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## **Healios Announces Plans to Initiate a Clinical Trial of Somatic Stem Cell Regenerative Medicine HLCM051 in patients with ARDS in Japan**

HEALIOS K.K. (“Healios”) announces that it has submitted a clinical trial notification in relation to somatic stem cell regenerative medicine product HLCM051\*<sup>1</sup> for patients with Acute Respiratory Distress Syndrome (ARDS) \*<sup>2</sup> to Japan's Pharmaceuticals and Medical Devices Agency (PMDA).

This clinical trial investigates the efficacy and safety of HLCM051 for patients with pneumonia induced ARDS. The trial will be conducted under non-blind conditions using a standard therapy as a control.

The overview of the trial is as follows:

Trial conditions	Open-label trial Standard therapy used as a control
Subjects	Patients with pneumonia induced ARDS
Enrollment	30
Primary endpoint	The number of days out of 28 in which a ventilator was not used for the patient (i.e. ventilator free days)
Study period	Approximately 2 years

Healios has started all necessary procedures, including the examinations by the Institutional Review Board of each medical institution where the trial will be conducted. Based on current information, we anticipate beginning to administer HLCM051 to patients with ARDS in the first half of 2019.

\*1. 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<sup>®</sup> to treat ARDS in Japan.

## \*2. Acute Respiratory Distress Syndrome (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 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. However, it is known that prolonged use of a ventilator worsens a patient's prognosis. There is demand for a new treatment for ARDS that will lead to improvement in patients' symptoms and prognosis.