Overview of Aastrom RESTORE-CLI and IMPACT-DCM Clinical Results Presented Today at the Conference on Cell Therapy for Cardiovascular Disease

ANN ARBOR, Mich., Jan. 20, 2011 (GLOBE NEWSWIRE) -- Amit N. Patel, MD, MS, associate professor of surgery at the University of Utah School of Medicine and national principal investigator in Aastrom's U.S. Phase 2 IMPACT-DCM clinical trial, and Sharon Watling, Pharm.D., Aastrom's vice president of clinical and regulatory, today reviewed findings from the company's IMPACT-DCM and RESTORE-CLI clinical studies in presentations at The Sixth International Conference on Cell Therapy for Cardiovascular Disease in New York City.

Dr. Patel reviewed six-month interim results from the Phase 2 IMPACT-DCM clinical trial investigating the surgical administration of the company's expanded autologous mixed-cell therapy in patients with dilated cardiomyopathy (DCM). Dr. Patel reviewed previously reported results indicating that treatment is safe and showing that adverse events were minor and associated only with the surgical procedure. No AEs were reported associated with the therapy and AEs were similar in the treatment and control groups. Dr. Patel also reviewed findings showing consistent and positive trends in quality of life, functional and structural parameters in the treatment group. Aastrom expects to report 12-month data from the IMPACT-DCM clinical study in the second quarter of 2011 and six-month results from the DCM catheter Phase 2 clinical study in the third quarter of 2011.

Dr. Watling provided a summary of previously reported interim results from the company's U.S. Phase 2b RESTORE-CLI clinical trial investigating treatment with the company's expanded autologous mixed-cell therapy in patients with critical limb ischemia (CLI). Aastrom plans to conduct two Phase 3 clinical studies of its expanded autologous therapy in patients with CLI and has received Fast Track designation from the FDA for this program. The company has received initial responses from the FDA regarding the special protocol assessments for the two Phase 3 studies, which were submitted in October 2010.

"We are pleased with the initial responses from the FDA, especially for the no-option CLI study. We look forward to continuing to work with the FDA to finalize both special protocol assessments for the Phase 3 CLI program in the months ahead," said Tim Mayleben, president and CEO of Aastrom Biosciences. The Company expects to initiate the no-option Phase 3 trial by mid-2011.

About Aastrom Biosciences

Aastrom Biosciences is developing expanded autologous cellular therapies for the treatment of severe cardiovascular diseases. The company's proprietary cell manufacturing technology enables the production of cellular therapies expanded from a patient's own bone marrow and delivered directly to damaged tissues. Aastrom has advanced its cell therapies into late-stage clinical development, including a planned Phase 3 clinical program for the treatment of patients with critical limb ischemia and two ongoing Phase 2 clinical trials in patients with dilated cardiomyopathy. For more information, please visit Aastrom's website at www.aastrom.com.

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

This document contains forward-looking statements, including without limitation, statements concerning clinical trial plans and progress, objectives and expectations, clinical activity timing, intended product development, the performance and contribution of certain individuals and expected timing of collecting and analyzing treatment data, all of which involve certain risks and uncertainties. These statements are often, but are not always, made through the use of words or phrases such as "anticipates," "intends," "estimates," "plans," "expects," "we believe," "we intend," and similar words or phrases, or future or conditional verbs such as "will," "would," "should," "potential," "could," "may," or similar expressions. Actual results may differ significantly from the expectations contained in the forward-looking statements. Among the factors that may result in differences are the inherent uncertainties associated with clinical trial and product development activities, regulatory approval requirements, competitive developments, and the availability of 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, Quarterly Reports on Form 10-Q and other filings with the Securities and Exchange Commission. These forward looking statements reflect management's current views and Aastrom does not undertake to update any of these forward-looking statements to reflect a change in its views or events or circumstances that occur after the date of this release except as required by law.

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