Aastrom

Updates and Results From Aastrom's Vascular Program Presented at an American Heart Association Satellite Symposium

Physicians Present Continued Progress in Company's Vascular Clinical Program

ANN ARBOR, Mich., Nov. 16, 2009 (GLOBE NEWSWIRE) -- Aastrom Biosciences, Inc. (Nasdaq:ASTM), a leading developer of autologous cell products for the treatment of severe, chronic cardiovascular diseases, announced that two oral presentations regarding the Company's vascular clinical program were given Sunday evening at an American Heart Association Satellite Symposium titled "Can We Really Grow New Blood Vessels?" in Orlando, FL:

* Timothy Henry, M.D., Director of Research at the Minneapolis Heart Foundation, Interventional Cardiologist at the Minneapolis Heart Institute and a site Principal Investigator in the Company's U.S. Phase IIb RESTORE-CLI clinical trial, presented an update on Aastrom's clinical trial that is evaluating Vascular Repair Cells (VRCs) in the treatment of patients suffering from critical limb ischemia (CLI), the most severe form of peripheral arterial disease (PAD).

* Subhash Thakur, M.D., Clinician Scientist at Jobst Vascular Center in Toledo, Ohio, and a member of the clinical team led by Anthony J. Comerota, M.D., F.A.C.S., F.A.C.C., Director of the Jobst Vascular Center and Adjunct Professor at the University of Michigan, presented results of complete wound healing in a case study of one compassionate use patient treated with VRCs for upper extremity CLI.

Dr. Henry provided an overview of Aastrom's prospective, controlled, randomized, double-blind, multi-center RESTORE-CLI clinical trial protocol and design. This trial is evaluating Aastrom's VRCs in the treatment of patients suffering from the most severe form of PAD, a condition known as CLI. To date, 78 patients have been enrolled in the study and enrollment continues at 18 sites across the U.S.

Dr. Thakur presented the case study of a compassionate use patient treated with Aastrom's VRCs for upper extremity CLI, a very rare condition with an extremely negative prognosis and no current treatment options. This patient was treated under a single-patient Investigational New Drug (IND) submission.

The 64-year-old male patient suffered from diabetes for 46 years, had several previous amputations in both the upper and lower extremities and presented with progressive gangrene in the fingers of both hands. Dr. Thakur presented the following post-treatment findings:

* The patient experienced a reduction in pain within one month of treatment and became pain- and narcotic-free within three and a half months;
* There was a notable decrease in the loss of healthy tissue on both hands and an increase in healing of the patient's fingers at three months post-treatment;
* An objective improvement in blood flow was measured by laser doppler imaging in the patient's fingers at nine and a half months; and,
* The most important finding is that the patient showed wound healing at nine and a half months.

"We are encouraged by the wound healing shown in the compassionate use of VRCs in this patient with upper extremity CLI.

These findings will supplement our interim analysis from a subset of RESTORE-CLI clinical trial patients planned for early calendar year 2010," said Elmar R. Burchardt, M.D., Ph.D., Vice President, Medical Affairs of Aastrom

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's U.S. Phase IIb RESTORE-CLI Clinical Trial

Aastrom's prospective, controlled, randomized, double-blinded, multi-center trial is expected to enroll 150 patients at up to 20 sites, randomized into two patient groups, to evaluate the safety and efficacy of the TRC-based product in the treatment of CLI. Patients from both groups will be followed for a period of 12 months, post-treatment. The primary objective of the clinical trial is to assess the safety of the TRC-based product in CLI patients. Secondary objectives include assessing amputation rates, wound closure and blood flow in the affected limbs, patient quality of life, and the reduction of pain and analgesic use.

About Aastrom Biosciences, Inc.

Aastrom is a leader in regenerative medicine developing autologous cell products for the treatment of severe, 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). Aastrom has also recently announced that the Company will initiate its U.S. Phase II clinical trial to evaluate the catheter delivery of CRCs for the treatment of DCM.

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.

CONTACT: Aastrom Biosciences, Inc.
Investor Relations
Kris M. Maly
Kimberli O'Meara
(734) 930-5777

Cameron & Associates
(Investors)
Kevin McGrath
(212) 245-4577

Berry & Company
(Media)

Stephen Zoegall
(212) 253-8881