August 5, 2024

Company Name:	HEALIOS K.K.
Representative:	Hardy TS Kagimoto, Chairman & CEO (TSE Growth Code: 4593)
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First Patient Enrolled in Clinical Study for RPE Tears Using RPE Cells Derived from Allogeneic iPS Cells (HLCR011)

HEALIOS K.K. ("Healios") is developing a treatment using retinal pigment epithelial (RPE) cells[*1] (development code: HLCR011) derived from allogeneic iPS cells with Sumitomo Pharma Co., Ltd. (hereinafter "Sumitomo Pharma"). We are pleased to announce that Sumitomo Pharma has enrolled the first subject in part 1 of the phase 1/2 study in patients with RPE tear[*2] (hereinafter the "clinical study") at Kyushu University Hospital (Principal Investigator: Prof. Kohei Sonoda, Department of Ophthalmology). If no safety issues are observed after a certain period of follow-up, we plan to move on to the part 2 randomized phase of the study.

Please refer to the press release "Start of phase 1/2 study in RPE tear using RPE cells derived from allogeneic iPS cells (HLCR011)" we issued on June 23, 2023 for an overview of the clinical study.

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.

Press Release by Sumitomo Pharma announced on August 5, 2024
"First Transplantation in Phase 1/2 Study of Allogeneic iPS Cell-Derived Retinal Pigment Epithelial Cells"

There is no confirmed impact of this matter on our business performance for the fiscal year ending December 31, 2024 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 is a single-layer structure that comes into contact with photoreceptors and exert physiological functions to maintain and protect the functions of the photoreceptors. Dysfunction or deficiency of RPE cells induce diseases such as age-related macular degeneration and RPE tear, leading to

impairment or decline in visual function. Therefore, therapies that transplant stem cell derived RPE cells have garnered attention in the field of regenerative medicine.

*2 Retinal pigment epithelium (RPE) tear
An 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.