

Basic agreement with Thyas Co. Ltd. for the manufacturing of iPS cell-derived T cells Joint research on the utilization of my iPS® has also begun

Kyoto, Japan, 1 February 2021 - The CiRA Foundation® (CiRA_F) today has signed the following two agreements with Thyas Co. Ltd. ("Thyas"; located in Sakyo-ku, Kyoto)

(1) Basic agreement on the manufacturing of autologous regenerated T cells by Thyas

(2) Joint research on the my iPS Project for the production of autologous regenerated T cells

(1) Basic agreement on the manufacturing of autologous regenerated T cells by Thyas

CiRA_F has conducted a basic agreement with Thyas to manufacture intravenous autologous iPS cell-derived cytotoxic T cells (hereinafter referred to as "autologous regenerative T cells") for use in clinical trials. The term of the consignment is planned to be from March 2022 to February 2024, with aim for a clinical trial scheduled to start in the second half of 2022. Currently, Thyas and CiRA_F are negotiating the conclusion of a formal outsourcing contract.

It is said that thousands of cancer cells are generated every day in the body of a healthy person, but these cells are regularly eradicated by the immune system. If the immune function does not work properly, however, cancer cells persist and proliferate, eventually leading to cancer. In recent years, immunotherapies have been developed to treat cancer patients by strengthening their immune systems.

T cells are a type of white blood cell that attacks foreign substances in the body. However, T cells in cancer patients are chronically stimulated and exhausted by cancer cells. Professor Shin KANEKO and his colleagues at the Center for iPS Cell Research and Application (CiRA), Kyoto University, are using iPS cell technology to develop a new form of immunotherapy, in which T cells are reprogrammed into iPS cells, which are then expanded and differentiated into T cells that can effectively suppress cancer. As part of this research, they have developed a technology to manufacture such T cells in large quantities. Thyas is working with Professor Kaneko to put this technology into practical use by preparing autologous regenerated T cells.

(2) Joint research on the my iPS Project to produce autologous regenerated T cells

Currently, CiRA_F is working on the "my iPS Project", with the goal of delivering patient iPS cells and cells derived from them by 2025. Although it is possible to produce patient iPS cells, the current cost is about 40 million yen (about US\$400,000) per production. In the my iPS Project, the CiRA_F aims to provide safe patient iPS cells at 1 million yen (around US\$10,000) per case by automating the cell manufacturing and improving the efficiency of quality control.

In this joint research, Thyas and CiRA_F will study the manufacturing method so that patient iPS cells can be used as the raw material for autologous regenerated T cells. Specifically, biomarkers and other properties will be analyzed to evaluate the best iPS cell lines for T cell differentiation. Accordingly, the differentiation method of my iPS to T cells will also be intensively investigated.

The CiRA Foundation collaborates with academia and industry to provide iPS cell-derived regenerative medicines to clinical practice as soon as possible.

About the CiRA Foundation

Recognized as a public interest incorporated foundation in April 2020, it manages the iPS Cell Stock for Regenerative Medicine Project, which was started by the Center for iPS Cell Research and Application (CiRA), Kyoto University, in 2013. The aim of this project is to prepare multiple clinical-grade iPS cell lines manufactured from healthy donors homozygous for human leukocyte antigens (HLA). These lines will expand the number of people who can receive related therapies with minimal immune reactions and are provided to academia and industry. CiRA_F also contributes to the commercialization of regenerative medicine by providing services including the manufacturing of iPS cell-derived products, quality assessment, storage, and the publication of SOPs for manufacturing.

About Thyas

Thyas is a Kyoto University-launched venture that is advancing research and development for the clinical application of regenerative T cells based on the research results of Professor Shin KANEKO at CiRA. In recent years, cancer immunotherapies such as immune checkpoint inhibitors and chimeric antigen receptor transgenic T cells have shown great efficacy. However, T cells in terminal patients are in a state of exhaustion, making it difficult to expand their culture, and safe and effective responses have not been achieved in the treatment of solid tumors. Thyas' technology enables the acquisition of many killer T cells that have high aggressiveness against tumors by first reprogramming exhausted anti-cancer killer T cells into iPS cells and then differentiating the iPS cells back into killer T cells. By applying this technology to a patient's own killer T cells, we aim to establish personalized cancer immunotherapy with high therapeutic efficacy against solid tumors.

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