



CiRA Foundation members at the start of FY2026

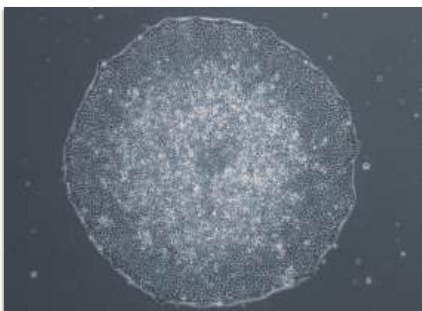
iPSC-based Medical Products Become Eligible for Public Health Insurance Coverage ～Conditional Approval Granted for Amschepry and ReHeart～

In March, the Ministry of Health, Labour and Welfare granted conditional and time-limited approval in Japan to manufacture and market Amschepry, an iPSC-derived product developed by Sumitomo Pharma Co. for the treatment of Parkinson's disease, and ReHeart, an iPSC-derived cardiomyocyte sheet developed by Cuorips Inc. for the treatment of ischemic cardiomyopathy. In May, Amschepry was also approved for coverage under Japan's public health insurance system (as of June 2026), marking a major step

forward in the clinical application of iPSC-based therapies. Both products use clinical-grade iPSCs produced by the CiRA Foundation.

The iPS Cell Stock Project was launched in 2013 at the Center for iPS Cell Research and Application (CiRA), Kyoto University, to produce clinical-grade iPSCs with support from the government. In 2020, the project was transferred to the Foundation, and staff members responsible for manufacturing and quality evaluation at CiRA also joined the organization. Since then, the project has become one of the Foundation's core activities.

Today, researchers and companies around the world are utilizing these iPSCs for R&D and clinical trials. The Foundation will continue to contribute to the realization of iPSC-based therapies.



iPS Cell Colony

Marking the 20th Anniversary of the Publication of the Mouse iPSC Paper

This year marks the 20th anniversary of the publication of the landmark paper in which Professor Shinya Yamanaka of Kyoto University, who also serves as the President of the CiRA Foundation, and his research team reported the successful generation of mouse iPSCs. Commemorative events are planned to celebrate this important milestone.

Message from President Shinya Yamanaka

“It has been 20 years since we published our paper reporting the generation of mouse iPSCs. During this period, clinical trials using iPSCs have been conducted in Japan for more than 10 diseases, and in March this year, two iPSC-derived products for Parkinson’s disease and heart disease received conditional and time-limited approval as regenerative medicine products. (See page 1.) Clinical-grade iPSC stock manufactured by the CiRA Foundation has been used in these clinical trials as well as in the two approved products. The creation of this clinical-grade iPSC stock was extremely challenging. However, thanks to the support of many stakeholders and the tireless efforts of our members, we have been able to reach this important milestone. I would like to take this opportunity to express my sincere gratitude to everyone involved.

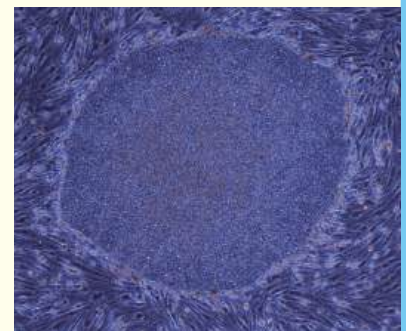
The full potential of iPSCs has yet to be realized. We will continue working together as one team to support researchers and companies in bringing iPSC-based therapies to patients.”



History

Major Milestones Related to the CiRA Foundation

- 2006— Publication of mouse iPSC paper
- 2007— Publication of human iPSC paper
- 2010— Completion of the Facility for iPS Cell Therapy (FiT) at CiRA
- 2015— Start of clinical-grade iPSC stock distribution
- 2020— CiRA Foundation begins activities as a public interest incorporated foundation
- 2023— Start of clinical-grade HLA genome-edited iPSC stock distribution
- 2024— Launch of the Uehiro Laboratory for my iPS® Research at Nakanoshima Qross (NQ), Osaka
- 2025— Launch of the Yanai Facility for my iPS Therapy at NQ



Human iPS cell Colony
Photo: Shinya Yamanaka

Anniversary Events

- 1 A public symposium will be held on Saturday, October 17, 2026, at the Kyoto University Centennial Clock Tower Memorial Hall. The event is jointly hosted by Kyoto City, CiRA, and the CiRA Foundation. Speakers include President Yamanaka. For details, please visit the Foundation website.
- 2 The iPSC 20th Anniversary Symposium for researchers will take place at the Kyoto International Conference Center on October 20-22, 2026. It is co-hosted by the International Society for Stem Cell Research (ISSCR) and CiRA. The CiRA Foundation will host an exhibition booth at the event. For more information, please visit the ISSCR website.



Giving Report 2025

The CiRA Foundation is financed by public funds, business revenue and donations. In fiscal year 2025, we received approximately ¥6.08 billion in donations from individuals and corporations. Thank you very much for supporting us.

Donation Amount (April 1, 2025 – March 31, 2026)

	Number of donations	Amount of donations
Membership	214	60,300,000 yen
Donations	448,306	6,021,306,660 yen
Total	448,520	6,081,606,660 yen

The Foundation supports the development of new therapies by providing high-quality iPSC cells to companies and research institutions at affordable cost. The Foundation's total expenditure for FY2025 was approximately ¥5 billion, of which 3.4 billion, or 70 %, was covered by donations. Thanks to your donations, we were able to purchase equipment necessary for iPSC manufacturing and quality assessment. In this report, we will introduce some of the achievements we made in FY2025.



1 iPSC Stock Provided to 32 Institutes in Japan and Overseas

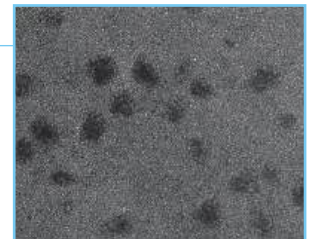
We supplied the iPSC stock to 32 research institutes in Japan and overseas. Reflecting the growing international demand in recent years, we made our first shipment to Germany. As iPSC research advances around the world, the development and clinical application of iPSC-based therapies is expected to progress even further.



Preparing iPSC Stock for Shipment

2 Contributing to an Ovarian Cancer Clinical Trial through the iPSC Production for Transplantation

We are engaged in the production of transplantable cells derived from iPSCs. Before iPSCs can be used in clinical settings, they must first be differentiated into the specific cell types required for each therapeutic application. In FY2025, as part of a collaborative research project with Professor Shin Kaneko of CiRA, Kyoto University, we manufactured CAR-NK cells, specialized immune cells derived from iPSCs, for use in a clinical trial for ovarian cancer.



CAR-NK Cells Manufactured by the CiRA Foundation

3 Progress in Research and Development Under the my iPS® Project

Under the “my iPS® Project,” we are advancing the development of manufacturing technologies that employed closed automated systems to reduce the cost of iPSC production. The project has progressed steadily, leading to the successful establishment of the world's first automated process for generating iPSCs using a closed-system device. The technology has been granted a patent. This achievement represents a significant step forward toward realizing more efficient and reliable iPSC manufacturing.



Patent Certificates

Once again, we would like to express our heartfelt gratitude for your generous and unwavering support. With the continued dedication of our staff, we will continue striving to advance the future of medicine. We sincerely appreciate your continued support in years ahead.

January

Publication of a Paper on an Automated, Closed-System Manufacturing Process for Autologous iPSCs

A paper reporting the first successful establishment of a GMP*-compliant manufacturing process under the “my iPS® Project” has been published in *Cytotherapy*.

*GMP (Good Manufacturing Practice): Regulatory standards for manufacturing and quality control designed to ensure the safety and quality of pharmaceutical and medical products.

April

Visit to Sumitomo Pharma’s Regenerative Medicine and Cell Therapy Manufacturing Facility

CiRA Foundation President Shinya Yamanaka visited the manufacturing facility for Amschepry®, a regenerative medicine product manufactured using clinical-grade iPSC stock produced by the Foundation. During the visit, he exchanged views with Mr. Toru Kimura, President of Sumitomo Pharma, and Mr. Atsushi Ikeda, President of RACTHERA Inc.



Commemorative Photo

CiRA Foundation Representatives Visit CGT Catapult in the U.K.

President Shinya Yamanaka visited Cell and Gene Therapy Catapult (CGT Catapult), a long-standing collaborative partner in the U.K. in April. Two Foundation staff members, Naosuke Nakamura, Group Leader of the Planning Promotion Office, and Tsuguharu Omura, Deputy Manager of the Contract Management Office, also visited the organization in March. During their visits, they provided updates on the Foundation’s activities and discussed ways to further strengthen collaboration between the two organizations.



Commemorative Photo
Photo: CGT CATAPULT

May

CiRA Foundation President Yamanaka Addresses the Japan National Press Club Annual Meeting

President Shinya Yamanaka delivered a lecture titled “20 Years Since the Publication of the First iPSC Paper: The Journey toward Clinical Application.” He highlighted advances in iPSC research being conducted at research institutions, including CiRA and other research organizations.



During the Lecture

