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CHUGAI

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# Chugai Announces 2022 3rd Quarter Results

- Record-high core revenues and core operating profit for the first nine months at ¥729.5 billion (+7.7%) and ¥299.0 billion (+2.9%), respectively
- Full-year financial forecasts were maintained while revenues and operating profit for the third quarter (Jul - Sep) declined against the same period last year due to the supply of Ronapreve to the government
- Good progress in R&D includes the world's first filing of the regulatory application for anti-C5 recycling antibody crovalimab in China, out-license of NXT007, the next-generation project following Hemlibra, to Roche and initiation of clinical development of DONQ52

TOKYO, Oct 24, 2022 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced its financial results for the third quarter of fiscal year 2022.

"Chugai achieved record-high revenues and profits for the first nine months of 2022 following the strong first half of the year. Domestic sales were driven by growing market penetration of new products including Vabysmo®, the new ophthalmic drug launched in May 2022, while Hemlibra® continued to increase overseas sales. Research and Development also progressed well in the third quarter, particularly for in-house projects which are expected to propel our medium- to long-term growth. The world's first filing for regulatory approval of our anti-C5 recycling antibody, crovalimab, was accepted in China. In addition, clinical development was initiated for DONQ52, a new bispecific antibody. We will continue to focus all our efforts on innovation to address unmet medical needs so that we can contribute to patients waiting for new treatments," said Dr. Osamu Okuda, Chugai's President and CEO.

**Third Quarter Financial Results (Core results, January to September 2022)**

Chugai reported record-high financial results for the first nine months in 2022, as revenues increased by 7.7% and operating profit increased by 2.9% over the same period last year.

An increase in domestic and overseas sales outweighed a decrease in royalties and other operating income, resulting in a 7.7% increase in total revenues. Domestic sales increased by 6.9%. Sales in the Oncology field decreased by 2.4% as the impact of the NHI drug price revision and biosimilars in mature products, including Avastin® and Herceptin®, exceeded the sales growth from a new product Polivy®, which was approved for an additional indication in August this year, and a mainstay product Kadcyla® as well as Foundation Medicine business. In the Specialty field, renamed from the Primary field following the organizational change in July, sales increased by 17.1% due to the contributions from the supply of Ronapreve® to the government in the first quarter, as well as an approximately 20% increase in sales of the mainstay product Hemlibra. Steady market penetration of new products, including Vabysmo launched in May, also contributed. The increase in overseas sales was driven by a 2-times increase of Hemlibra owing

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to the full-scale export to Roche at regular shipping price and a more than 20% increase in Actemra®, which obtained emergency use authorization and regulatory approval for severe COVID-19 in the U.S. and Europe, respectively, since last June. On the other hand, royalties and other operating income decreased by approximately 40%, mainly due to a significant decrease in royalty income related to the initial shipments of Hemlibra.

Cost to sales ratio improved by 1.2 percentage points year-on-year to 40.7%, mainly due to a change in the product mix. Operating expenses grew by 4.3% as both marketing and distribution and research and development expenses increased, while general and administration expenses decreased. Marketing and distribution expenses increased mainly due to foreign exchange effects. Research and development expenses increased mainly due to the progress of projects under development and foreign exchange effects. General and administration expenses decreased primarily due to decreases in various expenses, as well as recognizing gains on sales of property, plant and equipment. As a result, Core operating profit totaled ¥299.0 billion (+2.9%).

**Quarterly Financial Results (Core results, July to September 2022)**

Revenues and operating profit for the third quarter (Jul-Sep) both decreased by approximately 20% against the same period last year. The leading cause of the decreases were that the supply of Ronapreve to the government, which was ¥42.8 billion yen in the same period last year, did not occur in the quarter under review, along with the significant decrease in royalty income related to the initial shipments of Hemlibra. Sales decreased by approximately 20%. While overseas sales increased by 3.7%, domestic sales decreased by less than 30% with the impact of Ronapreve, resulting in a decrease in overall sales. In domestic sales, the Oncology field reported a 5.1% decrease as mature products such as sales of Avastin and Herceptin decreased due to the NHI drug price revision and biosimilar impact, despite increases in a new product Polivy and a mainstay product Kadcyla. Sales of the Specialty field decreased by more than 40%, primarily for the supply of Ronapreve to the government last year. Excluding Ronapreve, sales of the Specialty field increased by 1.4%, driven by the contribution from new products including Vabysmo, which was launched in May this year. Overseas sales increased by 3.7% as the increase of Hemlibra owing to the full-scale export to Roche at regular shipping price outweighed a more than 30% decrease in sales of Actemra caused by a delay in production. In addition, we launched Edirol® in China in July. Royalties and other operating income decreased by less than 40% chiefly due to the significant decrease in royalty income related to the initial shipments of Hemlibra. The cost to sales ratio improved by approximately eight percentage points against the same period last year, mainly due to a higher proportion of in-house products in total sales. Operating expenses were flat against the same period last year. No changes have been made in the full-year forecasts announced at the beginning of the fiscal year, while revenues and operating profit both decreased for the quarter under review.

**R&D activities**

The Company also made good progress in research and development. Among in-house projects, which will contribute to the Company's medium-to long-term growth, Maruho launched the anti-IL-31 receptor antibody Mitchga® in August as a treatment for itching associated with atopic dermatitis. Maruho is the licensee of the product in Japan. The world's first filing of regulatory application for the anti-C5 recycling antibody, crovalimab, was accepted in China with a priority review designation for the treatment of

paroxysmal nocturnal hemoglobinuria (PNH). Clinical development of an existing product Enspryng® has started for new indications, myelin oligodendrocyte glycoprotein antibody-associated disease (MOGAD) and autoimmune encephalitis (AIE). In addition, clinical development of a new bispecific antibody project, DONQ52, has been initiated for celiac disease, a disease with no approved drug treatments available. Furthermore, Chugai entered into an agreement with Roche to out-license NXT007, which is being developed as the next-generation project following Hemlibra.

As for in-licensed products from Roche, an additional indication for Polivy was approved as the first new treatment in 20 years for previously untreated diffuse large B-cell lymphoma. Chugai also filed an application for approval of RG6264, a fixed-dose subcutaneous combination of pertuzumab and trastuzumab, for the treatment of HER2-positive breast and colorectal cancer. Pertuzumab and trastuzumab are the same monoclonal antibodies as in Perjeta® and Herceptin, respectively. Several new oncology projects have been added to our pipeline, including SHP2 inhibitor RG6433 and KRAS G12C inhibitor RG6330 for solid tumors.

In drug discovery research, Chugai entered into a license agreement with Noile-Immune Biotech in August for their PRIME CAR-T technology, making steady progress in its efforts toward multi-modality drug discovery through external collaboration.

**2022 third quarter results (January to September)**

| Billion JPY | 2022 Jan – Sep | 2021 Jan - Sep | % change |
|---|---|---|---|
| Core results | | | |
| Revenues | 729.5 | 677.5 | +7.7% |
| Sales | 644.7 | 538.7 | +19.7% |
| Royalties and other operating income | 84.9 | 138.8 | -38.8% |
| Operating profit | 299.0 | 290.7 | +2.9% |
| Net income | 213.0 | 209.7 | +1.6% |
| IFRS results | | | |
| Revenues | 821.5 | 677.5 | +21.3% |
| Operating profit | 383.8 | 282.8 | +35.7% |
| Net income | 272.0 | 204.2 | +33.2% |

**Sales breakdown**

| Billion JPY | 2022 Jan – Sep | 2021 Jan – Sep | % change |
|---|---|---|---|
| Sales | 644.7 | 538.7 | +19.7% |
| Domestic sales | 387.6 | 362.6 | +6.9% |
| Oncology | 186.5 | 191.1 | -2.4% |
| Specialty | 201.0 | 171.6 | +17.1% |
| Overseas sales | 257.1 | 176.0 | +46.1% |

## Progress in R&D activities from Jul 22nd, 2022 to Oct 24th, 2022

Letters in orange : in-house projects (global development)  Letters in blue : in-licensed from Roche (development and distribution in Japan)  As of October 24, 2022

| | | | |
|---|---|---|---|
| Launched | Mitchga* | Itching associated with atopic dermatitis (only when existing treatment is insufficiently effective) (JP) | August 2022 |
| Approved | Edirol | Edirol tablet (Additional dosage form) | August 2022 |
| | Polivy | Previously untreated DLBCL | August 2022 |
| Filed | SKY59/crovalimab | PNH (China) (priority review designation) | Q3 2022 |
| | Actemra | Systemic sclerosis with interstitial lung disease (EU) | August 2022 |
| | RG6264** | HER2-positive breast and colorectal cancer | September 2022 |
| | FoundationOne Liquid CDx cancer genomic profile | Expanded use of the results in the detection of genetic alterations "copy number alterations" in 324 genes related to cancer and the information of "bTMB scores" as a comprehensive genomic profiling | October 2022 |
| New to pipeline | SA237/Enspryng | MOGAD | P3(August 2022) |
| | SA237/Enspryng | AIE | P3(September 2022) |
| | RG7828/mosunetuzumab | r/r aNHL (in combinationn with Polivy) | P3(October 2022) |
| | RG6396/pralsetinib | Solid tumors | P2(October 2022) |
| | DONQ52 | Celiac disease | P1(September 2022) |
| | RG6330/KRAS G12C inhibitor | Solid tumors | P1(September 2022) |
| | RG6433/SHP2 inhibitor | Solid tumors | P1(September 2022) |
| Medical conference | DONQ52 | Non-clinical study results including MOA and results of clinical research : ICDS2022 | October 2022 |
| Others | Introduction of PRIME technology | A license agreement for Noile-Immune's PRIME CAR-T technology | August 2022 |
| | NXT007 | Out-licensing agreement with Roche | August 2022 |
| Development discontinued | RG7446/Tecentriq | RCC (adjuvant) (IMmotion010 study) | |

* Out-licensed to Maruho in Japan  ** HER/PER fixed-dose subcutaneous combination

### 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. Chugai's recognition of non-recurring items may differ from that of Roche due to the difference in the scale of operations, the scope of business and other factors. Core results are used by Chugai as an internal performance indicator, for explaining the underlying business performance both internally and externally, and as the basis for payment-by-results such as a return to shareholders.



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