Press Release

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A Bridge from Japan to Korea:
CiRA Foundation's First Provision of Clinical-Grade iPS Cell Stock Overseas

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Key Points

- CiRA Foundation® ("CiRA_F"; located in Kyoto, Japan) has provided the clinical-grade iPS cell stock (iPSC stock) to iPS Bio, Inc ("iPS Bio"; located in Pangyo, Korea). This is the first time that CiRA_F has provided the clinical-grade iPSC stock to an overseas.
- iPS Bio plans to conduct clinical trials using GMP-grade iPSC products for treating Huntington's disease, stroke, Alzheimer's disease, as well as immune-oncology diseases, in the next few years.
- Based on this incredible collaboration with iPS Bio, CiRA_F will make further efforts to manufacture high-quality iPSC stock for regenerative medicine to meet global standards, and will continue to contribute to the practical application of iPS cell technology through providing the iPSC stock to global partners of CiRA_F such as iPS Bio.
- To accomplish the ultimate goal of "providing the top iPS cell technologies at affordable prices," CiRA_F has been supplying iPSC stock, SOPs, and quality evaluation services for regenerative medicine. CiRA_F is always open to collaborating with partners.

1. Overview

The clinical-grade HLA homozygous iPSC stock manufactured by CiRA_F, which is believed to prevent or minimize immune rejection in many Japanese patients, was provided to iPS Bio, a start-up biotech company in Korea.

iPS Bio plans to use CiRA_F's iPSC stock to conduct clinical trials for treating Huntington's disease, stroke, Alzheimer's disease, as well as immune-oncology diseases, in the next few years.

The HLA types in Japanese and Korean populations are highly similar, so it is expected that CiRA_F's iPSC stock will reduce the risk of immune rejection when transplanted into HLA-matched patients in Korea as well as in Japan.

2. Background

■ The iPSC Stock Project

The iPSC Stock Project is a national project in Japan, initiated at the Center for iPS Cell Research and Application (CiRA), Kyoto University, in 2013, and was transferred to CiRA_F in April 2020. The aim of this project is to manufacture multiple iPS cell lines from healthy donors who are homozygous for human leukocyte antigens (HLA) in order to increase the number of patients who can receive cell therapies with minimal immune reactions. The manufactured iPS cells will be shipped after quality evaluation.

■ Promotion of the use of iPS cell-based therapies

・These lines are provided free of charge to academic institutions and at a reasonable price to industrial organizations in Japan.

・CiRA_F has obtained prior consent from blood donors for the commercialization of iPS cell-based therapies and for their use in clinical research and trials.

・Wherever possible, insights gained from iPSC stock-provided companies will be shared with other iPSC stock user companies through CiRA_F.

■ Experience in providing the iPSC stock in Japan

These iPS cells have been used in clinical research and clinical trials, such as age-related macular degeneration led by Kobe City Eye Hospital and Parkinson's disease led by Kyoto University Hospital.

■ On-going collaborative relationship between Prof. Song and CiRA_F:

・CHA University in Korea and CiRA_F signed a collaborative research agreement for the provision of research-grade iPSC stock on April 14, 2021. Using CiRA_F's two iPS cell lines, Prof. Song, who is also the CEO of iPS Bio, Inc., has conducted extensive research on the optimization of culture and neuronal differentiation conditions in order to develop iPSC-based therapies for several neurodegenerative diseases, including Huntington's and Alzheimer's diseases, as well as stroke, in the near future.

・Based on this experience, iPS Bio plans to take the next step and manufacture GMP-grade iPS cells and related products in order to conduct clinical trials for neurodegenerative diseases, such as Huntington's disease, in the next few years. Given the high similarity of HLA types between the Korean and Japanese populations, it will be useful to utilize the well-characterized clinical-grade iPSC stock from CiRA_F. To facilitate this collaboration, CiRA_F shipped two kinds of clinical-grade iPSC stock on February 21, 2022, which arrived at iPS Bio on February 24, 2022.

3. Summary of Collaboration Plans

1) Research Title:

Development of cell therapy for various neurological and immunological diseases using human iPS cells

2) Research Period:

February 2022 to October 2024

3) Key Members:

・ **CiRA_F**

Naoko Takasu, Head of Facility for iPS Cell Therapy
Shusuke Hira, Manufacturing Supervisor of FiT
Shuhei Deguchi, Quality Supervisor of FiT

・ **iPS Bio**

Jihwan Song, CEO
Sungsook Yu, Director of Research
Miju Lee, Senior Investigator
Taekhee Jung, Team Leader
Woongbin Joo, Team Leader

4. Comments from Jihwan Song, CEO, iPS Bio, Inc.

We are highly excited about this great opportunity to use CiRA_F's iPSC stock to develop stem cell therapies and clinical applications for intractable or incurable neurodegenerative diseases, such as Huntington's disease, in the near future. For this, we really appreciate Prof. Shinya Yamanaka and CiRA Foundation's great support. We strongly believe that our concerted efforts will give rise to new hopes and novel therapies for currently incurable diseases, such as Huntington's disease, in the next few years.

5. Comments from Shinya Yamanaka, Representative Director, CiRA_F

We have been deepening our cooperative relationship with various companies in order to bridge the university's research results to the industrial world for practical use. In particular, we believe that providing iPSC stock for clinical use overseas is a new direction for CiRA_F. To support our partner institutions, we will continue to make such efforts to bring iPS cell technology to clinical application.

6. About CiRA Foundation

CiRA Foundation (CiRA_F) was established as a public foundation in April 2020. CiRA_F has contributed to the commercialization of regenerative medicine by continuing the iPSC stock project, as well as providing services including the manufacturing of iPS cell-derived products, quality assessment, storage, and publication of SOPs for manufacturing.

7. About iPS Bio, Inc.

iPS Bio, a start-up stem cell company in Korea, was founded by Prof. Jihwan Song in 2019 in order to develop novel iPSC-based therapies for treating intractable neurodegenerative diseases, including Huntington's and Alzheimer's diseases, as well as stroke. iPS Bio is also developing novel drug screening platforms using neural cells differentiated from patient-derived iPSCs with various neurodegenerative diseases, including Alzheimer's, Huntington's, and Parkinson's diseases.

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