Aastrom

Aastrom Proactively Places Phase II IMPACT-DCM Clinical Trial On Hold Following Report of Serious Adverse Event

Treatment Patient Released From Hospital Later Dies; Investigation Underway to Determine Cause of Death

ANN ARBOR, Mich., May 22, 2009 (GLOBE NEWSWIRE) -- Aastrom Biosciences, Inc. (Nasdaq:ASTM), a leading developer of autologous adult stem cell treatments for severe chronic cardiovascular diseases, today announced that the Company has temporarily suspended enrollment and patient treatment in its U.S. Phase II IMPACT-DCM clinical trial following a report that a patient died at home after being released from the hospital following treatment in the trial. The patient's cause of death has not yet been determined and is the subject of a pending investigation at the clinical site. An independent Data Safety Monitoring Board (DSMB) will also assess the circumstances of the event.

In accordance with standard operating procedures, the Company has informed the U.S. Food and Drug Administration (FDA) of the following: the death of the patient after being released from the hospital; the initiation of an investigation into the cause of death; and that the Company has voluntarily suspended patient enrollment and treatment in the trial. Subsequently, the FDA placed the trial on temporary clinical hold pending an investigation. Follow-up of patients previously enrolled in the IMPACT-DCM trial will continue in accordance with study protocol.

"Patient safety has been and continues to be our primary concern," stated Elmar R. Burchardt, M.D., Ph.D., Vice President, Medical Affairs at Aastrom. "We will continue to work closely with the trial site, the DSMB and the FDA to review the events surrounding the death of one of the patients in this clinical trial. We remain committed to ensuring patient safety and will work to resume patient enrollment and treatment in the IMPACT-DCM trial as soon as possible."

Upon completion of the investigation, Aastrom will work closely with the FDA to provide any information required in order to expedite its review and to resolve this matter so that patient enrollment into the IMPACT-DCM trial can resume as soon as possible. Aastrom will provide updated guidance regarding projected patient enrollment once the FDA has made its determination.

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 Cardiac Repair Cells (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.

DCM is a condition where enlargement 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. 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).

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.

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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