



## **Aastrom Biosciences Expands Bone Graft Clinical Trial to Include University of Michigan**

### **-- Enrollment Open for Repair of Severe Leg Fractures at Orthopedic Trauma Center Using Company's Adult Stem Cell Product --**

**Ann Arbor, Michigan, June 30, 2004** -- Aastrom Biosciences, Inc. (NasdaqSC: ASTM) today announced that its lead U.S. clinical trial of the Company's bone generation Tissue Repair Cell (TRC) adult stem cell product has been initiated at a second site, the University of Michigan Health System (UMHS) in Ann Arbor. The trial, to be conducted at UMHS's orthopedic trauma center, opens for patient enrollment on the heels of the previously announced site at Lutheran General Hospital in Park Ridge, IL, outside Chicago. Both sites are included under the clinical trial protocol for the Company's FDA-approved Investigational New Drug (IND). Aastrom is also actively engaged in similar clinical trials of its bone graft product in Germany and Spain.

The Principal Investigator at this new clinical site is James A. Goulet, M.D., Professor, Orthopedic Trauma and Joint Reconstruction, at the University of Michigan Health System. Dr. Goulet has practiced orthopedic surgery at UMHS for over 17 years. He is the author or co-author of more than 100 publications in medical journals, and is a member of the American Academy of Orthopedic Surgeons, the Orthopedic Trauma Association and the Michigan Orthopedic Society, among others. Dr. Goulet lectures frequently on the subject of bone fracture repair and management, and has conducted numerous grant-supported studies in this area.

Under the provisions of the IND for this U.S. clinical trial, as many as 20 patients can be treated who have either long-term (a minimum of 8 months) non-healing tibial leg fractures, or tibial non-union fractures that are severe enough to require a bone graft to aid repair. The IND allows up to three centers to participate.

"The initiation of a second U.S. site in this bone graft trial represents further progress for our stem cell-based TRCs for tissue generation, and our goal of bringing this product into standard medical practice," said R. Douglas Armstrong, Ph.D., President, Chief Executive Officer and Chairman of Aastrom. "We are pleased to collaborate with Dr. Goulet, who is highly respected in the orthopedic community, and the University of Michigan, a leading healthcare institution. This orthopedic trauma referral center services a large number of patients and therefore should provide immediate access to patients targeted for this study. With this center in place, and continued supportive results from our active clinical sites, we expect to add a third U.S. center for our bone grafting clinical trial."

Aastrom's active clinical trials of its bone graft product for large bone fractures are currently underway in the United States, Germany and Spain. Although the specific protocols for each trial vary, the goal of all three trials is to demonstrate the safety, feasibility and efficacy of Aastrom's bone generation stem cell product. The patients in the clinical studies will be followed for 12 to 24 months, post surgery, depending on the individual site protocol. All three trials are enrolling patients, and will proceed based on the pace of accrual. The time that must elapse before investigators can identify initial results will vary from patient to patient, and begins when the mixture of Aastrom's TRCs and a matrix are surgically applied at the fracture site.

### **About Stem Cells**

Stem cells are human cells that have the capability to form multiple, or in some cases, all types of tissues. Therefore, stem cells represent potentially powerful agents for repairing damaged or diseased tissues.

Stem cells are found in every individual's bone marrow; access is simple and without controversy. Stem cells are also found in embryonic tissues as part of a developing fetus, but access to these cells has proven controversial. As a result, researchers seeking potential novel treatments for a wide variety of diseases and disorders are increasingly investigating bone marrow-derived "adult stem cells" in clinical research. Aastrom's stem cell therapeutics program uses adult stem cells, typically derived from the patient's own bone marrow, which can be successfully grown to the increased number of cells required for certain clinical applications, using the patented technology embodied in the AastromReplicell® System.

### **About Aastrom Biosciences, Inc.**

Aastrom Biosciences, Inc. (NasdaqSC: ASTM) is developing proprietary stem cell-based products for the regenerative repair of damaged human tissues and other medical disorders. Aastrom's strategic position in the tissue regeneration and cell therapy sectors is enabled by its proprietary Tissue Repair Cells (TRCs), a mix of bone marrow stem and progenitor cells, and the AastromReplicell System, an industry-unique automated cell production platform used to produce cells for clinical use. Together TRCs and the AastromReplicell System provide a foundation that the Company is leveraging to produce multiple

Prescription Cell Products, the first of which is now in the clinical stage in the U.S. and EU.

TRCs are the core component of the Prescription Cell Products Aastrom is developing for the bone grafting, peripheral vascular disease and cartilage markets. The Company also markets the AastromReplicell System and disposable dendritic cell production kits to researchers and institutions developing vaccines to treat cancer and infectious diseases, under its Cell Production Products line.

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

This document contains forward-looking statements, including without limitation, statements concerning planned clinical trials, 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 "intended," "expect," "can," "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 patient accrual rates, future clinical trial results, regulatory approval requirements, the availability of 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.

#### CONTACTS:

Kris M. Maly or Becky Anderson  
Investor Relations Department  
Aastrom Biosciences, Inc.  
Phone: (734) 930-5777

Kevin McGrath  
Cameron Associates  
Phone: (212) 245-4577