



## **Initial Data From Aastrom's IMPACT-DCM Trial Presented At International Society for Cellular Therapy Annual Meeting by Amit N. Patel, M.D.**

### **Encouraging Early Data Reported in Severe Heart Failure Patients With Dilated Cardiomyopathy**

ANN ARBOR, Mich., May 5, 2009 (GLOBE NEWSWIRE) -- Aastrom Biosciences, Inc. (Nasdaq:ASTM), a leading developer of autologous adult stem cell treatments for severe chronic cardiovascular diseases, announced today that Dr. Amit N. Patel, Associate Professor of Surgery at the University of Utah School of Medicine and the National Principal Investigator of the Company's U.S. Phase II IMPACT-DCM clinical trial, presented initial trial data during an oral presentation today at the International Society for Cellular Therapy (ISCT) annual meeting in San Diego, California. The clinical trial is evaluating Aastrom's Cardiac Repair Cells (CRCs) for the treatment of patients suffering from both ischemic and non-ischemic dilated cardiomyopathy (DCM), a severe form of chronic heart failure. Currently, 13 of 40 patients have been enrolled in the trial, and enrollment is on target to be completed by the end of calendar year 2009.

The IMPACT-DCM trial is the first trial to evaluate both ischemic and non-ischemic DCM patients. Preliminary findings from this trial are as follows:

- \* Three treatment patients have completed the 3-month follow-up visit. All of these treatment patients improved from New York Heart Association (NYHA) class III to class II. This indicates clinically meaningful improvement in these patients. In contrast, NYHA class did not improve in 2 of 3 control patients.
- \* Overall quality of life scores (Minnesota Living with Heart Failure Questionnaire) improved in all treatment patients. Physical and emotional well-being of all treatment patients also improved based on patient responses to this questionnaire. There was no consistent trend in the control patients.
- \* No CRC-related serious adverse events were reported in any of the 4 treatment patients who have completed at least their 1-month follow-up visit.

"The observations from this trial, although still early, are very encouraging for patients with end-stage DCM who have no alternative therapeutic options other than heart transplantation or implantation of a mechanical assist device. The clinical improvements we have seen in our study patients so far indicate that CRC therapy is safe in cardiac applications and has the potential to provide a therapeutic alternative for these end-stage patients," said Dr. Patel. "The improvement from NYHA class III to class II has a major impact on the way these patients can be managed; with successful treatment it is possible that these patients will not face the prospect of being on a waiting list for a heart transplant with the need for life-long immune suppression nor the need to implant an externally-powered mechanical device to sustain the heart's pump function. This is a very important trial both in terms of the anticipated scientific findings and the rigor applied in its execution."

To date, the four clinical sites actively enrolling patients into the IMPACT-DCM trial are: The Methodist Hospital, Houston, TX, Baylor University Medical Center, Dallas, TX, The University of Utah School of Medicine, Salt Lake City, UT, and Cleveland Clinic Heart & Vascular Institute, Cleveland, OH. The initiation of another clinical site is currently in progress.

"We are pleased with the early clinical data that are being reported from our trial sites. The enthusiasm at the clinical sites is reflected in the patient enrollment rate we are seeing," said Elmar R. Burchardt, M.D., Ph.D., Vice President, Medical Affairs of Aastrom. "We are optimistic that the positive trends presented at ISCT today will be reflected in the extensive interim analysis of safety, clinical status and cardiac function of the patients which will be performed after all patients complete 6 months of follow-up. We look forward to reporting the 6 month results which are of critical importance to the future development of our cardiovascular programs."

The Phase II study seeks to enroll 20 patients with ischemic DCM and 20 patients with non-ischemic DCM at five clinical sites in the U.S. Participants must have a left ventricular ejection fraction (LVEF) of less than or equal to 30% (60-75% is typical for a healthy person) and meet certain other eligibility criteria. The study protocol states that patients in each group will receive

standard medical care and approximately 75% of patients will be treated with CRCs through direct injection into the heart muscle during minimally invasive open heart surgery. While the primary objective of this study is to assess the safety of CRCs in patients with DCM, efficacy measures including LVEF, heart failure stage and other measures of cardiac function will be monitored. The Company intends to follow patients in the study for 12 months post treatment.

IMPACT-DCM is the first clinical trial in the U.S. to evaluate the surgical delivery of autologous cells directly into the human heart muscle for the treatment of congestive heart failure associated with DCM in both ischemic and non-ischemic patients. Patients randomized into the treatment group of the IMPACT-DCM trial are treated with Aastrom's CRCs, an autologous, mixed-cell product containing expanded populations of stem and early progenitor cells produced from a small sample of the patient's own bone marrow.

#### About Dilated Cardiomyopathy (DCM)

Many of the 5.5 million people in the U.S. suffering from severe heart failure have DCM, a condition where expansion of the patient's heart reduces pump function, making it impossible to maintain normal blood circulation. Patients with DCM typically have symptoms of congestive heart failure, including severe limitations in physical activity and shortness of breath. DCM generally occurs in patients who have ischemic heart failure due to multiple heart attacks, though it can also be found in patients with non-ischemic heart failure caused by hypertension, viral infection or alcoholism. Patient prognosis depends upon the stage of the disease but is typically characterized by numerous health problems and a very high mortality rate.

#### About Aastrom Biosciences, Inc.

Aastrom is a leader in the development of autologous cell products for the repair or regeneration of human tissue. The Company's proprietary Tissue Repair Cell (TRC) technology involves the use of a patient's own cells to manufacture products to treat a range of chronic diseases and serious injuries. Aastrom's TRC-based products contain increased numbers of stem and early progenitor cells, produced from a small amount of bone marrow collected from the patient. The TRC technology platform has positioned Aastrom to advance multiple products into clinical development. The Company's ongoing development activities focus on applying TRC technology to cardiac and vascular tissue regeneration. A Phase II clinical trial with dilated cardiomyopathy (DCM) patients (the IMPACT-DCM trial) and a Phase IIb clinical trial with critical limb ischemia (CLI) patients (the RESTORE-CLI trial) are currently underway.

The Aastrom Biosciences, Inc. logo is available at <http://www.globenewswire.com/newsroom/prs/?pkgid=3663>

For more information, visit Aastrom's website at [www.aastrom.com](http://www.aastrom.com).

This document contains forward-looking statements, including without limitation, statements concerning planned clinical trials and activities and anticipated timing of clinical events, product development objectives, and potential product applications, which involve certain risks and uncertainties. The forward-looking statements are also identified through use of the words "expected," "anticipated," "planned," and other words of similar meaning. Actual results may differ significantly from the expectations contained in the forward-looking statements. Among the factors that may result in differences are potential patient accrual difficulties, clinical trial results, potential product development difficulties, the effects of competitive therapies, regulatory approval requirements, the availability of financial and other 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 and other filings with the Securities and Exchange Commission.

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