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

Publication of JAMA Neurology Article on Clinical Trial for Ischemic Stroke in Japan

HEALIOS K.K. (“Healios”) conducted the TREASURE study*¹ to investigate the safety and efficacy of HLCM051*² (Multistem®) in patients with ischemic stroke. We are pleased to announce that an academic article on the results of this clinical trial has been published in the medical journal “JAMA Neurology*³”.

This article was compiled by Dr. Kiyohiro Houkin, President, Hokkaido University and Dr. Toshiya Osanai, Hokkaido University, Department of Neurosurgery, who are the coordinating physicians for the TREASURE study, and the results were obtained with the cooperation of 48 clinical sites, Data Safety Monitoring Committee, Image Evaluation Committee, etc. across Japan. The publication of the TREASURE study in a famous medical journal indicates that the trial has received a certain level of academic recognition for its potential in the treatment of stroke, and that further progress is being made toward the future commercialization of the new medicine.

With regard to the future direction of the ischemic stroke clinical trial using HLCM051, [Athersys Inc. has been conducting a clinical trial \(trial name: MASTERS-2 study\)](#) in the U.S. and Europe and completed the interim analysis of the clinical trial. Additional data analysis with independent statisticians will be conducted and Healios will await the results of this analysis before taking any further action.

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.

<Article>

Title: [Allogeneic Stem Cell Therapy for Acute Ischemic Stroke
-The Phase 2/3 TREASURE Randomized Clinical Trial-](#)

Journal: [JAMA Neurology](#)

DOI: 10.1001/jamaneurol.2023.5200

Please refer to [the press release from Hokkaido University Hospital](#) for more information.

***1 TREASURE study**

The TREASURE study was conducted to investigate the safety and efficacy of HLCM051 (Multistem®) in patients with ischemic stroke. The study targeted patients with moderate to moderate severe strokes (baseline NIHSS score 8-20), with administration of a single dose of HLCM051 intravenously within 18 to 36 hours from stroke onset. 48 medical institutions participated in the trial and 206 patients were administrated.

*2 HLCM051

HLCM051 is an off-the-shelf, somatic stem cell regenerative medicine product. Healios added it to its pipeline by signing an exclusive licensing agreement with the United States-based Athersys, Inc. (“Athersys”) in January 2016, whereby Healios acquired rights to develop and distribute Athersys’ proprietary stem cell product MultiStem® to treat ischemic stroke in Japan. Further, in June 2018, Healios and Athersys expanded their collaboration broadly, and as part of this expansion Healios acquired the development and distribution licenses to use MultiStem® to treat ARDS in Japan which is currently expanded to cover global territories.

*3 JAMA Neurology

JAMA Neurology is an international peer-reviewed journal for physicians caring for people with neurologic disorders and those interested in the structure and function of the normal and diseased nervous system. The Archives of Neurology & Psychiatry began publication in 1919 and, in 1959, became 2 separate journals: Archives of Neurology and Archives of General Psychiatry. In 2013, their names changed to JAMA Neurology and JAMA Psychiatry, respectively.

One measure of the relative influence a journal has within its field is its Impact Factor. JAMA Neurology has an extremely high Impact Factor of 29.9, indicating that articles published in the journal are highly regarded for their academic value.

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>

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