Aastrom

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

Trial to Resume At Four Clinical Sites for Patients Suffering From Dilated Cardiomyopathy

ANN ARBOR, Mich., March 3, 2009 (GLOBE NEWSWIRE) -- Aastrom Biosciences, Inc. (Nasdaq:ASTM), a leading regenerative medicine company, 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 the four 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 March 3, 2009, the FDA informed Aastrom that it had completed its review of the Company's response to the issue cited in the FDA clinical hold letter and that the clinical hold had been lifted; therefore, the IMPACT-DCM clinical trial could resume. To date, nine of 40 patients have been enrolled in the IMPACT-DCM trial at the first three 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 site, the Cleveland Clinic Heart and Vascular Institute in Cleveland, OH, was recently initiated and trained for participation in the IMPACT-DCM trial. Activation of the fifth clinical site is underway.

"We are very grateful to the FDA for completing this review quickly and efficiently," stated George W. Dunbar, President and Chief Executive Officer at Aastrom. "With the hold removed, we will be able to resume the IMPACT-DCM trial and continue to treat these critically ill patients who have no other treatment options available. Even with this short delay, we still anticipate completing patient enrollment in this trial by the end of calendar year 2009."

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. All patients in each group will receive standard medical care and 75% of the 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 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. The Company's ongoing development activities focus on applying TRC technology to cardiac and vascular tissue regeneration, and 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

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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