



## **Aastrom Biosciences to Initiate U.S. Clinical Trial for Bone Formation in Spine Under Approved IND From the FDA**

### **-- Spine Fusion Trial at William Beaumont Hospital to Use Aastrom's Adult Stem Cell TRC Product --**

**Ann Arbor, Michigan, November 30, 2005** -- Aastrom Biosciences, Inc. (Nasdaq: ASTM) today announced it will initiate a human clinical trial for the evaluation of the Company's Tissue Repair Cell (TRC) product to form new bone tissue in the spine. The Phase I/II trial will be conducted under an Investigational New Drug (IND) application approved by the U.S. Food and Drug Administration (FDA), and initially conducted at a single clinical center, the William Beaumont Hospital in Royal Oak, MI (Beaumont Hospital). Aastrom's TRCs, a proprietary bone marrow-derived adult stem cell product, will be used in posterior-lateral lumbar spinal fusions for treatment of degenerative spondylolisthesis. This is the Company's second FDA-approved, human clinical trial for local bone regeneration using TRCs.

This spine fusion clinical trial will be conducted under the direction of Principal Investigator Harry Herkowitz, M.D., Department Chair of Orthopedic Surgery at Beaumont Hospital. Spine fusion is a procedure in which new bone tissue is induced to fuse two or more vertebrae together to treat conditions such as fractures of the vertebrae, or ruptured or lost disks. Current therapy uses surgically transplanted bone tissue, as well as other artificial bone materials and bone growth factors, to induce the growth of new bone tissue. Aastrom proposes to use its TRCs in combination with a carrier matrix to induce sufficient bone growth to fuse or merge two vertebrae in the lower back, and potentially eliminate the requirement for other more invasive or less effective approaches. By stabilizing the spine, this procedure reduces debilitating back pain, and helps a patient regain more normal use of their legs. The primary purpose of this approved clinical trial is to confirm that Aastrom's TRC product, when used as a bone graft, is safe for use in posterior-lateral lumbar spinal fusion surgery, and is able to generate new bone at the fusion site, based on defined radiographic and clinical data.

"With clinical studies already using TRCs to generate jaw bone and to repair severe bone fractures, we are very enthusiastic about this new FDA-approved study to extend the evaluation of TRCs to a third type of bone tissue," noted R. Douglas Armstrong, Ph.D., Chief Executive Officer and Chairman of Aastrom. "We are also gratified that this study is being conducted by an outstanding clinical team led by Dr. Herkowitz at Beaumont Hospital."

Aastrom's autologous (patient-derived) TRC cell product is already being evaluated to treat severe long bone fractures in an FDA-approved, multi-center clinical trial in the United States, and the Company has reported positive bone growth results from its fracture trial in Spain. TRCs are also being evaluated for their ability to generate jaw bone in a single center trial in Spain, to enable the placement of dental implants. In addition, Aastrom recently announced that the first clinical trial utilizing TRCs to treat limb ischemia in diabetic patients was initiated at a center in Bad Oeynhausen, Germany.

### **About William Beaumont Hospital Department of Orthopedic Surgery**

Beaumont's Department of Orthopedic Surgery offers leading edge treatments and technology including minimally invasive surgery, implants and trauma surgery. Beaumont is Michigan's most experienced orthopedic hospital specializing in surgeries of the back, neck, foot, ankle, hand and upper extremities, hip and knee replacement, scoliosis treatment, tumor surgery, pediatric orthopedics and sports medicine. Beaumont has been named among the country's top hospitals for orthopedic care by U.S. News & World Report and Solucient.

Beaumont-Royal Oak is a 1,061-bed tertiary care, teaching, research and referral center with Level I trauma designation. It ranks first in the United States for outpatient surgeries and second for inpatient surgeries.

### **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](http://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 "potentially," 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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