



Aastrom Stem Cell Therapy Demonstrates Positive Results in Severe Long Bone Non-Union Fracture Trial

Phase I/II Study Results Presented Today at the Orthopaedic Trauma Association Annual Meeting Show a Healing Rate of 91 Percent in Patients With Non-Union Tibia, Humerus or Femur Fractures Who Failed to Heal After One or More Medical Procedures

ANN ARBOR, Mich., Oct 18, 2007 (PrimeNewswire via COMTEX News Network) -- Aastrom Biosciences, Inc. (Nasdaq:ASTM), a leading regenerative medicine company, today announced final results from a U.S. Phase I/II clinical trial designed to collect safety and efficacy data utilizing Bone Repair Cells (BRCs) in the treatment of severe non-union fractures. In the study, patients with non-union tibia, humerus or femur fractures that had failed to heal after one or more medical procedures showed an overall healing rate of 91% after one year. Final results of the study were presented today by Matthew L. Jimenez, M.D., of the Illinois Bone & Joint Institute, during a podium presentation at the Orthopaedic Trauma Association annual meeting in Boston, MA.

In the study a total of 36 eligible patients with severe long bone non-union fractures of the tibia, humerus or femur, that had failed to heal with one or more (average of 1.75) prior medical procedures, were enrolled in the multi-center, prospective, open-label clinical trial and treated with BRCs. Overall, 34 patients completed six-month post-treatment follow-up and 33 completed 12-month follow-up. The 33 patients followed for 12 months showed an overall healing rate of 91%, as determined by bone bridging observed with radiographic imaging or computed tomography. Final results showed healing success in 91% (21 of 23) of tibia fractures, 100% (3 of 3) of humerus fractures, and 86% (6 of 7) of femur fractures. In addition to the 91% healing rate observed after 12 months, results at six months showed that bone bridging successfully occurred in 85% (29 of 34) of patients and that signs of early healing (callus formation) were present in 97% (33 of 34) of patients. Three patients failed to complete the required follow-up visits. Though final data could not be collected from these three patients, two showed healing by 18 weeks. No cell-related adverse events were reported.

"The results suggest that BRCs are efficacious for the treatment of recalcitrant long bone non-union fractures," said Dr. Jimenez, the lead investigator for the study. "BRCs have the potential to become a powerful new tool for bone regeneration and to improve the management of severe fractures."

BRCs are derived from a small sample of the patient's bone marrow that is processed using Aastrom's Tissue Repair Cell (TRC) Technology to generate larger numbers of stem and early progenitor cells with enhanced therapeutic potential. In the study, patients underwent a standard open reduction and internal fixation surgery in which BRCs were applied directly to the fracture site, together with an allograft bone matrix, to promote local bone regeneration.

"The positive results from this study, along with early clinical data reported from osteonecrosis patients two weeks ago, further supports the broad application of our proprietary TRC Technology in the field of orthopedics," said George Dunbar, President and Chief Executive Officer of Aastrom. "We believe these early successes with our technology are important for attracting an experienced orthopedics partner to commercialize our BRC product for bone regeneration."

In addition to bone regeneration, Aastrom is currently developing TRC-based therapies for vascular, cardiac and neural tissue regeneration applications. The Company recently reported positive early data from a German study evaluating the use of BRCs to treat patients suffering from osteonecrosis of the femoral head. Also reported were positive interim results from a German Phase I/II trial utilizing Vascular Repair Cells (VRCs) to treat diabetic patients with critical limb ischemia (CLI), the most severe form of peripheral arterial disease.

The Orthopaedic Trauma Association annual meeting does not provide audio or webcasting services. However, interested parties may access Dr. Jimenez' slide presentation at www.aastrom.com; click on the Clinical Programs heading, then click on the Publications link, and finally click on the link to the slides for this meeting.

Aastrom Conference Call Information

George Dunbar, President and Chief Executive Officer, and Elmar R. Burchardt, M.D., Ph.D., Vice President, Medical Affairs of Aastrom, and Thomas R. Lyon, M.D., principal investigator at Lutheran Medical Center, Brooklyn, NY, will host a conference call to review and discuss the results of the trial at 9:00 a.m. (EDT), October 22, 2007. Interested parties should call toll-free (877) 407-9205, or from outside the U.S. (201) 689-8054, fifteen minutes before the start of the call to register and identify themselves as registrants of the "Aastrom Conference Call". Any registered caller on the toll-free line may ask to be placed in the queue for the Question & Answer session. The call will be simulcast on the Internet at <http://www.vcall.com/IC/CEPage.asp?>

[ID=122247](#). A podcast of the call may be downloaded from the web at the internet address above. If you are unable to participate during the live call, the webcast will be available for replay at <http://www.investorcalendar.com/> until January 22, 2008. Through November 1, 2007, an audio replay of the call will be available by dialing toll-free (877) 660-6853, or from outside the U.S. (201) 612-7415; when prompted on the phone line, the Account # is: 286 and the Conference ID# is: 259045.

About Aastrom Biosciences, Inc.

Aastrom is a leader in the development of autologous cell products for the repair or regeneration of human tissue. The company's proprietary Tissue Repair Cell (TRC) Technology involves the use of a patient's own cells to manufacture products to treat a range of chronic diseases and serious injuries affecting bone, vascular, cardiac, and neural tissues. Aastrom's TRC-based products contain increased numbers of stem and early progenitor cells, produced from a small amount of bone marrow collected from the patient. The TRC Technology platform has positioned Aastrom to advance multiple products into clinical development. Currently, the company has a bone regeneration product in Phase III development for the treatment of osteonecrosis of the femoral head (called the ON-CORE trial), a vascular regeneration product in clinical development for the treatment of critical limb ischemia (called the RESTORE-CLI trial), and preclinical research programs targeting unmet needs in cardiac and neural health. Aastrom product candidates to treat osteonecrosis of the femoral head and dilated cardiomyopathy have been designated for orphan drug status by the FDA. 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 clinical trial strategies, potential partnering activities, 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 "believe," "potential," "could," 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 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.

This news release was distributed by PrimeNewswire, www.primenewswire.com

SOURCE: Aastrom Biosciences, Inc.

Aastrom Biosciences, Inc.

Investor Relations Department
Kris M. Maly
(734) 930-5777

Cameron & Associates
(Investors)
Kevin McGrath
(212) 245-4577

Berry & Company
(Media)
Stephen Zoegall
(212) 253-8881

(C) Copyright 2007 PrimeNewswire, Inc. All rights reserved.

News Provided by COMTEX