

April 22, 2019

Company Name: HEALIOS K.K.  
Representative: Hardy TS Kagimoto,  
Chairman & CEO  
(TSE Mothers Code: 4593)  
Contact: Masanori Sawada  
Executive officer CMO in charge of administration  
(TEL: 03-5777-8308)

**First Patient is Enrolled  
in a Clinical Trial of Adult Stem Cell Regenerative Medicine HLCM051  
in Patients with Acute Respiratory Distress Syndrome in Japan  
(ONE-BRIDGE study)**

HEALIOS K.K. (“Healios”) today announces that the first patient has been enrolled in a clinical trial of adult stem cell regenerative medicine HLCM051<sup>\*1</sup> in patients with Acute Respiratory Distress Syndrome (ARDS)<sup>\*2</sup> in Japan, named ONE-BRIDGE study.

The ONE-BRIDGE study is designed to confirm the efficacy and safety for patients with pneumonia induced ARDS. The trial is conducted under non-blind conditions using a standard therapy as a control. The overview of the trial is as follows:

Trial conditions	Open-label Randomized Standard therapy used as a control
Subjects	Patients with pneumonia induced ARDS
Enrollment	30 (HLCM051: 20, Standard therapy: 10)
Primary endpoint	The number of days out of 28 in which a ventilator was not used for the patient (i.e. ventilator free days)

If matters to be disclosed arise in the future regarding the effect on fiscal year 2019 financial performance, Healios will make an announcement without delay.

**\*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 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.