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Company Name: HEALIOS K.K.
Representative: Hardy TS Kagimoto, Chairman & CEO
(TSE Mothers Code: 4593)

Athersys Announces Positive Results From Its Exploratory Clinical Study of MultiStem® Cell Therapy For Treatment of Acute Respiratory Distress Syndrome

HEALIOS K.K. ("Healios") is developing new treatments for acute ischemic stroke and acute respiratory distress syndrome (ARDS) in Japan using the stem cell product MultiStem®, for which the patent and licensing rights are held by Athersys, Inc. ("Athersys").

We are delighted to announce that Athersys announced positive data from its exploratory clinical study conducted in the United States and United Kingdom of the intravenous administration of MultiStem cell therapy to treat patients who are suffering from ARDS.

Data highlights from the initial evaluation include the following results from the double-blind, randomized, placebo-controlled portion of the study;

- Lower mortality of 25% in the MultiStem treatment group vs. 40% in the placebo group;
- 40.2% higher ventilator-free (VF) days, (12.9 VF days in the MultiStem treatment group vs. 9.2 VF days for the placebo group);
- 27.2% higher ICU-free days, (10.3 days in MultiStem subjects vs. 8.1 days for subjects receiving placebo);
- In more severe ARDS patients (as evident in a prospectively defined analysis), the difference between MultiStem treatment and placebo was greater – 25% mortality in MultiStem group vs. 50% in placebo group, 14.6 VF days in MultiStem group vs. 8.0 VF days in placebo group, and 11.4 ICU-free days in MultiStem group versus 5.9 ICU-free days in placebo group; and
- MultiStem treatment was well tolerated in this very sick ARDS patient population, with no serious adverse events related to administration.

Athersys will continue to evaluate the data as the one-year follow-up period is completed for all patients in the trial. Athersys and the study investigators plan to present more detailed and comprehensive results at a medical science conference after additional analyses.

For more details, please refer Athersys' press release:

As announced in the press release on November 8, 2018, "Healios Announces Plans to Initiate a Clinical Trial of Somatic Stem Cell Regenerative Medicine HLCM051 in patients with ARDS in Japan," Healios has submitted a clinical trial notification using MultiStem for patients with ARDS and has started all necessary procedures. Certain aspects of our trial design differ from the exploratory trial conducted by Athersys: the clinical trial investigates the efficacy and safety for patients with pneumonia induced ARDS and will be conducted under non-blind conditions using a standard therapy as a control.

Healios will make an announcement when patient enrollment begins.

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