



## Aastrom Reports Interim Results From Critical Limb Ischemia Trial

*Study meets composite endpoint of reduction in time to treatment failure with statistical significance*

*Company concludes patient enrollment early to accelerate study completion and Phase 3 planning*

*Aastrom to hold investor conference call at 9 a.m. ET to discuss results*

ANN ARBOR, Mich., Feb. 24, 2010 (GLOBE NEWSWIRE) -- Aastrom Biosciences, Inc. (Nasdaq:ASTMD), a leading developer of autologous cellular therapies for the treatment of severe cardiovascular diseases, today reported results from a planned interim analysis of the company's multi-center, randomized, double-blind, placebo-controlled U.S. Phase 2b clinical trial designated RESTORE-CLI. According to the interim analysis the safety profile was similar between the treatment and placebo arms. Based on a composite efficacy endpoint assessing time to treatment failure (including major amputations, wound size and gangrene), Aastrom's autologous vascular repair cells (VRCs) were more effective than placebo ( $P<0.05$ ). Other clinically meaningful endpoints (e.g., major amputation rate, complete wound closure) approached but did not reach statistical significance at interim analysis. Forty-six critical limb ischemia (CLI) patients who had at least 6-month follow up, including 33 patients with 12-month follow up, contributed to the interim analysis.

Aastrom's RESTORE-CLI trial is the largest blinded, randomized cell therapy study currently being conducted for CLI. The interim analysis was planned to assess performance of the cell therapy and to help plan further studies. Based on the interim findings, Aastrom will conclude enrollment of new patients in order to complete the study as soon as possible, and begin planning and discussions with the U.S. Food and Drug Administration for pivotal clinical trials with VRCs.

"These encouraging data have demonstrated an excellent safety profile and indicate that Aastrom's autologous cellular therapy could be an important addition to what is now a limited range of treatment options for patients with CLI," said Anthony J. Comerota, MD, FACS, FACC, director of the Jobst Vascular Center in Toledo, OH.

CLI is typically identified as the end stage of peripheral arterial disease. People with CLI face a high risk of amputation and in some cases death. Approximately 1 million patients in the U.S. suffer from CLI. The disease results in more than 160,000 amputations each year.

"Based on these results, we can now move ahead with plans to advance this program into Phase 3 clinical testing," said Tim Mayleben, president and CEO of Aastrom. "We look forward to presentation of the full data at an appropriate medical meeting and initiating the next phase of testing as soon as possible."

Aastrom will host an investor conference call today at 9:00 am ET to discuss these results. Interested parties should call (877) 407-9210 (international: (201) 689-8049) 15 minutes before the start of the call and identify themselves as registrants of the 'Aastrom Conference Call'. The call will be simulcast on the web at <http://www.investorcalendar.com/IC/CEPage.asp?ID=155867> and archived for 90 days at the same website.

### 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](http://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, Quarterly Reports on Form 10-Q and other filings with the Securities and Exchange Commission.*

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