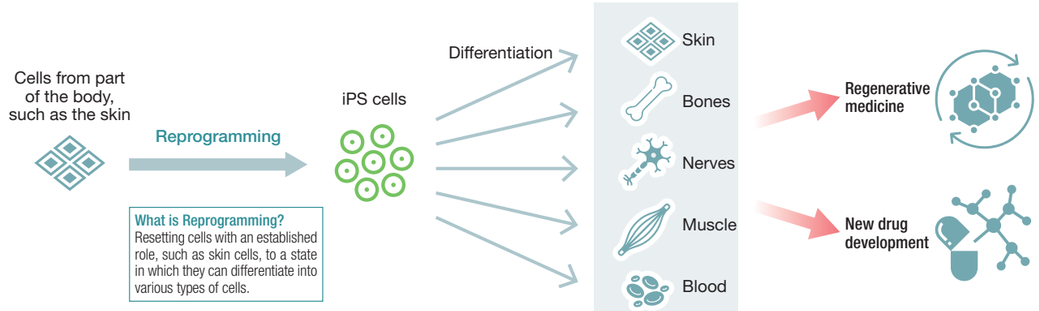
Sumitomo Chemical's regenerative medicine/cell therapy business

Sumitomo Chemical is working to address four material issues, which could help create social value. In the healthcare field in particular, we position the regenerative medicine/cell therapy business as one of the core new growth areas over the medium to long term, and the entire Group has focused for many years on stem cell research and on bringing regenerative medicine/cell therapy into practical use. To deliver innovative new therapies to patients, the Group will work as one to expand the regenerative medicine/cell therapy business and contribute to solving social issues.

What are iPS cells?

Induced pluripotent stem (iPS) cells are cells created by reprogramming cells of the body, such as skin or blood cells. Since they have properties close to those of a fertilized egg, they can change into a wide variety of cells and continue to proliferate over a long period. Through differentiation, diverse cell types, including nerve cells, cardiomyocytes, blood cells and hepatocytes can be produced from iPS cells. In addition to regenerative medicine through transplantation, the cells obtained in this way also serve drug discovery research that examines the efficacy and toxicity of new drugs.



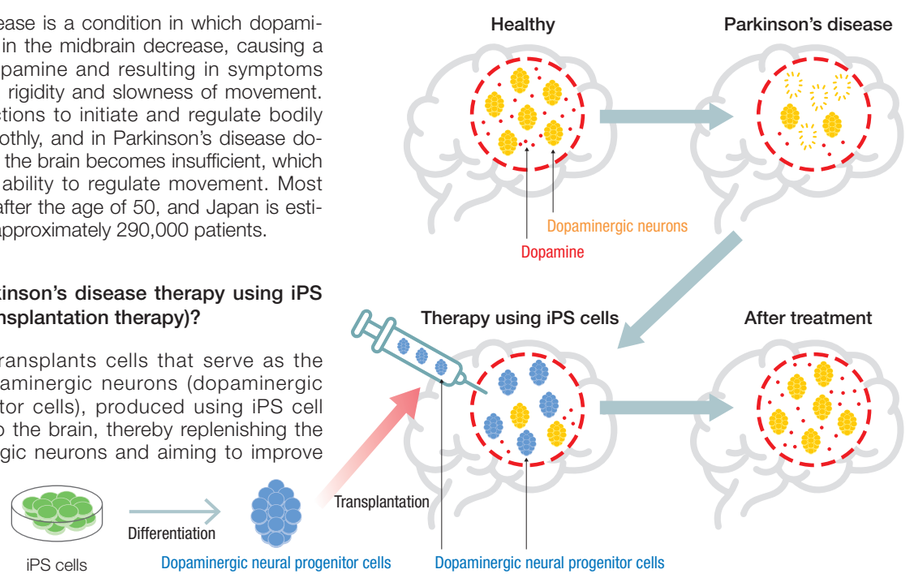
Parkinson's Disease Therapy Using iPS Cells

What is Parkinson's disease?

Parkinson's disease is a condition in which dopaminergic neurons in the midbrain decrease, causing a shortage of dopamine and resulting in symptoms such as tremor, rigidity and slowness of movement. Dopamine functions to initiate and regulate bodily movement smoothly, and in Parkinson's disease dopamine levels in the brain becomes insufficient, which diminishes the ability to regulate movement. Most cases develop after the age of 50, and Japan is estimated to have approximately 290,000 patients.

What is Parkinson's disease therapy using iPS cells (cell transplantation therapy)?

This therapy transplants cells that serve as the source of dopaminergic neurons (dopaminergic neural progenitor cells), produced using iPS cell technology, into the brain, thereby replenishing the lost dopaminergic neurons and aiming to improve motor function.



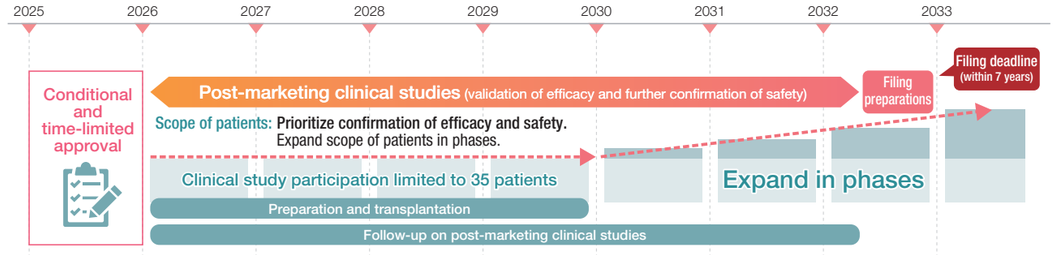
The world's first iPS cell-derived pharmaceutical product, originating in Japan (AMCHEPRY)



AMCHEPRY allogeneic iPS cell-derived dopaminergic neural progenitor cell product, consists of non-frozen dopaminergic neural progenitor cells produced from allogeneic iPS cells. Sumitomo Pharma obtained conditional and time-limited approval for AMCHEPRY in Japan on March 6, 2026, for the improvement of motor symptoms in patients with Parkinson's disease who do not achieve sufficient benefit from existing pharmacological therapies.

Expansion of the scope of facilities and patients from conditional and time-limited approval to full approval

Until around 2029, we will perform transplantation only for patients participating in post-marketing clinical studies. After completing transplantation for patients in the post-marketing clinical studies, we will expand the scope of facilities and patients.



About conditional and time-limited approval

Approval conditioned upon the collection over a set period of time of additional clinical data (efficacy and safety)

Conditions	● Post-marketing clinical studies ● Post-marketing surveillance
Deadline	● 7years (end of FY 2032) from approval

About post-marketing clinical studies

Clinical studies conducted after obtaining conditional approval that are designed to collect the efficacy and safety data needed to obtain formal approval

- Transfuse into 35 patients
- Follow up (Monitoring of 35 transfusion patients)

Promoting Expansion of the Regenerative Medicine/Cell Therapy Business as One Group

As one group, we will foster this business on the basis of cutting-edge technologies and our experience, and open up a new world. Each company leverages its own strengths and supports the advancement of the business in the areas where it contributes most.

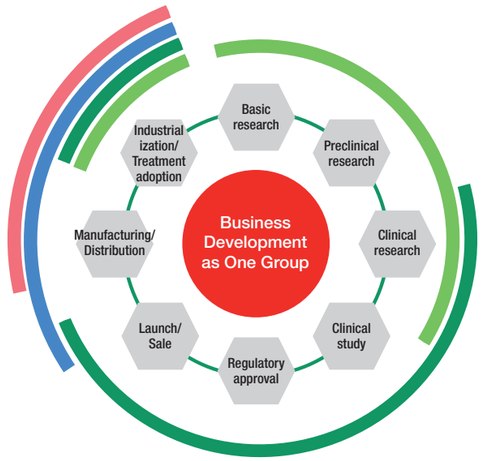
SUMITOMO CHEMICAL

Industrialization Technology	
Strength	● Advanced analytical technology and quality control ● Engineering
Role	● Mass production and stable supply ● Quality control leveraging advanced analytical technology

S-RACMO

Cell Manufacturing & CDMO Business	
Strength	● Cutting-edge manufacturing technologies for iPS cell–derived products ● Extensive track record in manufacturing of commercial/clinical products (JP/US) ● Regulatory affairs capabilities originating in Sumitomo Pharma
Role	● Stable supply of high-quality products ● Process development for commercialization ● Reduction of manufacturing costs through scale-up/automation

Joint venture with Sumitomo Pharma (**66.6**% owned by Sumitomo Chemical)



*The arcs on the outer perimeter indicate the areas to which each company contributes most

RACTHERA

Research Platform & Business Execution	
Strength	● iPS cell differentiation-inducing technologies ● Robust external network ● Deep expertise and talent in regenerative medicine/cell therapies
Role	● Strategic Planning & Business Development ● Collaboration with academia and industry partners ● Research on differentiation-inducing technologies ● Quality and efficacy evaluation

Joint venture with Sumitomo Pharma (**66.6**% owned by Sumitomo Chemical)

Sumitomo Pharma

Pharmaceutical Business platform	
Strength	● Clinical development platform ● Experience in regulatory affairs and commercialization in Japan and the U.S.
Role	● Conducting clinical studies in collaboration with medical institutions ● Regulatory affairs and consultations with authorities for regulatory approval ● Post-marketing activities including commercial and reliability assurance

We expect it to **grow into a global blockbuster (more than 100 bn. yen in sales)** in the 2030s