Aastrom

Aastrom Phase II IMPACT-DCM Clinical Trial Placed On Clinical Hold Pending Review of Isolated Serious Adverse Event Related to Anesthesia Management in One Patient

ANN ARBOR, Mich., Feb. 2, 2009 (GLOBE NEWSWIRE) -- Aastrom Biosciences, Inc. (Nasdaq:ASTM), a leading regenerative medicine company, today reported that one patient enrolled in the Company's U.S. Phase II IMPACT-DCM clinical trial experienced a serious adverse event associated with anesthesia management during treatment at one of the active clinical sites. According to the results of an internal review conducted at the clinical site, and a second review by the trial's independent Data Safety Monitoring Board (DSMB), this event has been attributed to anesthesia administration and management in this single patient. Furthermore, these two reviews separately determined that this event was not related to the surgical approach or the use of Aastrom's Cardiac Repair Cells (CRCs) in this procedure. This patient has received appropriate treatment, has fully recovered from this isolated event and continues to be monitored in accordance with the study protocol. In compliance with regulatory requirements and standard operating procedures, this event was reported directly to the U.S. Food and Drug Administration (FDA) and Aastrom immediately took the initiative to suspend patient enrollment at the clinical site where the event took place, pending an internal review and the implementation of a corrective action plan.

In accordance with our commitment to the highest safety standards for participants in this trial, Aastrom has complied with a subsequent verbal communication from the FDA that the IMPACT-DCM trial be placed on clinical hold at all trial sites pending completion of a more comprehensive review of this event. Aastrom is working closely with the FDA to provide any information required in order to expedite this review and to resolve this matter so that patient enrollment into the IMPACT-DCM trial can resume as soon as possible.

Notwithstanding the hold, the FDA authorized Aastrom to proceed with the CRC treatment for one patient previously enrolled in the IMPACT-DCM clinical trial. This patient was treated last week. In addition, follow-up monitoring of patients who have previously been treated in the IMPACT-DCM trial is continuing in accordance with the study protocol.

"Patient safety has been and continues to be the highest priority for everyone involved in Aastrom clinical trials," stated Elmar R. Burchardt, MD, PhD, Vice President, Medical Affairs at Aastrom. "We believe, and all available information indicates, that this is an isolated incident unrelated to the safety of our CRC cell product. We are proactively and rapidly supporting the FDA review of this event and look forward to continuing treatment of this critically ill patient population in the IMPACT-DCM trial."

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 dilated cardiomyopathy (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. Ongoing development activities are focused on applying TRC technology to cardiac and vascular tissue regeneration. The company is currently focused on cardiovascular regeneration and is conducting 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).

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 strategies, potential partnering activities, product development objectives, potential advantages of TRC technology and TRC-based products, and potential product applications, which involve certain risks and uncertainties. The forward-looking statements are also identified through use of the words "intends," "expect," "expected," "should," "anticipated," 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 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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