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The Status of a Clinical Trial of Adult Stem Cell Regenerative Medicine HLCM051 in Patients with Ischemic Stroke in Japan (TREASURE study)

HEALIOS K.K. (“Healios”) announces that the patient enrollment of the clinical trial of adult stem cell regenerative medicine HLCM051^{*1} in patients with acute ischemic stroke in Japan, named the TREASURE study^{*2}, has been resumed after a temporary suspension due to a deviation in the placebo control. The replacement placebo material has been newly manufactured and distributed to the clinical trial sites, then patient screening has resumed.

Healios continues to work closely with Athersys to ensure the thorough management of manufacturing and quality control and oversight of Athersys’ contract manufacturer, and to facilitate the TREASURE study in cooperation with the clinical trial sites.

If matters to be disclosed arise in the future regarding the effect on fiscal year 2017 financial performance, Healios will make an announcement without delay.

***1: HLCM051**

Healios holds a development pipeline for treating ischemic stroke using the stem cell product HLCM051 (MultiStem) in Japan. Ischemic stroke is a condition in which a blockade in blood vessels in the brain precludes the delivery of oxygen and nutrients beyond the blockade, causing necrosis of nerve cells over time. Currently, ischemic stroke is treated with t-PA (a thrombolytic agent) that dissolves clots lodged in a blood vessel in the brain, mechanical reperfusion therapy, or other treatment options; however, there is a need for a new drug that can be used during a longer period of time after the onset of ischemic stroke and that also provides the potential for improved outcomes for patients.

Healios has introduced HLCM051 by signing an exclusive licensing agreement with a biopharmaceutical company, Athersys, Inc., in the United States in January 2016 on the domestic development and distribution of regenerative medicine products in Japan for ischemic stroke using the Athersys’ proprietary stem cell product, MultiStem.

***2: TREASURE study**

TREASURE is an abbreviation for “Treatment Evaluation of Acute Stroke Using Regenerative Cell Elements”.