April 4, 2025

Company Name: HEALIOS K.K.
Representative: Hardy TS Kagimoto, Chairman & CEO
(TSE Growth Code: 4593)

Sarah Busch, PhD, appointed as CSO of Healios NA, Inc.

HEALIOS K.K. ("Healios") is pleased to announce the appointment of Sarah Busch, PhD as the Chief Scientific Officer (CSO) of its United States based subsidiary, Healios NA, Inc., effective April 1, 2025.

1. Background of the appointment

Dr. Busch is a neuroscientist with extensive expertise in translational science from early research and development through late-stage clinical trials. Dr. Busch was the Vice President of Regenerative Medicine and Head of Business Development at Athersys, Inc.*1. Over her 14-year tenure, she held various roles of increasing responsibility, and brings a wealth of direct experience with MultiStem®*2 (HLCM051) therapy.
Her appointment underscores Healios' commitment to scientific excellence as we advance HLCM051 for acute respiratory distress syndrome (ARDS*3) and other indications.
We welcome her to the team and look forward to the continued growth and success of Healios under her scientific leadership.

In making this appointment, Dr. Sarah Busch stated, "I am thrilled to join Healios at this pivotal time," and "The potential for HLCM051 and the REVIVE-ARDS study*4 to transform acute critical care is closer than ever. I look forward to working alongside the talented team at Healios to continue advancing the science and innovation that will result in meaningful benefit for patients."

2. Personal record

Name	Record
Sarah Busch, PhD	Dr. Busch holds a Bachelor of Science degree in Biology from Canisius University, with minors in Music, Neuroscience and Classics, and earned her PhD in Neurosciences from Case Western Reserve University in the laboratory of Dr. Jerry Silver focusing on neurological injury.

*1 Athersys, Inc.
U.S. biopharmaceutical company. In January 2016, Healios entered into an exclusive license agreement for the development and marketing of MultiStem, a stem cell product developed by Athersys, Inc., in Japan and introduced this pipeline. In April 2024, Healios acquired nearly all of the assets of Athersys, Inc. and became the owner of MultiStem and related assets (announced on April 4, 2024, "Healios Acquires Substantially All of the Assets of Athersys, Inc. Free and Clear of Liabilities, Becomes Sole Owner of MultiStem®")

*2 MultiStem®
MultiStem (HLCM051) is a somatic stem cell regenerative medicine product comprised of multipotent adult progenitor cells ("MAPCs") derived from the bone marrow of healthy adult donors. MultiStem has been shown to exhibit powerful anti-inflammatory and immunomodulatory properties with applicability in a range of disease states, has been tested in hundreds of patients in late stage clinical trials, is manufactured consistently at scale in 3D bioreactors, and has demonstrated both safety and suggested efficacy in hundreds of patients across multiple indications. MultiStem is a proprietary technology wholly owned by Healios. Healios has a long history developing MultiStem. It originally added MultiStem to its pipeline in 2016 through an exclusive license to develop and distribute the product to treat ischemic stroke in Japan. Further, in 2018 Healios expanded its license to include development and distribution to treat ARDS in Japan, and in 2023 it expanded its ARDS license to include global territories. Having acquired the full technology platform in April 2024, Healios is seeking to advance MultiStem on a global basis for ischemic stroke, ARDS, and trauma. In the U.S., MultiStem for the treatment of ischemic stroke and ARDS has received Fast Track and RMAT designation from the FDA, which allows for expedited approval of drugs that meet certain criteria for serious or life-threatening diseases or those for which no treatment is available.

*3 Acute Respiratory Distress Syndrome (ARDS)
ARDS is a general term for respiratory failure that occurs suddenly in a variety of critically ill patients. Although there are many causes of ARDS, approximately one-third of ARDS cases are caused by pneumonia, and it has been confirmed that ARDS also occurs in critically ill patients with COVID-19. There is currently no approved drug therapy that can directly improve the prognosis of patients with ARDS, and respiratory failure is treated with mechanical ventilation. The mortality rate after the onset of ARDS is 30~58%[*a], and there is a need for new therapies that can improve the prognosis of patients with ARDS. Currently, the number of patients in Japan is estimated to be approximately 28,000[*b] per year, and ARDS is designated as a rare disease. However, it is estimated that 262,000[*c] patients in the United States, 133,000[*d] in Europe, 670,000 in China, and more than 1.1 million people worldwide are affected annually[*e].
(Source)
*a ARDS Diagnostic Guidelines 2016
*b Healios Estimates Based on the Incidence Rate of Epidemiological Data and the Total Population of Japan by Demography
*c Diamond M et al. 2023 Feb 6. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2023 Jan–. PMID: Estimates for our company based on 28613773 Data and US Population Based on the Ministry of Foreign Affairs Basic Data
*d Community Research and Development Information Service (CORDIS) 2020 7-9.
*e song-et-al-2014-acute-respiratory-distress-syndrome-emergingresearch-in-china

*4 REVIVE-ARDS study
A pivotal, global Phase 3 study to demonstrate and confirm the efficacy and safety of MultiStem for ARDS caused by pneumonia, primarily in the United States. We held an End-of-Phase 2 consultation with the FDA (Food and Drug Administration) in September, 2024. As for the study design, we agreed with the FDA on the use of a primary endpoint based on VFD (Ventilator Free Days: the number of days a patient does not require mechanical ventilation out of 28 days post administration in REVIVE-ARDS study), which is consistent with that utilized in the ONE-BRIDGE study previously completed in Japan. Interim analyses will be conducted at the 300 and 400 patient stages, and the REVIVE-ARDS study can be completed when statistical significance is confirmed. The maximum number of patients is 550.

We also confirmed the framework for utilizing 3D investigational product in this study.

Contact:
IR & PR Division
HEALIOS K.K.
E-mail: ir@healios.jp