Athersys Provides Update on One-Year ARDS Study Data

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One-year results support positive 28-day findings and suggest further benefits for ARDS patients

CLEVELAND, Jan. 14, 2020 (GLOBE NEWSWIRE) -- Athersys, Inc. (NASDAQ: ATHX) announced today the one-year follow-up summary results from its exploratory clinical study of the intravenous administration of MultiStem® cell therapy to treat patients who are suffering from acute respiratory distress syndrome (ARDS). Participants in the MUST-ARDS study were evaluated through 28 days for the primary clinical assessment and further assessed through a one-year follow-up period. The one-year results were consistent with the positive day-28 results announced last year, and an evaluation of quality-of-life over the one-year period suggests further potential benefits from MultiStem treatment.

Highlights from the new and previously disclosed data include:

- Previously observed lower mortality for MultiStem-treated subjects compared to placebo (particularly among the prospectively defined subset of more severe ARDS patients) persisted out to one-year of follow-up;
- Day-365 Quality of Life (QoL) outcomes, assessed by the EQ-5D, were meaningfully better among all survivors who received MultiStem treatment compared to those who received placebo;
- Within the prospectively defined group of patients with more severe ARDS, MultiStem treatment was
associated with a markedly greater rate of survival and progression to functional independence at one year (i.e., self-care);

- As measured at day-28, MultiStem treatment was associated with a higher mean ventilator-free day (VFD) score of 12.9 vs. 9.2 in the placebo group, and a higher mean intensive care unit (ICU)-free day score of 10.3 vs. 8.1 in the placebo group;
- As measured at day-28, among more severe ARDS patients, mean VFD in the MultiStem subgroup was 14.6 vs. 8.0 in placebo subgroup. Mean ICU-free days were 11.4 vs. 5.9 for MultiStem and placebo recipients, respectively;
- Lower inflammatory cytokine levels at day-7 in the MultiStem group relative to the placebo group, including IFNg, IL-6 and IL-1b among others, suggest the potential for MultiStem treatment to abate the severe inflammatory response associated with ARDS; and
- MultiStem treatment was well tolerated in this very sick ARDS patient population, with no serious adverse events related to administration through one year of follow-up.

“We believe that the more favorable outcomes, as reflected in the patient reported self-assessments, particularly among patients recovering from more severe ARDS, suggest that administration of MultiStem has the potential to meaningfully enhance the ability of these patients to reestablish functional independence and restore quality of life,” noted Dr. Anthony Ting, Vice President of Regenerative Medicine and Head of Cardiopulmonary Programs at Athersys. “Frequently, ARDS patients have a very challenging road to recovery, suffering depression or decreased physical abilities. Many are unable to return to work or engage in other activities. The prospect of being able to help many patients overcome these difficulties is very exciting, and we look forward to publishing these results.”

The MUST-ARDS study was designed to evaluate the impact of MultiStem treatment in subjects with acute onset of moderate to severe ARDS and was conducted at sites in the United States and United Kingdom. Treatment was required to begin within four days of ARDS diagnosis with an average treatment time of approximately two days from the diagnosis. In the Phase 2a portion of the study, 20 subjects were treated with an intravenous administration of 900 million MultiStem cells and 10 subjects received placebo; the study was not powered for the efficacy outcomes. Based on the study results, the Company is planning further development in this area and intends to submit for publication the detailed study data.

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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