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Progress Update in Relation to Application for Approval for HLCM051 for ARDS

HEALIOS K.K. ("Healios") is currently conducting two clinical trials using stem cell product HLCM051[*1] for ischemic stroke and acute respiratory distress syndrome (ARDS)[*2] (the "ONE-BRIDGE" study) patients in Japan. ONE-BRIDGE is a Phase II efficacy and safety trial for patients with pneumonia induced ARDS. In November 2019, HLCM051 for ARDS was designated as an orphan regenerative medicine product by the Ministry of Health, Labour and Welfare ("MHLW"). In August and November 2021, Healios announced 90 and 180-day results from the ONE-BRIDGE study, which demonstrated promising efficacy and safety outcomes. Healios prepared application materials to seek approval of HLCM051 as an orphan regenerative medicine product for ARDS in Japan and began consultations with the Pharmaceuticals and Medical Devices Agency (hereinafter, "PMDA", and together with the MHLW the "regulatory authorities").

As part of this process, at the end of March Healios held a pre-application consultation meeting with the PMDA to obtain guidance and advice pertaining to its application for product approval. During the consultation, although a certain level of agreement was reached in relation to the efficacy and safety of HLCM051 for ARDS, Healios was advised that when making a future application for approval for the ARDS indication, it needs to add certain supporting data to the proposed application data package. In light of this guidance, Healios will continue to discuss with the regulatory authorities the nature of the supporting data required, including the potential use of certain clinical data from the MACoVIA[*3] study for the product in the ARDS indication currently being conducted in the United States.

Healios does not currently plan to apply for approval in Q2 2022. Healios will promptly proceed with the above-described matters and continue to work toward early application. While it is

undetermined at this time, it is expected that an application for approval is unlikely to take place in the current fiscal year. Healios will promptly inform you as soon as we identify additional circumstances to be disclosed in the future, such as the results of important consultations with the regulatory authorities.

This matter has no impact on our business performance for the fiscal year ending December 2022 at this time. Healios shall promptly announce all future matters that require disclosure, including any potential impact on expenses associated with additional PMDA requirements.

*[1] 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, Inc. ("Athersys") in January 2016, whereby Healios acquired rights to develop and distribute Athersys' proprietary stem cell product MultiStem® 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 to treat ARDS in Japan.

*[2] 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 to 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.

*[3] MACoVIA study

Athersys is currently enrolling a pivotal phase 2/3 clinical trial evaluating the safety and efficacy of MultiStem cell therapy in COVID-19 and other pathogen-induced ARDS patients. The MACoVIA study features an open-label lead-in followed by double-blinded, randomized, placebo-controlled Phase 2 and 3 portions, and the study is currently designed to enroll up to approximately 400 patients at leading pulmonary critical care centers.