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Company Name: HEALIOS K.K.  
Representative: Hardy TS Kagimoto,  
President, Representative Director & CEO  
(TSE Mothers Code: 4593)  
Contact: Ken Ishikawa  
Director in charge of administration  
(TEL: 03-5777-8308)

**First Patient is Enrolled  
in a Clinical Trial of Adult Stem Cell Regenerative Medicine  
HLCM051 in Patients with Ischemic Stroke in Japan  
(TREASURE study)**

HEALIOS K.K. (“Healios”) today announces that the first patient has been enrolled and treated in a clinical trial of adult stem cell regenerative medicine HLCM051<sup>\*1</sup> in patients with acute ischemic stroke in Japan, named TREASURE study<sup>\*2</sup>.

The TREASURE study is designed to confirm the efficacy and safety of HLCM051 in treating patients with ischemic stroke. Patients with a persistent neurologic deficit will be randomized 1:1 to receive a single intravenous infusion of HLCM051 or placebo within 18-36 hours of stroke onset. The primary efficacy outcome is the proportion of subjects achieving an Excellent Outcome<sup>\*3</sup> at day 90. A total of 220 patients will be enrolled.

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.

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.”

\*3: Excellent Outcome

Functional and neurological deficit and recovery following the ischemic stroke are evaluated using three standard methods: the modified Rankin Scale (mRS), the NIH Stroke Scale (NIHSS), and the Barthel Index (BI).

“Excellent Outcome” is defined as achieving  $mRS \leq 1$ ,  $NIHSS \leq 1$ , and  $BI \geq 95$ .

modified Rankin Scale (mRS)

The mRS measures the degree of disability or dependence in the daily living activities of people who have suffered a stroke or other causes of neurological disability. It is used to categorize the level of functional independence with reference to pre-stroke activities. The scale runs from 0-6, running from perfect health without symptoms of disability (i.e. a score of 0), to death (a score of 6). The lower the score, the lower the degree of disability.

NIH Stroke Scale (NIHSS)

The NIH Stroke Scale (NIHSS) is a systematic assessment tool that provides a quantitative measure of stroke-related neurologic deficit in the following areas: level of consciousness, facial paralysis, visual acuity and function, arm and leg motor function, limb coordination, language and speech, sensory loss, and other parameters. In the NIHSS, the higher the score, the more impaired a stroke patient is. The score for each function is a number between 0 and 4, with 0 reflecting normal function (i.e. no deficit) and 4 being completely impaired (Note that some functional assessments use a scale of 0-2, or 0-3). The patient’s total NIHSS is calculated by adding the number for each element on the scale, based on the individual assessments – 42 is the highest score possible, reflecting the patient exhibits maximum disability in each category.

Barthel Index (BI)

The Barthel Index is a 100-point scale that is used to assess the patient’s ability to independently perform activities of daily living, and evaluates a range of different functions. These include the ability of the patient to walk, dress, feed, bathe, climb stairs, use a toilet, self-groom, and certain other metrics. The patient is evaluated for each activity to assess for independence, partial dependence, or complete dependence, and a score of 0 – 10 is then assigned (10 points = independence, 5 points = partially dependent, 0 points = completely dependent). The Barthel Index score ranges from 0 – 100, with 100 reflecting no dependence on any activity, and the lower the score the greater the need for assistance.

(Source) Prepared by Healios based on the materials provided by The Japan Stroke Society etc.