Innovation all for the patients

CHUGAI

Roche A member of the Roche group

Chugai Announces 2024 2nd Quarter (Interim) Results

- Core revenue, core operating profit, and core net income at ¥552.9 billion (-4.6%), ¥262.8 billion (+13.3%), and ¥189.5 billion (+10.6%), respectively (all changes year-on-year)
  - Excluding Ronapreve's temporary impact, which its supply to the government has completed last year, both revenue and profit increased. Solid growth in the core business, including good progress in export to Roche
- Steady progress in R&D activities for both early and late-stage development of in-house products
  - PiaSky has been launched in Japan for the first time in the world
  - Alecensa has been approved in Europe and China for adjuvant treatment of ALK-positive non-small cell lung cancer
  - Initiation of new clinical studies for early-stage development projects, GYM329 and DONQ52

TOKYO, July 25, 2024 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced its financial results for the second quarter (interim results) of fiscal year 2024.

"In the interim period of 2024, revenue decreased year-on-year while profit grew. Although the temporary impact of the COVID-19 treatment Ronapreve®, for which its supply to the government had been completed last year, remained significant, profit increased steadily due to solid business momentum. In Japan, sales of new products Phesgo® and Vabysmo® and a mainstay product Actemra® grew, however, impacted by Ronapreve, NHI drug price revision, and the market penetration of biosimilars, domestic sales decreased by 30.7%. Overseas sales increased by 28.2%, with the substantial increase in exports of Hemlibra® outweighing the decrease in Actemra exports. In research and development, PiaSky® was launched in Japan ahead of other countries, followed by approval in the United States, and recommendation for approval in Europe. In addition, Alecensa® received approval for an additional indication in Europe and China following the approval in the United States as a post-operative adjuvant therapy for ALK-positive non-small cell lung cancer, and has started to contribute to the treatment of patients. Early development also advanced, including the initiation of new clinical trials such as GYM329 for obesity and DONQ52 for celiac disease. Also, under the alliance with Roche, we have started new clinical trials, making progress in research and development in order to provide value to patients. Regarding our growth strategy "TOP I 2030," the initially planned initiatives have generally been progressing smoothly over the past three years. On the other hand, we recognize the need for further efforts in light of overall progress and changes in the business environment. We reconfirmed the path to achieve our challenging goals of "Double R&D output" and "Launch global in-house products every year" in 2030, and refined the details of the reforms. We will continue our efforts to realize the reforms and ensure

CHUGAI PHARMACEUTICAL CO., LTD. Corporate Communications Dept.
1-1, Nihonbashi-Muromachi 2-chome, Chuo-ku Tokyo, 103-8324 Japan
Media Relations Group TEL:+81-(0)3-3273-0881 E-mail:pr@chugai-pharm.co.jp
Investor Relations Group TEL:+81-(0)3-3273-0554 E-mail:ir@chugai-pharm.co.jp

achievement of our goals, aiming to become a top innovator," said Dr. Osamu Okuda, Chugai's President and CEO.

< Second quarter (interim) results for 2024 and progress of TOP I 2030 >
Chugai reported decreased revenue and increased operating profit year-on-year for the second quarter (interim period, Core-basis).

Regarding revenue, domestic sales decreased by 30.7% year-on-year. In the oncology field, although mature products such as Avastin® were impacted by the NHI drug price revision and biosimilars, the overall decrease was 6.1% contributed by growth of new product Phesgo. In the specialty field, sales decreased by 47.4%, mainly due to continued impact of the completion of Ronapreve supply to the government, which recorded ¥81.2 billion last year, while our new product Vabysmo, mainstay products including Actemra, Evrysdi®, Enspryng® performed well. Overseas sales increased by 28.2% year-on-year, greatly exceeding the same period last year, which was contributed by the increase in Hemlibra export which grew by 54.6% year-on-year. Other revenue increased by 18.9%, driven by the increase in Hemlibra related income and one-time income.

Cost to sales ratio improved by 13.3 percentage points year-on-year to 33.0%, mainly due to a change in the product mix. Research and development expenses increased mainly due to investments into drug discovery and early development, and increases associated with the progress of development projects. Selling, general and administration expenses increased by 3.6% due mainly to foreign exchange rate fluctuations and an increase in the enterprise tax (pro forma standard taxation). Other operating income (expense) was ¥0.8 billion in income. As a result, Core operating profit totaled ¥262.8 billion (+13.3%).

In addition, we refined our growth strategy TOP I 2030 launched in 2021. The initiatives we initially envisioned are steadily progressing. Given that this is a 10-year long-term strategy, we have reviewed progress over the past three years, current environmental changes and other factors, and reconfirmed the path toward our 2030 goals for the purpose of achieving our challenging goals with greater certainty. Specifically, we have updated the five reforms (Drug Discovery, Development, Pharmaceutical Technology, Value Delivery, and Foundation for Growth) and the mid-term milestones. To achieve the challenging goals of "Double R&D output" and "Launch global in-house products every year" set forth in TOP I 2030, each employee will strive to take the transformations as their own issue and to steadily make changes, in order to contribute to patients.

<R&D activities>
Chugai also made good progress in research and development, both in the early and late stages of developments, particularly in maximizing the value of in-house developed products and mainstay products.

For in-house products, PiaSky, an anti-complement (C5) Recycling antibody, has been launched in Japan for a rare disease paroxysmal nocturnal hemoglobinuria (PNH), for the first time in the world. This marks the second launch in Japan of an antibody drug applying Chugai's proprietary Recycling Antibody® technology. PiaSky has been approved in the U.S., and received a recommendation for approval from the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) in EU.

Also, the drug is undergoing review by other regulatory authorities including Taiwan. In addition, the anti-IL-31RA, a humanized monoclonal antibody Mitchga® (generic name: nemolizumab), has been launched in a new formulation in Japan by Maruho, the domestic out-licensing partner of nemolizumab, for the new indication of pruritus associated with atopic dermatitis in children and prurigo nodularis in adults and children. Furthermore, Alecensa has been granted additional indication in Europe and China following the U.S. for adjuvant treatment of ALK-positive non-small cell lung cancer. Additionally, rolling submission to the U.S. Food and Drug Administration (FDA) was initiated for the combination therapy of avutometinib, a RAF/MEK clamp being developed by Verastem Oncology, and defactinib, a selective FAK inhibitor, for the treatment of recurrent KRAS mutant low-grade serous ovarian cancer. In early development, a phase I clinical trial for the latent myostatin-sweeping antibody GYM329 has been initiated the treatment of obesity. A Phase Ic clinical trial has been initiated for the multi-specific antibody DONQ52 to evaluate its suppressive effect on the immune response induced by wheat intake in patients with celiac disease.

For projects in-licensed from Roche, a new Phase III clinical trial has been initiated for RG6299 in IgA nephropathy, and a new Phase I/II clinical trial has been initiated for zilebesiran in hypertension.

[2024 second quarter (interim) results]

Billion JPY	2024 Jan - Jun	2023 Jan - Jun	% change
Core results			
Revenue	552.9	579.7	-4.6%
Sales	485.5	523.0	-7.2%
Other revenue	67.3	56.6	+18.9%
Operating profit	262.8	232.0	+13.3%
Net income	189.5	171.4	+10.6%
IFRS results			
Revenue	552.9	579.7	-4.6%
Operating profit	258.2	210.9	+22.4%
Net income	186.3	156.7	+18.9%

[Sales breakdown]

Billion JPY	2024 Jan - Jun	2023 Jan - Jun	% change
Sales	485.5	523.0	-7.2%
Domestic sales	217.2	313.6	-30.7%
Oncology	118.8	126.5	-6.1%
Specialty	98.4	187.1	-47.4%
Overseas sales	268.4	209.4	+28.2%

[Oncology field (Domestic) Top5-selling medicines]

Billion JPY	2024 Jan - Jun	2023 Jan - Jun	% change
Tecentriq	31.1	31.6	-1.6%
Avastin	17.4	26.2	-33.6%
Polivy	15.7	15.9	-1.3%
Alecensa	14.9	14.5	+2.8%
Perjeta	11.3	16.1	-29.8%

[Specialty field (Domestic) Top5-selling medicines plus Ronapreve]

Billion JPY	2024 Jan - Jun	2023 Jan - Jun	% change
Hemlibra	27.4	26.7	+2.6%
Actemra	22.4	21.1	+6.2%
Enspryng	11.6	10.9	+6.4%
Vabysmo	9.1	6.7	+35.8%
Evrysdi	7.5	6.6	+13.6%
Ronapreve*	-	81.2	-100.0%

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

[Progress in R&D activities from Apr 25th, 2024 to Jul 25th, 2024]

As of July 25, 2024

Launched	PiaSky	Paroxysmal nocturnal hemoglobinuria (PNH)	May 2024 (Japan)
	Mitchga	Pruritus associated with atopic dermatitis (children aged ≧6 and <13 years), Prurigo nodularis*1	June 2024 (Japan)
Approved	Sigmart Injection	Unstable angina	April 2024 (China)
	Alecensa	ALK-positive early-stage NSCLC (adjuvant)	June 2024 (EU/China)
	PiaSky	PNH	June 2024 (U.S.)
	FoundationOne Liquid CDx Cancer Genomic Profile	Copy number alterations of cancer-related genes, and blood tumor mutational burden (bTMB) score	May 2024
	CellCept	Systemic sclerosis-associated interstitial lung disease (public knowledge-based application)	June 2024
Filed	avutometinib	Recurrent KRAS mutant low-grade serous ovarian cancer in combination with defactinib, who received at least one prior systemic therapy*2	May 2024 (U.S.: initiation of rolling NDA submission)
Initiation of Study	GYM329	Obesity	P1 study (May 2024)
	DONQ52	Celiac disease (evaluation of safety, PK/PD)	P1c study (July 2024)
	RG6299(ASO Factor B)	IgA nephropathy	P3 study (May 2024)
	zilebesiran	Hypertension	P1/2 study (June 2024)

*1 Conducted by Maruho, a domestic licensee, *2 Conducted by Verastem, a global licensee
Letters in orange : in-house projects (global development) Letters in blue : in-licensed from Roche (development and distribution in Japan)
NSCLC: non-small cell lung cancer

Removed from Pipeline	PiaSky	Lupus nephritis: development discontinued	
	tiragolumab+Tecentriq +chemotherapy	Non-squamous NSCLC (1st Line, SKYSCRAPER-06 study): development discontinued	
	Tecentriq + Avastin	Hepatocellular carcinoma (adjuvant, IMbrave050 study): development discontinued	
	migoprotafib (SHP2 inhibitor)	Solid tumors: development discontinued	
	pralsetinib	NSCLC, solid tumors: development discontinued	
Medical Conference	Evrysdi	FIREFISH study (five-year data for Type I SMA): Cure SMA Research & Clinical Care Meeting	June 2024
	Vabysmo	RHONE-X extension study (four-year data for diabetic macular edema): American Society of Retina Specialists Annual Meeting	July 2024
China Breakthrough Therapy Designation	AP306 (EOS789)	Hyperphosphatemia in patients with chronic kidney disease*	June 2024
Business Transfer	Monilac Syrup	Transfer of the business in Japan: Maruishi Pharmaceutical Co., Ltd.	July 2024

*Conducted by Alebund, a global licensee
Letters in orange : in-house projects (global development) Letters in blue : in-licensed from Roche (development and distribution in Japan)
NSCLC: non-small cell lung cancer, SMA: spinal muscular atrophy

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.

###