Aastrom

Update On Aastrom's Cardiovascular Programs to be Presented At Transcatheter Cardiovascular Therapeutics Annual Meeting by Amit N. Patel, M.D.

Momentum of Current Clinical Trial Recruitment Continues; Clinical Trial Pipeline for Severe Heart Failure Patients Expanding

ANN ARBOR, Mich., Sept. 22, 2009 (GLOBE NEWSWIRE) -- Aastrom Biosciences, Inc. (Nasdaq:ASTM), a leading developer of autologous adult stem cell treatments for severe chronic cardiovascular diseases, announced today that Dr. Amit N. Patel, Associate Professor of Surgery at the University of Utah School of Medicine and National Principal Investigator of the Company's U.S. Phase II IMPACT-DCM clinical trial, will provide an overview of Aastrom's cardiovascular programs at the Transcatheter Cardiovascular Therapeutics (TCT) annual meeting in San Francisco, California. Dr. Patel's presentation is part of the session entitled "Session III -- Changing the Course of End-Stage Chronic Heart Failure," and will take place at approximately 3:17 p.m. (PDT) today, September 22, 2009.

Dr. Patel's presentation at the TCT meeting will include the following updates:

* Cardiac Regeneration:

  -- U.S. Phase II IMPACT-DCM clinical trial (surgical delivery)

    * The IMPACT-DCM trial is the first trial to evaluate the surgical delivery of autologous cells directly into the human heart muscle for the treatment of congestive heart failure associated with dilated cardiomyopathy (DCM) in both ischemic and non-ischemic patients.
    * To date, the trial has enrolled 22 patients at five sites across the U.S.
    * Consistent with previous guidance, the Company anticipates that patient enrollment will be completed by the end of December 2009.

  -- Anticipated U.S. Phase II clinical trial for DCM patients (catheter delivery)

    * Aastrom is expanding its ongoing clinical program to evaluate Cardiac Repair Cells (CRCs) in the treatment of severe heart failure patients.
    * The Company intends to file an Investigational New Drug (IND) application with the U.S. Food and Drug Administration (FDA) to initiate its second clinical trial to treat DCM patients.
    * The second cardiac regeneration trial is designed to explore a catheter-based approach for the delivery of CRCs to treat DCM patients, in addition to the ongoing surgical delivery approach in the IMPACT-DCM trial.

* Vascular Regeneration:

  -- U.S. Phase IIb RESTORE-CLI clinical trial

    * The RESTORE-CLI trial is a prospective, controlled, randomized, double-blind, multi-center clinical trial to treat patients suffering from critical limb ischemia (CLI), the end stage of peripheral arterial disease (PAD).
    * To date, the trial has enrolled 74 patients at 21 sites across the U.S.

* Consistent with previous guidance, the Company anticipates reporting interim clinical data during the first quarter of calendar year 2010.

"Aastrom's current cardiovascular programs provide a powerful base to build upon," said Dr. Patel. "I'm impressed with Aastrom's cell-based product and the progress the Company is making in its ongoing cardiac and vascular regeneration clinical trials. The upcoming initiation of a second cardiac regeneration trial demonstrates the commitment Aastrom has made to developing new treatments for these end-stage patients who currently have limited treatment options available to them."

About Dilated Cardiomyopathy (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 Critical Limb Ischemia (CLI)

Peripheral arterial disease (PAD) is a chronic disease that progressively restricts blood flow in the limbs and can lead to serious medical complications. This disease is often associated with other clinical conditions, including hypertension, cardiovascular disease, hyperlipidemia, diabetes, obesity and stroke. The term critical limb ischemia (CLI) is used to describe patients with chronic ischemia-induced pain (even at rest), ulcers, tissue loss or gangrene in the limbs. CLI is the most severe form of PAD, and is typically the end stage of the disease. Patients suffering from this condition are critically ill, with a high risk of amputation. These patients are extremely limited in their ambulatory capacity, experience constant and chronic ischemia-induced pain, ulcers, tissue loss or gangrene to the limbs, which lead to approximately 160,000 amputations per year.

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 expanded 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. TRC-based products have been used in over 350 patients with over 10 years of positive safety data. The Company's ongoing development activities focus on applying TRC technology to cardiac and vascular tissue regeneration. The Company is currently 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

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

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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