Innovation all for the patients

CHUGAI

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Chugai Announces 2020 3rd Quarter Results

- Record-high revenues and core operating profit for the third quarter at ¥576.5 billion (+13.3%) and ¥231.9 billion (+35.5%), respectively
- Double-digit increase in both revenues and profits due to the contribution of overseas sales and royalties and other operating income that outweighed a decrease in domestic sales
- Good progress in research and development especially for in-house projects including the initiation of phase III clinical trials for crovalimab (SKY59/RG6017) in paroxysmal nocturnal hemoglobinuria and the start of clinical development of a new anticancer agent SPYK04

TOKYO, October 22, 2020 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced its financial results for the third quarter of fiscal year 2020.

“As in the second quarter, strong growth in exports and royalty revenue far outpaced the decline in domestic product sales, helping Chugai to maintain high growth in the third quarter. The launch of the first recycling antibody Enspryng® in Japan and the United States was a major milestone. In terms of research and development, in-house projects that will come after Enspryng are progressing well as crovalimab and SPYK04 have advanced to new development stages. We will continue pursuing innovation based on our unique strength in science and technology to satisfy unmet medical needs and increase corporate value continuously,” said Tatsuro Kosaka, Chugai’s Chairman and CEO.

[Third quarter results for 2020]

Despite domestic sales decreased by about 7% affected by the NHI drug price revisions and the market penetration of generic drugs, Chugai reported a double-digit growth year-on-year in both revenues and operating profit for the third quarter (Core-basis), driven by increases in overseas sales, and royalties and other operating income by approximately 40% and 60%, respectively.

Revenues increased by 13.3%. Among sales, domestic sales decreased by 6.5% since sales of mainstay products in the Oncology, Bone and joint diseases, and Renal diseases areas decreased continuously from the second quarter. This resulted from the NHI drug price revisions in April this year and the market penetration of generic drugs. Domestic sales of Enspryng, a neuromyelitis optica spectrum disorder treatment newly launched in August were ¥300 million. On the other hand, overseas sales increased by 39.3% due to an increase in export of Actemra® to Roche, including those for clinical trials for COVID-19 pneumonia, and export of Hemlibra®, a treatment for hemophilia A, to Roche at a regular shipment price. Royalties and other operating income increased by 63.3% due to a significant increase in royalties for

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Hemlibra and its profit-sharing income as well as an increase in other operating income resulting from one-time income.

Cost to sales ratio improved by 2.6 percentage points at 43.1% despite the NHI price revisions mainly due to a larger proportion of in-house products including Hemlibra in the total product mix. Operating expenses increased by 5.7% in total. Marketing and distribution expenses and general and administration expenses decreased due to lower business activities caused by the spread of COVID-19. Research and development expenses recorded a double-digit increase with the projects progressing well. Operating profit increased by 35.5% due to the strong increase in revenues and a better cost to sales ratio.

The Company also made good progress in research and development. As the main progress, Chugai submitted a regulatory application in Japan for the SMN2 splicing modifier risdiplam for the treatment of spinal muscular atrophy in October. Progresses in in-house projects included the start of phase III clinical trials of an anti-C5 recycling antibody crovalimab in paroxysmal nocturnal hemoglobinuria, and the start of clinical development of a small molecule anticancer agent SPYK04. For nemolizumab, an anti-IL-31 receptor A humanized monoclonal antibody created by Chugai, a regulatory application was filed in Japan for the treatment of atopic dermatitis by Maruho Co., Ltd., the licensee in Japan. As for the line extensions of existing products, anti-PD-L1 humanized monoclonal antibody Tecentriq® and anti-VEGF humanized monoclonal antibody Avastin® have been approved for hepatocellular carcinoma and anti-HER2 antibody-tuberin polymerization inhibitor conjugate Kadcyla® has been approved for postoperative adjuvant therapy of HER2-positive early breast cancer.

[**Initiatives for COVID-19 and impact on performance]**
Regarding the impact of COVID-19 on performance during the nine months under review, there were no major negative impacts on revenues and profits. However, the pandemic has been affecting the progress of certain business activities as described below.

- Product supply system maintained stable by taking measures to prevent infection of employees and business partners. No impacts on the product supply have been seen both in Japan and overseas up to now.
- Delay of the introduction of new products and those with additional indications, such as Tecentriq and Hemlibra, in the domestic market due to various reasons including restrained sales activities and decrease in the number of hospitalizations and outpatients.
- Continuous increase in export of Hemlibra to Roche.
- Significant increase in export of Actemra to Roche, including those for clinical trials for COVID-19 pneumonia.
- Some expenses were curbed mainly due to cancellation of overseas travels and restrained sales activities in Japan.

- No major impacts on the timing of regulatory filing or approval.
- Some delays in the initiation and progress of clinical trials for projects under development. These delays are expected to be resolved in time.
- No delays in drug discovery activities for high-priority projects.
- Construction for Chugai Life Science Park Yokohama temporarily suspended. All construction resumed with limited impacts on the overall construction schedule.
- A domestic phase III clinical trial of Actemra for COVID-19 is currently being conducted, and its impact on performance is unclear at this point.

[2020 third quarter results]

Billion JPY	2020 Jan - Sep	2019 Jan - Sep	% change
Core results			
Revenues	576.5	508.9	+13.3%
Sales	464.8	440.5	+5.5%
Royalties and other operating income	111.7	68.4	+63.3%
Operating profit	231.9	171.1	+35.5%
Net income	165.6	124.5	+33.0%
IFRS results			
Revenues	576.5	508.9	+13.3%
Operating profit	227.3	160.9	+41.3%
Net income	162.4	117.4	+38.3%

[Sales breakdown]

Billion JPY	2020 Jan - Sep	2019 Jan - Sep	% change
Sales	464.8	440.5	+5.5%
Domestic sales	303.2	324.4	-6.5%
Oncology	167.4	179.7	-6.8%
Bone and joint diseases	72.7	80.5	-9.7%
Renal diseases	21.0	25.9	-18.9%
Others	42.1	38.4	+9.6%
Overseas sales	161.6	116.0	+39.3%

[Progress in R&D activities from Jul 28th, 2020 to Oct 22nd, 2020]

Approved	**Enspryng**	Neuromyelitis optica spectrum disorder (NMOSD)	August, 2020*1
	Kadcyla	HER2+ Breast Cancer (adjuvant)	August, 2020
	Tecentriq	Hepatocellular carcinoma (HCC)	September, 2020
	Avastin	Hepatocellular carcinoma (HCC)	September, 2020
Filed	**F1CDx**	CDx for larotrectinib (*NTRK1/2/3* fusion gene)	July, 2020
	F1CDx	CDx for pemigatinib (*FGFR2* fusion genes)	September, 2020
	Risdiplam	Spinal muscular atrophy (SMA)	October, 2020
Phase Progress	**crovalimab**	Paroxysmal nocturnal hemoglobinuria (PNH)	P3 study
	RG6171 (SERD)	Breast cancer	P3 study
New to Pipeline	**SPYK04**	Solid tumors	P1 study
	Tecentriq	Renal cell carcinoma (combination with cabozantinib)	P3 study (CONTACT-03)
	TIR / Tecentriq	Stage III NSCLC	P3 study (SKYSCRAPER-03)
	TIR / Tecentriq	Esophageal cancer	P3 study (SKYSCRAPER-07)
Late-stage Readouts	**Actemra**	COVID-19 pneumonia	P3 study (COVACTA)
	Actemra	COVID-19 pneumonia	P3 study (EMPACTA)
	Tecentriq	Triple negative breast cancer (TNBC)	P3 (IMpassion131)
Medical Conference	**Enspryng**	SAkuraStar / SAkuraSky studies (data from open-label extension period)	ACTRIMS-ECTRIMS
	Tecentriq	IMpassion031, IMpassion130, IMpassion131studies	ESMO
	risdiplam	FIREFISH study part 1 (after two-year treatment)	World Muscle Society
Others	**nemolizumab**	Atopic dermatitis (Japan) filed*2	Q3, 2020
	STA551	Solid tumors / non-clinical research	Published in Cancer Discovery
	Joint development	combination therapy of Tecentriq and cabozantinib (domestic)	Takeda
	Technology transfer	Antibody engineering technologies	argenx / Novo Nordisk

*1 Approved in U.S. and launched in Japan
F1CDx: FoundationOne CDx; NTRK: neurotrophic tyrosine receptor kinase; FGFR: fibroblast growth factor receptor; NSCLC: non-small cell lung cancer; TIR: tiragolumab

Letters in orange: **in-house projects***3
*2 conducted by Maruho, licensee in Japan
*3 Includes projects that Chugai owns / retains domestic and overseas development rights

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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