December 17, 2013

Athersys' MultiStem(R) Stem Cell Therapy Receives Orphan Drug Designation in Europe for Prevention of Graft-Versus-Host Disease

European Orphan Designation Complements U.S. Orphan Designation for MultiStem Cell Therapy for Treatment of Patients with Leukemia or Related Malignancies Undergoing Allogeneic Hematopoietic Stem Cell Transplantation

CLEVELAND, Dec. 17, 2013 (GLOBE NEWSWIRE) -- Athersys, Inc. (Nasdaq:ATHX) announced today that the Committee for Orphan Medicinal Products of the European Medicines Agency (EMA) has issued a positive opinion (EMA/OD/146/13) for the Company's allogeneic, multipotent adult progenitor cell, or MultiStem® therapy, for the prevention of graft-versus-host disease (GvHD). The Company is developing its MultiStem cell therapy as a GvHD prophylaxis in patients undergoing allogeneic hematopoietic stem cell (HSC) transplant and is currently preparing for a Phase II/III clinical study in the area. The MultiStem therapy for the prevention of GvHD has also previously been granted orphan drug designation by the U.S. Food and Drug Administration (FDA).

"We are pleased to have been granted the benefits of orphan drug designation in Europe," said Dr. Manal Morsy, Head of Global Regulatory Affairs at Athersys. "Together with our U.S. orphan designation for this indication, this EMA designation has the potential to facilitate our development of MultiStem therapy to help patients at risk of GvHD associated with HSC transplantation."

Patients with leukemia or other related malignancies are typically treated by radiation and chemotherapy, which are administered to destroy cancerous cells, but also substantially impair the blood forming and immune system of the patient. These procedures are followed by a HSC transplant to reconstitute the immune system to fight infection and any remaining malignancy. Patients undergoing donor derived, or allogeneic, HSC transplants are at significant risk for serious complications, including GvHD, which results when transplanted immune cells attack various tissues and organs in the patient. GvHD can be severe and life-threatening, with substantial impact on overall treatment requirements and costs, as well as on the patient's quality of life. Annually, there are estimated to be more than 25,000 allogeneic HSC transplants in the developed countries.

Athersys has completed a Phase I clinical study of the administration of MultiStem cells to certain patients having allogeneic HSC transplants. The study demonstrated the safety of MultiStem therapy in this indication and suggested that MultiStem may have a beneficial effect in reducing the incidence and severity of GvHD, as well as providing other benefits. These results build on the work of Athersys scientists and collaborators who have demonstrated that MultiStem cells suppress undesired T-cell-mediated immune responses that are an important factor in causing GvHD and support tissue repair and regeneration, leading to a significant increase in survival in preclinical models.

Currently, the Company is preparing for a Phase II/III clinical study in the area. It has met with the FDA and received feedback regarding proposed plans for the next phase of clinical development and is finalizing the study design. Based on current plans, the Company is preparing to be ready to start this study in 2014, but the initiation will depend on the progress in other clinical trials and the achievement of certain business development and financial objectives.

Orphan drug designation, which is intended to facilitate drug development, provides substantial potential incentives to the sponsor, such as fee reductions for agency meetings, study-design assistance, opportunities for expedited product development, orphan grant access, tax incentives and market exclusivity for the product upon regulatory approval (7 years for the U.S. and up to 10 years for the EU).

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.

CONTACT: William (B.J.) Lehmann, J.D.

President and Chief Operating Officer

Tel: (216) 431-9900

bjlehmann@athersys.com

Investor Relations:

Lisa M. Wilson

In-Site Communications

Tel: (917) 543-9932

lwilson@insitecony.com

Source: Athersys, Inc.

News Provided by Acquire Media