



Aastrom Submits Special Protocol Assessment to FDA for Its Phase 3 CLI Program

ANN ARBOR, Mich., Oct. 20, 2010 (GLOBE NEWSWIRE) -- Aastrom Biosciences, Inc. (Nasdaq:ASTM), a leading developer of expanded autologous cellular therapies for the treatment of severe cardiovascular diseases, today announced that it has submitted to the U.S. Food and Drug Administration (FDA) a special protocol assessment (SPA) describing the company's proposed Phase 3 clinical development program in critical limb ischemia (CLI). If the FDA concurs with the protocols outlined in the SPA, Aastrom expects to initiate the Phase 3 program in early 2011.

"We are pleased to have reached this important milestone for our CLI program and our plans for the Phase 3 pivotal clinical program remain on track," said Tim Mayleben, president and CEO of Aastrom. "Proceeding through the FDA's SPA process will help ensure consensus with FDA on trial design and endpoints, and will provide a clear and objective path forward as we advance our first-of-a-kind therapy for severely ill CLI patients."

CLI is the most severe form of peripheral artery disease, leading to over 160,000 major limb amputations per year in the U.S. Approximately 25% of patients will die within the 6-12 months following diagnosis, and less than 25% of patients survive four years. Therapeutic and surgical options are limited and often ineffective for the most severely affected patients.

Earlier this week, Aastrom announced that the FDA has granted fast track designation for the company's CLI program. The FDA's fast track program is designed to facilitate the development and expedite the review of new drugs and biologics intended to treat serious or life-threatening conditions and that demonstrate the potential to address unmet medical needs.

About Special Protocol Assessments

An SPA is a written agreement between the FDA and a drug sponsor concerning clinical trial design, endpoints and other clinical trial issues that can be used to support regulatory approval of a therapeutic product candidate. The process is intended to increase the likelihood that if the specified clinical trial protocols 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 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, disease treatment and progression, operating results, spending activities, patient symptoms and responses to treatment, treatment options 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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