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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)

Athersys Announced Status of Interim Analysis of Clinical Trial for Ischemic Stroke in the U.S. and Europe

HEALIOS K.K. ("Healios") conducted the TREASURE study*1 to investigate the safety and efficacy of HLCM051*2 (Multistem®) in patients with ischemic stroke. Healios is continuing discussions with the regulatory authority (PMDA) regarding future data acquisition and submission policies.

Athersys Inc. ("Athersys") is conducting a clinical trial (trial name: MASTERS-2 study) in the U.S. and Europe using the same drug for ischemic stroke and completed the interim analysis of the clinical trial. The interim analysis was conducted in the middle of the clinical trial to review the reestablishment of the required number of patients. As a result of the analysis based on the one-year follow-up of approximately half of the 300 patients in the trial, Athersys concluded that the current sample size of 300 patients is insufficiently powered to achieve the primary endpoint of mRS*3 Shift analysis at Day 365. There were no safety issues identified. Because the sample size required to achieve statistical significance is considerably larger, Athersys intends to conduct additional data analysis with independent statisticians. Athersys plans to pause enrollment of new patients while this analysis is being conducted. Healios will await the results of this analysis before taking any further action.

Please refer to the press release from Athersys for more information.

Healios shall promptly announce all future matters that require disclosure.

*1 TREASURE study
The TREASURE study was conducted to investigate the safety and efficacy of HLCM051 (Multistem®) in patients with ischemic stroke. The study targeted patients with moderate to moderate-severe strokes (baseline NIHSS score 8-20), with administration of a single dose of HLCM051 intravenously within 1836 hours from stroke onset. The trial was conducted at 48 sites in Japan and enrolled 206 patients. HLCM051 is an off-the-shelf, somatic stem cell regenerative medicine product that Healios is developing for both ischemic stroke and acute respiratory distress syndrome in Japan.

*2 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.

The following is a summary of the results of the TREASURE study that have been published to date.

- No significant difference was demonstrated in the primary endpoint of Excellent Outcome after 90 days of treatment.
- The drug effect was stronger as time passed from 7, 30, 90 and 365 days after administration of the drug compared to the placebo group. In particular, the increase in the percentage of patients who are able to live independently without the need for nursing care, as indicated by BI and Global Recovery after one year, was statistically significant.
- Although the placebo group tended to be slightly larger in the distribution of subjects' stroke volume, compared to no effect for stroke volumes of less than 25 mL, there was a trend toward a stronger drug effect for larger volumes of 25, 50 and 75 mL, with a statistically significant difference, especially for volumes of 50 mL or larger.
- Though a small sample size, patients under 64 years of age appear to achieve better results.

*3 mRS

The mRS measures the degree of disability or dependence in the activities of daily living of people who have had a stroke or have a neurological disability due to other reasons. It is used to categorize the level of functional independence with reference to pre-stroke activities. The scale includes scores from 0 to 6, ranging from perfect health without symptoms of disability (i.e., a score of 0) to death (a score of 6). A lower score indicates a lower degree of disability. In the TREASURE study, mRS was set as a secondary evaluation item.

(Source) Prepared by Healios on the basis of materials provided by The Japan Stroke Society.

Contact: Department of IR Finance and Accounting
E-mail: ir@healios.jp