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Chugai Announces 2021 3rd Quarter Results

- Record-high revenues and core operating profit for the third quarter at ¥677.5 billion (+17.5%) and ¥290.7 billion (+25.4%), respectively
- Forecasts for FY2021 raised following the strong nine-month results
- Clinical development started for the first mid-size molecule project LUNA18. The new modality expected as the third pillar of Chugai's drug discovery technology
- Regulatory application for Ronapreve filed in Japan for line extensions relating to COVID-19

TOKYO, October 22, 2021 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced its financial results for the third quarter of fiscal year 2021.

"We achieved robust double-digit growth in both revenues and profits in the nine months under review. This was due to significant increases in both domestic and overseas sales, driven by new products and mainstay products, as well as continued growth in royalty income. As a result, we raised our full year forecast for FY2021. In terms of R&D, I am very pleased that our first mid-size molecule project, LUNA18, has entered the clinical development phase. Mid-size molecule drugs are expected to become the third modality to drive our future growth. Concerning COVID-19, we have filed Ronapreve® for subcutaneous administration and the additional indications of treatment for asymptomatic patients and prophylaxis. In order to satisfy unmet medical needs through innovation, we will continue pursuing world-leading science and technology to contribute to patients awaiting treatments." said Dr. Osamu Okuda, Chugai's President and CEO.

[Third quarter results for 2021]

Revenues and Core operating profit increased by approximately 17% and 25%, respectively, for the third quarter (nine months, Core-basis), mainly due to increases in sales and royalty and profit-sharing income.

Revenues increased by approximately 20% in total since sales, which recorded flat year-on-year growth for the first half, turned to double-digit growth. Domestic sales increased by double digits as the strong oncology field grew further with a mainstay product Tecentriq® maintaining high growth despite the NHI price revision in August this year, and the contribution of a new product Polivy®. In the primary field, sales increased approximately 30% after reporting a decrease by roughly 10% in the first half. The growth was driven by new products, with the supply of Ronapreve to the government and the market penetration of Enspryng®, and double-digit growth of mainstay products, Actemra® and Hemlibra®. Overseas sales recovered growth and increased by approximately 10% as the further growth of Hemlibra outweighed the decrease in the sales of Actemra. Royalties and other operating income increased by approximately 20% mainly due to increases in royalty and profit-sharing income related to Hemlibra, despite a continued

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decrease in other operating income resulting from one-time income.

Cost to sales ratio improved by 1.2% points year-on-year to 41.9%, mainly due to an increase in the proportion of in-house products including Hemlibra. Operating expenses increased approximately by 10% as research and development, marketing and distribution, and general and administration expenses all increased. Research and development expenses increased by double digits, continued from the first half, associated with the progress of projects. The increases in marketing and distribution expenses were affected by last year's decrease in activities due to the spread of the COVID-19. General and administration expenses increased owing to the enterprise tax and various expenses. As a result, core operating profit increased by approximately 25%.

The Company also made good progress in research and development. Its first mid-size molecule project, LUNA18, has entered the clinical development phase. Chugai has been focusing on mid-size molecule drugs as a new modality to constitute the mainstay for driving its medium-to long-term growth. LUNA18 is an oral cyclic peptide RAS inhibitor, and a Phase I clinical trial has been initiated for solid tumors. As for other in-house projects, Chugai has started development of Enspryng in generalized Myasthenia Gravis (gMG), initiating a Phase III clinical trial.

In the efforts to develop treatments for COVID-19, Chugai filed an application for the antibody cocktail Ronapreve, which had received Special Approval in July. The filing is to obtain approval for additional indications for prophylaxis of COVID-19 and treatment of asymptomatic COVID-19, and additional subcutaneous administration. In addition, an application for approval was filed in Europe for Actemra for an additional indication of COVID-19 pneumonia.

[Revision of Full-Year Forecast for 2021]

Chugai raised forecasts (Core-basis) for FY2021 following the strong nine-month results. Regarding domestic sales, the sales forecast attributable to the supply of Ronapreve to the government, which was not expected at the beginning of the fiscal year, has been included, and the progress and revised assumptions have been reflected for each product including Avastin® and Tecentriq, which are progressing ahead of the initial forecast. The forecast for overseas sales has been revised upward reflecting that sales of Actemra and Hemlibra should exceed the original forecast. Royalties and other operating income have been also revised upward. As a result, the revenues have been raised to ¥970 billion, an increase of ¥170 billion from the initial forecast. Operating profit forecast has been revised to ¥400 billion, up ¥80 billion from the initial forecast, taking into account a higher cost to sales ratio due to a change in the product mix, and increases in some expenses including the foreign exchange effects.

In accordance with the revision of the financial forecast, year-end dividends forecast was also revised to an undecided value. Reflecting the significant changes in the profit structures, year-end dividends will be decided based on the Company's dividend policy* after the fiscal year ends.

*Regarding income distribution, taking into account the strategic funding needs and earning prospects, Chugai aims for a consolidated dividend payout ratio of 45% on average in comparison with Core EPS to provide a stable allocation of profit to all shareholders.

[2021 3rd quarter results]

Billion JPY	2021 Jan - Sep	2020 Jan - Sep	% change
Core results			
Revenues	677.5	576.5	+17.5%
Sales	538.7	464.8	+15.9%
Royalties and other operating income	138.8	111.7	+24.3%
Operating profit	290.7	231.9	+25.4%
Net income	209.7	165.6	+26.6%
IFRS results			
Revenues	677.5	576.5	+17.5%
Operating profit	282.8	227.3	+24.4%
Net income	204.2	162.4	+25.7%

[Sales breakdown]

Billion JPY	2021 Jan - Sep	2020 Jan - Sep	% change
Sales	538.7	464.8	+15.9%
Domestic sales	362.6	303.2	+19.6%
Oncology	191.1	169.4	+12.8%
Primary	171.6	133.8	+28.3%
Overseas sales	176.0	161.6	+8.9%

[Forecasts for 2021 Jan-Dec]

Billion JPY	Revised forecast on Oct 22	Original forecast on Feb 4	Growth vs original forecast	Growth vs 2020 actual
Core-basis				
Revenues	970.0	800.0	+170.0	+183.1 +23.3%
Sales	781.5	631.0	+150.5	+148.2 +23.4%
Royalties and other operating income	188.5	169.0	+19.5	+34.9 +22.7%
Operating profit	400.0	320.0	+80.0	+92.1 +29.9%

[Progress in R&D activities from Jul 27th, 2021 to Oct 22nd, 2021]

Launch	**FoundationOne Liquid CDx**	Blood-based CGP test for solid tumors, CDx	August
	Evrysdi	Spinal muscular atrophy (SMA)	August
Approved	**Rituxan**	Systemic sclerosis	September
Filed	**Actemra**	COVID-19 pneumonia (EU)	September
	Ronapreve	Prophylaxis and treatment of asymptomatic COVID-19	October
	Ronapreve	Subcutaneous administration	October
Pipeline entry	**RG6171 / giredestrant**	Breast cancer (adjuvant)	P3 (August)
	Enspryng	Generalized myasthenia gravis (gMG)	P3 (October)
	LUNA18	Solid tumors (RAS inhibitor)	P1 (October)
Topline results	**Polivy**	Previously untreated diffuse large B-cell lymphoma : Primary endpoint met	P3 (POLARIX)
Medical conference	**Enspryng**	SAkuraStar/SAkuraSky studies: four-year data	ECTRIMS** (October)
Others	**Hemlibra**	Acquired Hemophilia A	Orphan drug designation (October)
	nemolizumab	Pruritus for dialysis patients	Out-license of domestic development and marketing rights to Maruho (September)
	OBP-301*	Oncolytic virus therapy	Agreement on termination of exclusive license agreement
	Evrysdi	SMA: FIREFISH study Part 2	Published in NEJM
	Ronapreve	COVID-19: REGN-COV 2067 study	Published in NEJM

*in-licensed (Oncolys BioPharma Inc.) **Congress of the European Committee for Treatment and Research in Multiple Sclerosis Letters in orange : in-house projects、Letters in blue : in-licensed(Roche)

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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