



## Aastrom Receives FDA Fast Track Designation for Phase 3 CLI Program

ANN ARBOR, Mich., Oct. 18, 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 the U.S. Food & Drug Administration (FDA) has granted fast track designation for the company's critical limb ischemia (CLI) cell therapy development program. Aastrom plans to initiate Phase 3 clinical testing of its treatment for CLI in early 2011.

"Fast track designation is an important step for our CLI program and underscores the importance of finding an effective treatment option for this devastating disease," said Tim Mayleben, president and CEO of Aastrom. "It may also accelerate the timing of our regulatory submissions to the FDA and expedite FDA review of our marketing application once Phase 3 testing is completed. We greatly appreciate the FDA's support of this important clinical 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. Fast track-designated drugs and biologics ordinarily qualify for priority review, thereby expediting the review process. In addition, the designation may allow Aastrom to submit portions of the Therapeutic Biologic Application on a rolling submission basis.

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.

### 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](http://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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