August 5, 2025

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

Announcement on the Submission of the Application of Manufacturing and Marketing Authorization for Allogeneic iPS Cell-Derived dopaminergic neural progenitor cells in Japan

Sumitomo Pharma Co., Ltd. (Head Office: Osaka, Japan; "Sumitomo Pharma") and RACTHERA Co., Ltd. (Head Office: Chuo-ku, Tokyo, Japan;, "RACTHERA") hereby announce that on August 5, 2025, they have submitted an application of manufacturing and marketing authorization for allogeneic iPS cell-derived dopaminergic neural progenitor cells (INN: "raguneprocel", "the Product") for indication of the improvement of motor functions during the off-time period of patients with advanced Parkinson's disease. The applicant for the authorization is Sumitomo Pharma.

This submission was based on the data from the investigator-initiated trial conducted by Kyoto University Hospital, and its results were published in the journal *Nature** in April 2025. The Product is to be manufactured by S-RACMO Co., Ltd. (Head Office: Suita, Osaka, Japan) and marketed by Sumitomo Pharma. The Product has been designated by the Ministry of Health, Labour and Welfare as a product for priority review under the SAKIGAKE Designation System.

Sumitomo Pharma and RACTHERA will strive to provide new medical value that cannot be expected from existing treatments, and will further contribute to the treatment of Parkinson's disease.

Phase I/II trial of iPS-cell-derived dopaminergic cells for Parkinson's disease, Nature*
https://doi.org/10.1038/s41586-025-08700-0

(Reference)

Allogeneic iPS cell-derived dopaminergic neural progenitor cells (INN; raguneprocel):

Dopamine is a neurotransmitter, which is produced in the dopamine neurons. Dopaminergic neural progenitor cells are cells that have not yet differentiated into dopaminergic neurons. The Product contains non-frozen dopaminergic neural progenitor cells manufactured through differentiation from 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.

RACTHERA:

RACTHERA is a joint venture between Sumitomo Chemical Co., Ltd. (“Sumitomo Chemical”) and Sumitomo Pharma. It began operations on February 1, 2025, after inheriting intellectual property and other assets related to the regenerative medicine and cell therapy business from Sumitomo Pharma.

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 the development of manufacturing processes and the production of regenerative medicine and cell therapy products.

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