January 4, 2021

Company Name: HEALIOS K.K.
Representative: Hardy TS Kagimoto, Chairman & CEO
(TSE Mothers Code: 4593)
Contact: Richard Kincaid, Executive Officer CFO
(TEL: 03-5962-9440)

TREASURE and ONE-BRIDGE patient enrollment progress

HEALIOS K.K. ("Healios") is currently conducting two clinical trials using stem cell product HLCM051[*1] for ischemic stroke (the "TREASURE" study) and acute respiratory distress syndrome (ARDS)[*2] (the "ONE-BRIDGE" study) patients in Japan. We previously announced that we aimed to complete the enrollment of patients for both clinical trials by the end of the fourth quarter of 2020 (by December 31, 2020). The patient enrollment progress in both clinical trials exceeds 90% of the target enrollment, however, the enrollment of patients is still underway as of today.

As a result of the ongoing third and thus far largest wave of COVID-19 infections in Japan, the medical resources at hospitals where the clinical trials are being conducted have been allocated to the treatment of COVID-19 patients. In this environment, the recent progress of enrolling patients in clinical trials, especially from December onward, has been slower than expected. Under such circumstances, we would like to express our sincere gratitude to all medical professionals including doctors who have assisted with the clinical trials.

Healios will continue to cooperate with all related parties to enroll patients with the aim of completing the clinical trials as soon as possible.

If matters to be disclosed arise in the future that would impact fiscal year 2021 financial performance, Healios will make an announcement without delay.

*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.