



April 17, 2013

Athersys Announces Authorization of Stem Cell Clinical Trial for Stroke in the United Kingdom

MHRA Authorizes Athersys to Expand Ongoing Phase 2 Clinical Trial of MultiStem Cell Therapy in Ischemic Stroke

CLEVELAND, April 17, 2013 (GLOBE NEWSWIRE) -- Athersys, Inc. (Nasdaq:ATHX) announced today that the Medicines and Healthcare products Regulatory Agency (MHRA) has approved Athersys' application to expand its ongoing Phase 2 study evaluating the administration of MultiStem[®] therapy to patients who have suffered an ischemic stroke. Enrollment at United Kingdom sites is expected to commence following final Ethics Committee review and the completion of final preparations at participating clinical centers.

"The MHRA authorization will enable us to bring several leading United Kingdom stroke centers into the study, which will help us to speed the completion of the stroke clinical trial," said Dr. Gil Van Bokkelen, Chairman and Chief Executive Officer of Athersys. "The authorization is also noteworthy as it marks the initiation of MultiStem clinical development activity in the United Kingdom."

The Phase 2 study is a double blind, placebo-controlled trial evaluating the safety and efficacy of MultiStem cells when administered to patients who have suffered a moderate to moderately severe stroke, as defined by a National Institutes of Health Stroke Scale (NIHSS) score of 8 to 20. Patients enrolled in the study receive a single intravenous dose of MultiStem therapy or placebo in the 24 to 36 hours following the stroke, which is a significant extension of the current treatment window over existing standard of care. The study is expected to enroll approximately 136 patients in total and is currently being conducted at multiple centers throughout the United States.

About MultiStem

MultiStem[®] cell therapy is a patented 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 cell therapy for use with 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" 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.

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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Source: Athersys, Inc.

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