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Healios and NEI enter into the Collaborative Research and Development Agreement

HEALIOS K.K. (“Healios”) today announces that it has executed the Collaborative Research and Development Agreement (“CRADA”) with the National Eye Institute (NEI), an institute of the National Institutes of Health (NIH) in the United States. The scope of this collaboration is the development of an allogeneic induced pluripotent stem cell (iPSC)-derived retinal pigment epithelium (RPE) cell therapy for age-related macular degeneration.

*NEI leads the federal government's research on the visual system and eye diseases. NEI supports basic and clinical science programs that result in the development of sight-saving treatments. (For more information, visit <http://www.nei.nih.gov>.)

NEI Principal Investigator for this CRADA, Dr. Kapil Bharti and his laboratory, have expertise in the preparation of iPSC lines, manufacturing of clinically relevant, transplantable, fully polarized, and functionally validated intact RPE monolayers on biodegradable scaffolds.

Healios has recently established allogeneic iPSC master cell banks (MCBs) that are expected to be applicable for global clinical use.

The primary goal of the CRADA is to prepare an RPE cell sheet that is derived from Healios’ allogeneic iPSC MCB with NEI’s RPE differentiation protocols and, further, to evaluate its characteristics as a therapy for age-related macular degeneration. Healios will provide support for this CRADA, the costs of which will be charged in FY2018. The total term of the CRADA is two years. Based on the results obtained, Healios will consider the implementation of clinical trials in the United States.

In Japan, Healios is developing a new therapy for age-related macular degeneration using Allogeneic iPSC-derived RPE cell suspension under the joint research and development with Sumitomo Dainippon Pharma Co., Ltd. An allogeneic iPSC line is provided from the Center for iPS Cell Research and Application, Kyoto University (CiRA) as raw material for domestic RPE development.

<Outlook>

Healios considers that a proper and reasonable forecast is difficult because there can be several pending plans that may influence our financial situation, such as business collaborations, etc. Therefore Healios does not disclose a forecast for the current term or the full financial year. Instead, we will disclose financial results and a summary of our business each quarter in a timely manner.

If matters to be disclosed arise in the future, Healios will promptly make relevant announcements.