Aastrom

Aastrom Initiates Adult Stem Cell Clinical Trial for Peripheral Arterial Disease

FDA-Approved Phase IIb Trial Underway in U.S. to Treat Critical Limb Ischemia

ANN ARBOR, Mich., Apr 30, 2007 (PrimeNewswire via COMTEX News Network) -- Aastrom Biosciences, Inc. (Nasdaq:ASTM), a regenerative medicine company, today announced that it has initiated its U.S. Phase IIb prospective, controlled, randomized, double-blind, multi-center clinical trial to treat patients suffering from peripheral arterial disease (PAD). The Company will use its Tissue Repair Cell (TRC)-based product to treat critical limb ischemia (CLI) in this patient population. Approximately 10 million people in the U.S. suffer from PAD; of this group, 900,000 suffer from the most severe form, CLI, which leads to 100,000 amputations per year.

"Receiving FDA approval to initiate our U.S. PAD clinical trial, and commencing patient recruitment are major milestones for Aastrom's vascular regeneration program," said George Dunbar, Chief Executive Officer and President of Aastrom. "This is a key program for us as we develop and commercialize cell-based therapies for regenerative medicine. We expect our TRC-based product for vascular regeneration to be an important part of our expanding therapeutic portfolio."

PAD is a chronic disease that progressively restricts blood flow in the limbs and can lead to serious medical complications. This disease is often associated with other clinical conditions, including hypertension, cardiovascular disease, hyperlipidemia, diabetes, obesity and stroke. The term CLI is used to describe patients with chronic ischemia-induced pain (even at rest), ulcers, tissue loss or gangrene in the limbs. CLI represents the end stage for PAD patients.

"This is a landmark study in terms of the number of patients to be enrolled, and the scientific rigor of its design. If this therapy proves successful in these critically ill patients, it will have implications beyond the treatment of limb ischemia, which may apply to all ischemic diseases," stated Anthony J. Comerota, M.D., F.A.C.S., F.A.C.C., Director, Jobst Vascular Center and Adjunct Professor at the University of Michigan. "This is an intuitively attractive treatment concept as it takes advantage of the patients' own cells to restore blood flow and to regenerate blood vessels in patients whose native arterial circulation is thought to be irreversibly damaged."

Aastrom's double-blind study is expected to enroll 120 patients, randomized into two patient groups, to evaluate the safety and efficacy of the TRC-based product in the treatment of CLI. The treatment group will receive intramuscular injections of the TRC product into the affected limb; the control group will receive intramuscular injections with an electrolyte solution (without cells). Both groups will receive the standard of care appropriate for their medical condition.

Patients from both groups will be followed for a period of 12 months, post-treatment. The primary objective of the clinical trial is to assess the safety of the TRC-based product in CLI patients. Secondary objectives include assessing amputation rates, wound closure and blood flow in the affected limbs, patient quality of life, and the reduction of pain and analgesic use. Once the first 30 patients have completed the 12-month follow-up, Aastrom will analyze the interim results from these patients. Data gathered from this clinical trial will provide the scientific and statistical basis for an anticipated pivotal trial in the vascular regeneration area.

Aastrom initiated patient enrollment in this clinical trial after receiving Investigational New Drug (IND) approval from the U.S. Food & Drug Administration (FDA) and Institutional Review Board (IRB) approval from several clinical sites. Aastrom will update its website as each clinical site, of the anticipated 20 sites, is initiated for patient enrollment.

This is Aastrom's second study evaluating the Company's TRC-based therapy in patients with critical limb ischemia. Aastrom's TRC-based product is also being used in a clinical trial being conducted at the Heart and Diabetes Center North Rhine-Westphalia in Bad Oeynhausen, Germany.

About Aastrom Biosciences, Inc.

Aastrom is a regenerative medicine company 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 of stem and progenitor cells, produced from a small amount of bone marrow taken from the patient. TRC-based products have been used in over 240 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 suggesting both the clinical safety and the ability of TRC-based products to promote healing in bone regeneration applications. The Company is also developing programs for TRC-based therapies to address cardiac and neural regeneration indications. TRC products have received Orphan Drug Designation from the FDA for use in the treatment of osteonecrosis of the femoral head and the treatment of dilated cardiomyopathy, a severe chronic

disease of the heart.

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

The Aastrom Biosciences, Inc. logo is available at http://www.primenewswire.com/newsroom/prs/?pkgid=3663

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 "expect," "expected," "can," "anticipated," 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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