December 29, 2014

Athersys Finishes Enrollment of Phase 2 Study of MultiStem(R) Cell Therapy for Ischemic Stroke

Top-Line Data Readout Expected Around the End of the First Quarter, 2015

CLEVELAND, Dec. 29, 2014 (GLOBE NEWSWIRE) -- Athersys, Inc. (Nasdaq:ATHX) today announced that it has concluded patient enrollment of its Phase 2 clinical study involving administration of Athersys' MultiStem® cell therapy to ischemic stroke patients. The study is a randomized, double-blind, placebo-controlled, multi-center clinical trial evaluating the safety and efficacy of MultiStem therapy in subjects suffering moderate to moderate-severe ischemic strokes. Athersys expects initial results from the study to be disclosed around the end of the first quarter of 2015.

"With enrollment now finished, we look forward to the initial 90-day results from this study," commented Dr. Gil Van Bokkelen, Chief Executive Officer at Athersys. "An ischemic stroke can be a devastating event for a patient, and effective treatments for stroke are limited, resulting in substantial opportunities for new therapies. Based upon MultiStem's preclinical efficacy profile, its novel mechanisms of action, and a favorable safety profile demonstrated in preclinical and clinical settings, we believe that MultiStem could provide meaningful benefit to these patients. The results from this study are expected to provide significant insight into the potential for MultiStem therapy for the treatment of ischemic stroke."

Ischemic stroke is caused by a blockage of blood flow to the brain. A leading cause of death and disability globally, each year more than 15 million people are estimated to suffer a stroke, including more than two million people in the United States, Japan and European Union, combined. According to the American Heart Association, ischemic strokes comprise more than 85% of all strokes. Current standard of care for ischemic stroke involves the administration of a thrombolytic (clot dissolving) agent within three to four hours after a stroke has occurred, a narrow window that results in only a small percentage of patients receiving such treatment.

In this Phase 2 trial, stroke victims were administered MultiStem cells or placebo intravenously one to two days after the stroke had occurred. If this study shows that MultiStem treatment is both safe and effective following such administration, as was demonstrated in non-clinical studies, the treatment window could be expanded significantly, from hours to days, providing an important new therapeutic option for stroke patients. Based on preclinical studies, Athersys believes that MultiStem treatment has the potential to substantially improve neurological and functional recovery following stroke by attenuating the inflammatory activity that follows the stroke, accelerating the return to immune system homeostasis, supporting protection of at-risk neurons, and by supporting conditions for neuronal recovery and growth, thereby enhancing repair and patient recovery. The MultiStem treatment's potential multidimensional impact distinguishes the cell therapy from other pharmaceutical therapies focused on a single mechanism of benefit.

The randomized, double-blind, placebo-controlled Phase 2 clinical trial is being conducted by Athersys at sites in the United States and United Kingdom, and has enrolled subjects who received either MultiStem treatment or placebo one to two days following the stroke. The primary endpoints for the study include safety over the first seven days following treatment and global stroke recovery at day 90, which assesses global disability (modified Rankin Score), neurological deficit (NIH stroke scale) and activities of daily living (Barthel Index). Additionally, there are multiple secondary and exploratory endpoints evaluating multiple elements of recovery and dysfunction, including biomarkers associated with the condition and recovery, and safety variables over the study period.

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. It 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.

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" stem cell product platform 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.

The Athersys, Inc. logo is available at: http://www.globenewswire.com/newsroom/prs/?pkgid=4548

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 lysosomal storage disorders, 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; 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; the success of our efforts to enter into new strategic partnerships and advance our programs; 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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