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Aastrom Announces Positive Interim Results From Phase I/II Study Involving Use of Vascular Repair Cells in Patients With Critical Limb Ischemia

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Results Presented Today At the Congress of the German Society for Stem Cell Research in Wurzburg, Germany

Early Clinical Data Supporting Use of Aastrom Bone Repair Cells (Brcs) in Treatment of Osteonecrosis of the Femoral Head Also Presented

ANN ARBOR, Mich., Oct. 4, 2007 (PRIME NEWSWIRE) -- Aastrom Biosciences, Inc. (Nasdaq:ASTM), a leading regenerative medicine company, today announced positive interim results from two separate research groups utilizing autologous stem cell products manufactured with the Company's proprietary Tissue Repair Cell (TRC) Technology platform. The first study reported positive results from the use of Aastrom Vascular Repair Cells (VRCs) in the treatment of chronic diabetic foot wounds associated with critical limb ischemia (CLI). In another presentation, positive results from the use of Aastrom Bone Repair Cells (BRCs) in the treatment of osteonecrosis of the femoral head were presented. Primary investigators from each of these research groups presented data today at the 2nd Congress of the German Society for Stem Cell Research in Wurzburg, Germany.

In an oral presentation, Dr. Bernd Stratmann of the Diabetes Center at the Heart and Diabetes Center in North Rhine-Westphalia (Center), Bad Oeynhausen, Germany, presented interim results from the first 13 patients treated in a multi-arm Phase I/II single-center clinical trial to evaluate the safety of VRCs and normal bone marrow cells in the treatment of chronic diabetic foot wounds associated with CLI. Results reflect treatment experience from: four diabetic patients with ischemia-related chronic tissue ulcers who were treated with Aastrom VRCs, a cell mixture derived from the patient's bone marrow that is processed using TRC Technology to generate large numbers of predominantly mesenchymal stem and early progenitor cells; seven patients who were treated with normal bone marrow cells; and two standard of care patients who received no cells. All patients received standard wound care as described by the American Diabetes Association.

Twelve months post-treatment, all patients in the interim analysis who were treated with VRCs reported no major amputations, no cell-related adverse events, and healing of all open wounds. Of the seven patients treated with normal bone marrow cells, five reported results similar to the VRC-treated patients 12 months post-treatment, one reported similar results to the VRC-treated patients 18 months post-treatment, and one patient received a major amputation. For the two standard of care patients who only received wound care (no cells), one patient received a major amputation and one patient experienced no improvement in wound healing after 12 months.

"These encouraging results indicate that VRCs are safe for therapeutic use and could offer potential advantages over the current standard of medical care in closing chronic wounds and in reducing the risk of amputation for diabetic patients with CLI," said Dr. Stratmann, who is a primary investigator in the trial along with Stanley Kirana, M.D., and Prof. Diethelm Tschope, M.D., medical director of the Center.

In a second oral presentation at the same meeting, clinical results were presented by Ulrich Noth, M.D. of the Orthopaedic Institute, Konig-Ludwig-Haus, University of Wurzburg, Germany, involving the first use of Aastrom BRCs to treat patients suffering from osteonecrosis of the femoral head. Osteonecrosis of the femoral head involves the death of cells in the bone and marrow within the femur head and in many cases leads to total hip replacement. Dr. Noth presented data from 4 patients. All patients tolerated the procedure well, have reported a reduction in hip pain with no signs of disease progression, as determined by MRI and X-Ray, and were back to work within 6 months after treatment. In addition, no cell-related adverse events were observed and none of these patients have required hip replacement surgery.

"There are currently no effective treatment options for terminating or reversing this disease process. The use of cell-based therapies has great potential and could play an important role in the treatment of femoral head necrosis in the future," said Dr. Noth.

"In both of these studies, we see more encouraging safety and efficacy data suggesting clinical benefits from treatment

involving products derived from Aastrom's Tissue Repair Cell Technology platform. These data demonstrate, for the first time, that Aastrom's cell products may have a beneficial long-term effect in these two key indications: critical limb ischemia and osteonecrosis of the femoral head. Although still early, the results presented here lend substantial scientific support to our entire clinical development program that is focused on autologous stem cell products for regenerative medicine," said Elmar R. Burchardt, M.D., PhD., Vice President, Medical Affairs of Aastrom.

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 Phase IIb 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 the timing of planned clinical trials, clinical trial strategies, 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 "potential," "could," "suggesting," "may," 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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