株式会社メガカリオン
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News Release

26th April 2021

Megakaryon Corporation announces the completion of 30-day review of Clinical trial notification submitted for human iPS cell-derived HLA homozygous platelets (MEG-002).

Overview

Megakaryon Corporation today announces the completion of 30-day review of the clinical trial notification submitted for human iPS cell-derived HLA homozygous platelets (Development Code: MEG-002) by Japan's Pharmaceutical and Medical Devices Agency (PMDA). Megakaryon Corporation has planned this trial MEG-002 in collaboration with Kyoto University Hospital, Center for iPS Cell Research and Application, Kyoto University（CiRA）and CiRA Foundation（CiRA_F）. We will continue to work closely with related parties and work diligently toward conducting the clinical trial.

Background

The Department of Hematology, Kyoto University Hospital (Professor Akifumi Takaori) and CiRA (Professor Koji Eto) have conducted clinical research for the transfer of autologous iPS cell-derived platelets to a thrombocytopenia patient to verify the safety of iPS cell-derived platelet preparations. The clinical trial announced today is for an allogeneic transplant, which will enable industrialization of iPS cell-derived platelet and subsequent availability to a large number of people.

Summary of the clinical trial

In the clinical trial, we will confirm the safety and estimate the efficacy of MEG-002 to thrombocytopenia patients. MEG-002 is prepared from an iPS cell provided by CiRA (currently CiRA_F) and consists of platelets with the HLA type most common in Japanese people. The technology for producing platelets from iPS cells invented by Professor Koji Eto is used for the development of MEG-002. The clinical trial will be conducted at multiple medical institutions, including the Department of Hematology, Kyoto University Hospital using product manufactured by CiRA_F.

Support for the clinical trial

The practical application of human iPS cell-derived HLA homozygous platelets will be implemented with the support of the 5th Cyclic Innovation for Clinical Empowerment (CiCLE) program of Japan Agency for Medical Research and Development (AMED).

Notes

・Megakaryon Corporation

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President: Kenichi Akamatsu
URL：http://www.megakaryon.com/
Megakaryon Corporation was established in 2011 with the aim of utilizing technologies invented by Professor Koji Eto and others 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.

・Human iPS-derived platelets

Human iPS cell-derived platelets are produced by maturing megakaryocytes cultured from a master cell bank (MCB). MCB is made from cryopreservable immortalized megakaryocyte precursor cells obtained by introducing three genes into hematopoietic precursor cells differentiated from human iPS cells.

・Platelets, Thrombocytopenia

Platelets, also known as thrombocytes, are major blood components that play a crucial role in hemostasis. Upon endothelial damage, platelets are activated leading to adhesion and aggregation at the wound site, thereby stopping bleeding.
Thrombocytopenia is a condition in which the number of platelets in the blood is low. If the platelet count drops below a certain level or if there is a high risk of bleeding, treatment with blood transfusion platelet preparations is given.

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