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CHUGAI

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Chugai Announces 2020 Half Year Results

- Record-high revenues and core operating profit for the first half at ¥368.1 billion (+14.9%) and ¥143.7 billion (+38.8%), respectively
- Double-digit increases in both revenues and profits mainly driven by the contribution of overseas sales and royalties and other operating income
- Good progress in research and development including the regulatory approval for Ensprying in Japan and the initiation of a clinical study for Hemlibra in acquired hemophilia A

TOKYO, July 27, 2020 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced its financial results for the first half of fiscal year 2020.

“We had another successful quarter with a limited impact from the COVID-19 pandemic on financial performances though we saw wide-ranging influences on our activities. We obtained approval for the first recycling antibody Ensprynq®, one of our next growth drivers. Also, structural reforms of corporate functions progressed well to enhance the business platform. Under increasingly uncertain business conditions, we will continue striving to realize innovation that is only possible at Chugai,” said Tatsuro Kosaka, Chugai’s Chairman and CEO.

[Half year results for 2020]

Despite the slight decrease in domestic sales affected by the NHI drug price revisions and the market penetration of generic drugs, Chugai reported a double-digit growth year-on-year in revenues and operating profit for the half year (Core-basis), due to increases both in overseas sales and royalties and other operating income.

Revenues increased by 14.9%. Among sales, domestic sales decreased by 2.6% due to a decrease in sales of mainstay products mainly in the Oncology and Renal diseases areas affected by the NHI drug price revisions in April this year, and the market penetration of generic drugs. On the other hand, overseas sales increased by 39.5% due to an increase in export of Actemra® to Roche, including those for clinical trials for COVID-19 pneumonia, and the export of Hemlibra® to Roche at a regular shipment price. Royalties and other operating income increased by 64.9% due to a large increase in royalties for Hemlibra and its profit-sharing income as well as an increase in other operating income resulting from one-time income.

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Cost to sales ratio improved by 2.2 percentage points at 42.9% mainly due to a larger proportion of in-house products in the total product mix. Operating expenses increased slightly 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 largely as expected at the beginning of the year. Operating profit increased by 38.8% due to the strong increase in royalties and profit-sharing income, and a better cost to sales ratio.

The Company also made a good progress in research and development. Chugai obtained regulatory approval for the anti-IL-6 receptor recycling antibody Enspryng, created by Chugai for the prevention of relapses of neuromyelitis optica spectrum disorder (including neuromyelitis optica) in Japan in June. Also, Chugai started domestic Phase III study for Hemlibra for the treatment of acquired hemophilia A. Regarding projects for COVID-19, a domestic Phase III study for Actemra for the hospitalized patients with severe COVID-19 pneumonia is underway, and Chugai aims to submit a regulatory application in 2020. Chugai Pharmabody Research Pte. Ltd. (CPR) began a joint research on a therapeutic antibody to fight COVID-19 with the Agency for Science, Technology and Research (A*STAR).

[**Initiatives for COVID-19 and impact on performance]**
Regarding the impact of COVID-19 on performance during the six months under review, there were no major negative impacts on revenues and profits. However, the company faced a range of influences on the progress of business activities as 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 decreases in hospitalizations and outpatients.
- Increase in export of Actemra to Roche, including those for clinical trials for COVID-19 pneumonia.
- 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. Construction resumed entirely from June with limited impacts on the overall construction schedule.
- Some expenses suppressed mainly due to cancellation of overseas travels and restrained sales activities in Japan.

[2020 half year results]

Billion JPY	2020 Jan - Jun	2019 Jan - Jun	% change
Core results			
Revenues	368.1	320.3	+14.9%
Sales	305.7	282.4	+8.3%
Royalties and other operating income	62.5	37.9	+64.9%
Operating profit	143.7	103.5	+38.8%
Net income	104.5	75.1	+39.1%
IFRS results			
Revenues	368.1	320.3	+14.9%
Operating profit	140.6	95.1	+47.8%
Net income	102.3	69.3	+47.6%

[Sales breakdown]

Billion JPY	2020 Jan - Jun	2019 Jan - Jun	% change
Sales	305.7	282.4	+8.3%
Domestic sales	204.6	210.0	-2.6%
Oncology	112.2	114.6	-2.1%
Bone and joint diseases	50.5	52.0	-2.9%
Renal diseases	13.7	17.2	-20.3%
Others	28.2	26.2	+7.6%
Overseas sales	101.0	72.4	+39.5%

[Progress in R&D activities from Apr 24th, 2020 to Jul 27th, 2020]

Approved	Enspryng **F1CDx**	NMOSD (Japan, Canada, Switzerland) CDx for Capmatinib (*MET* ex14 + NSCLC)	JPN: June, CH: July, 2020 May, 2020
Filed	**polatuzumab vedotin** **F1CDx**	r/r DLBCL CDx for Lynparza (HRR-related gene alterations + CRPC)	June, 2020 June, 2020
New to Pipeline	Actemra Hemlibra	COVID-19 pneumonia Acquired hemophilia A	P3 domestic study (J-COVACTA) P3 domestic study (AGEHA)
Development Discontinued	**Tecentriq + Avastin** **Kadcyla + Perjeta** **balovaptan**	Renal cell carcinoma HER2+ breast cancer (adjuvant) Autism spectrum disorder	P3 study (IMmotion151) P3 study (KAITLIN) P1 study
Late-stage Readouts	**Tecentriq** **ipatasertib**	Triple negative breast cancer (neo-adjuvant) CRPC (loss of PTEN)	P3 (IMpassion031) P3 (IPATtential150)
Medical Conference	Enspryng **risdiplam** **risdiplam** Alecensa **tiragolumab**	SAkuraStar / SAkuraSky studies (long-term safety) FIREFISH study part 2 (after one-year treatment) SUNFISH study part 1 (after two-year treatment) ALEX study (5-year survival rate) CITYSCAPE study (combination with Tecentriq)	EAN AAN CureSMA ASCO ASCO
Others	nemolizumab **Technology transfer** **Joint research** **Joint development**	Atopic dermatitis / domestic P3 study* Antibody engineering technology Antibody-drug against COVID-19 Digital technology for pain scoring in endometrosis	NEJM Eli Lilly and Company A*STAR Biofourmis

NMOSD: neuromyelitis optica spectrum disorder; r/r DLBCL: relapsed or refractory diffuse large B-cell lymphoma; F1CDx: FoundationOne CDx;
NSCLC: non-small cell lung cancer; HRR: homologous recombination repair; CRPC: castration-resistant prostate cancer;
PTEN: phosphatase and tensin homolog SMA: spinal muscular atrophy; A*STAR: Agency for Science, Technology and Research

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

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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