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Company Name: HEALIOS K.K.  
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Chairman & CEO  
(TSE Mothers Code: 4593)

## **Athersys Announces Fast Track Designation from FDA for MultiStem® Program for Acute Respiratory Distress Syndrome**

HEALIOS K.K. (“Healios”) is developing a new treatment for Acute Respiratory Distress Syndrome (ARDS) <sup>\*1</sup> in Japan using the stem cell product HLCM051 (MultiStem®) <sup>\*2</sup>, for which the patent and licensing rights are held by Athersys, Inc. (“Athersys”).

We are delighted to announce that Athersys announced that its clinical program evaluating MultiStem® cell therapy for the treatment of Acute Respiratory Distress Syndrome (“ARDS”) has received Fast Track designation from the United States Food and Drug Administration (“FDA”).

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

<https://www.athersys.com/investors/press-releases/press-release-details/2019/Athersys-Announces-Fast-Track-Designation-From-FDA-for-MultiStem-Program-for-Acute-Respiratory-Distress-Syndrome/default.aspx>

### About Fast Track Designation

Fast Track is a process designed by the FDA to facilitate the development and expedite the review of drugs that have the potential to treat serious conditions and address recognized areas of unmet medical need. The purpose is to help speed development of new drugs that are evaluated to be safe and effective, making them available to the patient earlier. For more information on the Fast Track process, please visit:

<https://www.fda.gov/ForPatients/Approvals/Fast/ucm405399.htm>

### \*1. 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.

\*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 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.

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