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NEWS RELEASE

Athersys Announces Fast Track Designation From FDA for MultiStem® Program for Acute Respiratory Distress Syndrome

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Dr. Geoff Bellingan to present the Phase 1/2 Acute Respiratory Distress Syndrome Data Next Week at the American Thoracic Society International Conference

CLEVELAND, May 14, 2019 (GLOBE NEWSWIRE) -- Athersys, Inc. (Nasdaq: ATHX) announced today that its clinical program evaluating MultiStem® cell therapy for the treatment of Acute Respiratory Distress Syndrome ("ARDS") has received Fast Track designation from the United States Food and Drug Administration ("FDA"). This important designation is given to qualified investigational therapies that show promise in providing benefit to patients in areas of significant unmet medical need. Fast Track designation allows for an expedited regulatory review process after the clinical data is submitted to help speed development of promising therapies to the market in order to help patients in areas where current standard of care is limited.

In January 2019, the Company announced favorable top-line results from a randomized, double-blind placebo-controlled exploratory Phase 2 clinical study evaluating MultiStem administration to patients with ARDS, referred to as the MUST-ARDS study. 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 level of mortality. Many patients that do survive face extended stays in the ICU and experience difficult and challenging recoveries. In the MUST-

ARDS study, patients who received MultiStem treatment within several days after being diagnosed with ARDS and being placed on a ventilator experienced lower mortality, increased ventilator-free days, and increased ICU-free days during the initial 28-day clinical assessment period relative to patients receiving placebo. Additional data from the trial will be presented on May 20, 2019 at the annual American Thoracic Society meeting. The Company's collaborator in Japan, HEALIOS K.K., has initiated and is enrolling patients in its clinical trial evaluating administration of MultiStem to pneumonia-induced ARDS patients in Japan.

In addition to the ARDS Fast Track announcement, Athersys is hosting an Investor Day event today for shareholders, potential investors, analysts and other invited guests to highlight the Company's capabilities, technologies, research programs, clinical trials and plans. A summary video from the Investor Day event will be available on the Company's website approximately one week after the event.

"We are honored to have received Fast Track designation from the FDA for our ARDS program, which supports the promise of our cell therapy for treating patients in an area where new and more effective treatments are needed. This designation complements other indications where we have received important regulatory designations, including Fast Track and RMAT designations for our ongoing Phase 3 program for ischemic stroke," commented Dr. Gil Van Bokkelen, Chairman and CEO, at Athersys. "We share the same priorities and goals as the FDA, including putting patient safety and well-being first and foremost, and a desire to see safe and effective new therapies developed in areas where standard of care is limited or simply unavailable for many patients.

"Our Investor Day event will highlight some of the exciting progress we are making in several key areas, and will provide an opportunity for clinical experts, patient advocates, and others to share their perspective alongside members of the Athersys leadership team, and we are truly grateful for the many expressions of support that we have received," concluded Dr. Gil Van Bokkelen.

Also, on May 20, 2019, Dr. Geoff Bellingan, Medical Director at University College London Hospitals, will be presenting additional data from the exploratory Phase 1/2 ARDS study, ("MUST-ARDS") at the American Thoracic Society International Conference in Dallas, Texas. Dr. Bellingan's talk is titled, "Primary Analysis of a Phase 1/2 Study to Assess MultiStem® Cell Therapy, a Regenerative Advanced Therapy Medicinal Product (ATMP), in Acute Respiratory Distress Syndrome (MUST-ARDS)".

About Fast Track Designation

Fast Track is a process designed by the FDA to facilitate the development and expedite the review of drugs that have the potential to treat serious conditions and address recognized areas of unmet medical need. The purpose is to help speed development of new drugs that are evaluated to be safe and effective, making them available to the patient earlier. For more information on the Fast Track process, please visit:

<https://www.fda.gov/ForPatients/Approvals/Fast/ucm405399.htm>

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. It has significant implications, as it prolongs ICU and hospital stays and requires convalescence in the hospital and rehabilitation. There are limited interventions and no effective drug treatments for ARDS, making it an area of high unmet clinical need with high treatment costs. Given ARDS high treatment costs, a successful cell therapy could be expected to generate significant savings for the healthcare system by reducing days on a ventilator and in the ICU and importantly, could reduce mortality and improve quality of life for those suffering from the condition. The medical need for a safe and effective treatment of ARDS is significant due to its high mortality rate, and it affects approximately 400,000 - 500,000 patients in Europe, the United States and Japan annually.

MultiStem cell therapy has demonstrated the capacity to reduce inflammation, support tissue regeneration and promote homeostasis in acute immunological and injury settings. Preclinical data suggests that MultiStem cells may have a protective effect by shifting the physiological response from pro-inflammatory to anti-inflammatory, and through the promotion of key reparative mechanisms. In animal models, MultiStem cells have demonstrated an ability to reduce inflammation, reduce fluid retention in the lungs and return lung function to normal. Intravenous MultiStem treatment early following the onset of ARDS may ameliorate the initial inflammation and reduce the fibrotic activity that follows, thereby speeding the return to and improving the likelihood of more normal lung function and helping patient recovery.

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 produced 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 an international 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, cardiovascular, and inflammatory and immune disease areas, 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.

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 work with Healios to reach an agreement for an option in China; 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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