



Aastrom Presents Positive Second Interim Analysis of Phase 2b RESTORE-CLI Clinical Trial Company Continues Its Plans to Rapidly Move Into a Phase 3 Program in 2011

ANN ARBOR, Mich., Nov. 18, 2010 (GLOBE NEWSWIRE) -- Aastrom Biosciences, Inc. (Nasdaq:ASTM), a leading developer of expanded autologous cellular therapies for the treatment of severe cardiovascular diseases, today announced that an interim analysis of all 86 patients enrolled in the company's Phase 2b RESTORE-CLI clinical trial shows that the study achieved both its primary safety endpoint and primary efficacy endpoint of time to first occurrence of treatment failure. The findings related to time to first occurrence of treatment failure were statistically significant ($p=0.0132$). Further analyses show a clinically meaningful reduction of 56% in treatment failure events. The RESTORE-CLI trial is the largest fully controlled cell-therapy study ever conducted in critical limb ischemia (CLI).

This interim analysis includes results from all 86 patients who were randomized and enrolled in the trial, 72 of whom were eligible for treatment and have completed at least six months of follow-up and 62 of whom completed 12 months of follow-up. Analysis of the data for amputation-free survival, a secondary measure which the study was not powered to demonstrate, showed a clinically meaningful reduction in event rates of 24%, but did not show statistical significance ($p=0.5541$). Importantly, analysis of the data between the interim results shows similar treatment event rates (22-25%) for the treated group, but an unexpected reduction in event rates for the control group from 50% to 29%.

In February 2010, Aastrom reported results from an interim analysis of data from this trial that showed a statistically significant clinical benefit favoring Aastrom's autologous cellular therapy for the first 46 patients enrolled in the trial, in both time to first occurrence of treatment failure (a composite endpoint consisting of major amputation of treated leg, all-cause mortality, doubling of total wound surface area from baseline and *de novo* gangrene; $p=0.005$) and amputation-free survival ($p=0.038$).

Results of the second interim analysis were presented today in a non-CME satellite session of the VEITHsymposium™ in New York City by principal investigator Richard Powell, M.D., chief of vascular surgery at Dartmouth-Hitchcock Medical Center in Lebanon, NH. An archived webcast of the presentation will be available at www.aastrom.com/investor.cfm.

"I am very optimistic about the treatment response rates we have seen in patients in this trial so far. These interim data suggest that there is a clear and clinically meaningful therapeutic effect at work in treated patients. I look forward to examining the benefits of this treatment in the context of a larger Phase 3 study," said Dr. Powell.

The two interim analyses were done to provide information to support the design and execution of Aastrom's Phase 3 CLI program. In October, Aastrom announced plans to initiate a Phase 3 CLI clinical development program under special protocol assessments (SPA) with a Fast Track designation by the FDA.

"We believe these interim results provide further evidence supporting the use of our autologous cell therapy to treat patients with this devastating disease," said Tim Mayleben, president and CEO of Aastrom Biosciences. "As expected, these data provide essential guidance as we refine and finalize the sample sizes and patient selection criteria for our Phase 3 program."

About Aastrom Biosciences

Aastrom Biosciences is an emerging biotechnology company developing expanded autologous cellular therapies for use in the treatment of severe cardiovascular diseases. The company's proprietary cell-processing technology enables the manufacture of mixed-cell therapies expanded from a patient's own bone marrow and delivered directly to damaged tissues. Aastrom has advanced its cell therapies into late-stage clinical development, including a planned Phase 3 clinical program for the treatment of 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/?pkqid=3663>

This document contains forward-looking statements, including without limitation, statements concerning employment opportunities, clinical trial plans and progress, objectives and expectations, clinical activity timing, intended product development, disease treatment and progression, operating results, spending activities, patient symptoms and responses to

treatment, treatment options 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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