Innovation all for the patients

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Chugai Announces 2021 Full Year Results and Forecasts for 2022

- Record-high revenues and Core operating profit for the fifth consecutive year at ¥999.8 billion (+27.1%) and ¥434.1 billion (+41.0%), respectively
- Major R&D milestones in 2021 include the first mid-size molecule project LUNA18, which entered the clinical development phase
- Planned 2021 year-end dividends are ¥46 per share (annual dividends for the fiscal year: ¥76 per share)
- Revenues and Core operating profit are expected to grow in 2022 to ¥1,150.0 billion (+15.0%) and ¥440.0 billion (+1.4%), respectively

TOKYO, February 3, 2022 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced its consolidated financial results for the fiscal year ended December 31, 2021, and forecasts for the fiscal year ending December 31, 2022.

“2021 marked a successful first year of Chugai’s growth strategy TOP I 2030. We achieved record-high revenues and profits for the fifth consecutive year, and strategies in each business area made steady progress. In terms of financial performance, mainstay products such as Hemlibra®, Tecentriq®, and a new product Enspryng® drove revenue growth in addition to the contribution of four newly launched products, including antibody cocktail Ronapreve® for COVID-19. In R&D, the first project in mid-size molecules, a top priority for Chugai, entered the clinical development phase, enhancing our substantial pipeline of approximately 70 projects in a variety of modalities. In 2022, revenues are forecasted to exceed one trillion yen for the first time. Also, we’re aiming to make a full-scale entry into the ophthalmology field with faricimab, for which a regulatory application was filed last year. Moreover, the construction of our new core research laboratory, Chugai Life Science Park Yokohama, will finally be completed in October. We will continue pursuing innovation in order to provide better value to patients,” said Dr. Osamu Okuda, Chugai’s President and CEO.

<Full year results for 2021>

Chugai reported financial results for 2021 (Core-basis) with revenues of ¥999.8 billion (+¥212.9 billion, +27.1%). Sales and royalties and other operating income both increased by less than 30%. Domestic sales were ¥518.9 billion (+¥109.8 billion, +26.8%), driven by strong sales of mainstay products such as Tecentriq and Kadcyla® in the oncology field, and Hemlibra and Actemra® in the primary field. Penetration of new products, Enspryng, Polivy® and Evrysdi®, and the supply of Ronapreve to the government also contributed as well as an increase in comprehensive genomic profiling tests including the blood-based FoundationOne® Liquid CDx cancer genomic profile. Overseas sales were ¥283.9 billion (+¥59.7 billion, +26.6%). In addition to the foreign exchange impact of a depreciation of the yen compared to the previous year, significant growth of Hemlibra due to full-scale export at regular shipment price and the strong sales

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of Alecensa® outweighed the significant decline in Actemra (which is owing to the previous year's significant increase in sales for reasons including clinical trials for COVID-19 pneumonia). Royalties and other operating income increased by less than 30%, mainly due to a significant increase in Hemlibra's royalty and profit-sharing income, despite a decrease in one-time income.

The cost to sales ratio improved by 1.2% points year-on-year to 41.8%, mainly due to changes in the product mix. Marketing and distribution, research and development, and general and administration expenses have increased, resulting in an overall increase of operating expenses by approximately 10%. Marketing and distribution expenses increased due to promotion of digital marketing. Research and development expenses increased due to progress of projects. General and administration expenses increased due to the enterprise tax and various expenses. As a result, Core operating profit totaled ¥434.1 billion (+¥126.2 billion, +41.0%).

Reflecting the favorable results and based on our dividend policy, Chugai plans to pay year-end dividends of ¥46 per share. As a result, the annual dividend will be ¥76 per share, and the Core dividend payout ratio is 42.9% on a five-year average basis (40.1% on a single fiscal year basis).

Regarding research and development, the Company made good progress in both early and late-stage development toward achieving the two goals stated in TOP I 2030 – "Double R&D output" and "Launch in-house global products every year." As for in-house projects, which will be the foundation for future growth, an anti-cancer agent LUNA18 entered the clinical development phase as the first mid-size molecule project, which Chugai has been focusing on as its third modality following antibodies and small molecule drugs. There was also progress in projects applying Chugai's proprietary antibody engineering technologies. Global phase III clinical trials started for Enspryng in generalized myasthenia gravis (gMG) and crovalimab in atypical hemolytic uremic syndrome (aHUS). A new investigational anti-cancer agent SOF10 entered the clinical development phase. In addition, Chugai filed a regulatory application for its mainstay product Hemlibra, for an additional indication of acquired hemophilia A. As for in-licensed projects, Chugai submitted a regulatory application for faricimab for two indications (diabetic macular edema (DME) and neovascular age-related macular degeneration (nAMD)), aiming full-scale entry in the ophthalmology field. Chugai in-licensed a project with a new modality from Roche, an investigational gene therapy SRP-9001, which is under development for Duchenne muscular dystrophy (DMD) by Sarepta Therapeutics. Furthermore, regulatory applications were filed for line extensions of Polivy and Tecentriq, respectively, both in the oncology field.

In the efforts to develop treatments for COVID-19, Chugai's anti-IL-6 receptor monoclonal antibody Actemra was authorized for emergency use in the United States and approved in Europe for severe COVID-19 in 2021. In Japan, the drug was approved for the additional indication of the treatment of SARS-CoV-2 pneumonia (limited to patients requiring oxygen intervention) in January 2022. As for Ronapreve, the antibody cocktail in-licensed from Roche, Chugai received special approval in July and additional approval for prophylaxis and subcutaneous injection in November 2021.

<Full year forecast for 2022>

In 2022, the Company expects revenues and profits to mark a record high for the sixth consecutive year. Revenues, Core operating profit, and Core net income are expected to be ¥1,150.0 billion (+¥150.2 billion,

+15.0%), ¥440.0 billion (+¥5.9 billion, +1.4%), and ¥312.5 billion (+¥1.0 billion, +0.3%), respectively. Sales are expected to increase both in Japan and overseas, totaling ¥1,031.5 billion (+¥228.7 billion, +28.5%). New products (such as Ronapreve, Enspryng, Polivy, and Evrysdi) and mainstay products including Hemlibra are expected to drive the growth of domestic sales despite impacts from biosimilars and generics as well as NHI drug price revisions. Overseas sales of Hemlibra are expected to increase by approximately 60% as exports at regular shipment price started in the previous year. Likewise, overseas sales of Actemra are expected to increase by approximately 40% due to increased demand for COVID-19. Royalties and other operating income are expected to decrease significantly to ¥118.5 billion (-¥78.4 billion, -39.8%) due to decreases in royalty related to the stock of initial shipment of Hemlibra and one-time income.

For the fiscal year 2022, Chugai expects the annual dividends per share of ¥76 with the Core dividend payout ratio of 41.9% on a five-year average basis (40.0% on a single fiscal year basis).

[2021 full year results]

Billion JPY	2021	2020	% change
Core results			
Revenues	999.8	786.9	+27.1%
Sales	802.8	633.3	+26.8%
Royalties and other operating income	196.9	153.6	+28.2%
Operating profit	434.1	307.9	+41.0%
Net income	311.5	219.4	+42.0%
IFRS results			
Revenues	999.8	786.9	+27.1%
Operating profit	421.9	301.2	+40.1%
Net income	303.0	214.7	+41.1%

[2022 full year forecast]

Billion JPY	2022 Forecast	2021 Actual	% change
Core-basis			
Revenues	1,150.0	999.8	+15.0%
Operating profit	440.0	434.1	+1.4%
Net income	312.5	311.5	+0.3%

[Progress in R&D activities for Oct 23rd, 2021-Feb 3rd, 2022]

Approved	Ronapreve	Prevention of symptomatic COVID-19, Subcutaneous administration	November 2021
	Herceptin	Advanced or recurrent HER2-positive salivary gland cancer not amenable to curative resection	November 2021
	FoundationOne CDx	pembrolizumab* : advanced or recurrent solid tumors with Tumor mutational burden-high	November 2021
	Rituxan	Refractory pemphigus vulgaris and pemphigus foliaceus	December 2021
	Actemra	COVID-19 pneumonia (EU)	December 2021
	Actemra	COVID-19 pneumonia (JP)	January 2022
Filed	Hemlibra	Acquired Hemophilia A	November 2021
	Polivy	Previously untreated diffuse large B-cell lymphoma (DLBCL)	December 2021
	FoundationOne CDx	- dacomitinib hydrate: NSCLC (Activated *EGFR* gene alterations)	December 2021
		- brigatinib: NSCLC (*ALK* fusion genes)	
		- dabrafenib mesilate, trametinib dimethyl sulfoxide: NSCLC (*BRAF* V600E alterations)	
		- encorafenib, binimetinib: Malignant melanoma (*BRAF* V600E and V600K alterations)	
Phase transition	RG7828/ mosunetuzumab	Follicular lymphoma	P3 study (October 2021)
	RG6396/pralsetinib	Non-small cell lung cancer (NSCLC)	P3 study (November 2021)

* Application under review and not yet approved for the drug indication

Pipeline entry	SKY59/crovalimab	Atypical hemolytic uremic syndrome (aHUS)	P3 study (October 2021)
Development discontinued	PCO371	Hypoparathyroidism	
	RG6422 (AT-527)	COVID-19	
	Suvenil	Knee osteoarthritis/Shoulder periarthritis (China)	
	AMY109	Solid tumors	
Medical conference	Hemlibra	HAVEN 6 study: interim data	ASH (December 2021)
	Polivy	POLARIX study: previously untreated DLBCL	ASH (December 2021)
Others	Edirol	Osteoporosis	Launch of authorized generic version of Edirol by Towa Pharmaceutical (December 2021)
	OWL833	Type 2 diabetes: advanced to Phase 2**	September 2021
	OWL833	Obesity: initiation of Phase 2 study**	September 2021
	SRP-9001/RG6356*	Duchenne muscular dystrophy (DMD)	License-in agreement (December 2021)
	faricimab	DME: P3 studies (YOSEMITE / RHINE)	Published in Lancet
	faricimab	nAMD: P3 studies (TENAYA / LUCERNE)	Published in Lancet

Letters in orange : in-house projects Letters in blue : in-licensed (Roche)

DME: Diabetic Macular Edema nAMD: neovascular Age-related Macular Degeneration

*Global P3 study for DMD is managed by Sarepta Therapeutics including Japan, while Chugai will be responsible for the regulatory filing and marketing in Japan.
** Managed by licensee, Eli Lilly and Company

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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