Aastrom Reports Positive 12-Month Results from the RESTORE-CLI Phase 2 Clinical Trial for Ixmyelocel-T in Patients with Critical Limb Ischemia

Results Presented Today at the American Heart Association Scientific Sessions Show Ixmyelocel-T Met Primary Safety and Efficacy Endpoints in CLI Patients With No Revascularization Options

ANN ARBOR, Mich., Nov. 14, 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 reported positive 12-month final results from the RESTORE-CLI Phase 2 clinical trial of ixmyelocel-T in the treatment of critical limb ischemia (CLI) patients with no revascularization options. The results were presented today by William Marston, M.D., chief, Division of Vascular Surgery, and professor, Department of Surgery, University of North Carolina, in an oral presentation at the 2011 American Heart Association Scientific Sessions in Orlando, FL.

The randomized, double-blind, placebo-controlled, multicenter study assessed the safety and efficacy of ixmyelocel-T, a patient-specific, expanded multicellular therapy for the treatment of CLI, in a group of 72 patients at one year after treatment. Patients in the treatment arm showed a 62% reduction in risk relative to placebo in the primary efficacy endpoint of time to first occurrence of treatment failure ($p = .0032$). Treatment failure was defined as the first occurrence of any one of the following: major amputation of the treated leg, all-cause mortality, doubling of wound total surface area from baseline, or *de novo* gangrene. While the study was not powered to show statistical significance in the secondary endpoint of amputation-free survival (AFS; major amputation of the treated leg or all-cause mortality), results from a subgroup of 45 patients with wounds at baseline showed a positive trend in this measure (21% ixmyelocel-T treated vs 44% control event rate; $p = 0.0802$). The study also met the primary safety endpoint with no differences between the treated and control groups.

"These results provide substantial additional evidence that treatment with ixmyelocel-T significantly reduces the risk of disease progression for CLI patients with no options for revascularization. Importantly, the efficacy results demonstrate concordance across all of the defined measures of treatment failure in the trial," said Dr. Marston. "In addition, the results related to AFS in the subgroup of patients with tissue loss similar to those who will be studied in the upcoming pivotal Phase 3 clinical trial show a strong and clinically relevant positive trend for such a small number of patients. These results are especially encouraging since the primary endpoint for the planned REVIVE-CLI pivotal Phase 3 clinical trial for ixmyelocel-T in no-option CLI patients will be amputation-free survival."

The RESTORE-CLI Phase 2 clinical trial involved 72 CLI patients treated at 18 active centers in the United States. Patients were randomized 2:1 treatment versus placebo. Patients were treated with a one-time course of 20 intra-muscular injections in the lower thigh, calf and foot and were then followed for 12 months.

Forty percent of patients treated with ixmyelocel-T in this study had a treatment failure event compared to 67% of patients in the placebo group (a statistically significant risk reduction of 62%, $p = .0032$). In addition, 29% of the placebo group in the trial experienced their first event to be a doubling in total wound surface area from baseline in comparison to 10% of patients treated with ixmyelocel-T. Among patients whose first treatment failure event was *de novo* gangrene, the median time that patients treated with ixmyelocel-T reported the event was day 205 of the study, while the median time that patients in the placebo group reported the event was day 19 of the study (a difference of 186 days).

Aastrom will initiate the REVIVE-CLI Phase 3 clinical trial for ixmyelocel-T this quarter. The study will include 594 CLI patients with no option for revascularization and existing tissue loss. The primary endpoint of this study will be amputation-free survival at 12 months. Patients will be followed for a total of 18 months from the time of treatment.

"The 12-month results from our RESTORE-CLI Phase 2 clinical trial provide compelling clinical evidence that ixmyelocel-T could represent a major advance in the treatment of patients with CLI who have no option for revascularization. We look forward to initiating our pivotal Phase 3 clinical trial for ixmyelocel-T this quarter," said Tim Mayleben, Aastrom's president and chief executive officer.

The presentation slides will be available on the Aastrom web site today at http://investors.aastrom.com/events.cfm.

About Aastrom Biosciences

Aastrom Biosciences is the leader in developing patient-specific, expanded multicellular therapies for use in the treatment of patients with 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 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

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