



## **Aastrom Receives Orphan Drug Designation from FDA for Dilated Cardiomyopathy**

### **- Up to 150,000 People in U.S. Currently Suffer from this Severe Chronic Heart Disease**

ANN ARBOR, Mich., Feb 01, 2007 /PRNewswire-FirstCall via COMTEX News Network/ -- Aastrom Biosciences, Inc. (Nasdaq: ASTM), a company focused on the use of autologous cells for regenerative medicine, today announced that the Company's proprietary Tissue Repair Cells (TRCs) received an Orphan Drug Designation from the U.S. Food and Drug Administration (FDA) for use in the treatment of dilated cardiomyopathy (DCM), a severe chronic disease of the heart. In the U.S., Orphan Drug Designation provides a variety of incentives, including 7 years of market exclusivity, should TRCs receive FDA approval for this indication.

(Logo: <http://www.newscom.com/cgi-bin/prnh/20070117/CLW099LOGO> )

DCM is a chronic cardiac disease that leads to enlargement of the heart and reduces pump function to a point that normal blood circulation cannot be maintained. Typically patients with DCM present with symptoms of congestive heart failure, including limitations in their physical activity and shortness of breath. DCM often represents the end stage of chronic ischemic heart disease in patients who have experienced multiple heart attacks. Patient prognosis depends on the stage of the disease but is characterized by a high mortality rate. Other than heart transplant, there are no effective long-term treatment options for end stage patients with this disease. The New England Journal of Medicine estimates that in the U.S. alone 120,000 people currently suffer from this disease; other sources report estimates of up to 150,000.

Scientific and early clinical evidence suggest that high doses of stem and progenitor cells may possibly slow down or reverse disease progression in the heart of DCM patients. It is intended that Aastrom's TRCs, a proprietary product containing large numbers of stem and progenitor cells derived from a small sample of the patient's own bone marrow, will be used as a therapeutic to induce heart tissue regeneration in these patients. If successful, TRC treatment may eliminate or delay the need for a heart transplant.

"We are pleased to receive an orphan drug designation from the FDA for our TRC-based product as a potential new treatment option for patients faced with this severe chronic heart disease," said George Dunbar, Chief Executive Officer and President of Aastrom. "Achieving this milestone is the first step in building the foundation for our clinical program in cardiac regeneration. The next anticipated milestone for our cardiac program is to initiate a clinical trial that treats patients with dilated cardiomyopathy."

The orphan drug designation is granted to development-stage novel therapeutics that offer potential value in the treatment of rare diseases and medical conditions. Above and beyond assistance from the Office of Orphan Products Development in furthering its TRC tissue regeneration program, Aastrom may receive other benefits. In particular, Aastrom may be entitled to an expedited FDA review, the reduction or elimination of filing fees, and the availability of possible tax credits.

About Aastrom Biosciences, Inc.

Aastrom Biosciences, Inc. develops autologous cell products for the repair or regeneration of multiple human tissues, based on its proprietary Tissue Repair Cell (TRC) technology. Aastrom's TRC-based products are a unique cell mixture containing stem and progenitor cell populations, produced from a small amount of bone marrow taken from the patient. TRC-based products have been used in over 230 patients, and are currently in clinical trials for bone regeneration (osteonecrosis of the femoral head, long bone fractures and spine fusion) and vascular regeneration (critical limb ischemia) applications. Aastrom has reported positive interim clinical trial results for TRCs suggesting both the clinical safety and the ability of TRCs to promote healing in bone regeneration applications. The Company is developing programs for TRC-based therapies to address cardiac and neural regeneration indications. TRCs have received Orphan Drug Designation from the FDA for use in the treatment of osteonecrosis of the femoral head and dilated cardiomyopathy.

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

This document contains forward-looking statements, including without limitation, statements concerning the timing of planned clinical trials, clinical trial strategies, product development objectives, potential advantages of TRCs, and potential product applications, which involve certain risks and uncertainties. The forward-looking statements are also identified through use of the words "intended," "may," "possible," "potential," "should," 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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