Aastrom

Aastrom Announces Treatment of First Patient in U.S. Phase II IMPACT-DCM Trial

ANN ARBOR, Mich., Nov. 20, 2008 (GLOBE NEWSWIRE) -- Aastrom Biosciences, Inc. (Nasdaq:ASTM), a leading regenerative medicine company, today announced that the first patient has been treated in its randomized, controlled, prospective, open-label IMPACT-DCM clinical trial. Currently enrolling patients at The Methodist Hospital in Houston, TX, Baylor University Medical Center in Dallas, TX and The University of Utah School of Medicine in Salt Lake City, UT, the U.S. Phase II clinical trial is designed to evaluate the Company's Cardiac Repair Cells (CRCs) in the treatment of dilated cardiomyopathy (DCM), a severe form of chronic heart failure. Dr. Amit Patel, Associate Professor of Surgery at the University of Utah School of Medicine, is the National Principal Investigator for this trial.

IMPACT-DCM is the first clinical trial in the U.S. to evaluate the surgical delivery of autologous cells directly into human heart muscle for the treatment of DCM-related congestive heart failure. Patients are treated with Aastrom's CRCs, an autologous, mixed-cell product containing expanded populations of stem and early progenitor cells designed to treat patients with end-stage DCM. CRCs, manufactured using Aastrom's Tissue Repair Cell (TRC) technology, previously received Orphan Drug Designation from the FDA for the treatment of DCM.

"Following our initial positive experience with compassionate use treatments in Germany, we are pleased to advance this promising cardiac regeneration treatment to the clinic in the U.S.," said George Dunbar, President and Chief Executive Officer of Aastrom. "We are pleased with the momentum this trial is gathering. Three of the five clinical sites are currently ready to enroll patients, and we look forward to having all five sites actively recruiting patients into this multi-center study."

The first patient surgery in the IMPACT-DCM trial took place at the Methodist DeBakey Heart & Vascular Center (Methodist) in Houston, TX. The procedure was performed by Dr. Brian Bruckner, Cardiac Surgeon at Methodist and Principal Investigator of the trial at the clinical site; Dr. Michael Reardon, Chief of Cardiac Surgery at Methodist and a Co-Investigator of the trial; and Dr. Matthias Loebe, Transplant Surgeon at Methodist and a Co-Investigator of the trial.

The Phase II study seeks to enroll 20 patients with ischemic DCM and 20 patients with non-ischemic DCM at five clinical sites in the U.S. Participants must have a left ventricular ejection fraction (LVEF) of less than or equal to 30% (60-75% is typical for a healthy person) and meet certain other eligibility criteria. The study protocol states that patients in each group will receive standard medical care and 75% of patients will be treated with CRCs through direct injection into the heart muscle during minimally invasive open heart surgery. While the primary objective of this study is to assess the safety of CRCs in patients with DCM, efficacy measures including LVEF, heart failure stage and other measures of cardiac function will be monitored. The Company intends to follow patients in the study for 12 months post treatment.

"This is the first clinical trial designed to target both ischemic and non-ischemic DCM," said Dr. Elmar Burchardt, Vice President, Medical Affairs of Aastrom. "In the U.S. alone, there are 1.8 million patients with severe heart failure, which includes 120,000-150,000 patients suffering from DCM."

Many of the 5.5 million people in the U.S. suffering from severe heart failure have DCM, a condition where expansion of the patient's heart reduces pump function, making it impossible to maintain normal blood circulation. Patients with DCM typically have symptoms of congestive heart failure, including severe limitations in physical activity and shortness of breath. DCM generally occurs in patients who have ischemic heart failure due to multiple heart attacks, though it can also be found in patients with non-ischemic heart failure caused by hypertension, viral infection or alcoholism. Patient prognosis depends upon the stage of the disease but is typically characterized by numerous health problems and a very high mortality rate.

About Orphan Drug Designation

The Orphan Drug Designation is granted to development-stage products, such as Aastrom's CRCs, that offer potential therapeutic value in the treatment of rare diseases and conditions. With this designation, Aastrom may be entitled to several benefits prior to approval, including an expedited FDA review, the reduction or even elimination of filing fees, and the availability of possible tax credits, and will be entitled to seven years of marketing exclusivity once the product receives FDA approval.

About Aastrom Biosciences, Inc.

Aastrom is a leader in the development of autologous cell products for the repair or regeneration of human tissue. The Company's proprietary Tissue Repair Cell (TRC) technology involves the use of a patient's own cells to manufacture products to treat a range of chronic diseases and serious injuries. Aastrom's TRC-based products contain increased numbers of stem and early progenitor cells, produced from a small amount of bone marrow collected from the patient. The TRC technology

platform has positioned Aastrom to advance multiple products into clinical development. Ongoing development activities are focused on applying TRC technology to cardiac and vascular tissue regeneration. The company is currently focused on cardiovascular regeneration and is conducting a Phase II clinical trial with dilated cardiomyopathy (DCM) patients (the IMPACT-DCM trial) and a Phase IIb clinical trial with critical limb ischemia (CLI) patients (the RESTORE-CLI trial).

The Aastrom Biosciences, Inc. logo is available at http://www.globenewswire.com/newsroom/prs/?pkgid=3663

This document contains forward-looking statements, including, without limitation, statements concerning clinical trial strategies, potential partnering activities, product development objectives, potential advantages of TRC technology and TRC-based products, and potential product applications, which involve certain risks and uncertainties. The forward-looking statements are also identified through use of the words "intends," "expect," "expected," "should," "anticipated," and other words of similar meaning. Actual results may differ significantly from the expectations contained in the forward-looking statements. Among the factors that may result in differences are clinical trial results, potential product development difficulties, the effects of competitive therapies, regulatory approval requirements, the availability of financial and other resources and the allocation of resources among different potential uses. These and other significant factors are discussed in greater detail in Aastrom's Annual Report on Form 10-K and other filings with the Securities and Exchange Commission.

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