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(TSE Mothers Code: 4593)

COVID-19 Induced Acute Respiratory Distress Syndrome Announcement by Athersys of Authorization in the United States to Initiate a Phase II/III 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 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) and, as recently announced, it has established [a new cohort in the ONE-BRIDGE study](#) to include COVID-19 induced ARDS patients.

On April 13, 2020, Athersys announced that it has been authorized by the U.S. Food and Drug Administration (FDA) to initiate a phase II/III clinical trial evaluating the safety and efficacy of Multistem for the treatment of COVID-19 induced ARDS patients in the United States.

An announcement from Athersys can be found at the following link:

<https://www.athersys.com/investors/press-releases/press-release-details/2020/FDA-Authorizes-WAthersys-to-Initiate-a-Pivotal-Clinical-Trial-Evaluating-MultiStem-Cell-Therapy-in-Patients-With-COVID-19-Induced-Acute-Respiratory-Distress-Syndrome/default.aspx>

***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.

***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.

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