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Two New Publications Highlight the Potential for MultiStem® Treatment of Ischemic Stroke

Lancet Neurology/Stem Cells publications provide further clarity of MultiStem mechanisms of benefit - modulating inflammatory response and immune system - enhancing recovery

CLEVELAND, March 20, 2017 (GLOBE NEWSWIRE) -- Athersys, Inc. (NASDAQ:ATHX) announced today that clinical investigators have published results from Athersys' Phase 2 trial of MultiStem cell therapy for treating ischemic stroke patients (the "MASTERS" trial) in the peer-reviewed journal, *The Lancet Neurology*. The article highlights the feasibility and safety of intravenous MultiStem treatment for patients who have suffered a moderate to severe stroke, the progressive improvements in recovery experienced by these patients through one year, and the increased benefit for those patients receiving MultiStem treatment within 36 hours of their stroke. In addition, the article describes how patients receiving intravenous MultiStem treatment demonstrated a significant reduction in inflammatory cytokines and immune cells and a decrease in infections associated with immunodepression, compared to patients receiving placebo. These trial findings, together with the article below, provide further clarity about important mechanisms of benefit when treating stroke patients with MultiStem - the modulation of the inflammatory response and preservation of immune system homeostasis - promoting accelerated recovery.

"As described in the clinical paper, there were several important observations from the MASTERS study, including evidence that intravenous administration of MultiStem was associated with a substantial increase in the proportion of stroke victims who achieved an Excellent Outcome (defined below) at one year, particularly when treatment occurred within 36 hours of the ischemic event," commented Dr. David Hess, stroke specialist and Professor & Chairman of the Department of Neurology at the Medical College of Georgia at Augusta University, primary author of the article and lead clinical investigator in the MASTERS trial. "The combination of these observations in conjunction with the clinical safety data and supportive biomarker data from the trial provide a clear basis for moving forward in the MASTERS-2 study."

This publication coincides with another independent article highlighting additional evidence from preclinical studies of how MultiStem cell therapy provides multiple biological benefits following an ischemic stroke, including data supporting key mechanisms of action. The preclinical research, published in the journal, *Stem Cells,* demonstrates that following a stroke, administration of the cell therapy modulates the inflammatory response initiated by the stroke injury, by down-regulating inflammatory cytokines and immune cells that cause extensive damage in the brain following a stroke or other neurological injury. The publication describes how MultiStem cells minimize this acute inflammatory response by interacting with peripheral immune organs, most notably the spleen. By inhibiting the body's inflammatory response to the stroke injury and stimulating key reparative mechanisms, MultiStem treatment results in less damage in the brain and promotes more effective recovery.

"A strong foundation of data has been established that illustrates the importance of the spleen and peripheral immune system following an acute neurological injury such as a stroke," commented Dr. Sean Savitz, Professor of Neurology and Chair of the Department of Neurology at University of Texas, Health Science Center at Houston and McGovern Medical School. "Our preclinical work demonstrates that administration of MultiStem cell therapy has a profound effect on neutralizing the inflammatory-mediated damage that occurs acutely following an ischemic stroke, as well as upregulating reparative pathways, which is consistent with the biomarker data from the MASTERS trial," concluded Dr. Savitz.

Athersys is planning a Phase 3 study entitled, MultiStem Administration for Stroke Treatment and Enhanced Recovery Study-2 ("MASTERS-2"). The MASTERS-2 study has received authorization from the U.S. Food and Drug Administration ("FDA") under a Special Protocol Assessment ("SPA") for the design and planned analysis of the pivotal Phase 3 clinical trial. The SPA provides formal agreement from the FDA that the protocol design, clinical endpoints, planned conduct and statistical analyses in the Phase 3 study are acceptable to support a regulatory submission for marketing approval of MultiStem cell therapy as a product for treating ischemic stroke patients, if the trial is successful. Additionally, the Ministry of Health Labor and Welfare recently provided public notification that the TREASURE Phase 2/3 stroke study being conducted in Japan by Athersys' partner, HEALIOS K.K., has received a priority review designation, enabling acceleration of the

potential assessment time to six months for Japan's Pharmaceutical and Medical Devices Agency review (under the recently implemented accelerated review pathway for innovative medicines, or *Sakigake*).

The MASTERS-2 clinical trial is a randomized, double-blind, placebo-controlled Phase 3 clinical trial designed to enroll 300 patients at stroke clinical centers in North America and Europe. These patients will have suffered a moderate to severe stroke and will receive either a single intravenous dose of MultiStem cell therapy or placebo, administered within 18-36 hours of the occurrence of the stroke, in addition to the standard of care. The primary endpoint will evaluate disability using modified Rankin Scale ("mRS") scores at three months, comparing the distribution, or the "shift", between the MultiStem treatment and placebo groups. The mRS shift analysis considers disability across the full spectrum, enabling recognition of large and small improvements in disability and differences in mortality and other serious outcomes, among strokes of different severities. The study will also assess the defined Excellent Outcome (mRS ≤1, NIHSS ≤1, and Barthel Index ≥95) at three months and one year as key secondary endpoints. Additionally, the study will consider other measures of functional recovery, biomarker data and clinical outcomes, including hospitalization, mortality and life-threatening adverse events and post-stroke complications such as infection.

About Ischemic Stroke
Stroke represents an area where the clinical need is particularly significant, since it is a leading cause of death and serious disability worldwide, with a substantially impaired quality of life for many stroke victims. Currently, there are nearly 17 million people who suffer a stroke globally and more than 2 million stroke victims each year in the United States, Europe and Japan, combined. Ischemic strokes, which represent the most common form of stroke, are caused by a blockage of blood flow in the brain that cuts off the supply of oxygen and nutrients and can result in long-term or permanent disability due to neurological damage. Unfortunately, current therapeutic options for ischemic stroke victims are limited because the only available therapies, administration of the clot dissolving agent tPA, or "thrombolytic," or surgical intervention using mechanical reperfusion to remove the clot, must be conducted within several hours of the occurrence of the stroke. As a consequence of this limited time window, only a small percentage of stroke victims are treated with the currently available therapy—most simply receive supportive or "palliative" care. The long-term costs of stroke are substantial, with many patients requiring extended hospitalization, extensive physical therapy or rehabilitation (for those patients that are capable of entering such programs), and many require long-term institutional or family care.

About MultiStem
MultiStem cell therapy is a patented regenerative medicine product 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 product 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 both preclinical and clinical settings, MultiStem therapy could provide a meaningful benefit to patients, including those suffering from serious diseases and conditions with unmet medical need. Athersys has forged strategic partnerships and a broad network of collaborations to develop MultiStem cell therapy for a variety of indications, with an initial focus in the neurological, cardiovascular and inflammatory and immune disorder areas.

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, inflammatory and immune disease areas, and has several ongoing clinical trials evaluating this potential regenerative medicine product. Athersys has forged strategic partnerships and collaborations with leading pharmaceutical and biotechnology companies, as well as world-renowned research institutions to further develop its platform and products. 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, such as 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: the establishment of a license agreement with an animal healthcare company, including our ability to reach milestones and receive milestone payments, and whether any products are successfully developed and sold so that we earn royalty payments under any such license agreement; our possible inability to realize commercially valuable discoveries in our collaborations with pharmaceutical and other biotechnology companies; our collaborators' ability to continue to fulfill their obligations under the terms of our collaboration agreements; the success of our efforts to enter into new strategic partnerships or collaborations and advance our programs; our ability to raise additional capital; the possibility of delays in, adverse results of, and excessive costs of the development process; changes in external market factors; changes in our industry's overall performance; our ability to protect our intellectual property portfolio; 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 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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