

PRESS RELEASE**Rebirthel Co., Ltd.**

Room 304, Creation Core Kyoto Mikuruma, 448-5,

Kajii-cho, Kamigyo-ku, Kyoto 602-0841 Japan

Phone: (81)75-212-3770

Fax: (81)75-212-378

URL: <https://rebirthel.com/en/>

Rebirthel concludes the research license agreement with Otsuka Pharmaceutical

Kyoto, October 1 2020: Rebirthel Co., Ltd.¹⁾ (hereafter Rebirthel) has announced today that they have concluded the research license agreement with Otsuka Pharmaceutical Co., Ltd.²⁾ (hereafter Otsuka Pharmaceutical) on October 1st 2020. Under this agreement, Rebirthel will provide its patented technology to Otsuka Pharmaceutical, and Otsuka Pharmaceutical will utilize this technology for the development of the cancer immunotherapy using allogeneic T cells.

Otsuka Pharmaceutical has been developing the adoptive immunotherapy using autologous T cells, and is currently conducting several clinical trials.

Professor Hiroshi Kawamoto's laboratory (Laboratory of Immunology, Institute for Frontier Life and Medical Sciences, Kyoto University) has been developing the technology to produce a universal allogeneic T cell preparation using pluripotent stem cells such as iPS (induced pluripotent stem) cells or ES (embryonic stem) cells as materials, and some inventions have been filed as patents. The present agreement allows Otsuka Pharmaceutical to exclusively use these patents, of which Rebirthel has the exclusive license, in a basic research for the development of a cell therapy using the allogeneic T cell preparation. In addition, the agreement gives Otsuka Pharmaceutical the priority negotiation right for commercial license.

Rebirthel itself also aims at the in-house cell manufacturing for sale. However, by transferring technology to the uncompetitive treatment strategy by Otsuka Pharmaceutical, Rebirthel expects that their technology will become widely used for cancer treatments.

[Epexegesés]

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, 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, 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, and Department of Transfusion Medicine and Cell Therapy.

2) Adoptive immunotherapy using autologous T cells

Firstly, T cells are collected from patient’s peripheral blood, and then stimulated in vitro to promote proliferation and activation. After such an expansion process, T cells are given back to the patient. As another type of T cell source, tumor-infiltrating T cells isolated from tumor tissue are also used. In addition, a method has recently been often applied, which genetically engineers T cells that had originally been collected from patients, and thus endows the T cells with the ability to find out and kill cancer cells. 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 (Novartis’ s CD19-CAR-T cell therapy costs more than 30 million yen for one time), 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 solves the above three problems.