

December 1, 2021

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

Data from Athersys' clinical trial evaluating MultiStem® cell therapy for ARDS published in *Intensive Care Medicine*

HEALIOS K.K. (“Healios”) is currently conducting two clinical trials in Japan using the somatic stem cell regenerative medicine product Multistem (HLCM051) – the TREASURE study for patients with ischemic stroke, which completed enrolment in August 2021, and the ONE-BRIDGE study for patients with acute respiratory distress syndrome (ARDS)*, for which we announced positive top line results in August 2021. Healios has entered into an exclusive license agreement with the United States based Athersys (“Athersys”) for the development, sale and manufacturing of Multistem for ischemic stroke and ARDS in Japan

Healios is pleased to report that data from Athersys' MUST-ARDS clinical trial for ARDS patients has been published in the peer-reviewed journal *Intensive Care Medicine*. MUST-ARDS was a randomized, double-blind placebo-controlled Phase 1/2 trial evaluating the safety and efficacy of MultiStem cell therapy in patients with ARDS in the United States and the United Kingdom. The results showed that the therapy was well-tolerated and support potential benefits in mortality, ventilator-free days, ICU-free days and quality of life outcomes. Mechanisms of action were further explored by comparing acute changes in plasma inflammatory and lung injury biomarkers in the cell treatment group through Day 7 and show their reduction.

For more details, please refer [Athersys' press release](#).

※ARDS

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%. Artificial respiration using an endotracheal tube or mask is used to treat respiratory failure in an intensive care unit.

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. Its near-term pipeline includes the somatic stem cell product HLCM051, which is currently being 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 Mothers: 4593). <https://www.healios.co.jp/en> .

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