PRESS RELEASE

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Rebirthel and Otsuka Sign Licensing Agreement for iPSC-derived CAR-T / TCR-T Production Technology

Rebirthel Co., Ltd. (Rebirthel) announces that it entered into an exclusive commercial licensing agreement with Otsuka Pharmaceutical Co., Ltd. (Otsuka) for its technologies on CAR-T/TCR-T genetically engineered cell production using induced pluripotent stem (iPS) cells. The agreement covers multiple therapeutic areas worldwide.

Professor Kawamoto's laboratory at Kyoto University has been conducting joint research with Otsuka on iPS cell-derived CAR-T production technology. Last year, Rebirthel also signed a research licensing agreement with Otsuka for research use of iPS cell-derived CAR-T/TCR-T production technology.

Under the terms of the commercial licensing agreement, Rebirthel will grant an exclusive license to Otsuka to use the technology for the generation of iPS cell-derived CAR-T/TCR-T for commercial use in multiple therapy areas. Otsuka will pay Rebirthel an upfront payment, development milestone payments and royalties based on sales.

Otsuka is engaged in the research and clinical development of autologous CAR-T/TCR-T therapies. In parallel with these efforts, Otsuka will continue to research and develop allogeneic CAR-T and TCR-T therapies that may enable rapid administration using the technology licensed under this agreement.

Rebirthel itself also aims at the in-house cell manufacturing for sale. However, by transferring technology outside its field of business to Otsuka, Rebirthel expects that its technologies will become widely used for treatments.

[Epexegeses]

1) Rebirthel Co., Ltd.

Rebirthel Co., Ltd (hereafter Rebirthel) is a venture company which aims at the clinical application of the therapy using “universal” and “off-the-shelf” killer T cell preparation, which has been developed by Professor Hiroshi Kawamoto, Kyoto University. Rebirthel was founded in October 2019 by Professor Kawamoto.

Killer T cells are a type of T cells that have the ability to find cancer cells or virus-infected cells, and kill them. Rebirthel’s technology mainly uses such killer T cell (hereafter T cell). Rebirthel is pursuing the strategy to deliver T cells “as drug” “to everyone” “very soon” and “at low cost”. T cell preparation will be regenerated from iPS cells, so a mass production becomes possible.

Using universal iPS cells that have the low risk of rejection as a material, it will be possible to produce a T cell preparation that can be given to anyone. We will produce these T cells in large numbers and cryopreserve them. When needed, T cells will be thawed and administered to patients. Moreover, a mass production will make it possible to cut cost.

Currently, at Kawamoto lab in Kyoto University, therapeutic strategy is being developed for acute myeloid leukemia targeting the WT1 antigen. Rebirthel is supporting this development. This strategy is being prepared for clinical trials at Kyoto University Hospital in collaboration with Department of Hematology and Oncology, Center for Research and Application of Cellular Therapy（C-RACT）, and Institute for Advancement of Clinical and Translational Science (iACT), planned to be realized in 2024.

In parallel with the above WT1 project, Prof Kawamoto also leads a laboratory in Fujita Health University, where a novel cell therapy against COVID-19 is being developed by using the regenerated killer T cells that are specific for SARS-Cov-2. Rebirthel also supports this project.

2) Adoptive immunotherapy using autologous T cells

Firstly, T cells are collected from a patient’s peripheral blood, and genetically engineered so that they can recognize cancer cells. These cells are then stimulated in vitro to promote proliferation and activation. After such an expansion process, T cells are given back to the patient. One example is the T cells to which a chimeric antigen receptor (CAR) gene, targeting CD19 (cell-surface molecule), has been transferred. This method has been shown to be highly effective on a certain type of leukemia, and was approved in 2019 in Japan. However, such strategies using autologous T cells have faced problems: 1) time-consuming (It takes 1 – 2 months including preparation period of patient), 2) costly, and 3) uneven in quality because it depends on the quality of T cells from patients. The strategy using allogeneic T cells but not autologous T cells may solve the above three problems.