June 28, 2024

Company Name:	HEALIOS K.K.
Representative:	Hardy TS Kagimoto, Chairman & CEO (TSE Growth Code: 4593)
Contact:	Richard Kincaid, Executive Officer CFO (TEL: 03-4590-8009)

Extension of the Term of the Letter of Intent with Nobelpharma for the Development and Commercialization of MultiStem® for ARDS in Japan

HEALIOS K.K. ("Healios") today announces that Healios, its wholly owned subsidiary ProcellCure Inc. ("ProcellCure") and Nobelpharma Co., Ltd. ("Nobelpharma" https://www.nobelpharma.co.jp/en/) have extended the deadline for the scheduled date of conclusion of a definitive agreement under the letter of intent ("LOI") for a development and marketing alliance in Japan for MultiStem®*1 ("Alliance"), a somatic stem cell regenerative medicine therapy for the treatment of acute respiratory distress syndrome (ARDS)*2.

Extended deadline for the scheduled date of conclusion of the definitive agreement
Before extension: End of June, 2024
After extension: End of September, 2024

As announced in the April 4 press release titled "Healios Acquires Substantially All of the Assets of Athersys, Inc. Free and Clear of Liabilities, Becomes Sole Owner of MultiStem", Healios has acquired substantially all of the assets of Athersys, Inc.. As we build a business strategy to utilize the acquired assets, we are considering development in the global region, with a focus on the U.S. and plan to hold discussions with the Food and Drug Administration (FDA) during the third quarter, from July to September, of the fiscal year ending December 31, 2024 regarding the conduct of a global phase III clinical trial.

This agreement with Nobelpharma relates to a development and marketing alliance in Japan for the treatment of ARDS. However, since the development strategy including clinical trials in the U.S. will affect the development approval process in Japan, we are extending the period of time until the conclusion of this agreement in order to consider and establish the development strategy in Japan based on the details of the agreement with the FDA.

Future Outlook.
This matter has no impact on our consolidated financial results of the fiscal year ending December 31, 2024 at this time. We will promptly announce any matters that should be disclosed in the future.

Reference:
"Announcement of Letter of Intent with Nobelpharma for the Development and Commercialization of HLCM051 for ARDS in Japan", announced on December 27, 2023.

*1 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.

*2 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