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CHUGAI

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# Chugai Announces 2020 Full Year Results and Forecasts for 2021

- Record-high revenues and Core operating profit for the fourth consecutive year at ¥786.9 billion (+14.7%) and ¥307.9 billion (+36.9%), respectively
- Planned 2020 year-end dividends are ¥30 per share (total dividends for the fiscal year: ¥55 per share*)
- Revenues and Core operating profit are expected to grow in 2021 to ¥800.0 billion (+1.7%) and ¥320.0 billion (+3.9%), respectively. Clinical development for a mid-size molecule drug is planned to start
- The new growth strategy “TOP I 2030” has been announced following the conclusion of mid-term business plan “IBI 21” one year ahead of schedule due to favorable results

*Based on the assumption that the stock split was implemented at the beginning of the fiscal year

TOKYO, February 4, 2021 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced its financial results for the fiscal year ended December 31, 2020 and forecasts for the fiscal year ending December 31, 2021.

“The COVID-19 pandemic had a dramatic impact on the world in 2020, but Chugai was able to achieve record high revenues and profits for the fourth consecutive year, mainly driven by the expansion of overseas revenues related to in-house products Actemra® and Hemlibra®. Among many achievements in the year, we successfully completed the domestic and overseas launch of Enspryng®, a treatment for neuromyelitis optica spectrum disorder and the fourth global product under the strategic alliance with Roche. Our foundation for future growth has also been strengthened with progress in multiple in-house projects in both early and late development stages, including the start of clinical development for the novel antibody engineering technology Switch Antibody™. Based on our unique scientific and technological capabilities, including a mid-size molecule drug that is expected to start clinical development this year, we will continue to make strong progress in 2021 under our new growth strategy, TOP I 2030, aiming to achieve innovation that addresses unmet medical need with world-class drug discovery capabilities,” said Tatsuro Kosaka, Chugai’s Chairman and CEO.

**<Full year results for 2020>**

Chugai reported financial results in 2020 (Core-basis) with revenues of ¥786.9 billion (+¥100.7 billion, +14.7%) and the overseas revenues ratio of 46.8% given significant increases in overseas sales and royalties and other operating income, despite a decrease in domestic sales by approximately 7% year on year mainly due to the impact of the NHI drug price revisions in April 2020. Overseas sales increased by approximately 50% due to an increase in export of Actemra, including those for clinical trials for COVID-19, the start of export at a regular shipping price and the market penetration of hemophilia A treatment

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Hemlibra, and the start of export of Enspryng, the first drug using recycling antibody technology. Royalties and other operating income increased by approximately 60%, primarily due to a significant increase in royalty and profit-sharing income for Hemlibra.

The cost to sales ratio continued to improve mainly due to a larger proportion of in-house products including Hemlibra in the total product mix. The increase in operating expenses was limited to approximately 5% as marketing and distribution expenses decreased chiefly by restrained sales activities in Japan owing to the spread of COVID-19. As a result, Core operating profit was ¥307.9 billion (+¥83.0 billion, +36.9%).

Reflecting the favorable results and based on our dividend policy, we plan to pay year-end dividends of ¥30 per share. As a result, the annual dividend will be ¥55 per share*, and the Core dividend payout ratio is 44.9% on a five-year average basis (41.2% on a single fiscal year basis).

* Based on the assumption that the stock split was implemented at the beginning of the fiscal year.

The Company also made good progress in research and development. Achievements in in-house projects include the start of Phase III global clinical trials of anti-C5 recycling antibody crovalimab for the treatment of paroxysmal nocturnal hemoglobinuria, and a regulatory application was filed in Japan for nemolizumab, an anti-IL-31 receptor A antibody created by Chugai, for the treatment of atopic dermatitis by Maruho Co., Ltd., the licensee in Japan. In addition, AMY109, STA551, and SPYK04 have entered Phase I clinical trials for solid tumors. Line extensions were approved for some core products including anti-PD-L1 antibody Tecentriq®, which received approval for the treatment of hepatocellular carcinoma in combination with Avastin®, and the HER2-positive breast cancer treatment Kadcyla®, which received approval for HER2-positive postoperative breast cancer. Mid-size molecule drugs technologies, which are expected to become the third drug discovery technology platform following small molecules and antibodies, also made steady progress toward commencing clinical development in 2021.

**<Initiatives for COVID-19 and impact on performance>**

Regarding the impact of COVID-19 on performance during the fiscal year under review, there were no major negative impacts on revenues and profits. However, the pandemic has affected 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.
- Increase in export of Actemra to Roche, including those for clinical trials for COVID-19 pneumonia.
- Steady increase in export of Hemlibra to Roche, however royalties were affected due to the overseas market penetration of Hemlibra taking longer than initially expected.
- 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.

**<Full year forecast for 2021>**

In 2021, the Company expects revenues and profits to mark a record high for the fifth consecutive year. Revenues, Core operating profit, and Core net income are expected to be ¥800.0 billion (+¥13.1 billion, +1.7%), ¥320.0 billion (+¥12.1 billion, +3.9%), and ¥232.0 billion (+¥12.6 billion, +5.7%), respectively. Sales are expected to decrease slightly to ¥631.0 billion (-¥2.3 billion, -0.4%) as the negative impact on domestic sales mainly due to intensifying competition associated primarily with launches of biosimilars and generics as well as NHI drug price revisions, will exceed the expected increase in overseas sales assuming a steady growth of the export of Hemlibra to Roche. Overseas sales of Actemra are expected to decrease, for which a large amount of additional exports was made in the previous fiscal year. Royalties and other operating income are expected to increase by a double-digit percentage driven by Hemlibra-related income from Roche.

Chugai expects the annual dividends per share of ¥60 with the Core dividend payout ratio of 43.8% on a five-year average basis (42.6% in a single fiscal year basis).

**<Formulation of a new growth strategy TOP I 2030>**

Substantially exceeding the performance targets for three years in only two years, Chugai has decided to conclude the mid-term business plan IBI 21 one year ahead of the initial schedule of 2021. The Group has formulated a new growth strategy TOP I 2030 to become “the top innovator” in 2030 with a view toward realizing the Envisioned Future set out in its Mission Statement.

**[2020 full year results]**

| Billion JPY | 2020 | 2019 | % change |
|---|---|---|---|
| Core results | | | |
| Revenues | 786.9 | 686.2 | +14.7% |
| Sales | 633.3 | 588.9 | +7.5% |
| Royalties and other operating income | 153.6 | 97.3 | +57.9% |
| Operating profit | 307.9 | 224.9 | +36.9% |
| Net income | 219.4 | 167.6 | +30.9% |
| IFRS results | | | |
| Revenues | 786.9 | 686.2 | +14.7% |
| Operating profit | 301.2 | 210.6 | +43.0% |
| Net income | 214.7 | 157.6 | +36.2% |

**[2021 full year forecast]**

| Billion JPY | 2021 Forecast | 2020 Actual | % change |
|---|---|---|---|
| Core-basis | | | |
| Revenues | 800.0 | 786.9 | +1.7% |
| Operating profit | 320.0 | 307.9 | +3.9% |
| Net income | 232.0 | 219.4 | +5.7% |

**[Progress in R&D activities for Oct 23rd, 2020-Feb 4th, 2021]**

| | | | |
|---|---|---|---|
| **Approved** | **Enspryng** | Neuromyelitis optica spectrum disorder (NMOSD) | December, 2020 (Taiwan) |
| | **Edirol** | Osteoporosis | December, 2020 (China) |
| | **Tecentriq (monotherapy)** | PD-L1-positive NSCLC (1st line treatment) | December, 2020 |
| | **FoundationOne CDx** | olaparib: prostate cancer (*BRCA1/2* alterations) | November, 2020 |
| | | larotrectinib: Solid tumors (*NTRK1/2/3* fusion gene) | January, 2021 |
| **Filed** | **FoundationOne CDx** | nivolumab: Colorectal cancer (MSI) | December, 2020 |
| | | pembrolizumab: Solid tumors (MSI) | December, 2020 |
| **New to pipeline** | **Tecentriq+Actemra** | Pancreatic adenocarcinoma | P1 study (Morpheus platform) |
| | **Tecentriq+tiragolumab** | Pancreatic adenocarcinoma | P1 study (Morpheus platform) |
| | **OBP-301+Tecentriq+Avastin** | Hepatocellular carcinoma (HCC) | P1 study |
| | **Anti-HER2/CD3 bispecific antibody** | Solid tumors | P1 study |
| **Development Discontinued** | **Tecentriq** | TMB-positive NSCLC (1st line treatment) | P2/3 study (B-FAST) |
| | **Tecentriq+paclitaxel** | Triple negative breast cancer | P3 study (IMpassion131) |
| | **ipatasertib** | Triple negative breast cancer, HR+ breast cancer | P3 study (IPATUnity130 / IPATUnity170) |
| | **FAP-IL2v FP** | Solid tumors | P1 study |
| | **fenebrutinib** | Rheumatoid arthritis (RA) | P1 study |
| **Late-stage Readout** | **faricimab** | Diabetic macular edema (DME) | P3 studies (YOSEMITE / RHINE) |
| | | Neovascular age related macular degeneration (nAMD) | P3 studies (TENAYA / LUCERNE) |
| **Medical Conference** | **Hemlibra** | HAVEN1/2/3/4 studies (three-year follow-up data) | ASH2020 |
| **Others** | **nemolizumab** | Prurigo nodularis (overseas) the start of P3 study* | October, 2020 |
| | | Prurigo nodularis (JPN) the start of P2/3 study** | December, 2020 |
| | **CKI27** | RAS/RAF-mutated solid tumors and multiple myeloma/P1 study | Published in The Lancet Oncology |
| | **In-license** | Antibody cocktail (casirivimab / imdevimab) | Roche |

Letters in orange: in-house projects
*Conducted by Galderma S.A., the overseas licensee **Conducted by Maruho Co., Ltd., the licensee in Japan
NSCLC: non-small cell lung cancer
FAP-IL2v FP: Anti-FAP humanized antibody-engineered IL-2 variant fusion protein
MSI: Microsatellite Instability-High
TMB: tumor mutational burden

**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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