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First COVID-19 Induced ARDS Patient Enrolled in HEALIOS ONE-BRIDGE study

HEALIOS K.K. ("Healios") today announces that the first COVID-19 Induced Acute Respiratory Distress Syndrome (ARDS) [*1] patient has been enrolled in its ONE-BRIDGE clinical trial testing the safety and efficacy of adult stem cell regenerative medicine HLCM051[*2] in patients with pneumonia-induced ARDS in Japan.

As announced on April 13, 2020, Healios decided to add a new cohort to its ONE-BRIDGE study for which it will recruit an additional approximately five pneumonia-induced ARDS patients with COVID-19 as the causative disease and investigate the safety of the therapy in these patients. Regarding the overview of the trial, please refer to our company's press release on April 13, 2020. Healios will assess the results of the approximately five newly added COVID-19 Induced ARDS cases separately from the 30 originally planned ONE-BRIDGE patients.

If matters to be disclosed arise in the future regarding the effect on fiscal year 2020 financial performance, Healios will make an announcement without delay.

*1 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.

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 ARDS complications were confirmed in 54 to 93% of fatal cases※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.

*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, 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.