



November 25, 2015

Foundation for Biomedical Research and Innovation

RIKEN

Kobe City Medical Center General Hospital

Termination of subject enrollment for the “Clinical study of autologous induced pluripotent stem cell-derived retinal pigment epithelium (RPE) cell sheets for exudative age-related macular degeneration (AMD)”

In accordance with Japan’s Ministry of Health, Labour and Welfare notice on the “Guidelines on clinical research using human stem cells (hereafter referred to as ‘Guidelines’),” the above-mentioned study began recruiting subjects in August 2013, and the first transplant was conducted in September 2014. The study initially planned to conduct transplants in six subjects; however, the Act on the Safety of Regenerative Medicine came into effect in November 2014, and the one-year grace period to conduct the clinical study under the Guidelines ended November 24, 2015. Thus, the enrollment of subjects for this study, which is conducted jointly between the Foundation for Biomedical Research and Innovation (FBRI), RIKEN, and Kobe City Medical Center General Hospital has been terminated. The progress of the first subject who received the transplant has been good (see Oct. 2, 2015 press release), and the subject will continue to be monitored.

The execution of future clinical studies are being deliberated among the relevant institutions.