May
	FoundationOne CDx [2]	nivolumab: MSI-High colorectal cancer	June
		pembrolizumab: MSI-High tumors	June
filed	Faricimab	DME/nAMD	June
	Tecentriq	NSCLC [adjuvant]	July
	Herceptin	HER 2 positive salivary gland cancer	April
	Perjeta / Herceptin	HER 2 positive colorectal cancer	April
	FoundationOne CDx[2]	pembrolizumab: TMB-High tumors	May

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

r/r: relapsed/refractory, DLBCL: diffuse large B-cell lymphoma, NMOSD: neuromyelitis optica spectrum disorder, SMA: spinal muscular atrophy, GVHD: graft-versus-host disease, MSI: microsatellite instability, DME: diabetic macular edema, nAMD: neovascular age-related macular degeneration, NSCLC: non-small cell lung cancer, TMB: tumor mutational burden

1: FoundationOne Liquid CDx Cancer Genomic Profile
2: FoundationOne CDx Cancer Genomic Profile

Initiation of study	Tecentriq	Muscle-invasive bladder cancer [adjuvant] (ctDNA positive)	P3 study (IMvigor011)(May)
		HCC [2nd line] (in combination with TKI)	P3 study (IMbrave251)(April)
	RG6422 (AT-527)	COVID-19	P3 study (April)
	ERY974	HCC (in combination with Tecentriq + Avastin)	P1 study (June)
	SOF10 (RG6440)	Solid tumors	P1 study (June)
	RG7992	Non-alcoholic steatohepatitis	P1 study (June)
	RG6102 (Brain Shuttle Gantenerumab)	Alzheimer's disease	P1 study (July)
	RG6396 (pralsetinib)	Solid tumors	P1 study (July)
BTD	VS-6766 (CKI27)	Recurrent low-grade serous ovarian cancer*	May
License-out	EOS789	Option and license agreement (Alebund Pharmaceuticals)	July
Removed from pipeline	ipatasertib	Breast cancer	P3 study (IPATunity150)
Medical conference	Tecentriq	IMpower010 interim analysis	American Society of Clinical Oncology (June)
Others	Actemra	COVID-19 (US EUA/WHO Guidelines recommendation list)	June/July
	License agreement	Alaglio (photodynamic diagnostic agent)	Terminate agreement (SBI Pharm)
	Joint research	Antibody-drug against COVID-19	Ended joint research (A*STAR)

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ctDNA: circulating tumor DNA, HCC: hepatocellular carcinoma, TKI: tyrosine kinase inhibitor, EUA: emergency use authorization
* In combination with FAK inhibitor.

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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