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Athersys Announces Grant to Support Clinical Advancement of Its MultiStem(R) Regenerative Medicine Program for Heart Attack Patients

Athersys Receives SBIR Fast Track Grant to Fund Phase 2 Clinical Trial of Its Stem Cell Therapy for Acute Myocardial Infarction

CLEVELAND, Aug. 6, 2013 (GLOBE NEWSWIRE) -- Athersys, Inc. (Nasdaq:ATHX) announced today that it has received a SBIR Fast Track grant from the National Heart, Lung, and Blood Institute, which will support a Phase 2 clinical study evaluating the administration of MultiStem[®] therapy to patients who have suffered a heart attack, or acute myocardial infarction (AMI). The grant is expected to provide up to \$2.8 million in support over the course of the study in connection with study progress and milestone achievement.

"We are pleased to receive this SBIR award as it will support us in moving our AMI program forward into Phase 2 development," said Dr. Anthony Ting, Senior Director of Cardiovascular and Pulmonary at Athersys. "The Phase 2 clinical study will build on the promising results demonstrated previously in our AMI Phase 1 trial completed in collaboration with the Cleveland Clinic, Columbia University Medical Center, Henry Ford, and other leading cardiovascular centers, and is intended to establish definitive proof-of-concept. We expect to initiate the study early next year."

In January 2012, *Circulation Research* published results of Athersys' Phase 1 clinical study, which found that the administration of MultiStem was safe and well tolerated in patients who had recently suffered an AMI and also suggested that MultiStem can help improve heart function. Patients who exhibited significant myocardial damage and received > 50 million cells demonstrated strong trends for improvement in both ejection fraction and left ventricular stroke volume during the follow-up period, which, based on historical results, are believed to correlate with improved clinical outcomes.

Previously published preclinical studies of MultiStem have shown that administration of MultiStem can convey substantial therapeutic benefits through multiple distinct mechanisms, such as protecting and preserving at risk tissue in the heart, reducing inflammation, and promoting revascularization over time. Studies in both rodent and porcine models of AMI have shown meaningful improvements in cardiac function and increased capillary density in the heart.

Acute myocardial infarction is a leading cause of morbidity and mortality worldwide. A myocardial infarction occurs when the blood supply to the heart is interrupted or diminished, leading to ischemic myocardial tissue. Myocardial infarction is the leading cause of death in the United States, with more than 1.25 million individuals suffering a heart attack each year. Approximately 450,000 people in the United States die from coronary disease each year.

This research will be supported by the National Heart, Lung, And Blood Institute of the National Institutes of Health.

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 multiple therapeutic factors produced in response to signals of inflammation and tissue damage. MultiStem has demonstrated therapeutic potential for the treatment of inflammatory and immune disorders, neurological conditions, and cardiovascular disease, as well as other areas, and 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. The product is extensively characterized for safety, consistency and potency. Athersys has forged strategic partnerships with Pfizer Inc. to develop MultiStem for inflammatory bowel disease and with RTI Biologics, Inc. to develop a bone allograft product in the orthopedic market.

About Athersys

Athersys is a clinical stage 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" regenerative medicine therapy for disease indications in the cardiovascular, neurological, inflammatory and immune disease areas. The Company currently has several clinical stage programs involving MultiStem, including for treating inflammatory bowel disease, ischemic stroke, damage caused by myocardial infarction, and for the prevention of graft versus host disease. Athersys has also developed a diverse portfolio that includes other technologies and product development opportunities, and has forged strategic partnerships and collaborations with leading pharmaceutical and biotechnology companies, as well as world-renowned research institutions in the United States and Europe to further develop its platform and products. 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 human therapeutics, such as the uncertainty regarding market acceptance of our product candidates and our ability to generate revenues, including MultiStem for the treatment of inflammatory bowel disease, acute myocardial infarction, stroke and other disease indications, including traumatic brain injury, and the prevention of graft-versus-host disease. 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 additional capital; final results from our MultiStem clinical trials including for ischemic stroke; the possibility of delays in, adverse results of, and excessive costs of the development process; our ability to successfully initiate and complete clinical trials; changes in external market factors; changes in our industry's overall performance; changes in our business strategy; our ability to protect our intellectual property portfolio; our possible inability to realize commercially valuable discoveries in our collaborations with pharmaceutical and other biotechnology companies; our ability to meet milestones under our collaboration agreements; our collaborators' ability to continue to fulfill their obligations under the terms of our collaboration agreements; 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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