

August 28, 2023

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

Publication of Academic Article on Clinical Trial for ARDS in Japan

HEALIOS K.K. (“Healios”) is developing a treatment for patients with pneumonia induced ARDS*¹ (trial name: ONE BRIDGE) using HLCM051*², a somatic stem cell regenerative medicine. The efficacy and safety of the medicine have been confirmed to be favorable (Note 1). We are pleased to announce that an academic article on the results of this clinical trial has been published in the peer-reviewed journal “Stem Cell Research & Therapy”.

This article was compiled by Dr. Kazuya Ichikado, Director, Department of Respiratory Medicine, Saiseikai Kumamoto Hospital, and Dr. Satoru Hashimoto, President of the NPO ICON, who are the coordinating physicians for the ONE-BRIDGE study, and the results were obtained with the cooperation of 29 clinical sites across Japan. The publication of the ONE-BRIDGE trial in a peer-reviewed journal indicates that the trial has received a certain level of academic recognition, and that further progress is being made toward the future commercialization of the new medicine.

With regard to the future direction of the ARDS clinical trial using HLCM051 for submission for approval, the Pharmaceuticals and Medical Devices Agency (PMDA) advised us that data reinforcement is required, and we have been in discussion to finalize the direction, including the design of an additional study. In March 2023, an agreement was reached on the outline of the clinical trial necessary to augment the data (Note 2), and preparations are currently underway to conduct the additional trial.

There is no confirmed impact of this matter on our business performance for the fiscal year ending December 31, 2023 at this time. We will promptly announce any matters that should be disclosed in the future.

<Article>

Title: [Clinical efficacy and safety of multipotent adult progenitor cells \(invimestrocel\) for acute respiratory distress syndrome \(ARDS\) caused by pneumonia: A randomized, open-label, standard therapy–controlled, phase 2 multicenter study \(ONE-BRIDGE\)](#)

Journal: [Stem Cell Research & Therapy](#)

DOI: 10.1186/s13287-023-03451-z

(Note 1)

[“ONE-BRIDGE Study: Results at 180 days post administration”](#)

See page 6, in FY2021 Q3 Financial Results (material)

[“Top Line Results of the ONE-BRIDGE Study in Patients with ARDS”](#)

Released in August 6, 2021

(Note2)

[“Next Clinical Trial for HLCM051 for ARDS”](#)

Released in March 2, 2023

*1 ARDS is a general term for the symptoms of acute respiratory failure suddenly occurring in seriously ill patients. The major causes are severe pneumonia, septicemia, trauma etc. Inflammatory cells are activated in response to these diseases or injuries, causing damage to the tissue of the lungs. As a result, water accumulates in the lungs, leading to acute respiratory failure. According to the ARDS treatment guideline 2016, the mortality rate is approximately 30 to 58%. The number of patients in Japan is estimated to be approximately 28,000 (Healios estimate based on epidemiological data on incidence and population statistics). Artificial respiration using an endotracheal tube or mask is used to treat respiratory failure in an intensive care unit.

*2 HLCM051 is a 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.

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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