Aastrom Announces Positive 12-Month Safety and Efficacy Data From IMPACT-DCM Phase 2 Clinical Trial for Ixmyelocel-T in Treatment of Dilated Cardiomyopathy

Results presented today at 15th Annual Heart Failure Society of America Scientific Meeting

Aastrom also announces results of six-month interim analysis of DCM patients treated with ixmyelocel-T via catheter administration.

ANN ARBOR, Mich., Sept. 19, 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 12-month follow up data from the IMPACT-DCM clinical trial for ixmyelocel-T showed that treatment was well-tolerated and that efficacy observations were consistent with improved function of impaired myocardium in patients with dilated cardiomyopathy (DCM) including ischemic cardiomyopathy (ICM) and idiopathic dilated cardiomyopathy (IDC). Results were reported today by Amit N. Patel, MD, MS, associate professor of surgery at the University of Utah School of Medicine and national principal investigator for Aastrom's U.S. Phase 2 IMPACT-DCM clinical trial, in a poster presentation at the 15th Annual Heart Failure Society of America Scientific Meeting in Boston.

In the study, 40 patients diagnosed with ICM or IDC were randomized 3 to 1 to either a single administration of ixmyelocel-T or standard of care and were followed for 12 months. In the ixmyelocel-T treatment group, bone marrow cells were cultured using Aastrom's proprietary technology to expand the number of mesenchymal cells, monocytes and macrophages while retaining many of the mononuclear cells. This combination has been associated with biological activity that promotes tissue remodeling, immunomodulation, and promotion of angiogenesis.

Twenty-one of the 25 (84%) ixmyelocel-T patients completed the 12-month visit. Seven of 15 (47%) of the control patients completed the 12-month visit, while an additional 5 of 15 (33%) of the control patients enrolled into the extension phase of the study and received ixmyelocel-T treatment. Results showed no difference in adverse events in treatment and control group patients after the initial post-operative period. ICM patients treated with ixmyelocel-T showed improved outcomes compared to control. Efficacy observations related to structural and functional end points including major adverse cardiovascular events (MACE), New York Heart Association (NYHA) functional classification, 6-minute walk distance, and septal wall thickening, were consistent with improved function of impaired myocardium.

"This study provides proof of principle that ixmyelocel-T can be delivered to the impaired myocardium despite the serious disease these patients have," said Dr. Patel, adding, "Cellular therapy could represent a viable treatment option for DCM patients who currently have no good options available."

Dr. Patel will present the poster, entitled: "Safety and Efficacy of Ixmyelocel-T, an Expanded Patient-Specific Mixed Cell Product, in Dilated Cardiomyopathy (IMPACT-DCM)," beginning at 5:45 P.M today. The poster will be on display from 9:30 A.M. to 7:00 P.M. (EDT).

In addition to the 12-month data from the IMPACT-DCM trial involving surgical administration of ixmyelocel-T, Aastrom also today announced positive results from a six-month interim analysis of DCM patients treated with ixmyelocel-T via catheter administration. In this analysis, functional improvements in efficacy parameters were consistent with those seen in the IMPACT-DCM trial results. In addition, the adverse event profile suggests that catheter administration of ixmyelocel-T is safe and appears to cause fewer adverse events compared to surgical administration of ixmyelocel-T.

"The positive results from our 12-month analysis and evidence of positive trends in our six-month analysis of patients with DCM are encouraging and support our plans to complete clinical development and pursue regulatory review of ixmyelocel-T for the treatment of severe chronic cardiovascular conditions," said Tim Mayleben, president and CEO of Aastrom. "Aastrom is currently conducting Phase 2 trials of ixmyelocel-T in patients with DCM and preparing to launch a pivotal Phase 3 clinical trial in the treatment of critical limb ischemia."

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 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 or Transition Report on Form 10-K or 10-K/T, 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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