Innovation all for the patients

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Chugai Announces 2023 3rd Quarter Results

- Core revenue and core operating profit for the first nine months at ¥837.6 billion (+14.8%) and ¥340.5 billion (+13.9%), respectively
- Steady progress in R&D activities for in-house projects, mainly in late-stage development, including acceptance of approval application of crovalimab for the treatment of paroxysmal nocturnal hemoglobinuria in the U.S., achievement of the primary endpoint in a phase III study of Alecensa for the adjuvant treatment of early-stage ALK-positive non-small cell lung cancer, and initiation of a phase III study of Enspryng for a new indication

TOKYO, October 24, 2023 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced its financial results for the third quarter of fiscal year 2023.

“In the third quarter of this year, we saw a continuation of the increase in both revenue and profits on a Core-basis from the first half. Sales increased both in domestic and overseas, driven by steady growth in new products such as Polivy®, Vabysmo® in Japan and by more than double-digit growth overseas in mainstay products Hemlibra® and Alecensa®. In R&D, Chugai made steady progress with in-house projects, mainly in late-stage development. An application for crovalimab in the treatment of paroxysmal nocturnal hemoglobinuria (PNH) was accepted for filing in the U.S. In addition, Alecensa achieved its primary endpoint in a global phase III study as a post-operative adjuvant therapy for early-stage ALK-positive non-small cell lung cancer (NSCLC), and Enspryng® started a global phase III study for thyroid ophthalmopathy (TED), its fifth indication, and is being simultaneously developed in multiple diseases. We will continue to drive innovation to deliver innovative new drugs to patients as quickly as possible,” said Dr. Osamu Okuda, Chugai’s President and CEO.

< Third Quarter Financial Results (Core results, January to September 2023) >

Chugai reported increased revenue and operating profit for the first nine months (Core-basis) compared to the same period of the previous fiscal year, consistent with second-quarter results.

Revenue increased in approximately 15% overall, with growth in both domestic and overseas sales and other revenue. Domestic sales increased by approximately 10%. In the oncology field, the growth was approximately 3% year-on-year due to the contribution of steady market penetration of new product Polivy, and the growth of mainstay product Tecentriq® despite the impact of biosimilars and NHI drug price revisions on mature products such as Avastin® and Herceptin®. In the specialty field, sales increased by approximately 20%, driven by the penetration of new products Vabysmo for ophthalmology and Evrysdi® for neuroscience, as well as the contribution of mainstay products Hemlibra for hemophilia and Enspryng for neuroscience, and the supply of Ronapreve® for COVID-19 treatment to the government in

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the first quarter. Overseas sales increased by approximately 20% due to solid growth in exports of Hemlibra and Alecensa. Other revenue increased by approximately 13%, mainly due to the increase in royalties and profit-sharing income related to Hemlibra. Revenue on IFRS basis, including Non-Core items, decreased due to the one-time impact of the lump-sum income from the settlement agreement with Alexion Pharmaceuticals, Inc in the previous year.

Cost to sales ratio rose by 2.4% points year-on-year to 43.1%, mainly due to the impact of foreign exchange. Research and development expenses increased due to investments into drug discovery and early development, including the start of operation of Chugai Life Science Park Yokohama, and the progress of development projects. Also selling, general and administration expenses increased mainly due to various expenses. For other operating income (expense), an income of ¥16.3 billion was recorded, mainly due to the recognition of income from disposal of product rights and gain on sale of property, plant and equipment. As a result, Core operating profit totaled ¥340.5 billion (+13.9%).

<R&D activities>

The company also made good progress in research and development. Among our in-house projects, Actemra obtained approval for an additional indication of cytokine release syndrome induced by cancer therapy. Late-stage projects progressed including the U.S. Food and Drug Administration (FDA) acceptance of application of crovalimab for the treatment of PNH, and Alecensa achieving the primary endpoint in a global phase III study in patients with early-stage ALK-positive NSCLC, demonstrating the efficacy in adjuvant therapy for the first time as an ALK inhibitor. A global phase III study for Enspryng for treatment of TED, an ophthalmic disease, has been initiated. The drug is now being developed for four diseases simultaneously. As for projects in-licensed from Roche, Phesgo®, a subcutaneous combination of Perjeta and Herceptin, which are standard treatments for HER2-positive breast cancer administered by intravenous injections, has received approval in Japan as a treatment for HER2-positive breast cancer and colorectal cancer. In addition, a new immune checkpoint inhibitor tobemstomig (RG6139) in solid tumors has entered the pipeline.

[2023 third quarter results]

Billion JPY	2023 Jan - Sep	2022 Jan - Sep	% Change
Core results			
Revenue	837.6	729.3	+14.8%
Sales	742.1	644.7	+15.1%
Other revenue	95.5	84.6	+12.9%
Operating profit	340.5	299.0	+13.9%
Net income	250.3	213.0	+17.5%
IFRS results*			
Revenue	837.6	821.2	+2.0%
Operating profit	317.6	383.8	-17.2%
Net income	234.3	271.9	-13.8%

*IFRS results in 2022 include non-Core items, such as the income and other related items, which totaled ¥90.7 billion associated with the settlement agreement between Chugai and Alexion Pharmaceuticals, Inc., which are excluded from the Core results Chugai adopts to manage

recurring business activities.

[Sales breakdown]

Billion JPY	2023 Jan - Sep	2022 Jan - Sep	% change
Sales	742.1	644.7	+15.1%
Domestic sales	429.2	387.6	+10.7%
Oncology	191.4	186.5	+2.6%
Specialty	237.9	201.0	+18.4%
Overseas sales	312.9	257.1	+21.7%

[Oncology field (Domestic) Top5-selling medicines]

Billion JPY	2023 Jan - Sep	2022 Jan - Sep	% change
Tecentriq	47.9	43.9	+9.1%
Avastin	38.2	50.9	-25.0%
Polivy	25.5	9.1	+180.2%
Perjeta	24.6	23.5	+4.7%
Alecensa	22.0	20.9	+5.3%

[Specialty field (Domestic) Top5-selling medicines]

Billion JPY	2023 Jan - Sep	2022 Jan - Sep	% change
Ronapreve*	81.2	60.8	+33.6%
Hemlibra	40.5	35.2	+15.1%
Actemra	32.2	31.2	+3.2%
Enspryng	16.9	11.5	+47.0%
Vabysmo	10.8	3.2	+237.5%

*Ronapreve has not been listed in the National Health Insurance (NHI) price list.

[Progress in R&D activities from Jul 28th, 2023 to Oct 24th, 2023]

As of October 24, 2023

Launched	Enspryng	NMOSD (Taiwan)	October 2023
Approved	Actemra	CRS induced by cancer therapy	September 2023
	Phesgo	"HER2+ BC" and "advanced or recurrent HER2+ CC that has progressed following cancer chemotherapy and is not amenable to curative resection	September 2023
	Rituxan	Lupus nephritis that has not responded sufficiently to existing therapies	August 2023
Initiation of study	Enspryng	TED	P3 study (Q3 2023)
	tiragolumab + Tecentriq + Avastin	1L HCC	P3 study (October 2023)
	Gazyva	Extra renal lupus	P3 study (October 2023)
	RG6139 (tobemstomig)	Solid tumors	P1 study (August 2023)
Phase transition	RG6102 (trontinemab)	Alzheimer's disease	P1 study → P1/2 study

Letters in orange : in-house projects (global development) Letters in blue : in-licensed from Roche (development and distribution in Japan)

Readout	Alecensa	ALINA study (adjuvant ALK+ NSCLC) met primary endpoint of DFS	September 2023
	Tecentriq + Avastin	BEAT-SC study (1L SCLC) met primary endpoint of PFS	October 2023
	Tecentriq	CONTACT-02 study (2L prostate cancer) met primary endpoint of PFS. Continuous assessment of OS.	August 2023
	tiragolumab + Tecentriq	SKYSCRAPER-01 (1L NSCLC): results from second interim analysis*	August 2023
Medical conference	nemolizumab	ARCADIA 1/2 studies** (AD), OLYMPIA 1 study** (PN): EADV	October 2023
	Alecensa	ALINA study (adjuvant ALK+ NSCLC): ESMO	October 2023
Withdrawal	Actemra	SSc-ILD (EU)	
Removed from pipeline	RG7906 (ralmitaront)	P2 study (schizophrenia): development discontinued	
	RG7802 (cibisatamab)	P1 study (solid tumors): temporary suspension of development	

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* The second interim analysis took place in February 2023 and was based on a data cut-off in November 2022.
** Conducted by Galderma, an overseas licensee

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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