June 23, 2023

Company Name: HEALIOS K.K.
Representative: Hardy TS Kagimoto, Chairman & CEO
(TSE Growth Code: 4593)
Contact: Richard Kincaid, Executive Officer CFO
(TEL: 03-4590-8009)

Start of phase 1/2 study in RPE tear using RPE cells derived from allogeneic iPS cells (HLCR011)

HEALIOS K.K. ("Healios") is developing a treatment with Sumitomo Pharma Co., Ltd. (hereinafter "Sumitomo Pharma") utilizing retinal pigment epithelial (RPE) cells[*1] derived from allogeneic iPS cells (development code: HLCR011). We are pleased to announce that after the completion of the 30-day review by the Pharmaceuticals and Medical Devices Agency (PMDA) regarding the protocol of the phase 1/2 study in patients with RPE tear[*2] (hereinafter referred to as "the clinical study"), the preparation of the clinical study has been completed and the study is being initiated.

Outline of the clinical study

Test product	HLCR011: iPS cell-derived retinal pigment epithelial (RPE) cells suspension
Development stage	Phase 1/2
Subjects	Patients with retinal pigment epithelium tear
Design for the clinical study (target number of cases)	Part 1: Unmasked, uncontrolled (one HLA-mismatched subject) Part 2: Unmasked, randomized (treatment/observation groups, 10 subjects/group, total 20 subjects)
Primary endpoint	Safety of subretinal administration of HLCR011 in patients with retinal pigment epithelium tear (number and ratio of subjects with observed adverse events)
Secondary endpoint (efficacy)	Visual function evaluation

The clinical study is a multicenter, unmasked, randomized study. Sumitomo Pharma is now selecting clinical study sites. Subjects will be enrolled immediately after the completion of the preparation, including conclusion of contracts with the clinical study sites.

Press Release by Sumitomo Pharma
"Start of Phase 1/2 Study of Allogeneic iPS Cell-Derived Retinal Pigment Epithelial Cells"

Sumitomo Pharma and Healios will promote this clinical study 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.

There is no confirmed impact of this matter on our business performance for the fiscal year ending December 31, 2023 at this time. We will promptly announce any matters that should be disclosed in the future.

*1 Retinal pigment epithelial (RPE) cells
RPE cells form the retinal pigment epithelium outside the neural retinal layer. RPE cells come into contact with photoreceptors, and exert physiological functions to maintain and protect the functions of the photoreceptors. Since RPE cells with a single-layer structure do not regenerate, visual functions will be permanently impaired if they are damaged. Therefore, RPE cells have recently attracted attention in the research of regenerative medicine for compensating for a loss or dysfunction due to age-related macular degeneration.

*2 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.