Aastrom

Aastrom Announces Achievement of Milestone in U.S. Phase IIb Critical Limb Ischemia Clinical Trial

ANN ARBOR, Mich., Oct. 30, 2008 (GLOBE NEWSWIRE) -- Aastrom Biosciences, Inc. (Nasdaq:ASTM), a leading regenerative medicine company, today announced that the 30th patient has been treated in the Company's U.S. Phase IIb RESTORE-CLI clinical trial. This milestone marks the first step toward interim data retrieval from this clinical trial evaluating Aastrom's Vascular Repair Cells (VRCs) in the treatment of patients suffering from the most severe form of peripheral arterial disease (PAD), critical limb ischemia (CLI). After the 30th patient has been followed for one year the Company will be able to unblind and analyze the interim data.

The RESTORE-CLI clinical trial is a prospective, controlled, randomized, double-blind, multi-center study that is reviewed quarterly by a sponsor-appointed, independent Data and Safety Monitoring Board (DSMB). The DSMB is composed of third-party experts in vascular surgery, cardiovascular medicine, stem cell research and biostatistics. The DSMB has unblinded access to all available patient data. They review patient safety as well as efficacy information on an ongoing basis. At their September 24, 2008 meeting, the independent DSMB unanimously recommended continuation of the study.

"Treating the 30th patient in the RESTORE-CLI trial is a significant clinical accomplishment for Aastrom as we are now able to target the timing for the next milestone -- reporting interim data from this first set of critically ill patients," said George Dunbar, President and Chief Executive Officer of Aastrom. "These patients face a high risk of major limb amputation and may benefit from Aastrom's VRC treatment."

Approximately 10 million people in the U.S. suffer from PAD; of this group, 900,000 suffer from the most severe form, CLI, which leads to 100,000 amputations per year. 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 CLI is used to describe patients with chronic ischemia-induced pain (even at rest), ulcers, tissue loss or gangrene in the limbs. CLI represents the end stage for PAD patients.

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 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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