Aastrom Demonstrates Statistically Significant Improvement in Time to First Occurrence of Treatment Failure at 12 Months in RESTORE-CLI Clinical Trial

RESTORE-CLI Results Meet Primary Safety and Efficacy Endpoints

ANN ARBOR, Mich., June 1, 2011 (GLOBE NEWSWIRE) -- Aastrom Biosciences, Inc. (Nasdaq:ASTM), the leading developer of patient-specific, expanded multicellular therapies for the treatment of severe, chronic, cardiovascular diseases, today announced that the final analysis of data from all 86 randomized patients in the RESTORE-CLI trial showed that the trial met its primary safety and efficacy endpoints, demonstrating a statistically significant improvement in the time to first occurrence of treatment failure (TTF) at 12 months. The RESTORE-CLI clinical trial assessed the safety and ability of ixmyelocel-T, Aastrom's expanded, bone marrow-derived cellular therapy, to restore damaged tissue in a lower extremity affected by critical limb ischemia (CLI).

In the clinical trial, the assessment of TTF included four components: major amputation of the treated leg, all-cause mortality, doubling of wound size from baseline, and *de novo* gangrene. All of these components together comprised the primary composite endpoint for this trial. CLI patients with tissue loss (i.e., *de novo* gangrene and increasing wound size) are five times more likely to experience amputation. As a result, tissue loss represents a widely accepted predictor of amputation risk in CLI patients. Aastrom plans to present the full data from the RESTORE-CLI trial at an appropriate medical meeting in the fourth quarter of 2011. The RESTORE-CLI trial is the largest, fully controlled cellular therapy clinical trial ever conducted in CLI.

"We are extremely pleased to report that the RESTORE-CLI trial met its primary safety and efficacy endpoints, providing substantial confirmation that ixmyelocel-T could represent an historic advance in the treatment of CLI for hundreds of thousands of patients who currently have no good treatment options available. I believe Aastrom is well positioned to advance this promising therapy through Phase 3 clinical testing and on to regulatory review," said Tim Mayleben, president and CEO of Aastrom.

Critical limb ischemia is considered the end-stage form of peripheral artery disease. It is the result of a chronic lack of blood flow to the lower extremities resulting in a variety of debilitating conditions, including severe rest pain, non-healing wounds, and gangrene. The double-blind, placebo-controlled RESTORE-CLI clinical trial randomized 86 men and women between the ages of 18 and 90 with a diagnosis of CLI and no previous major amputations. CLI was defined as persistent, recurring ischemic pain for at least two weeks, or ulcerations (grade 4 or 5 on the Wagner scale) or gangrene of the foot or toe. Participants in the clinical trial were randomized 2:1 to receive intramuscular injections of ixmyelocel-T or an electrolyte solution into the affected limb. Patients were followed for 12 months after treatment and otherwise received normal standard of care. The clinical trial was conducted at 20 medical centers throughout the U.S.

"Given the limited treatment options available in CLI, the results of this important Phase 2b study are encouraging for both patients and vascular physicians," said William R. Hiatt, MD, Novartis Foundation endowed professor for cardiovascular research at the University of Colorado School of Medicine and president of CPC Clinical Research, which has been chosen to collaborate with Aastrom on the upcoming Phase 3 clinical studies for ixmyelocel-T. "I look forward to working with Aastrom on what I believe is a very well-designed Phase 3 clinical development program for ixmyelocel-T in CLI, which also represents a translational step in the development of cellular therapies to treat human disease," Dr. Hiatt added.

Based on interim analyses from the RESTORE-CLI clinical trial, in October 2010 Aastrom announced plans to initiate a Phase 3 CLI clinical development program for ixmyelocel-T under special protocol assessments (SPA) and Fast Track designation by the FDA. Aastrom has been actively working with the FDA to finalize the special protocol assessment for the no option SPA and expects to conclude those discussions in the next several weeks.

About Aastrom Biosciences

Aastrom Biosciences is developing patient-specific, expanded multicellular therapies for use in the treatment of severe, chronic cardiovascular diseases. The company's proprietary cell-processing technology enables the manufacture of ixmyelocel-T, a patient-specific multicellular therapy expanded from a patient's own bone marrow and delivered directly to damaged tissues. Aastrom has advanced ixmyelocel-T into late-stage clinical development, including a planned Phase 3 clinical program to study patients with critical limb ischemia and two ongoing Phase 2 clinical trials in patients with dilated cardiomyopathy. 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 progress, objectives and expectations, clinical activity timing, intended product development, the performance and contribution of certain individuals and expected timing of collecting and analyzing treatment data, 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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