Aastrom

FDA Removes Clinical Hold From Aastrom Phase II IMPACT-DCM Clinical Trial

Patient Death Unrelated to Aastrom's CRCs; Trial to Resume At All Clinical Sites for Patients Suffering From Dilated Cardiomyopathy

ANN ARBOR, Mich., June 18, 2009 (GLOBE NEWSWIRE) -- Aastrom Biosciences, Inc. (Nasdaq:ASTM), a leading developer of autologous adult stem cell treatments for severe chronic cardiovascular diseases, today reported that the U.S. Food and Drug Administration (FDA) has removed the clinical hold from the Company's U.S. Phase II IMPACT-DCM clinical trial and that patient enrollment would resume at all five initiated clinical sites. The IMPACT-DCM trial is evaluating the use of Cardiac Repair Cells (CRCs), a mixture of stem and progenitor cells derived from a patient's own bone marrow, for the treatment of dilated cardiomyopathy (DCM), a severe form of chronic heart failure.

On June 17, 2009, the FDA informed Aastrom that it had completed its investigation into the death of a patient following treatment with the Company's CRCs and that the clinical hold had been lifted; therefore, the IMPACT-DCM clinical trial could resume. Based on autopsy results and medical records, the FDA, the clinical site's principal investigator and an independent Data Safety Monitoring Board (DSMB) have attributed the patient death to progression of the disease and determined it was unrelated to the CRC treatment.

"Patient safety is top priority for Aastrom. We are saddened by the loss of one of our patients. At the same time, we are grateful that this investigation was conducted in an efficient manner and that the FDA was able to provide prompt review and remove the clinical hold so quickly. This comprehensive review, along with the FDA's permission to carry on the trial without modifications, underscores the safety of the trial design and that our CRC product played no role in the patient's death," stated George W. Dunbar, President and Chief Executive Officer at Aastrom. "We do not expect that this short delay will interfere with our goal of completing patient enrollment in this trial by the end of calendar year 2009. We are eager to resume patient enrollment and treatment in the IMPACT-DCM trial and to continue evaluating the clinical data we gather from these patients."

To date, 14 of 40 patients have been enrolled in the IMPACT-DCM trial at the first three clinical sites: The Methodist DeBakey Heart & Vascular Center, Houston, TX, Baylor University Medical Center, Dallas, TX and The University of Utah School of Medicine, Salt Lake City, UT. In addition, the fourth and fifth sites, Cleveland Clinic Heart & Vascular Institute in Cleveland, OH and Emory University Hospital Midtown in Atlanta, GA, were recently initiated and trained for participation in the IMPACT-DCM clinical trial.

"As unfortunate as this death is, it illustrates the severity of this disease and the need for a new therapeutic option for these patients who currently have limited alternatives other than a heart transplant or the implantation of a mechanical assist device," said Dr. Amit Patel, Associate Professor of Surgery at the University of Utah School of Medicine and the National Principal Investigator of the IMPACT-DCM clinical trial. "At this time it is important to recall that the patients recruited into the IMPACT-DCM trial are in end-stage heart failure with ejection fractions below 30%. In contrast, many other comparable cardiac stem cell trials require an ejection fraction above this threshold. Therefore, we are only treating the most critically ill patients. The findings from the IMPACT-DCM trial could eventually have a significant impact on how congestive heart failure is treated in the future."

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. The randomized, controlled, prospective, open-label, 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 of less than or equal to 30% (60-75% is typical for a healthy person) and meet certain other eligibility criteria. Fifteen patients from each group (30 patients in total) will receive CRC treatment through direct injection into the heart muscle during minimally invasive open heart surgery, while five patients from each group (10 patients in total) will not receive any surgical or experimental intervention. All patients in each group will receive standard medical care. While the primary objective of this study is to assess the safety of CRCs in patients with DCM, efficacy measures including left ventricular ejection fraction and other cardiac function parameters as well as heart failure stage will be monitored. Patients will be followed for 12 months post treatment.

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. TRC-based products have been used in over 325 patients with over 10 years of positive safety data. The Company's ongoing development activities focus on applying TRC technology to cardiac and vascular tissue regeneration. The Company is currently focused on cardiovascular regeneration through 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).

For more information, 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 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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