



22nd June 2020

Contract for manufacturing of clinical trial formulations

Megakaryon Corporation (Head office: Shimogyo-ku, Kyoto; President: Kenichi Akamatsu), working towards the commercialization of platelet preparation from human iPS cells announced today that the company has signed an agreement to outsource the manufacturing of the drug product for the clinical trial scheduled to be implemented in 2021 to "CiRA Foundation" (hereinafter "CiRA_F").

The clinical research experience on autologous transfusion of iPS cell-derived platelets for thrombocytopenia conducted at Kyoto University Hospital makes CiRA_F the best contract manufacturer for our clinical trials.

Based on the concept of open innovation, we will combine outstanding Japanese technologies to obtain Japanese manufacturing and marketing approval for human iPS cell-derived platelet formulation, and consecutively promote international expansion to the United States, Europe and other foreign countries.

【About Megakaryon Corporation】

Megakaryon Corporation was established in 2011 with the aim of utilizing the technologies developed by Kyoto University and the University of Tokyo for producing platelets from human iPS cells for clinical application. By developing large-scale manufacturing of human iPS-derived platelets with no risk of infection, we aim to supply platelets to medical facilities around the world both in developed countries where declining birthrate and increased ageing population cause a concern due to decreased number of blood donations, and in developing countries where there is already a shortage of donated platelets.

Since 2013, Megakaryon Corporation is supported by Innovation Network Corporation of Japan (currently INCJ, Ltd.). In 2015, Megakaryon Corporation was certified by the Japanese Prime Minister as the first application of a specific core project under the National Strategic Special Zones Law for its initiative that contributes to strengthening Japan's competitiveness in the global medical field, as well as in research and development of innovative regenerative medicine, and the promotion of its commercialization.

In February 2020, our efforts for promoting open innovation was recognized by the Cabinet

Office of Japan at the 2nd Japan Open Innovation Award and Megakaryon along with its partner companies have won the Minister of State Science and Technology Policy Award.

【About the CiRA Foundation】

The CiRA Foundation was recognized as a public interest incorporated foundation in April 2020. Its principle purpose is to deliver high-quality iPS cells at low cost. The Foundation manages the iPS Cell Stock for Regenerative Medicine Project, which was started by the iPS Cell Research and Application (CiRA), Kyoto University, in 2013. The aim of this project is to prepare multiple 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 industries. The Foundation contributes to the commercialization of regenerative medicine by providing services including the manufacturing of iPS cell-derived products, quality assessment, storage, and publication of SOPs for manufacturing.

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