Aastrom Announces Treatment of Final Patient in RESTORE-CLI Clinical Trial

Company Plans to Initiate Phase 3 Planning Discussions With the FDA and Report Six-Month Interim Results for all Enrolled Patients Later This Year

ANN ARBOR, Mich., March 24, 2010 (GLOBE NEWSWIRE) -- Aastrom Biosciences, Inc. (Nasdaq:ASTM), a leading developer of autologous cellular therapies for the treatment of severe cardiovascular diseases, today reported that the final patient has been treated in the company's ongoing multi-center, randomized, double-blind, placebo-controlled U.S. Phase 2b clinical trial designated RESTORE-CLI. This patient received intramuscular injections of either Aastrom's tissue repair cells (TRCs) or electrolyte solution (placebo) for the treatment of critical limb ischemia (CLI), the end-stage of peripheral arterial disease. People with CLI face a high risk of amputation and, in some cases, death. Approximately 1 million people in the U.S. suffer from CLI, which results in more than 160,000 amputations each year.

Aastrom's RESTORE-CLI trial is the largest double-blind, randomized cell therapy study currently being conducted for CLI. The trial has enrolled a total of 86 patients at 18 sites in the United States. Patients in the treatment group received intramuscular injections of TRCs into the affected limb, while control patients received intramuscular injections with an electrolyte solution (without cells). Both groups also received appropriate standard of care for their condition. While the primary objective of this trial is to assess safety in patients with CLI, additional efficacy measures are also being monitored, including time to treatment failure (where failure is defined as major amputation, doubling of wound size or new gangrene), amputation rate, wound size and severity. Ankle brachial pressure index, pain and quality of life are also being monitored. Patients are being evaluated at both six months and 12 months following treatment.

"We are pleased to announce this milestone in our vascular regeneration program," said Tim Mayleben, president and CEO of Aastrom. "With the treatment of the final patient in this trial, we are well-positioned to report six-month interim results for all enrolled patients later this year and initiate planning for a pivotal Phase 3 vascular trial."

TRC-based cellular therapies are produced from a small sample of bone marrow taken from a patient. Aastrom's TRC technology greatly expands the cell populations for direct delivery to the damaged tissues of the same patient.

About Aastrom Biosciences

Aastrom Biosciences is developing autologous cellular therapies for use in the treatment of severe cardiovascular diseases. The company's proprietary cell-processing technology enables the production of cellular therapies using a patient's own bone marrow that can be delivered directly to damaged tissues. Aastrom has advanced this technology into late-stage clinical development and is conducting two Phase 2 clinical trials to treat dilated cardiomyopathy and a Phase 2b clinical trial to treat critical limb ischemia. For more information, please 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, expected timing of collecting and analyzing treatment data and possible communications with the U.S. Food and Drug Administration, 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, Quarterly Reports on Form 10-Q and other filings with the Securities and Exchange Commission. These forward looking statements reflect management's current views and Aastrom does not undertake to update any of these forward-looking statements to reflect a change in its views or events or circumstances that occur after the date of this release except as required by law.

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