News Release

Chugai Announces Consolidated 2025 2nd Quarter Results

- Core revenue of ¥578.5 billion (+4.6%), Core operating profit of ¥272.0 billion (+3.5%), and Core net income of ¥193.5 billion (+2.1%) (all changes year-on-year)
- Steady progress in R&D activities for in-house project GYM329 (obesity) has initiated Phase II clinical trial, and the mid-size molecule project AUBE00 (solid tumors) has entered clinical development
- To maximize the success rate of achieving TOP I 2030 goals, the management has decided to dynamically and strategically allocate resources to priority projects, thereby discontinuing the development of five in-house projects in the early-stage clinical development, LUNA18, SAIL66, SOF10, STA551, and AMY109

TOKYO, July 24, 2025 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced its financial results for the second quarter of fiscal year 2025.

<Second quarter Results (Core results, January to June 2025)>
Chugai reported increased revenue and operating profit year-on-year for the second quarter (Core-basis).

Regarding revenue, domestic sales increased by 2.8%. In the oncology field, sales decreased by 1.9%. While new products Phesgo® performed well and Lunsumio® steadily penetrated the market, this was offset by the decline in Perjeta® and Herceptin® along with the market penetration of Phesgo which includes the same active pharmaceutical ingredients. Additionally, products including our mainstay product Avastin® were affected by NHI drug price revisions and biosimilars. In the specialty field, sales increased by 8.4%, driven by significant growth of the mainstay product Vabysmo® and successful market penetration of the new product PiaSky®. Overseas sales increased by 7.3%, driven by a substantial increase in exports of Actemra® to Roche. Other revenue decreased by 0.4%, despite the increase in royalty income related to Hemlibra®, mainly due to a decrease in one-time income.

Cost to sales ratio increased by 1.3 percentage points year-on-year to 34.3%, mainly due to changes in the product mix. Research and development expenses increased by 2.7% due to investments into drug discovery and early development, and increase associated with the progress of development projects, while selling, general and administrative expenses decreased by 2.6% due to efficient management of various expenses. Other operating income (expense) resulted in income of ¥0.4 billion. As a result, Core operating profit was ¥272.0 billion (+3.5%).

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<R&D activities>
Chugai made good progress in both early and late-stage development activities.

In early-stage development of in-house projects that will drive mid to long-term growth, GYM329 (for obesity) and Hemlibra (for von Willebrand disease) have initiated Phase II and Phase III clinical trials, respectively. Additionally, AUBE00 (for solid tumors), the second clinical-stage project following LUNA18 in our mid-size molecule pipeline, has initiated Phase I clinical trials. In late-stage development, Alecensa® has been filed for approval for additional tumor agnostic indication in *ALK* fusion / rearrangement gene-positive solid tumors, including pediatric patients. In-house projects out-licensed to third parties excluding Roche also progressed steadily, with AVMAPKI™, out-licensed to Verastem Oncology, receiving approval from the U.S. Food and Drug Administration (FDA) for use in combination with FAKZYNJA™ for *KRAS*-mutated recurrent low-grade serous ovarian cancer, under the accelerated approval pathway* based on overall response rate and duration of response.

Chugai has made the management decision to discontinue our development of five projects from early-stage in-house clinical development pipeline; LUNA18, SAIL66, SOF10, STA551, and AMY109. Since the launch of TOP I 2030 in 2021, we have continuously generated new projects and built technological foundations through enhanced RED functions. The number of early-stage projects has been increasing, with nine in-house projects entering clinical development over the four-year period. For early-stage clinical development pipeline, we have prioritized in-house projects after considering obtained data and the current portfolio situation, resulting in the decision to discontinue these five projects. Through this decision, we aim to maximize the success rate of achieving TOP I 2030 goals through dynamic and strategic allocation of resources to priority projects.
*Continued approval may be contingent upon verification and description of clinical benefit in confirmatory trials.

For products in-licensed from Roche, Elevidys® has obtained regulatory approval as a regenerative medicine product for the treatment of Duchenne muscular dystrophy under the conditional and time-limited approval pathway in Japan. Vabysmo has received approval for an additional indication for angioid streaks, and Evrysdi® has launched a new formulation in Japan. Lunsumio has been filed for an additional indication in combination with Polivy® for relapsed or refractory aggressive B-cell non-Hodgkin lymphoma, and Tecentriq® has been filed for an additional indication for unresectable thymic cancer. Additionally, Vabysmo (for non-proliferative diabetic retinopathy) and inavolisib (for *PIK3CA* mutated breast cancer) have initiated new clinical trials.

[2025 second quarter results]

Billion JPY	2025 Jan-Jun	2024 Jan- Jun	% change
Core results			
Revenue	578.5	552.9	+4.6%
Sales	511.4	485.5	+5.3%
Other revenue	67.0	67.3	-0.4%
Operating profit	272.0	262.8	+3.5%
Net income	193.5	189.5	+2.1%
IFRS results			
Revenue	578.5	552.9	+4.6%
Operating profit	273.3	258.2	+5.8%
Net income	194.4	186.3	+4.3%

[Sales breakdown]

Billion JPY	2025 Jan-Jun	2024 Jan-Jun	% change
Sales	511.4	485.5	+5.3%
Domestic sales	223.3	217.2	+2.8%
Oncology	116.6	118.8	-1.9%
Specialty	106.7	98.4	+8.4%
Overseas sales	288.1	268.4	+7.3%

[Oncology field (Domestic) Top5-selling medicines]

Billion JPY	2025 Jan-Jun	2024 Jan-Jun	% change
Tecentriq	29.9	31.1	-3.9%
Polivy	17.0	15.7	+8.3%
Alecensa	15.8	14.9	+6.0%
Phesgo	15.4	8.6	+79.1%
Avastin	13.0	17.4	-25.3%

[Specialty field (Domestic) Top5-selling medicines]

Billion JPY	2025 Jan-Jun	2024 Jan-Jun	% change
Hemlibra	29.1	27.4	+6.2%
Actemra	23.8	22.4	+6.3%
Enspryng	13.3	11.6	+14.7%
Vabysmo	12.0	9.1	+31.9%
Evrysdi	7.9	7.5	+5.3%

[Progress in R&D activities from Apr 25th, 2025 to Jul 24th, 2025]

As of July 24, 2025

Launched	**Evrysdi**	Addition of dosage form (tablet)	May 2025 (Japan)
Approved	AVMAPKI™*	Adult patients with KRAS-mutated recurrent low-grade serous ovarian cancer who have received prior systemic therapy (combination with FAK inhibitor FAKZYNJA™ (defactinib tablet))	May 2025 (U.S.)
	Elevidys	Duchenne muscular dystrophy (ambulatory) (gene therapy product)	May 2025 (Japan)
	PiaSky	Paroxysmal nocturnal hemoglobinuria	May 2025 (Taiwan)
	Vabysmo	Angioid streaks (additional indication)	May 2025 (Japan)
Filed	**Lunsumio + Polivy**	Relapsed or refractory aggressive B-cell non-Hodgkin's lymphoma (additional indication)	May 2025 (Japan)
	Tecentriq	Unresectable thymic carcinoma (additional indication)	May 2025 (Japan)
	Alecensa	*ALK* fusion / rearrangement gene-positive unresectable advanced or recurrent solid tumors (additional indication)	June 2025 (Japan)
Initiation of Study	GYM329	Obesity (Phase II)	May 2025
	Vabysmo	Non-proliferative diabetic retinopathy (domestic Phase III)	May 2025
	Hemlibra	von Willebrand disease (Phase III)	June 2025
	AUBE00	Solid tumors (pan-KRAS inhibitor / mid-size molecule / oral) (Phase I)	June 2025
	RG6114/inavolisib	*PIK3CA*-mutated breast cancer (domestic Phase I/II)	July 2025

Orange: in-house projects (development in global) Blue: In-licensed from Roche (development and distribution in Japan) *Conducted by Verastem Oncology, a global licensee

Readout	**Tecentriq + Avastin**	Phase III TALENTACE study (unresectable hepatocellular carcinoma) : Met one of the primary endpoints (TACE PFS)	May 2025
	AVMAPKI™*	Phase II RAMP 205 study (pancreatic ductal adenocarcinoma): Positive results for safety and efficacy	May 2025
Conclusion of Agreement	**Joint Research and License Agreement**	Development of novel therapies for age-related diseases with Gero	July 2025
Removed from Pipeline	**tiragolumab**	Esophageal cancer (SKYSCRAPER-07 study): Discontinuation of development	
	Five early-stage in-house products	Discontinuation of in-house development: LUNA18, SAIL66, SOF10, STA551, AMY109	
Medical Conference	AVMAPKI™*	Phase II RAMP 205 study (pancreatic ductal adenocarcinoma (1st-line treatment), in combination with standard of care)	June 2025
	NEMLUVIO®**	Phase III ARCADIA long-term extension study (atopic dermatitis, 2-year data)	June 2025
	NEMLUVIO®**	Phase III OLYMPIA long-term extension study (prurigo nodularis, 2-year data)	June 2025
	NXT007	Phase I/II NXTAGE study (hemophilia A)	June 2025
	orforglipron***	Phase III ACHIEVE-1 study (type 2 diabetes)	June 2025
	Lunsumio + Polivy	Phase III SUNMO study (relapsed or refractory aggressive B-cell non-Hodgkin's lymphoma)	June 2025
Open Innovation	**Investment by Chugai Venture Fund, LLC****	- Stylus Medicine - Two U.S.-based companies	April 2025 May and July 2025

Orange: in-house projects (development in global) Blue: In-licensed from Roche (development and distribution in Japan)
*Conducted by Verastem Oncology, a global licensee **Conducted by Galderma, an overseas licensee *** Conducted by Eli Lilly and Company, a global licensee
****A cumulative total of 6 companies

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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