Aastrom

Aastrom to Initiate Phase II Clinical Trial Using Cardiac Repair Cells Derived From Patient's Own Bone Marrow for Treatment of Severe Chronic Heart Failure

FDA Authorizes IND Application for Aastrom's First Cardiac Regeneration Clinical Trial

ANN ARBOR, Mich., Jun 17, 2008 (PrimeNewswire via COMTEX News Network) -- Aastrom Biosciences, Inc. (Nasdaq:ASTM), a leading regenerative medicine company, today announced plans to initiate a 40 patient U.S. Phase II clinical trial to study the use of Cardiac Repair Cells (CRCs), a mixture of stem and progenitor cells derived from a patient's own bone marrow, for the treatment of dilated cardiomyopathy (DCM), a severe form of chronic heart failure. Aastrom is now authorized under U.S. Food & Drug Administration (FDA) regulations to initiate its first Investigational New Drug (IND) clinical trial for cardiac regeneration. CRCs, manufactured using Aastrom's Tissue Repair Cell (TRC) technology, previously received Orphan Drug Designation from the FDA for the treatment of DCM.

"This landmark trial is the first in the world to target both ischemic and non-ischemic DCM patients. It is also the first trial in the U.S. to evaluate the surgical delivery of autologous cells directly into the source of the problem, the heart muscle, for the treatment of congestive heart failure due to DCM," stated David A. Bull, M.D., Professor of Surgery and Chief of Cardiothoracic Surgery at the University of Utah School of Medicine. "Aastrom's unique technology is able to produce a mixed cell population that we believe may be efficacious for treating these end-stage patients and is our primary motivation for participating in the trial."

The randomized, controlled, prospective, open-label, Phase II study will seek 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 of less than or equal to 25% (60-75% is typical for a healthy person) and meet certain other eligibility criteria. All patients in each group will receive standard medical care and 75% of the patients will be treated with CRCs through direct injection into the heart muscle during open heart surgery. While the primary objective of this study is to assess the safety of CRCs in patients with DCM, efficacy measures including left ventricular ejection fraction and other cardiac function parameters as well as heart failure stage will be monitored. Patients will be followed for 12 months post treatment.

"Aastrom's trial is targeting critically ill patients with heart failure. These patients, with enlarged, weakened hearts, are at the end-stage of their disease and currently have no treatment options other than a heart transplant," said Mariell Jessup M.D., Professor of Medicine and Medical Director of Heart Failure and Transplantation, at the University of Pennsylvania Health System. "Without a new therapeutic approach the majority of these patients will continue to decline and less than 40% will survive five years."

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.

"After initial positive patient experience in the EU, we are pleased to be advancing our promising CRC program into the clinic in the U.S.," said George Dunbar, President and Chief Executive Officer of Aastrom. "The IND approval for a Phase II trial to treat patients suffering from DCM supports our decision to focus our efforts and resources primarily on cardiac regeneration. As we move our cardiac development program forward, we will stop enrolling patients in our ON-CORE clinical trial for bone regeneration until we identify a partner to work with us to complete that effort. Patients who have already been treated in the ON-CORE trial will be followed by their physicians for the full 24 month follow-up period. Our RESTORE-CLI clinical trial targeting critical limb ischemia will continue as planned."

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 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 affecting cardiovascular, bone and neural tissues. 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. Currently, the Company has a cardiovascular regeneration product in Phase II development for the treatment of dilated cardiomyopathy (DCM) (called the IMPACT-DCM trial) and critical limb ischemia (called the RESTORE-CLI trial), a bone regeneration product in Phase III development for the treatment of osteonecrosis of the femoral head (called the ON-CORE trial), and a preclinical research program targeting unmet needs in neural health. Aastrom product candidates to treat DCM and osteonecrosis of the femoral head have been designated for orphan drug status by the FDA. For more information, visit Aastrom's website at www.aastrom.com. (astmc)

The Aastrom Biosciences, Inc. logo is available at http://www.primenewswire.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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