



## **Aastrom Biosciences Reports Positive Human Jaw Bone Reconstruction Results from Feasibility Clinical Trial**

### **-- Results Indicate Company's Tissue Repair Cell Product Safely Builds New Bone for Dental Implants --**

**Ann Arbor, Michigan, December 21, 2005** -- Aastrom Biosciences, Inc. (Nasdaq: ASTM) announced today the interim results from its feasibility clinical trial conducted with the Teknon Hospital Maxillofacial Clinic in Barcelona, Spain, to evaluate the use of Aastrom's Tissue Repair Cells (TRCs) for maxillary (upper jaw) bone reconstruction in 5 patients, completed to support placement of dental implants. The study results showed clinical safety, and that the TRC treatment sites all exhibited bone growth that was statistically significant and had the desired initial integration with preexisting bone. An internal report of the clinical study, which provides more detailed information, is being filed today on Form 8-K with the SEC. This report may also be accessed on Aastrom's website using the link: [http://www.aastrom.com/pdf/Jaw\\_Barcelona-051220.pdf](http://www.aastrom.com/pdf/Jaw_Barcelona-051220.pdf).

The goal of this proof of concept, internally controlled clinical trial was to evaluate the safety and ability of TRCs - a proprietary autologous bone marrow-derived stem cell product - to increase bone height in the posterior maxilla (upper jaw) of 5 patients, who had severe bone loss in the region and minimal residual bone remaining. The patients were judged to have a poor prognosis with previously lost teeth due to periodontal disease and tooth decay, and additional risk factors that are known to compromise bone regeneration and preservation. These risk factors included many years of smoking, osteoporosis and advanced age. The intent of the TRC therapy was to help rebuild healthy bone so that there was enough bone to accommodate the length of the dental implants. A standard bone graft technique was used as an internal concurrent control on the other side of the maxilla.

All of the primary outcomes described by the trial protocol were successfully achieved. Results showed that all 5 patients treated locally with Aastrom's TRCs, exhibited a statistically significant increase in bone height at the 3-month evaluation point, and the cell graft had started to integrate with the surrounding preexisting bone of the upper jaw by 4 months, with no cell-related adverse events. The results were obtained from radiographs, and from biopsies taken at the interface of the original bone and the new tissue. All patients went on to receive 3-4 dental implants on each side of their maxilla.

The study employed an internal concurrent control, in which the patients were treated on one side of the maxilla with the TRC test treatment added to a standard of care procedure, and on the other side with the control standard of care procedure, a mixture of platelet-poor plasma and commercial bone mineral matrix. There was a statistically significant difference in bone formation and quality between test and control sides. Bone height in the grafted area and integration of graft into surrounding bone were increased in the TRC test maxilla, when compared with control sites receiving standard of care treatment. Post-operative bruising and swelling observed at some (3/5) of the control sites, were not observed in the TRC treated maxillae (0/5). This is the second clinical bone graft trial to report that surgical sites treated with TRCs appear to exhibit less inflammation or swelling than sites treated without TRCs.

"Edentulous patients who have lost this much jaw bone can be very difficult to treat," commented Dr. Federico Hernandez-Alfaro, Principal Investigator for the trial. "TRCs may offer an improved treatment over existing therapies because they appear to naturally accelerate integration of new bone with the existing bone in the patient, and increase bone mass for implant placement."

"Results such as these provide increasing evidence that TRCs can be safely used to regenerate bone in humans whose ability to maintain and repair their skeleton is impaired by disease or trauma," stated Janet M. Hock, B.D.S., Ph.D., Vice President Global Research and Chief Scientific Officer of Aastrom. "These early clinical studies explore tissue healing and regeneration in patients with compromised conditions, and teach us what to expect from stem cell therapy, and how to optimize the use of TRCs in clinical situations."

Aastrom is implementing a "proof of concept" clinical plan to evaluate the ability of TRCs to generate three different types of bone: long bone, jaw bone and spine. Trials involving multiple centers in both the U.S. and Europe are actively evaluating TRCs in the repair of severe non-union fractures, where preliminary results have demonstrated both safety and bone growth success. A trial for the regeneration of spine bone (vertebral fusion) has been initiated in the U.S. under a newly approved IND. In addition, the Company is now engaged in a human clinical trial in Germany evaluating the use of its TRCs to treat limb ischemia in diabetic patients through the regeneration of vascular tissue in extremities.

### **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 trial), and spine fusion (US: Phase I/II - single-center).

**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 product development objectives, planned clinical trials, potential advantages of TRCs and the AastromReplicell® System, and potential product applications, which involve certain risks and uncertainties. The forward-looking statements are also identified through use of the words "may," "expect," "can," "plan," "appear," 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 product development difficulties, clinical trial results, potential patient accrual 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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