



May 25, 2023

Sumitomo Pharma Co., Ltd. HEALIOS K.K.

Submission of clinical trial notification for RPE tear using RPE cells derived from allogeneic iPS cells (HLCR011)

Sumitomo Pharma Co., Ltd. (Head Office: Osaka; Representative Director, President and CEO: Hiroshi Nomura; hereinafter, "Sumitomo Pharma") and HEALIOS K.K. (Head Office: Chiyoda-ku, Tokyo; Chairman and CEO; Hardy TS Kagimoto; hereinafter, "Healios") announced today that Sumitomo Pharma has submitted to the Pharmaceuticals and Medical Devices Agency (PMDA) a clinical trial notification for a phase 1/2 study in patients with retinal pigment epithelium (RPE) tear regarding a treatment using retinal pigment epithelial (RPE) cells (development code: HLCR011) derived from allogeneic iPS cells which is being co-developed in Japan. This clinical trial is scheduled to start after a 30-day review period.

Sumitomo Pharma and Healios will promote this clinical trial with the aim of commercializing the treatment using RPE cells derived from allogeneic iPS cells and confirming its efficacy and safety at an early stage, in order to bring the treatment to patients as soon as possible.

Reference

About Retinal pigment epithelium (RPE) tear

RPE tear is a condition in which the RPE cell layer is torn, contracted, and partially defective due to age-related macular degeneration (AMD) or other causes. It causes visual field defects and vision loss, but currently no treatment for this condition has been established. If RPE cells are missing but photoreceptor function is preserved, RPE cell transplantation can be expected to maintain or restore visual function.

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