June 12, 2022

Company Name: HEALIOS K.K.
Representative: Hardy TS Kagimoto,
Chairman & CEO
(TSE Growth Code: 4593)

Exercise of Exclusive Option for a License Agreement with STEMAXON for the Development of UDC-Derived Photoreceptor Cells

HEALIOS K.K. (“Healios”) announces that it has exercised option rights and entered into exclusive negotiations with STEMAXON (Head office: Montreal, Canada; CEO: Gilbert Bernier, PhD; hereinafter referred to as "StemAxon"), a Canadian bio-venture company, in relation to a license agreement for technology to differentiate stem cells, including iPS cells, into photoreceptor cells.

The goal of this alliance between StemAxon and Healios is the commercialization of Universal Donor Cell (“UDC”)*[1] derived cone photoreceptors to be used in the treatment of macular degeneration and related retinal diseases, a disease area of severe unmet medical need that affects millions of patients each year globally.

Healios has been conducting research and development of UDC derived allogeneic iPS cells that enable suppression of immune rejection using gene editing technology, and has been conducting joint research*[2] with StemAxon for the establishment of a method to induce differentiation of UDC-based photoreceptor cells for retinal diseases. Following the confirmation of the visual functional recovery following the transplantation of UDC-derived photoreceptor cells in a large animal model, Healios exercised its option rights and entered exclusive negotiations in relation to exclusive worldwide licensing rights to StemAxon's intellectual property.

Photoreceptor cells are one of the cells that make up the retina and are particularly responsive to light, and in various retinal diseases their damage results in vision loss. The photoreceptor cells successfully produced by the two-dimensional mass culture combining StemAxon's and Healios’ technologies are color-sensing, cone cell-dominant, polarized photoreceptor cell sheets, and we have confirmed that there is little contamination of unnecessary cells such as bipolar cells, which can be an obstacle to improving visual acuity. It is expected to be used as a therapeutic agent for various retinal diseases in the future.

Under the mission of "Life Explosion", Healios is researching new treatment methods in various fields in order to deliver healing and hope to people suffering from intractable diseases with stem cell technology. We will utilize Helios' proprietary UDC-based iPSC platform to further enhance our pipeline and continue to partner with other pharmaceutical companies.

There is no payment associated with this exclusive negotiation and it has no impact on our consolidated financial results. 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 Joint research agreement with StemAxon
On November 24, 2017, we entered into an agreement with StemAxon, a company with technology for inducing differentiation of cone cell (color sensing cell) dominant photoreceptor cells, including a collaboration and the acquisition of an exclusive option on their intellectual property related to photoreceptor cell differentiation.

About StemAxon:
StemAxon is a Canadian biotechnology company located in Montreal that specializes in stem cell technology. The company's goal is to be a leader in drug development and disease modeling for sporadic Alzheimer's disease. StemAxon is also developing technology to differentiate iPS cells into photoreceptor cells for cell therapy applications. https://www.stemaxon.com/
Article:
Differentiation of human embryonic stem cells into cone photoreceptors through simultaneous inhibition of BMP, TGFβ and Wnt signaling

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

Contact:
Department of Corporate Communications, HEALIOS K.K.
E-mail: ir@healios.jp