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Full Enrolment of COVID-19 Induced ARDS Patient Cohort in ONE-BRIDGE study of HLCM051 for the Treatment of ARDS in Japan

HEALIOS K.K. ("Healios") today announces that it has fully enrolled the planned five patients in the COVID-19 induced Acute Respiratory Distress Syndrome (ARDS) [*1] cohort of its ONE-BRIDGE clinical trial of HLCM051[*2] to treat ARDS in Japan.

The group of five pneumonia-induced ARDS patients with COVID-19 was newly added to the ONE-BRIDGE study to test the safety of the treatment in patients with COVID-19 induced ARDS and the first patient was enrolled on July 29, 2020. The enrolment of these five patients was conducted separately from the original cohort of 30 ARDS patients. We continue to enroll patients in the 30 patient pneumonia induced ARDS cohort and expect to complete enrolment in the fourth quarter of this year. Regarding the overview of the trial, please refer to our company's press release on April 13, 2020.

Healios will decide further steps after conducting the safety assessment and discussing with medical specialists and relevant authorities.

"Amid the rapid increase in the number of patients in Japan with the novel coronavirus, and with the strong support of the physicians and other healthcare professionals involved, we were able to rapidly complete enrolment of the COVID-19 cohort of our trial. We are working to complete the ONE-BRIDGE study in consultation with relevant authorities so that this important medicine for ARDS can be delivered to patients as soon as possible," commented Hardy TS Kagimoto, MD, Chairman and CEO of Healios.

If matters to be disclosed arise in the future that would impact 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.