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


"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
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]**

<table>
<thead>
<tr>
<th></th>
<th>2020 Jan - Sep</th>
<th>2019 Jan - Sep</th>
<th>% change</th>
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<tbody>
<tr>
<td><strong>Core results</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Revenues</td>
<td>576.5</td>
<td>508.9</td>
<td>+13.3%</td>
</tr>
<tr>
<td>Sales</td>
<td>464.8</td>
<td>440.5</td>
<td>+5.5%</td>
</tr>
<tr>
<td>Royalties and other operating income</td>
<td>111.7</td>
<td>68.4</td>
<td>+63.3%</td>
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<tr>
<td>Operating profit</td>
<td>231.9</td>
<td>171.1</td>
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<tr>
<td>Net income</td>
<td>165.6</td>
<td>124.5</td>
<td>+33.0%</td>
</tr>
<tr>
<td><strong>IFRS results</strong></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Revenues</td>
<td>576.5</td>
<td>508.9</td>
<td>+13.3%</td>
</tr>
<tr>
<td>Operating profit</td>
<td>227.3</td>
<td>160.9</td>
<td>+41.3%</td>
</tr>
<tr>
<td>Net income</td>
<td>162.4</td>
<td>117.4</td>
<td>+38.3%</td>
</tr>
</tbody>
</table>

**[Sales breakdown]**

<table>
<thead>
<tr>
<th></th>
<th>2020 Jan - Sep</th>
<th>2019 Jan - Sep</th>
<th>% change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sales</td>
<td>464.8</td>
<td>440.5</td>
<td>+5.5%</td>
</tr>
<tr>
<td>Domestic sales</td>
<td>303.2</td>
<td>324.4</td>
<td>-6.5%</td>
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<tr>
<td>Oncology</td>
<td>167.4</td>
<td>179.7</td>
<td>-6.8%</td>
</tr>
<tr>
<td>Bone and joint diseases</td>
<td>72.7</td>
<td>80.5</td>
<td>-9.7%</td>
</tr>
<tr>
<td>Renal diseases</td>
<td>21.0</td>
<td>25.9</td>
<td>-18.9%</td>
</tr>
<tr>
<td>Others</td>
<td>42.1</td>
<td>38.4</td>
<td>+9.6%</td>
</tr>
<tr>
<td>Overseas sales</td>
<td>161.6</td>
<td>116.0</td>
<td>+39.3%</td>
</tr>
</tbody>
</table>
Progress in R&D activities from Jul 28th, 2020 to Oct 22nd, 2020

### Approved
- **Ensyrng**: Neurorvamyelitis optica spectrum disorder (NMOSD)
- **Kadyla**: HER2+ Breast Cancer (adjuvant)
- **Tecentriq**: Hepatocellular carcinoma (HCC)
- **Avastin**: Hepatocellular carcinoma (HCC)

### Filed
- **F1CDx**: CDx for larostratin (NTRK1/2/3 fusion gene)
- **F1CDx**: CDx for pemigatinib (FGFR2 fusion genes)
- **Risdiplam**: Spinal muscular atrophy (SMA)

### Phase Progress
- **crovalimab**: Paroxysmal nocturnal hemoglobinuria (PNH)
- **RG6171 (SERD)**: Breast cancer

### New to Pipeline
- **SPYK04**: Solid tumors
- **Tecentriq**: Renal cell carcinoma (combination with cabozantinib)
- **TIR / Tecentriq**: Stage III NSCLC
- **TIR / Tecentriq**: Esophageal cancer

### Late-stage Readouts
- **Actemra**: COVID-19 pneumonia
- **Actemra**: COVID-19 pneumonia
- **Tecentriq**: Triple negative breast cancer (TNBC)

### Medical Conference
- **Ensyrng**: SARK5302 (SARK5302 studies data from open-label extension phase)
- **Tecentriq**: Impassion031, Impassion130, Impassion131 studies
- **Risdiplam**: FIRESH study part 1 (after two-year treatment)

### Others
- **nemolizumab**: Antibody enginering technologies
- **STA551**: Combination therapy of Tecentriq and cabozantinib (domestic)
- **Joint development**: Tozakda argenx / Novo Nordisk

### Trademarks
- Trademarks used or mentioned in this release are protected by law.

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**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.

### Notes
- **Approved in U.S. and launched in Japan**
- **FTCDx**: FoundationOne CDx
- **NTRK**: Neurotrophic tyrosine kinase receptor kinase
- **FGFR**: Fibroblast growth factor receptor
- **NSCLC**: Non-small cell lung cancer
- **TIR**: Trastuzumab

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### Marks
- **crovalimab**: Patented by law
- **RG6171 (SERD)**: Patented by law

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### Timeline
- **Progress in R&D activities from Jul 28th, 2020 to Oct 22nd, 2020**
- **About Core results**
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