

New organizational framework for iPSC clinical research

June 8, 2016– The RIKEN Center for Developmental Biology (CDB) concluded an agreement with the Kobe City Medical Center General Hospital, Osaka University's Graduate School of Medicine/ Faculty of Medicine, and Kyoto University's Center for iPS Cell Research and Application (CiRA) on May 30, toward the launch of a new clinical research project aimed at establishing an induced pluripotent stem cell (iPSC)-based treatment for wet-type age-related macular degeneration. Masayo Takahashi, project leader of the CDB's Laboratory for Retinal Regeneration and representatives of the other signing institutions held a joint press conference announcing the new organizational framework on June 6, at the Kobe City Medical Center General Hospital, which will be the leading institution for the clinical research in planning.



The new clinical research project will continue to target the eye disease wet-type age-related macular degeneration, which primarily affects the elderly. Under the new partnership, Kyoto University's CiRA will take on the role of establishing autologous and allogeneic iPSC lines, RIKEN CDB will be responsible for the generation of retinal pigment epithelial (RPE) cells that will be used for transplantation from iPSCs, and the Kobe City Medical Center General Hospital and Osaka University Hospital will perform the transplantations. Whereas in the previous clinical study, an RPE cell sheet generated from patient-derived (autologous) iPSCs was transplanted into the patient, this time the team is planning to generate RPE cells from iPSCs derived from HLA matched donors (allogeneic) for transplantation, and will also consider transplanting RPE cells either as cell suspensions or a cell sheet depending on the recruited patient.

Their new clinical research proposal will need to be submitted for review and approval by the Kobe City Medical Center General Hospital's Institutional Review Board (IRB), the Osaka University's Certified Committee for Regenerative Medicine, and finally the Japanese Ministry of Health, Labour and Welfare before the project receives the green light.

"I am very happy that four institutions will be involved, and feel greatly encouraged (by the partnership)," stated Takahashi at the press conference.

In a written message to the media, CDB Director Hiroshi Hamada commented, "I am pleased about the signing of this agreement, and the RIKEN CDB intends to fully support this clinical research."