NEWS RELEASE

Healios Receives Notification of Orphan Designation for Acute Respiratory Distress Syndrome Clinical Program

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Designation will expedite review for HLCM051 (MultiStem® Cell Therapy) for ARDS program in Japan

CLEVELAND, Nov. 14, 2019 (GLOBE NEWSWIRE) -- Athersys, Inc. (Nasdaq: ATHX) announced today that its collaborator in Japan, HEALIOS K.K. (“Healios”) received notification this week from the Pharmaceutical Affairs and Food Sanitation Council (“PAFSC”) that its acute respiratory distress syndrome (“ARDS”) clinical program using HLCM051 (MultiStem® Cell Therapy), will receive the orphan regenerative medicine designation from the Ministry of Health, Labour and Welfare within the next few weeks. This designation may be given to investigational products being evaluated for indications that have a high unmet medical need and that occur in less than 50,000 patients in Japan. In addition to priority consultation and review for potential approval of the therapy, there are several financial incentives offered with the designation, such as subsidies to reduce the financial burden of product development, preferential tax treatment and extension of the re-examination period for Healios.

ARDS is a serious and life-threatening pulmonary condition that requires patients to be placed on a ventilator in the intensive care unit (“ICU”) and is associated with a high mortality rate. Many patients that do survive face extended stays in the ICU and experience difficult and challenging recoveries.

In June 2018, Healios and Athersys expanded their existing collaboration to include the rights to develop and commercialize MultiStem (HLCM051) to treat ARDS in Japan. In May 2019, Athersys announced positive results from its Phase 1/2 clinical study (known as "MUST-ARDS") at the annual American Thoracic Society meeting. MultiStem-treated patients experienced less mortality, more ventilator-free days and more ICU-free days compared to the placebo patients. After submitting these results, Athersys' ARDS program was granted Fast Track Designation by the United States Food and Drug Administration.

Healios is currently conducting the "ONE-BRIDGE" study to evaluate MultiStem treatment in pneumonia-induced ARDS patients at over 20 clinical sites in Japan. This trial began in April 2019 and is expected to enroll 30 patients. The primary endpoint is the amount of ventilator-free days at day 28 following treatment.

About Orphan Regenerative Medicine Designation in Japan

In Japan, drugs and medical devices can be designated as orphan drugs or medical devices based on the Article 77-2 of the Act on Securing Quality, Efficacy and Safety of Pharmaceuticals, Medical Devices, Regenerative and Cellular Therapy Products, Gene Therapy Products, and Cosmetics if they are intended for use in less than 50,000 patients in Japan and if there is a high unmet medical need. Programs are designated by the Minister of Health, Labour and Welfare based on the opinion of the PAFSC. While designation does not automatically lead to marketing approval, it provides certain priorities and financial incentives related to potential approval and product launch.

About ARDS

ARDS is a serious immunological and inflammatory condition characterized by widespread inflammation in the lungs. ARDS can be triggered by pneumonia, sepsis, trauma or other events and represents a major cause of morbidity and mortality in the critical care setting. ARDS is associated with a high mortality rate and significant sequelae among survivors. The condition prolongs ICU and hospital stays and often requires extended convalescence in the hospital and rehabilitation care settings. There are limited interventions and no effective drug treatments for ARDS. There is a large unmet need for a safe treatment that can reduced mortality and improve quality of life for those suffering with ARDS. Additionally, given the high treatment costs associated with ARDS, a successful therapy could be expected to generate significant savings for the healthcare system by reducing days on a ventilator and in the ICU.

About MultiStem

MultiStem cell therapy is a patented regenerative medicine product in clinical development that has shown the ability to promote tissue repair and healing in a variety of ways, such as through the production of therapeutic factors in response to signals of inflammation and tissue damage. MultiStem therapy's potential for

multidimensional therapeutic impact distinguishes it from traditional biopharmaceutical therapies focused on a single mechanism of benefit. The therapy represents a unique "off-the-shelf" stem cell product that can be manufactured in a scalable manner, may be stored for years in frozen form, and is administered without tissue matching or the need for immune suppression. Based upon its efficacy profile, its novel mechanisms of action, and a favorable and consistent safety profile demonstrated in clinical studies, MultiStem therapy could provide a meaningful benefit to patients, including those suffering from serious diseases and conditions with unmet medical need.

About Athersys

Athersys is a biotechnology company engaged in the discovery and development of therapeutic product candidates designed to extend and enhance the quality of human life. The Company is developing its MultiStem® cell therapy product, a patented, adult-derived "off-the-shelf" stem cell product, initially for disease indications in the neurological, inflammatory and immune, cardiovascular and other critical care indications and has several ongoing clinical trials evaluating this potential regenerative medicine product. Athersys has forged strategic partnerships and a broad network of collaborations to further advance the MultiStem cell therapy toward commercialization. More information is available at **www.athersys.com**. Follow Athersys on Twitter at **www.twitter.com/athersys**.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 that involve risks and uncertainties. These forward-looking statements relate to, among other things, the expected timetable for development of our product candidates, our growth strategy, and our future financial performance, including our operations, economic performance, financial condition, prospects, and other future events. We have attempted to identify forward-looking statements by using such words as “anticipates,” “believes,” “can,” “continue,” “could,” “estimates,” “expects,” “intends,” “may,” “plans,” “potential,” “should,” “suggest,” “will,” or other similar expressions. These forward-looking statements are only predictions and are largely based on our current expectations. A number of known and unknown risks, uncertainties, and other factors could affect the accuracy of these statements. Some of the more significant known risks that we face that could cause actual results to differ materially from those implied by forward-looking statements are the risks and uncertainties inherent in the process of discovering, developing, and commercializing products that are safe and effective for use as therapeutics, including the uncertainty regarding market acceptance of our product candidates and our ability to generate revenues. These risks may cause our actual results, levels of activity, performance, or achievements to differ materially from any future results, levels of activity, performance, or achievements expressed or implied by these forward-looking statements. Other important factors to consider in evaluating our forward-looking statements include: our ability to raise capital to fund our operations; the timing and nature of results from our

MultiStem clinical trials, including the MASTERS-2 Phase 3 clinical trial and Healios' TREASURE and ONE-BRIDGE clinical trials in Japan; the possibility of delays in, adverse results of, and excessive costs of the development process; our ability to successfully initiate and complete clinical trials of our product candidates; the possibility of delays, work stoppages or interruptions in manufacturing by third parties to us, such as due to material supply constraints, contaminations, or regulatory issues, which could negatively impact our trials and the trials of our collaborators; uncertainty regarding market acceptance of our product candidates and our ability to generate revenues, including MultiStem cell therapy for the treatment of stroke, acute respiratory distress syndrome, acute myocardial infarction and trauma, and the prevention of graft-versus-host disease and other disease indications; changes in external market factors; changes in our industry's overall performance; changes in our business strategy; our ability to protect and defend our intellectual property and related business operations, including the successful prosecution of our patent applications and enforcement of our patent rights, and operate our business in an environment of rapid technology and intellectual property development; our possible inability to realize commercially valuable discoveries in our collaborations with pharmaceutical and other biotechnology companies; our ability to meet milestones and earn royalties under our collaboration agreements, including the success of our collaboration with Healios; our collaborators' ability to continue to fulfill their obligations under the terms of our collaboration agreements and generate sales related to our technologies; the success of our efforts to enter into new strategic partnerships and advance our programs, including, without limitation, in North America, Europe and Japan; our possible inability to execute our strategy due to changes in our industry or the economy generally; changes in productivity and reliability of suppliers; and the success of our competitors and the emergence of new competitors. You should not place undue reliance on forward-looking statements contained in this press release, and we undertake no obligation to publicly update forward-looking statements, whether as a result of new information, future events or otherwise.

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