



Aastrom Announces Agreement From FDA on Special Protocol Assessment for Phase 3 Clinical Trial in No-Option Critical Limb Ischemia Patients

Aastrom Preparing to Begin Phase 3 Clinical Trial in Q4 2011

ANN ARBOR, Mich., July 26, 2011 (GLOBE NEWSWIRE) -- Aastrom Biosciences, Inc. (Nasdaq:ASTM), the leading developer of patient-specific, expanded multicellular therapies for the treatment of severe, chronic cardiovascular diseases, today announced that it has reached agreement with the U.S. Food and Drug Administration (FDA) on the Special Protocol Assessment (SPA) for the design of the Phase 3 REVIVE-CLI clinical trial of ixmyelocel-T, the company's expanded multicellular therapy, in patients with critical limb ischemia (CLI) who have no other treatment options.

Aastrom's Phase 3 clinical trial will enroll up to 594 no-option patients with CLI at approximately 80 clinical sites across the U.S. This multi-center study will be randomized, double-blinded, and placebo-controlled and will include only CLI patients with existing tissue loss (e.g., ulcerations and/or dry gangrene). In the U.S., there are approximately 250,000 CLI patients with tissue loss. Patients with CLI who have tissue loss are five times more likely to experience an amputation within 12 months of diagnosis.

"We greatly appreciate the guidance and support of the FDA staff, our Phase 2 investigators and our Phase 3 steering committee who have helped us reach final agreement on the SPA, a critical component to advancing ixmyelocel-T into Phase 3 clinical testing," said Tim Mayleben, president and CEO of Aastrom. "The SPA from the FDA confirms our confidence that the design of the Phase 3 clinical trial is suitable to support BLA approval for ixmyelocel-T in this under-served patient population. Given the positive results from our RESTORE-CLI Phase 2b trial, we have a great deal of confidence in our Phase 3 program and look forward to launching this pivotal study in the fourth quarter of this year."

CLI is the most severe form of peripheral artery disease, leading to over 160,000 limb amputations per year in the U.S. Approximately 25% of patients will die within the 12 months following diagnosis, and fewer than 25% of patients survive more than four years. Today, there are approximately 400,000 no-option CLI patients who have limited therapeutic and surgical options. Outcomes for these patients are extremely poor, especially those with existing tissue loss (patients classified as Rutherford 5).

In the RESTORE-CLI Phase 2b clinical trial, which was the largest fully controlled cell-therapy study ever conducted in CLI, patients who received treatment with ixmyelocel-T showed a favorable safety profile and clinically meaningful and statistically significant benefit in time to treatment failure events. Aastrom expects to present the data from the RESTORE-CLI Phase 2b clinical trial at a major medical meeting in November 2011.

About Special Protocol Assessments

A SPA is a formal, written agreement between the FDA and a drug sponsor concerning clinical trial design, endpoints and other clinical trial issues that are used to support regulatory review and approval of a therapeutic product candidate. The process is intended to increase the likelihood that if the specified clinical trial protocols from the SPA are followed, the clinical trial endpoints are achieved and there is a favorable risk-benefit profile, trial data may serve as the primary basis of an efficacy claim in support of a Biologic License Application (BLA). More information is available at:

<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm080571.pdf>.

About Aastrom Biosciences

Aastrom Biosciences is developing patient-specific, expanded multicellular therapies for use in the treatment of severe, chronic cardiovascular diseases. The company's proprietary cell-processing technology enables the manufacture of ixmyelocel-T, a patient-specific multicellular therapy expanded from a patient's own bone marrow and delivered directly to damaged tissues. Aastrom has advanced ixmyelocel-T into late-stage clinical development, including a planned Phase 3 clinical program to study patients with critical limb ischemia and two 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 or Transition Report on Form 10-K or 10-K/T, 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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