Innovation all for the patients

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Chugai Announces 2024 1st Quarter Results

- Core revenue, core operating profit, and core net income at ¥236.9 billion (-24.1%), ¥102.1 billion (-3.1%), and ¥76.0 billion (-3.1%), respectively (all changes year on year)
  - The main factor for the decrease in revenue and profit was completion of supply of Ronapreve in the previous year
  - Revenue grew with solid growth in the core business, excluding Ronapreve's temporary impact
- Steady progress in R&D activities for both early and late-stage development
  - Piasky, positioned as the Chugai originated 5th global product, approved in China and Japan for paroxysmal nocturnal hemoglobinuria
  - Alecensa approved by the U.S. FDA for adjuvant treatment of ALK-positive non-small cell lung cancer, for the first time in the world

TOKYO, April 24, 2024 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced its financial results for the first quarter of fiscal year 2024.

"Although revenue and profit decreased year on year due to the temporary impact of Ronapreve in the first quarter of 2024, the core business started off strong. In Japan, the sales of new products Phesgo® and Vabysmo® and a mainstay product Enspryng® grew, but was notably impacted by the COVID-19 treatment Ronapreve®, which its supply to the government has completed in the first quarter last year. As a result, domestic sales decreased by 46.4%. Overseas sales increased, with the substantial increase in exports of Hemlibra® to Roche, despite the decrease in Actemra® exports. In research and development, Piasky®, our fifth global product, was approved in China and Japan. Currently, reviews for approval of the medicine are underway in other areas including the United States, Europe, and Taiwan. We aim to contribute to the treatment of paroxysmal nocturnal hemoglobinuria by providing a new option that improves convenience for patients affected by the disease, around the world. In addition, Alecensa® was approved by the U.S. FDA for adjuvant treatment of ALK-positive non-small cell lung cancer. There are no other ALK inhibitors approved for this indication, bringing a new approach to patients. Regarding nemolizumab, another in-house project, development conducted by our out-licensing partners in Japan and overseas is making steady progress. In Japan, Mitchga® as its product name was approved for the treatment of pruritus associated with atopic dermatitis in children aged 6 to 12 years, and for prurigo nodularis. Outside of Japan, the application was accepted by the U.S. and European authorities for the treatment of atopic dermatitis and prurigo nodularis. We will continue to drive forward the development of innovative medicines to provide new value to patients," said Dr. Osamu Okuda, Chugai's President and CEO.

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< First quarter results for 2024>
Chugai reported decreased revenue and operating profit year on year for the first quarter (Core-basis).

Regarding revenue, domestic sales decreased by 46.4% 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 remained at 6.5% contributed by growth of new product Phesgo. In the specialty field, sales decreased by approximately 65%, mainly due to the completion of supply of Ronapreve to the government, which recorded ¥81.2 billion in the first quarter of last year, while our our new product Vabysmo grew and our mainstay product Enspryng performed well. Overseas sales increased year on year. Exports of Hemlibra increased by approximately 25%, exceeding the decrease in exports of Actemra. Other revenue increased substantially by approximately 60%, mainly driven by the increase in one-time income.

Cost to sales ratio improved by 16.3 percentage points year-on-year to 35.5%, 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 remained at the same level as the previous year. Other operating income (expense) was ¥0.2 billion in income. As a result, Core operating profit totaled ¥102.1 billion (-3.1%).

<R&D activities>
Chugai also made good progress in research and development, in both early and late stages of developments, particularly in maximizing the value of in-house developed products and mainstay products. Regarding approvals, our fifth global product Piasky, a humanized anti-complement (C5) monoclonal antibody discovered by Chugai, has been approved for the first time in China for the treatment of paroxysmal nocturnal hemoglobinuria (PNH), followed by approval in Japan. It is under review for PNH by other regulatory authorities, including in the United States, Europe, and Taiwan. Piasky is the second approved drug applying Chugai's Recycling Antibody® technology, following Enspryng. Another Chugai originated medicine, anti-IL-31RA, a humanized monoclonal antibody Mitchga (generic name: nemolizumab), has also been approved in Japan for additional indications including treatment for pruritus associated with atopic dermatitis (children aged ≥6 and <13 years) and prurigo nodularis (PN), only when existing treatment is insufficiently effective. Maruho, the out-license partner of nemolizumab in Japan has received these approvals. Additionally, Alecensa, which is also an in-house project, has been approved as an adjuvant therapy for ALK-positive non-small cell lung cancer, expanding its indication. As for projects in-licensed from Roche, Vabysmo, the only bispecific antibody in the ophthalmology field, has been approved for an additional indication for the treatment of macular edema associated with retinal vein occlusion. FoundationOne® CDx Cancer Genomic Profile has been approved as companion diagnostics for three additional products, respectively.
Regarding filings, Chugai originated nemolizumab, developed by Galderma outside of Japan, has been accepted for review as a treatment for patients with PN and atopic dermatitis, by the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA). For PN, priority review designation has been granted by the U.S. FDA. As for projects in-licensed from Roche, the anti-CD20xCD3 bispecific antibody mosunetuzumab has been filed in Japan for the treatment of patients with relapsed or refractory

follicular lymphoma. Furthermore, regulatory applications have been submitted for Evrysdi® and Tecentriq® for additional indications for pre-symptomatic spinal muscular atrophy and alveolar soft part sarcoma, respectively.
In addition, Chugai has in-licensed zilebesiran from Roche for the treatment of hypertension with high cardiovascular risk, and started a clinical study in Japan for RG6299, an antisense oligonucleotide targeting complement factor B, for the treatment of IgA nephropathy.

[2024 first quarter results]

Billion JPY	2024 Jan - Mar	2023 Jan - Mar	% change
Core results			
Revenue	236.9	312.2	-24.1%
Sales	204.5	291.5	-29.8%
Other revenue	32.5	20.7	+57.0%
Operating profit	102.1	105.4	-3.1%
Net income	76.0	78.4	-3.1%
IFRS results			
Revenue	236.9	312.2	-24.1%
Operating profit	99.9	98.3	+1.6%
Net income	74.4	73.5	+1.2%

[Sales breakdown]

Billion JPY	2024 Jan - Mar	2023 Jan - Mar	% change
Sales	204.5	291.5	-29.8%
Domestic sales	103.2	192.7	-46.4%
Oncology	56.1	60.0	-6.5%
Specialty	47.0	132.7	-64.6%
Overseas sales	101.3	98.8	+2.5%

[Oncology field (Domestic) Top5-selling medicines]

Billion JPY	2024 Jan - Mar	2023 Jan - Mar	% change
Tecentriq	14.5	15.1	-4.0%
Avastin	8.7	13.0	-33.1%
Polivy	7.4	7.2	+2.8%
Alecensa	6.6	6.6	-
Perjeta	6.1	7.5	-18.7%

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

Billion JPY	2024 Jan - Mar	2023 Jan - Mar	% change
Hemlibra	12.5	12.4	+0.8%
Actemra	10.2	9.9	+3.0%
Enspryng	5.8	4.7	+23.4%
Vabysmo	4.0	3.0	+33.3%
Evrysdi	3.4	3.0	+13.3%
Ronapreve*	-	81.2	-100.0%

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

[Progress in R&D activities from Feb 2nd, 2024 to Apr 24th, 2024]

As of April 24, 2024

Approved	Piasky	Paroxysmal nocturnal hemoglobinuria (PNH)	February 2024 (China) March 2024 (Japan)
	Alecensa	ALK-positive early-stage NSCLC (adjuvant)	April 2024 (U.S.)
	Mitchga	Pruritus associated with atopic dermatitis (children aged ≧6 and <13 years), Prurigo nodularis*1	March 2024 (Japan)
	Vabysmo	Macular edema associated with retinal vein occlusion (RVO)	March 2024
	FoundationOne Liquid CDx	Talazoparib for *BRCA* gene mutation-positive castration-resistant prostate cancer with distant metastases	February 2024
	FoundationOne Liquid CDx	Selpercatinib for *RET* fusion-positive solid tumors	February 2024
	FoundationOne Liquid CDx	Capivasertib for advanced HR-positive, HER2-negative breast cancer with *PIK3CA*, *AKT1* or *PTEN* alterations	March 2024
Filed	nemolizumab	Prurigo nodularis, Atopic dermatitis*2	February 2024 (filing accepted in U.S./EU)
	CellCept	Systemic sclerosis with interstitial lung disease (SSc-ILD)	February 2024
	Evrysdi	Pre-symptomatic spinal muscular atrophy (SMA)	February 2024
	mosunetuzumab	FL (3rd line)	March 2024
	Tecentriq	Alveolar soft part sarcoma	March 2024

Letters in orange：in-house projects (global development)　Letters in blue：in-licensed from Roche (development and distribution in Japan)
*1 Conducted by Maruho, a domestic licensee, *2 Conducted by Galderma, an overseas licensee

Initiation of study	RG6299(ASO Factor B)	IgA nephropathy	P1 study (February 2024)
	RG6356/SRP-9001	Duchenne muscular dystrophy (Non-ambulatory)	P3 study (March 2024)
	glofitamab+Polivy	Previously untreated large B-cell lymphoma	P3 study (April 2024)
Readout	Enspryng	Luminesce study (gMG) met its primary endpoint (the results did not reach our expectations on the degree of clinical benefit)	March 2024
	mosunetuzumab	Domestic phase I study in expansion cohort for FL (3rd line) met its primary endpoint	February 2024
	Vabysmo	NIHONBASHI study (AS) met its primary endpoint	April 2024
Removed from pipeline	Enspryng	Luminesce study (gMG): Development discontinued	
Medical conference	nemolizumab	OLYMPIA LTE study(Prurigo nodularis), ARCADIA 1&2 maintenance study (Atopic dermatitis)*: American Academy of Dermatology (AAD)	March 2024
	Vabysmo	BALATON study, COMINO study (RVO): Angiogenesis Exudation and Degeneration 2024	February 2024
Priority review designation	nemolizumab	Prurigo nodularis*	February 2024 (U.S.)
License-in agreement	zilebesiran (RNAi Therapeutic)	Hypertension (created by Alnylam Pharmaceuticals, Inc. and license-in from Roche)	April 2024

Letters in orange：in-house projects (global development)　Letters in blue：in-licensed from Roche (development and distribution in Japan)　*Conducted by Galderma, an overseas licensee　LTE: long-term extension

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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