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## **Full Enrolment of ONE-BRIDGE Study for Patients with ARDS**

HEALIOS K.K. (“Healios”) announces that it has fully enrolled the planned patients in its ONE-BRIDGE study for Acute Respiratory Distress Syndrome (ARDS)<sup>\*1</sup>, the clinical trial to test the safety and efficacy of HLCM051<sup>\*2</sup> in ARDS in Japan.

ONE-BRIDGE is an open-label study, the main cohort of which treated pneumonia induced ARDS patients with either HLCM051 or standard therapy. Regarding the overview of the trial, please refer to our company’s press release on [April 22, 2019](#).

In addition to the main cohort, a second cohort was established to test the safety of HLCM051 in COVID-19 induced ARDS patients. Its enrolment was completed in August, 2020. For more information regarding the second cohort, please refer to our company’s press release on [April 13, 2020](#) and [August 12, 2020](#).

Going forward, we plan to analyze and evaluate the data after a follow-up period of patient enrolment.

If matters to be disclosed arise in the future that would impact fiscal year 2021 financial performance, Healios will make an announcement without delay.

### **\*<sup>1</sup> 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.

### **\*<sup>2</sup> 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<sup>®</sup> 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.