

## Aastrom Biosciences' TRCs Used in New Clinical Trial for Regeneration of Vascular Tissue in Diabetic Patients

## -- Novel Treatment Utilizes Company's Adult Bone Marrow Stem Cell Product --

Ann Arbor, Michigan, October 6, 2005 - Aastrom Biosciences, Inc. (Nasdaq: ASTM) announced today that the first clinical trial utilizing Aastrom's proprietary Tissue Repair Cells (TRCs) to treat limb ischemia in diabetic patients has been initiated at the Diabetes Center at the Heart and Diabetes Center North Rhine-Westphalia (Diabetes Center) located in Bad Oeynhausen, Germany. Initiation of the trial followed the Diabetes Center's receipt of the licenses and the Investigational Medicinal Product Dossier (IMPD) necessary to manufacture and use cells for clinical trials in compliance with the new European Union directives.

The Bad Oeynhausen study is a collaborative effort between Aastrom and the Diabetes Center. The principal investigator is Prof. Dr. Diethelm Tschope, Director of the Diabetes Center. Senior Physician Dr. P. Minartz, Dr. D. Lammers and Dr. rer. nat. B. Stratmann, members of the Diabetes Center, will serve as the Study Management Committee.

The aim of this human study is to evaluate the safety and ability of Aastrom's bone marrow-derived TRCs to regenerate functioning blood vessels in the legs of diabetic patients with limb ischemia. It is intended that the patients may experience relief from clinical problems that are related to a loss of blood circulation, such as: deep "bed-sore type" ulcerated wounds of the feet, pain (or "claudication"), immobility, and infection. Diabetic non-healing, infected ulcers often lead to the amputation of the leg. Successful vascular regeneration may either delay or render such amputation unnecessary. Standard of care treatments offer limited relief and are usually restricted to wound management and antibiotic treatment of the infected ulcers, in combination with surgical interventions such as the implant of stents with vascular by-pass or skin grafting.

"The initiation of this trial is an important step in our business strategy to use our TRC cell products for multiple medical indications. We are extending our clinical evaluations of the ability of these powerful cells to regenerate not only blood and bone but now, vascular tissue," said R. Douglas Armstrong, Ph.D., Chief Executive Officer and Chairman of Aastrom. "The first phase of this study is intended to establish the safety of our TRCs in this application, and to evaluate their benefit to diabetic patients who have limited therapeutic options, and who may face eventual limb amputation."

It is expected that the first phase of the trial will be completed in approximately 12 months. All patients to be enrolled in the trial have been diagnosed with diabetes mellitus with ischemia-induced chronic tissue ulcers in the lower limbs (known as angiopathic or angioneuropathic diabetic foot syndrome), and are not suitable candidates for operative or interventional revascularization. Diabetics with such severe disease are the most difficult to treat and evaluate.

The design of this study includes control and treatment groups. The effects of TRCs will be compared to those of fresh, native bone marrow (active control), and to standard of care procedures. Two different routes of administration of the cells will be evaluated, with treatment patients receiving either direct injection into the ischemic limb at multiple sites, or a single intraarterial injection above the affected tissue location. Initially, the trial will enroll 5 patients into each of the groups. The first set of data will be evaluated; based on this data, improvements and amendments to the protocol are expected to be introduced for the remaining patients.

Over the 12 months following treatment, the trial will evaluate whether the TRC treatment results in improved or complete healing of the ulcers, as well as whether amputation can be avoided or delayed. The trial will also monitor the time to relapse if complete wound healing is not attained, and whether the prognosis for patient survival improves, compared to standard of care controls.

About Diabetes Center at the Heart and Diabetes Center North Rhine-Westphalia

The Diabetes Center at the Heart and Diabetes Center North Rhine-Westphalia is a world-leading institution in the fields of cardiac, circulatory and metabolic diseases located in Bad Oeynhausen, Germany, offering both comprehensive diagnostics and treatment under one roof. The Heart and Diabetes Center NRW is the University Hospital of the Ruhr University of Bochum, Germany.

## About Tissue Repair Cells

Tissue Repair Cells (TRCs) are Aastrom's proprietary mixture of bone marrow-derived adult stem and progenitor cells produced using patented single-pass perfusion technology in the AastromReplicell® System. The clinical procedure begins with

the collection of a small sample of bone marrow from the patient's hip in an outpatient setting. TRCs are then produced in the automated AastromReplicell System over a 12-day period. It has been demonstrated in the laboratory that TRCs are able to develop into different types of tissue lineages in response to inductive signals, including blood, bone, cartilage, adipose and vascular tubules. In previous clinical trials, TRCs have been shown to be safe and reliable in regenerating certain normal healthy bone marrow tissues.

About Aastrom Biosciences, Inc.

Aastrom Biosciences, Inc. (Nasdaq: ASTM) is developing patient-specific products for the repair or regeneration of human tissues, utilizing the Company's proprietary adult stem cell technology. Aastrom's strategic position in the tissue regeneration sector is enabled by its proprietary Tissue Repair Cells (TRCs), a mix of bone marrow-derived adult stem and progenitor cells manufactured in the AastromReplicell® System, an industry-unique automated cell production system. TRCs are the core component of the products Aastrom is developing for severe bone fractures, ischemic vascular disease, jaw reconstruction and spine fusion, with Phase I/II level clinical trials active in the U.S. and EU for some of these indications.

## 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, 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 "may," "intended," "expected," "can," 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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