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Chugai Announces 2019 3rd Quarter Results

- Record-high Core operating profit and Core net income for three consecutive quarters
- Forecasts for FY2019 raised following the strong nine-month results
- R&D activities showed steady progress including global filing for satralizumab

TOKYO, Oct 24, 2019 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced its financial results for the third quarter of the fiscal year ended December 31, 2019.

Chugai reported record high revenues, operating profit and net income for the third consecutive quarter (Core-basis). Revenues increased by 19.3% due to a double-digit sales growth driven by the contribution of new products including the hemophilia A treatment Hemlibra® and the immune checkpoint inhibitor Tecentriq®, mainstay products and strong exports as well as large increases in royalties and other operating income related to Hemlibra. Operating profit increased by 65.6% due to a better cost to sales ratio as the proportion of in-house products increased in the total product mix.

Chugai raised forecasts for FY2019 following the strong nine-month results. The revenues forecast was raised by ¥87.5 billion to ¥680.0 billion from the original forecast reflecting a strong progress in both domestic sales and export to Roche. The increase in domestic sales was mainly driven by mainstay products and new products in the oncology area as well as Hemlibra. Royalties related to Hemlibra and one-time income also progressed well-beyond the original expectations, resulting in the raised forecast for revenues. Forecast for Core operating profit was also raised by ¥75.0 billion to ¥218.0 billion from the original forecast due to reasons including a better cost to sales ratio expected due to changes in the product mix from the original forecast.

In addition, the dividend forecast was revised to undecided. 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.

R&D activities also progressed well. Satralizumab, the anti-interleukin-6 (IL-6) receptor recycling antibody created by Chugai, was filed for regulatory approval in EU and the U.S.. Satralizumab is a growth driver candidate following Actemra® and Hemlibra, and a regulatory filing in Japan is also planned this year. Clinical development for another in-house project NXT007 commenced for the treatment of hemophilia A. In addition, Tecentriq achieved line extensions as the first immune checkpoint inhibitor in Japan approved for the treatment of extensive-stage small cell lung cancer and PD-L1-positive triple negative breast cancer.

"We had a very good third quarter as sales of new products and mainstay products, including Hemlibra, Tecentriq and Perjeta, grew beyond our expectations. At the same time, the start of global regulatory

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filings for satralizumab, a future growth driver, is proceeding as planned. Although we revised the full-year forecast upward based on the strong nine-month performance, the negative growth of the prescription drug market in Japan will likely continue, increasing the severity of the environment in the future. We remain focused in our efforts to archive the targets of the mid-term business plan IBI 21," said Tatsuro Kosaka, Chugai's President and CEO.

*Regarding income distribution, taking into account the strategic funding needs and earning prospects, Chugai aims for a consolidated dividend payout ratio of 50% on Average in comparison with Core EPS to provide a stable allocation of profit to all shareholders.

[2019 3rd quarter results]

Billion JPY	2019 Jan-Sep	2018 Jan-Sep	% change
Core results			
Revenues	508.9	426.4	+19.3%
Sales	440.5	388.7	+13.3%
Royalties and other operating income	68.4	37.7	+81.4%
Operating profit	171.1	103.3	+65.6%
Net income	124.5	74.6	+66.9%
IFRS results			
Revenues	508.9	426.4	+19.3%
Operating profit	160.9	97.9	+64.4%
Net income	117.4	70.9	+65.6%

[Forecasts for 2019 Jan-Dec]

Billion JPY	Revised forecast on Oct 24	Original forecast on Jan 31	Growth vs original forecast	Growth vs 2018 actual
Core-basis				
Revenues	680.0	592.5	+87.5	+100.2, +17.3%
Sales	586.0	528.0	+58.0	+58.2, +11.0%
Royalties and other operating income	94.0	64.5	+29.5	+42.1, +81.1%
Cost of sales	-265.0	-252.5	-12.5	-3.1, +1.2%
Operating expenses	-197.0	-197.0	0	-9.4, +5.0%
Research and development	-102.5	-102.0	-0.5	-8.3, +8.8%
Operating profit	218.0	143.0	+75.0	+87.7, +67.3%

[Dividend forecast]

	Revised forecast on Oct 24	Original forecast on Jan 31	2019 actual	2018 actual
Dividend per share				
End of 2nd quarter	—	¥48.00	¥48.00	¥31.00
End of full year	Undecided	¥48.00	—	¥55.00
Total	Undecided	¥96.00	—	¥86.00

[Progress in R&D activities]

Launched	**Rozlytrek**	*NTRK*+ solid tumor	September, 2019
Approved	**Tecentriq**	ES SCLC	August, 2019
		PD-L1+ TNBC	September, 2019
	F1 CDx	CDx for Lynparza	September, 2019
Filed	**satralizumab**	NMOSD (US/EU)	August, 2019 (EU)
	Kadcyla	HER2+ early breast cancer (adjuvant)	August, 2019
	F1 CDx	CDx for Rozlytrek (*ROS1*+ NSCLC)	September, 2019
New to Pipeline	**NXT007**	Hemophilia A	P1 study
	RG7880	Inflammatory bowel disease	P1 study
Development Discontinued	**Tecentriq**	Castration resistant prostate cancer	-
Late-stage Readouts	**Tecentriq**	Urothelial carcinoma*	P3 study (IMvigor130)**
		Advanced NSCLC (NSQ/SQ)	P3 study (IMpower110)**
		Unresectable HCC	P3 study (IMbrave150)
	Perjeta/Herceptin	FDC (sc)	P3 study (FeDeriCa)
Medical Conference	**satralizumab**	NMOSD/SAkuraStar	ECTRIMS2019
	Alecensa	ALEX (update), B-FAST	ESMO2019
	nemolizumab	Prurigo nodularis/P2 study	EADV2019
Others	**satralizumab**	NMO/NMOSD(JP)	Orphan Drug Designation
	nemolizumab	Atopic dermatitis (overseas)	P3 initiated (Galderma)
	OWL833	Type 2 diabetes	P1 initiated (Eli Lilly)

ES SCLC: extensive-stage small cell lung cancer
TNBC: triple negative breast cancer
F1 CDx: FoundationOne CDx Cancer Genomic Profile
CDx: companion diagnostics
NSCLC: non-small cell lung cancer
NSQ/SQ: non-squamous/squamous
NMO: neuromyelitis optica
NMOSD: neuromyelitis optica spectrum disorder

HCC: hepatocellular carcinoma
FDC: fixed-dose combination
sc: subcutaneous injection
ECTRIMS: European Committee for Treatment and Research in Multiple Sclerosis
ESMO: European Society for Medical Oncology
EADV: European Academy of Dermatology and Venereology

Letters in orange: in-house projects

* previously untreated locally advanced or metastatic
** Data presented at ESMO2019

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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