

December 1, 2022

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(TSE Growth Code: 4593)  
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## **Provision of Universal Donor Cells to Sumitomo Pharma**

HEALIOS K.K. (“Healios”) announces that Healios and Sumitomo Pharma Co., Ltd. (Head office: Chuo-ku, Osaka; President and CEO: Hiroshi Nomura; hereinafter referred to as "Sumitomo Pharma") have agreed and decided that Healios will provide its universal donor cells\*<sup>1</sup> (hereinafter referred to as "UDCs") to Sumitomo Pharma for research to study the potential use of the UDCs in Sumitomo Pharma's business.\*<sup>2</sup>

Healios has been conducting research and development of UDCs as next-generation iPSCs that use gene editing technology to reduce the risk of immune rejection regardless of HLA type. Utilizing UDCs, we aim to establish a next-generation technology platform for the development of regenerative medicine products with enhanced efficacy and safety by suppressing rejection through iPS cells that are less likely to be recognized by the patient's immune cells. In 2020, [the clinical grade UDC line and master cell bank were established](#), and research is underway for specific clinical applications, including confirmation of the ability of UDCs to differentiate into various cell types and in relation to the hypo-immune profile of those cells. In addition to Healios’ own research, we have also provided our UDCs to domestic and overseas companies and research institutions for evaluation of various potential cell types to address different diseases.

Using the UDCs provided by Healios, Sumitomo Pharma plans to conduct research to study the potential use of the UDCs in three areas, including the ophthalmology area.

Under the mission of "Life Explosion", Healios is using stem cell technologies to research and develop new treatment methods in various fields in order to deliver healing and hope to people suffering from intractable diseases. As our lead engineered iPS cell asset, we are currently developing next-generation iPS cell-derived NK cells (eNK® cells) that are functionally enhanced to be highly effective in the treatment of solid tumors. In addition, we have conducted clinical trials in Japan on acute ischemic stroke and acute respiratory distress syndrome (ARDS) using a somatic stem cell regenerative medicine product. Among other programs we are advancing, we are developing iPS cell-derived RPE cells in collaboration with Sumitomo Pharma\*<sup>3</sup>, and will enhance our pipeline by utilizing our proprietary UDC-based iPSC platform.

This agreement derives the payment of consideration, but the impact of this matter on our consolidated financial results is expected to be immaterial. We will promptly make an announcement on any matter that requires disclosure in the future.

\*1 UDCs

UDCs are iPS cells created using gene-editing technology that allows them to avoid and / or

reduce the body's immune rejection response. The production of Healios' UDCs involve the removal of certain HLA genes that elicit a rejection response, the introduction of an immunosuppression gene to improve immune evasion, and the addition of a suicide gene serving as a safety mechanism, each in an allogeneic iPS cell. This next-generation technology platform allows for the creation of regenerative medicine products with enhanced safety and a lower risk of immune rejection, while preserving the inherent ability of iPS cells to replicate themselves continuously and their pluripotency in differentiating into various other kinds of cells.

\*2 We have entered into a material transfer agreement with Sumitomo Pharma for the provision and handling of UDC.

\*3 Joint research agreement with Sumitomo Pharma

In December 2013, we reached an agreement with Sumitomo Dainippon Pharma Co., Ltd. (currently Sumitomo Pharma Co., Ltd.) to collaborate exclusively in the Japan region to advance the development of therapies using iPS cell-derived RPE cells for age-related macular degeneration and other eye diseases. As a result of considering the effectiveness of our resource allocation amid the subsequent need for a long-term development structure, the co-development structure was changed in June 2019, and preparations for the start of clinical trials are currently underway, with Sumitomo Pharma taking the lead.

["Announcement of Changes in Joint Development Framework in Japan for the Treatment using iPSC-derived RPE cells"](#), announced on June 13, 2019

#### **About Healios:**

Healios is Japan's leading clinical stage biotechnology company harnessing the potential of stem cells for regenerative medicine. It aims to offer new therapies for patients suffering from diseases without effective treatment options. Healios is a pioneer in the development of regenerative medicines in Japan, where it has established a proprietary, gene-edited "universal donor" induced pluripotent stem cell (iPSC) line to develop next generation regenerative treatments in immuno-oncology, ophthalmology, liver diseases, and other areas of severe unmet medical need. Healios' lead iPSC-derived cell therapy candidate, HLCN061, is a next generation NK cell treatment for solid tumors that has been functionally enhanced through gene editing. Its near-term pipeline includes the somatic stem cell product HLCM051, which has been evaluated in Japan in Phase 2/3 and Phase 2 trials in ischemic stroke and acute respiratory distress syndrome (ARDS), respectively. Healios was established in 2011 and has been listed on the Tokyo Stock Exchange since 2015 (TSE Growth: 4593).

<https://www.healios.co.jp/en>