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Company Name: HEALIOS K.K.
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: President, Representative Director & CEO
(TSE Mothers Code: 4593)

HEALIOS Plans to Start a Clinical Trial of Somatic Stem Cell Regenerative Medicine HLCM051 in Patients with Ischemic Stroke in Japan

HEALIOS K.K. (HQ: Minato-ku, Tokyo, Japan; President Representative Director and CEO: Hardy TS Kagimoto, “Healios”) announces that its investigational plan for a clinical trial of HLCM051*, a somatic stem cell regenerative medicine product, in patients with acute ischemic stroke in Japan has been made public, as shown below, by the Pharmaceuticals and Medical Devices Agency (PMDA).

Category	Clinical trial ID	Target disease	Party submitting clinical trial notification	Planned trial period
Processed cells, etc.	HLCM051	Acute ischemic stroke	HEALIOS K.K.	September/15/2016~ October/31/2018

Note: Extracted from the “Information on Major Clinical Trials” on the PMDA website:

<http://www.pmda.go.jp/review-services/trials/0019.html#1>

About HLCM051

HLCM051 is a development pipeline for a somatic stem cell regenerative medicine product to treat patients with acute ischemic stroke 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 this pipeline by signing an exclusive licensing agreement with a bio-venture company Athersys, Inc. in the United States in January 2016 on the domestic development and distribution of regenerative medicine products for ischemic stroke using the Athersys’ proprietary stem cell product MultiStem®.

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