October 7, 2025

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

Collaboration Between Minaris Advanced Therapies and Healios for the Commercial Manufacturing of Invimestrocel

HEALIOS K.K. ("Healios") announces that Healios and Minaris Advanced Therapies (Headquarters: Philadelphia, Pennsylvania, USA; hereinafter referred to as "Minaris") have established a collaborative framework for the commercial manufacturing of invimestrocel (HLCM051), Healios' proprietary investigational multipotent adult progenitor cell (MAPC) therapeutic product for use in the treatment of acute respiratory distress syndrome (ARDS*) and potentially other critical care indications currently under development by Healios. In conjunction with this, the two companies have entered into a manufacturing agreement (hereinafter referred to as the "Agreement") to produce invimestrocel for commercial use utilizing Healios' proprietary 3D bioreactor based manufacturing process.

Minaris is a leading global contract development and manufacturing organization (CDMO) and testing provider. Today Minaris and Healios have announced their entry into the Agreement under which the parties will utilize Healios' advanced, large scale bioreactor process for enhanced quality, scalability, and cost efficiency. The work taking place under the Agreement marks a significant milestone towards meaningfully advancing an allogeneic cell therapy for large markets and areas of unmet medical need.

Healios selected Minaris as its manufacturing partner based on Minaris' extensive experience and proven track record in cell therapy manufacturing, including their significant bioreactor expertise. The commercial manufacturing will take place at Minaris' Yokohama facility and preparations are already underway towards the commercial launch of the product for ARDS and potentially other critical care indications in Japan.

In addition to its work with Minaris, as announced in the "Notice of Selection for FY2024 Supplementary Budget: "Subsidy Program to Support Capital Investment in Regenerative, Cell, and Gene Therapy Manufacturing Facilities" by METI" on July 16, 2025, Healios aims to build infrastructure and create a commercial CDMO business capable of serving the global market.

Future Outlook

This matter has no impact on our consolidated financial results of the fiscal year ending December 31, 2025. We will promptly announce any matters that should be disclosed in the future.

* 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

About Minaris Advanced Therapies:

Minaris Advanced Therapies is a global contract development and manufacturing organization with a focus on cell and gene therapies and a contract testing provider. Minaris Advanced Therapies is headquartered in Philadelphia, Pennsylvania, and has more than 600,000 square feet of infrastructure across the United States, Europe and Asia. The organization has manufactured over 7,500 GMP batches and has a global network that supports therapy developers through early-stage development, clinical trials and commercial manufacturing. Visit www.minaris.com.

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About Healios:

HEALIOS K.K. is Japan's leading clinical stage biotechnology company harnessing the potential of stem cells for regenerative medicine. It aims to offer new therapies for patients suffering from diseases without effective treatment options. Healios is a pioneer in the development of regenerative medicines in Japan and owns proprietary, global platforms utilizing both somatic stem cells and iPS cells.

In the somatic stem cell field, Healios is developing invimestrocel (HLCM051), a proprietary cell product comprised of multipotent adult progenitor cells ("MAPCs") derived from the bone marrow of healthy adult donors. Invimestrocel 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. Healios is seeking to advance invimestrocel on a global basis for ischemic stroke, ARDS, and trauma.

In the iPSC regenerative medicine field, Healios is developing HLCN061, a next generation NK cell treatment for solid tumors that has been functionally enhanced through gene-editing. These cells have demonstrated robust anti-tumor efficacy in animal models, benefit from a scalable 3D bioreactor manufacturing process, and are currently being prepared for initial

human testing in collaboration with Akatsuki Therapeutics. The company has also established a proprietary, gene-edited “universal donor” induced pluripotent stem cell line to develop next generation regenerative treatments in immuno-oncology, ophthalmology, liver diseases, and other areas of severe unmet medical need.

Healios was established in 2011 and has been listed on the Tokyo Stock Exchange since 2015 (TSE Growth: 4593). https://www.healios.co.jp/en

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