



Athersys Announces Positive Results from Phase I Study of MultiStem(R) in Heart Attack Patients

Stem Cell Therapy Well Tolerated at All Dose Levels

CLEVELAND, Jul 28, 2010 (GlobeNewswire via COMTEX News Network) -- Athersys, Inc. (Nasdaq:ATHX) announced today positive results from its phase I clinical trial of MultiStem(R), its allogeneic cell therapy product, administered to individuals following acute myocardial infarction (AMI), more commonly referred to as a heart attack. The study results, based on four months of post-treatment patient data, demonstrate that MultiStem was well tolerated at all dose levels and also suggest improvement in heart function in treated patients.

The phase I clinical trial is an open label, multi-center dose escalation trial evaluating the safety and maximum tolerated dose of a single administration of allogeneic MultiStem cells following an AMI. Enrolled patients received MultiStem delivered via a catheter into the damaged region of the heart 2-5 days following percutaneous coronary intervention (PCI), a standard treatment for heart attack. The study includes patients in three treatment cohorts or dose groups (20 million, 50 million and 100 million cells per patient) and a registry group where patients received only standard of care. Nineteen treated and six registry subjects participated in the study. The trial is being conducted at cardiovascular treatment centers in the United States, including the Cleveland Clinic, Columbia University Medical Center and Henry Ford Health System.

Highlights of the Study:

- Administration of MultiStem was found to be well tolerated at all dose levels
- No clinically significant changes in vital signs, allergic reactions, or infusion-related toxicities were associated with MultiStem administration
- Each dose group showed improvement in mean left ventricular ejection fraction (LVEF), a measure of heart function, compared to baseline and relative to the registry group
- Patients in the 50 million dose group had a statistically significant absolute improvement in mean 4-month LVEF relative to baseline (9.8 percentage points, representing a 23.4% improvement over baseline, $p < 0.02$)
- Among patients with more severe heart attacks -- as measured by baseline LVEFs less than or equal to 45% -- the 50 and 100 million dose groups each demonstrated better than a 25% improvement in mean LVEF at 4 months post treatment over baseline

"We are encouraged by the results of this phase I study, and based on these results, will work with our partner, Angiotech Pharmaceuticals, on plans for a phase II trial to further evaluate safety and assess improvement in cardiac function" said Gil Van Bokkelen, CEO of Athersys, Inc. "This study is an important step and provides additional validation of the clinical potential and therapeutic profile of MultiStem as an off-the-shelf, allogeneic stem cell therapy, and we look forward to building off these results."

Dr. Marc Penn, M.D., Ph.D., co-principal investigator of this study and Director of Cardiovascular Cell Therapy at the Cleveland Clinic, and Director of the Skirball Laboratory for Cardiovascular Cellular Therapeutics, plans to present additional data and results and further discuss the study on September 22, 2010 in Washington, D.C. at the Symposium "Strategies for Cardiovascular Repair: Stem Cell Therapy and Beyond," at the Transvascular Cardiovascular Therapeutics Conference.

"These phase I results suggest that MultiStem is well tolerated when administered to the damaged region of the heart following

a heart attack," said Dr. Penn. "MultiStem's safety profile, together with trends suggesting meaningful improvement in functional measures, illustrates the potential of this therapy in this area and supports further clinical study of MultiStem for the treatment of heart disease."

Safety

During the first 24 hours following MultiStem administration, patients were assessed for infusion-related toxicity and other acute adverse events. Subsequently, patients were evaluated for cardiac adverse events. The primary endpoints for the study were the assessment of acute adverse events during the first 24 hours following administration, post-acute adverse events up to 30 days, and catheter-related events.

The administration of MultiStem was found to be well tolerated at all dose levels evaluated. There were no dose limiting toxicities associated with the administration of MultiStem. Immediately following dosing, there were no clinically significant changes to vital signs or evidence of allergic reaction associated with MultiStem administration. Over the 30-day post-acute observation period, no infusional toxicities or clinically significant cardiac adverse events deemed to be definitely related to MultiStem occurred.

MultiStem had a favorable safety profile over the four-month period following treatment. There was no dose dependent effect of MultiStem on adverse events (AEs) and generally AEs were mild to moderate in nature. Overall, there were several observed AEs characterized as potentially related to MultiStem or catheter delivery. These were generally mild to moderate in nature and were not dose dependent.

Heart Function

While the primary objective of this phase I study is to evaluate the safety of MultiStem administered to AMI patients, echocardiogram data are being collected and evaluated for evidence of efficacy signals to facilitate planning for subsequent clinical studies, noting importantly that the study was not powered for efficacy endpoints. Specifically, following a heart attack, patients were screened by left ventriculogram and/or echocardiogram, analyzed at the clinical site, to determine if their LVEFs met inclusion criteria (30 to 45). Prior to MultiStem administration (and between 2-5 days following PCI for registry patients), an additional echocardiogram was performed, which served as the baseline for subsequent analysis. Additional echocardiogram data were collected at prescribed time points according to the protocol. Echocardiogram data collected for each patient were blinded, and evaluated at a central facility.

The preliminary echocardiogram data demonstrated that each group had improvement in mean LVEF at four months compared to mean baseline LVEF. Patients receiving 20, 50, or 100 million MultiStem cells demonstrated absolute improvements in mean LVEF at 4 months of 5.2, 9.8 and 1.5 percentage points, respectively, compared to an absolute improvement of 1.1 percentage points in the registry group. Although the study was not powered for efficacy endpoints, patients in the medium dose group exhibited a statistically significant improvement in LVEF over mean baseline for that group, 9.8 percentage points ($p < 0.02$), representing a 23.4% improvement over baseline. The improvement in mean LVEF for each group compared to the registry group, though meaningful, was not statistically significant.

Notably, several patients in the high dose group exhibited substantially higher baseline LVEFs than their initial screening LVEFs, which created a higher baseline mean for that patient group. Including only patients whose baseline LVEFs less than or equal 45, the absolute improvements in mean LVEF were 3.9, 13.5 and 10.9 percentage points for the 20, 50, or 100 million dose groups, respectively, compared to an absolute improvement of 0.9 percentage points in the registry group. Among these patients (i.e., LVEFs less than or equal 45), those in both the medium and high dose groups exhibited a substantial increases in LVEF, representing more than 25% improvements relative to baseline LVEF for those patient groups. Additional analysis of the echocardiogram data is ongoing, and we will evaluate possible effects on other measures of heart function.

"These preliminary phase I MultiStem results are consistent with the results obtained in preclinical studies and compare favorably to the results from other cell therapy treatments for AMI. This suggests that MultiStem could have a meaningful impact on improving heart function following heart attack," stated Dr. Warren Sherman, co-principal investigator and Director of Stem Cell Research and Regenerative Medicine, Center for Interventional Vascular Therapy at Columbia University Medical Center in New York.

Further Evaluation and Development

Athersys and its development partner, Angiotech Pharmaceuticals, will continue to evaluate the phase I results and intend to begin planning for a subsequent clinical study, which they currently anticipate will be initiated in 2011. Further guidance about subsequent clinical development, such as trial design and timing, will be provided after evaluation and planning are completed and discussion with the FDA has occurred.

Angiotech Pharmaceuticals is a global specialty pharmaceutical company that discovers, develops and markets innovative

treatment solutions for diseases or complications associated with medical device implants, surgical interventions and acute injury. To find out more about Angiotech (Nasdaq:ANPI, TSX:ANP), please visit its website at www.angiotech.com.

Conference Call

Athersys, Inc. will host a conference call today at 4:30 PM (Eastern Time) to review the top-line data results of the phase I clinical trial of MultiStem, its cell therapy treatment for individuals following AMI (or heart attack).

Gil Van Bokkelen, Chairman and Chief Executive Officer, William (B.J.) Lehmann, President and Chief Operating Officer, and John Harrington, Executive Vice President and Chief Scientific Officer, will host the call. Dr. Marc Penn will also participate in the call.

Investors and other interested parties are invited to listen to the conference call by dialing 800-273-1254 in the U.S. and Canada, 973-638-3440 from abroad, or via a live Internet broadcast on the Company's website at www.athersys.com, under the Investor Relations section.

A replay will be available for on-demand listening shortly after the completion of the call until 11:59 PM (Eastern Time) on August 11, 2010, at the aforementioned URL, or by dialing 800- 642-1687 in the U.S. and Canada, or 706- 645-9291 from abroad, and entering access code 90560271.

About MultiStem

MultiStem is a patented and proprietary cell therapy product consisting of a special class of stem cells that are obtained from the bone marrow or other tissue sources of healthy, consenting adult donors, and which have the demonstrated ability to produce a range of factors, as well as form multiple cell types. MultiStem appears to promote tissue repair and healing in multiple ways, such as through the production of multiple therapeutic factors produced in response to signals of inflammation and tissue damage. Athersys believes that MultiStem represents a unique "off-the-shelf" stem cell product based on work that demonstrates the ability to deliver multiple mechanisms of therapeutic benefit, administration of the product without tissue matching or immunosuppression, and its capacity for large-scale production. Athersys has forged strategic partnerships with Pfizer Inc. to develop MultiStem for inflammatory bowel disease and with Angiotech to develop MultiStem in acute myocardial infarction and other cardiovascular indications.

About Athersys

Athersys is a clinical stage biopharmaceutical 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 MultiStem(R), a patented, adult-derived "off-the-shelf" stem cell product platform for multiple disease indications, including damage caused by myocardial infarction, bone marrow transplantation and oncology treatment support, ischemic stroke, and inflammatory bowel disease. The Company is also developing a portfolio of other therapeutic programs, including orally active pharmaceutical product candidates for the treatment of metabolic and central nervous system disorders, utilizing proprietary technologies, including Random Activation of Gene Expression (RAGE(R)). Athersys has forged several key strategic alliances 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," "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 and other disease indications. 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: the possibility of delays in, adverse

results of, and excessive costs of the development process; our ability to successfully initiate and complete a phase II clinical trial of MultiStem for AMI; 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 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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