

# **Aastrom Biosciences Announces Second Clinical Trial for Bone Fractures in Spain**

### -- New Trial Expected to Further Company's Knowledge of Bone Regeneration --

Ann Arbor, Michigan, December 13, 2005 -- Aastrom Biosciences, Inc. (Nasdaq: ASTM) announced today the initiation of a new bone grafting clinical trial sponsored by Fundacion Teknon and ITRT (Institut de Terapia Regenerativa Tisular) at Hospital de Barcelona S.C.I.A.S., Hospital General de l'Hospitalet and Centro Medico Teknon located in Barcelona, Spain. The Phase I/II multi-center clinical trial has been approved by the Spanish Drug Agency (AEMPS) and is designed to further demonstrate the safety and effectiveness of the Company's Tissue Repair Cells (TRCs) to regenerate new, healthy bone in the repair of long bone fractures.

This study follows a successful pilot trial that included 5 patients conducted by the same clinical investigators, and will incorporate various procedure modifications learned from prior studies. The refinements are targeted at determining an improved TRC procedure to provide more uniform use at different clinical sites.

"This trial is significant on several levels," said R. Douglas Armstrong, Ph.D., Chief Executive Officer and Chairman of Aastrom. "On a regulatory level, the approval we have received from the AEMPS indicates that we have met the new stringent requirements that have been set in place by the recent adoption of the new clinical trial directive in the EU for cell product clinical trials."

Dr. Armstrong continued, "In addition, our ability to further refine our clinical protocol regarding the methodology of our TRC treatment constitutes further progress and resolution in our product development program."

The new trial will enroll a maximum of 10 patients who will be treated for non-hypertrophic pseudoarthrosis of long bones, or failure of a fracture to heal properly. After treatment, patients will be monitored over 24 months for callus and bridge formation at the fracture site, as determined radiographically and by CT scan. The Study Coordinator for this clinical trial is Dr. Carlos Solano-Puerta of ITRT, and the Principal Investigators are Dr. Lluis Orozco (Hospital de Barcelona S.C.I.A.S.), Dr. Joan Giros Torres (Hospital General de l'Hospitalet) and Dr. Robert Soler (Centro Medico Teknon).

#### **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. is developing patient-specific products for the repair or regeneration of human tissues, utilizing the Company's proprietary adult stem cell technology. Aastrom's proprietary Tissue Repair Cells (TRCs), a mix of bone marrow-derived adult stem and progenitor cells for tissue regeneration, are manufactured in the AastromReplicell® System, an industry-unique automated cell production system. Aastrom's TRC cell products are in clinical trials for the following therapeutic indications: severe bone fractures (US: Phase I/II - multi-center; EU: Phase I/II - multi-center), ischemic vascular disease (EU: Phase I/II), jaw reconstruction (EU: proof of concept) and spine fusion (US: Phase I/II - single-center).

## 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 "expected," "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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