March 26, 2020

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

Regarding HLCM051 for Acute Respiratory Distress Syndrome (ARDS) caused by COVID -19

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®). Healios continues to make enrolment progress in its Phase 2 clinical study in Japan to confirm the safety and efficacy of HLCM051 in pneumonia-induced ARDS patients (the ONE-BRIDGE study).

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 data published on the initial group of cases of the new coronavirus (COVID-19) in Wuhan, 31 to 41.8% of hospitalized patients developed ARDS and 54 to 93% of these patients died[※1][※2], indicating that ARDS is a major cause of mortality in COVID-19 patients.

※1 Zhou F, et al. Lancet. 2020 Mar 11. pii: S0140-6736(20)30566-3

※2 Wu C , et al. JAMA Intern Med. 2020 Mar 13. doi: 10.1001

(Note) As the above two reports studied the initial group of patients, the incidence rate and mortality of ARDS patients is expected to fluctuate depending on the current situation in each country.

In Healios' ONE-BRIDGE study, the current inclusion criteria provide that patients who develop pneumonia-induced ARDS caused by COVID -19 are eligible for enrolment. We are currently in discussions with medical specialists and the Pharmaceuticals and Medical Devices Agency (PMDA) regarding how to move forward with COVID-19 patients in relation to our clinical trial.

Healios has received inquiries from various stakeholders regarding this important subject and is therefore announcing the current situation. We will promptly disclose any additional information as required.

On March 16 (local time), Athersys, Inc., our partner company based in the United States, announced that Multistem was designated by the Biomedical Advanced Research and Development Authority (BARDA) [※3] as "Highly Relevant" for development as a therapeutic agent in relation to COVID-19 induced ARDS.

※3 BARDA is a division of the United States Department of Health and Human Services that deals primarily with bioterrorism, the threat of chemical weapons and radiation, pandemic influenza and emerging diseases.

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