December 19, 2013

Athersys Confirms Completion of Patient Enrollment of Pfizer's Phase II Study of MultiStem (R) Cell Therapy for Ulcerative Colitis

Top-Line Data Readout Expected in Second Quarter 2014

CLEVELAND, Dec. 19, 2013 (GLOBE NEWSWIRE) -- Athersys, Inc. (Nasdaq:ATHX) today announced that Pfizer Inc. has completed patient enrollment of a Phase II clinical study involving administration of Athersys' MultiStem® cell therapy to ulcerative colitis patients as part of a 2009 collaboration agreement between Athersys and Pfizer. The study is a randomized, double-blind, placebo-controlled, multi-center clinical trial evaluating the safety and efficacy of MultiStem therapy in subjects with moderate to severe ulcerative colitis. Athersys expects initial results from the study to be disclosed in the second quarter of 2014.

"With enrollment now completed, we and our partner, Pfizer, look forward to the results from this study," commented Dr. John Harrington, Chief Scientific Officer at Athersys. "Despite progress in recent years, there remains a substantial need for new and improved treatments for ulcerative colitis and Crohn's disease, especially among patients with more advanced disease. Based upon MultiStem's preclinical safety and efficacy profile and novel mechanisms of action, we believe that MultiStem could provide meaningful benefit to these patients. The results from this study should provide significant insight into the potential for MultiStem therapy for the treatment of inflammatory bowel disease."

Inflammatory bowel disease (IBD) is a group of inflammatory and autoimmune conditions that affect the colon and small intestine, typically resulting in severe abdominal pain, weight loss, vomiting and diarrhea. The most common IBD conditions include ulcerative colitis and Crohn's disease, which are estimated to affect four million people or more in the United States, the major European markets and Japan. IBD can be a severely debilitating condition, and advanced cases may require surgery to remove the affected region of the bowel, and may also require temporary or permanent colostomy or ileostomy. In many cases, surgery does not achieve a permanent or durable cure, and patients suffer a return of the disease.

The randomized, double-blind, placebo-controlled Phase II clinical trial is being conducted by Pfizer at sites in the United States, Canada and Europe. Subjects enrolled in the study have received either MultiStem treatment or placebo initially, followed by a second round of treatment with MultiStem cells or placebo at eight weeks, resulting in two groups for evaluation through eight weeks and four groups for evaluation through 16 weeks and beyond. The primary endpoints for the study include incidence and severity of adverse events over 16 weeks, change in endoscopic score (as measured by modified Baron score) at week eight, and changes in the Mayo rectal bleeding sub-score at weeks four and eight. Additionally, there are multiple secondary and exploratory endpoints evaluating disease indicators and markers over 16 weeks and through the entire study period.

Athersys expects that study data will be available in the second quarter 2014 in two parts. The first results, anticipated to be available in April or May, will describe the primary endpoints and certain secondary and exploratory endpoints for all subjects through eight weeks following the initial treatment. The second results, expected later in the second quarter, will cover additional data for subjects through 16 weeks following treatment.

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. Athersys has forged a strategic partnership with Pfizer Inc. to develop MultiStem for treating inflammatory bowel disease, while independently evaluating it as a novel therapeutic approach for indications in the neurological, cardiovascular and transplant support areas, as well as other potential opportunities.

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; the timing of the results from Pfizer's Phase II clinical study involving MultiStem cell therapy to ulcerative colitis patients; 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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Source: Athersys, Inc.

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