Aastrom

Aastrom to Initiate Second Phase II Clinical Trial for Treatment of Severe Chronic Heart Failure

Catheter-Based Delivery of CRCs by Cardiologists to Expand Company's Ongoing Cardiovascular Program

ANN ARBOR, Mich., Nov. 10, 2009 (GLOBE NEWSWIRE) -- Aastrom Biosciences, Inc. (Nasdaq:ASTM), a leading developer of autologous cell products for the treatment of chronic cardiovascular diseases, today announced that the Company will initiate its second clinical trial for the treatment of dilated cardiomyopathy (DCM), a severe disease associated with chronic heart failure, after a positive 30-day review of Aastrom's Investigational New Drug (IND) submission by the U.S. Food & Drug Administration (FDA). This second trial is a 24 patient U.S. Phase II clinical trial to evaluate the catheter delivery of Cardiac Repair Cells (CRCs) for the treatment of DCM. The new trial expands the Company's cardiovascular program that includes a U.S. Phase II IMPACT-DCM clinical trial evaluating the direct surgical delivery of CRCs. The FDA previously granted CRCs an Orphan Drug Designation for the treatment of DCM.

"Given the encouraging initial results in our surgical-based, open-label clinical trial, we are expanding our cardiovascular program to include a catheter-based delivery method for these critically ill patients," said Elmar R. Burchardt, M.D., Ph.D., Vice President, Medical Affairs of Aastrom. "Our catheter-based delivery method is less invasive than the surgical approach and therefore increases the number of potential patient candidates for CRC treatment. End-stage heart failure patients currently have limited therapeutic options other than heart transplantation and mechanical pump assist devices. By expanding the delivery options for CRCs to include the catheter delivery by cardiologists, we are complementing the surgical delivery by cardiac surgeons."

The randomized, controlled, prospective, open-label, Phase II study will seek to enroll 12 patients with ischemic DCM and 12 patients with non-ischemic DCM at two clinical sites in the U.S. Participants must have a left ventricular ejection fraction of less than or equal to 30% (60-75% is typical for a healthy person) and meet certain other eligibility criteria. All 24 patients will receive standard medical care and 16 of the patients (8 ischemic and 8 non-ischemic) will also be treated with CRCs via catheter injection. While the primary objective of this study is to assess the safety of CRCs delivered by catheter injection in patients with DCM, efficacy measures including heart failure stage and cardiac function parameters will also be assessed. Patients will be followed for 12 months post treatment.

There are currently 5.5 million people in the U.S. suffering from chronic heart failure. A subset of these patients has DCM, a chronic cardiac disease where expansion of the patient's heart reduces the pump function to a point that the normal circulation of blood cannot be maintained. Patients with DCM typically present with symptoms of congestive heart failure, including severe limitations in their 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 on the stage of the disease but is 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. The Company 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 should the product receive FDA approval.

About Aastrom Biosciences, Inc.

Aastrom is a leader in regenerative medicine developing autologous cell products for the treatment of chronic cardiovascular diseases. The Company's proprietary Tissue Repair Cell (TRC) technology expands the numbers of stem and early progenitor cells from a small amount of bone marrow collected from the patient. Bone marrow provides a rich source of diverse cell populations, is easily accessible and allows Aastrom to produce a personalized treatment for site-specific delivery to the patient's diseased tissues. Aastrom has treated more than 350 patients in various clinical trials over 10 years without any product safety issues. The Company is currently conducting a Phase II cardiac regeneration clinical trial (the IMPACT-DCM trial) in patients with dilated cardiomyopathy (DCM -- severe chronic heart failure) and a Phase IIb vascular regeneration clinical trial (the RESTORE-CLI trial) in patients with critical limb ischemia (CLI -- the most severe form of peripheral arterial disease).

For more information, visit Aastrom's website at www.aastrom.com.

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 plans and expectations, clinical activity timing, intended product development and commercialization objectives, adequacy of existing capital to support operations for a specified time, future capital needs, and potential advantages and application of Tissue Repair Cell (TRC) Technology, all of which involve certain risks and uncertainties. These statements are often, but are not always, made through the use of words or phrases such as "anticipates," "intends," "estimates," "plans," "expects," "we believe," "we intend," and similar words or phrases, or future or conditional verbs such as "will," "would," "should," "potential," "could," "may," or similar expressions. Actual results may differ significantly from the expectations contained in the forward-looking statements. Among the factors that may result in differences are the inherent uncertainties associated with clinical trial and product development activities, regulatory approval requirements, competitive developments, and the availability of 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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