

October 19, 2023

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(TSE Growth Code: 4593)
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Statement regarding delisting announced by Athersys

Athersys, Inc. of the United States (“Athersys”), with which HEALIOS K.K. (“Healios”) has an exclusive license agreement for the development, manufacture and marketing of cell therapy drug HL051 for global territories in Acute Respiratory Distress Syndrome (ARDS) and in Japan for ischemic stroke, among other rights, delisted from the NASDAQ on October 18, 2023 (U.S. time). Background on the relationship between Healios and Athersys and a statement regarding the delisting is as follows.

1. Relationship between Healios and Athersys

In 2016, Healios entered into an exclusive license agreement with Athersys for the development and marketing of its stem cell product MultiStem® (HL051) for ischemic stroke in Japan, and in 2018, Healios obtained a license to develop and market the product for acute respiratory distress syndrome (ARDS) in Japan and started clinical trials for both indications. In 2021, Healios entered into a comprehensive agreement with Athersys to expand its collaboration for commercialization, and in 2022, obtained licensing rights for the manufacturing of HL051 for ischemic stroke and ARDS, and subsequently performed a manufacturing technology transfer. In addition, in 2023, Healios agreed to expand the License Agreement for ARDS to cover global territories, dramatically increasing the number of ARDS patients Healios has the opportunity to treat with this therapy. Healios completed clinical trials in Japan to investigate the safety and efficacy of HL051 for ischemic stroke and ARDS. Building on two successful prior trials utilizing the HL051 for ARDS, Healios is currently preparing to launch a clinical trial in Japan towards the goal of obtaining approval of the therapy for ARDS the Japanese market and Healios is continuing to consult with regulatory authorities regarding the development path for ischemic stroke.

2. Statement regarding the delisting of Athersys

Healios currently has all rights to develop, manufacture, and market HL051 under its contract with Athersys. In addition, as recently announced, Healios has obtained all the 3D bioreactor manufactured investigational product it needs to pursue the upcoming Japanese ARDS trial. Under these circumstances, the delisting of Athersys is not expected to impact Healios. While Athersys has been delisted from Nasdaq, its shares will continue to trade on the OTC market and Athersys has announced that they are exploring strategic transactions for their company. They have also announced that if they do not consummate a strategic transaction, they may have to file for bankruptcy in the United States. From a Healios perspective, in such an event the rights held by Healios are protected by law, and we are confident we will be able to limit any risk associated with such an event. Healios has prepared for the potential scenarios and remains committed to advance HL051 for the benefit of patients with severe unmet medical needs.

Please refer to the [“SEC Filings, Oct. 18, 2023” in the Athersys website](#) for more information on this matter.

3. Future outlook

There is no impact of this matter on our consolidated financial results at this time. Healios shall promptly announce all future matters that require disclosure.