March 6, 2026

Sumitomo Pharma Co., Ltd.
RACTHERA Co., Ltd.

Announcement on the Approval for Manufacturing and Marketing Authorization of the Allogeneic iPS Cell-Derived Dopaminergic Neural Progenitor Cell Product "AMCHEPRY®" in Japan

Sumitomo Pharma Co., Ltd. (Head Office: Osaka, Japan; President and CEO: Toru Kimura; "Sumitomo Pharma") and RACTHERA Co., Ltd. (Head Office: Chuo-ku, Tokyo, Japan; President and CEO: Atsushi Ikeda; "RACTHERA") announce that Sumitomo Pharma has obtained, as of March 6, 2026, conditional and time-limited approval in Japan for the manufacturing and marketing authorization of the allogeneic iPS cell-derived dopaminergic neural progenitor cell product AMCHEPRY® (INN: raguneprocel; the "Product") for the indication of the improvement of motor symptoms in patients with Parkinson's disease who have an inadequate response to existing pharmacological therapies, including levodopa-containing products.

The Product is the world's first iPS cell-derived regenerative medicine. Based on the data from an investigator-initiated clinical study*1 conducted by Kyoto University Hospital, Sumitomo Pharma submitted its an application for manufacturing and marketing authorization on August 5, 2025, and has now obtained the conditional and time-limited approval.

Following the National Health Insurance price listing, Sumitomo Pharma will be responsible for marketing of the Product, and S-RACMO Co., Ltd. (Head Office: Suita, Osaka, Japan; President and CEO: Atsushi Tsuchida) will be responsible for manufacturing.
Sumitomo Pharma will conduct a post-marketing clinical study and a post-marketing surveillance to obtain full approval within the designated period.

Sumitomo Pharma and RACTHERA aim to provide patients with Parkinson's disease with a new treatment option that differs from conventional pharmacotherapies and to further contribute to advances in the treatment of Parkinson's disease.

*1 The results of the clinical study were published in *Nature* in April 2025
Phase I/II trial of iPS-cell-derived dopaminergic cells for Parkinson's disease | Nature 641, 971–977 (2025)
https://doi.org/10.1038/s41586-025-08700-0

* The Product has been receiving ongoing research support from the Japanese government through programs funded by the Japan Agency for Medical Research and Development (AMED), including the Research Center Network for Realization of Regenerative Medicine, the Research Project for Practical Applications of Regenerative Medicine, and the Project Focused on Developing Key Evaluation Technology, among others.

(Reference)
About AMCHEPRY®(INN: raguneprocel)

The Product contains non-frozen dopaminergic neural progenitor cells manufactured through differentiation of allogeneic iPS cells. Dopamine is a neurotransmitter, which is produced in dopaminergic neurons. Dopaminergic neural progenitor cells are cells that have not yet differentiated into dopaminergic neurons. The Product received the SAKIGAKE Designation for regenerative medical products in February 2017 and was designated as an orphan regenerative medical product in December 2025 from the Ministry of Health, Labour and Welfare.

RACTHERA

RACTHERA is a joint venture between Sumitomo Chemical Co., Ltd. (Head Office: Chuo-ku, Tokyo, Japan; "Sumitomo Chemical") and Sumitomo Pharma. The company began operations on February 1, 2025, after inheriting intellectual property and other assets related to the regenerative and cellular medicine business from Sumitomo Pharma. RACTHERA serves as the core organization for research and development in the Sumitomo Chemical Group's regenerative and cellular medicine business and is engaged in the development of innovative therapies utilizing iPS cells and other modalities.

S-RACMO

S-RACMO is a joint venture between Sumitomo Chemical and Sumitomo Pharma and operates as a Contract Development and Manufacturing Organization (CDMO) that undertakes process development and manufacturing of regenerative and cellular medicine products. The Product will be manufactured at "SMaRT" (Suita, Osaka), the world's first commercial-scale manufacturing facility dedicated to regenerative and cellular medicine products derived from allogeneic iPS cells.

The technology for manufacturing iPS cell-derived dopaminergic neural progenitor cells:

The Product contains the dopaminergic neural progenitor cells differentiated from iPS cells stock provided by CiRA Foundation based on differentiation and manufacturing technology owned by Kyoto University and other parties. In addition, the Product, in one of its production steps for dopaminergic neural progenitor cells, employs a proprietary cell purification technology discovered by KAN Research Institute, Inc. (currently Kobe Research Laboratories, Eisai Co., Ltd.) and owned by Eisai Co., Ltd.

Contact:
Corporate Communications, Corporate Governance Sumitomo Pharma Co., Ltd.
E-mail: prir@sumitomo-pharma.co.jp

Business Administration Department, RACTHERA Co., Ltd.
E-mail: contact@racthera.co.jp