Aastrom

Aastrom Treats Patients in Adult Stem Cell Clinical Trial for Osteonecrosis

- Pivotal Bone Regeneration Trial Underway in Spain -

ANN ARBOR, Mich., Jan 17, 2007 /PRNewswire-FirstCall via COMTEX News Network/ -- Aastrom Biosciences, Inc. (Nasdaq: ASTM), a company focused on the use of autologous cells for regenerative medicine, today announced that the first two patients have been treated in a pivotal clinical trial utilizing the Company's Tissue Repair Cells (TRCs) for the treatment of osteonecrosis (also known as avascular necrosis) of the femoral head. The pivotal trial sponsored by Aastrom is being conducted at Centro Medico Teknon (Teknon) located in Barcelona, Spain. Aastrom initiated patient enrollment and treatment after receiving written approval from the Spanish Drug Agency (AEMPS) and Teknon's Ethics Committee for the Company's Investigational Medicinal Product Dossier (IMPD).

(Logo: http://www.newscom.com/cgi-bin/prnh/20070117/CLW099LOGO)

"The initiation of this osteonecrosis clinical trial in Spain is an integral step for our overall bone regeneration program," said George Dunbar, Chief Executive Officer and President of Aastrom. "If successful, the patient data from this pivotal trial will support future registration applications submitted to the regulatory authorities in the EU, as well as to the FDA in the U.S."

This is Aastrom's first pivotal study evaluating the Company's TRC stem cell therapy in patients with osteonecrosis of the femoral head. Initially, ten patients will be accrued into this trial at Teknon and treated by Principal Investigator, Dr. Lluis Orozco and Co-Investigators, Dr. Robert Soler-Rich and Dr. Carles Solano. In general terms, the expected treatment approach will include the removal of the necrotic tissue from the interior of the patient's femoral head (top of the femur), followed by the implantation of TRCs. The expectation is that if the femoral head is strengthened by the re- growth of healthy bone, marrow and vascular tissue, the need for a hip replacement could be delayed or eliminated for patients suffering from this disease. The primary efficacy endpoint of this trial is to eliminate or delay the progression of osteonecrosis, which will be measured by MRI and X-ray. Patients will be followed for a total of 24 months, post treatment.

"The experience we acquired using the TRC cell product in prior studies of atrophic non-union long bone fractures gave us the confidence to apply the TRC technology to patients with osteonecrosis. We hope to demonstrate significant efficacy over existing therapies," said Dr. LluAs Orozco, Scientific Director, Orthopedics, of Institut de Terapia Regenerativa Tisular.

The tissues involved in the osteonecrosis disease process include bone, bone marrow and blood vessels (vascular), complicating the development of effective treatments in the past. Aastrom's TRCs, a proprietary mixture of stem and progenitor cells derived from a small sample of the patient's own bone marrow, have been used in separate clinical trials to regenerate all three of these tissues. With this capability, TRCs may offer a novel means to regenerate the tissues lost due to osteonecrosis.

In 2006, Aastrom's proprietary TRCs received an Orphan Drug Designation from the U.S. Food and Drug Administration (FDA) for use in the treatment of osteonecrosis of the femoral head. Aastrom is preparing a protocol for a U.S. pivotal osteonecrosis clinical trial with the FDA.

About Osteonecrosis

The National Osteonecrosis Foundation indicates that in the U.S. alone, there are up to 20,000 new people diagnosed with this debilitating disease each year, and current therapies are of limited effectiveness. Osteonecrosis is a painful medical condition where the tissue inside a bone is dying and unable to regenerate itself through natural processes. Ninety percent of the patients afflicted by this disease have osteonecrosis at the femoral head -- the ball at the top of the femur bone that rotates inside the hip socket. Left untreated the femoral head eventually collapses, leading to the requirement of a total hip joint replacement. In the U.S., it is estimated that up to 10% of all hip replacements are performed due to osteonecrosis. There are no established pharmaceuticals for the prevention or treatment of osteonecrosis. For more information, visit the National Osteonecrosis Foundation's website at www.nonf.org.

About Aastrom Biosciences, Inc.

Aastrom Biosciences, Inc. is developing autologous cell products for the repair or regeneration of multiple human tissues, based on its proprietary Tissue Repair Cell (TRC) technology. Aastrom's TRC-based products are a unique cell mixture containing stem and progenitor cell populations, produced from a small amount of bone marrow taken from the patient. TRC-based products have been used in over 230 patients, and are currently in clinical trials for bone regeneration (osteonecrosis of the femoral head, long bone fractures and spine fusion) and vascular regeneration (critical limb ischemia) applications.

Aastrom has reported positive interim clinical trial results for TRCs suggesting both the clinical safety and the ability of TRCs to promote healing in bone regeneration applications. The Company is developing plans for TRC- based therapies to address cardiac and neural regeneration indications.

For more information, visit Aastrom's website at www.aastrom.com. (astmc)

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," "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 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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