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

One-Year Study Data from Athersys' Acute Respiratory Distress Syndrome Clinical Trial

HEALIOS K.K. ("Healios") is developing new treatments for Acute Respiratory Distress Syndrome (ARDS)[*1] and Ischemic Stroke in Japan using the stem cell product HLCM051 (MultiStem®) [*2], which it has licensed in from the United States based Athersys, Inc ("Athersys"). Healios is currently enrolling patients in a Phase 2 clinical study in Japan to confirm the safety and efficacy of MultiStem in pneumonia induced ARDS patients (the ONE-BRIDGE study[*3]).

In January 2019, Athersys announced positive results evaluated through 28 days from its exploratory Phase 1/2 clinical study in the United States and United Kingdom, named the MUST-ARDS study, investigating the use of MultiStem for patients suffering from ARDS. Dr. Geoff Bellingan, a principal investigator of the MUST-ARDS study, subsequently presented at the American Thoracic Society International Conference held in May 2019 and explained that subjects who had received MultiStem treatment exhibited different biomarker results in terms of inflammatory markers/cytokines from subjects who had not, which provided deeper insights into the consistent immunomodulatory effects of MultiStem.

On January 14, 2020, Athersys announced the one-year follow-up summary results of the MUST-ARDS study. Participants in the MUST-ARDS study were evaluated through 28 days for the primary clinical assessment and further assessed through a one-year follow-up period. The one-year results were consistent with the positive day-28 results announced last year, and an evaluation of quality-of-life[*4] over the one-year period suggests further potential benefits from MultiStem treatment that realizes faster rehabilitation. Related to medical safety, no serious adverse events were observed.

For more details, please refer Athersys' press release:
https://www.athersys.com/investors/press-releases/press-release-details/2020/Athersys-Provides-Update-on-One-Year-ARDS-Study-Data/

*1. Acute Respiratory Distress Syndrome (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. However, it is known that prolonged use of a ventilator worsens a patient's prognosis. There is demand for a new treatment for ARDS that will lead to improvement in patients' symptoms and prognosis.

*2. HLCM051
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 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.

*3. ONE-BRIDGE study
Healios is conducting the ONE-BRIDGE study in Japan using MultiStem for patients suffering from pneumonia-induced ARDS, and its primary endpoint is the number of ventilator-free days (VFD) within a 28-day post-administration period. In November 2019, the Ministry of Health, Labour and Welfare officially designated HLCM051 as an orphan regenerative medicine for ARDS.

*4. Quality-of-life
The level of satisfaction and comfort that a person or group enjoys (Source: Cambridge Dictionary).

Contact:
Department of Corporate Communications, HEALIOS K.K.
Mail: ir@healios.jp