Aastrom Biosciences Announces Initiation of Patient Enrollment in REVIVE Phase 3 Clinical Trial of Ixmyelocel-T

ANN ARBOR, Mich., Feb. 29, 2012 (GLOBE NEWSWIRE) -- Aastrom Biosciences, Inc. (Nasdaq:ASTM), the leading developer of patient-specific expanded multicellular therapies for the treatment of severe chronic cardiovascular diseases, has begun patient enrollment in the REVIVE Phase 3 clinical trial to assess the efficacy and safety of ixmyelocel-T in the treatment of patients with critical limb ischemia (CLI). The primary endpoint of the trial will be amputation-free survival at 12 months. REVIVE is the largest randomized, double-blind, placebo-controlled, multicenter study ever conducted in patients with CLI.

The Phase 3 trial will be conducted at 80 sites in the United States and will include 594 CLI patients who have no option for revascularization and also have existing tissue loss due to ischemia. Patients will be followed for a total of 18 months, including 12 months from randomization for efficacy and an additional six months for safety.

"The initiation of our REVIVE Phase 3 trial represents a major achievement in our effort to advance ixmyelocel-T through the final phase of clinical development and regulatory review. We are all very excited about the potential to rapidly bring this important new therapy through development to benefit the hundreds of thousands of CLI patients who have no other good treatment options available," said Tim Mayleben, Aastrom Biosciences president and chief executive officer.

This REVIVE clinical trial is supported by an independent steering committee of renowned leaders in vascular medicine and clinical research who will provide independent oversight as well as medical and clinical guidance. Members of the steering committee assisted Aastrom in reaching final agreement on a Special Protocol Assessment (SPA) from the FDA for the Phase 3 study. The REVIVE clinical trial has also been granted Fast Track designation by the FDA.

"The initiation of this landmark study is the result of extensive interactions with the FDA in a Special Protocol Assessment review process designed to ensure the integrity of both the cellular therapy product and the clinical trial to evaluate a novel therapy in a critically ill patient population," said William R. Hiatt, MD, professor of medicine, University of Colorado, and president of CPC Clinical Research, a non-profit academic research organization. Dr. Hiatt is head of the independent steering committee for the REVIVE Phase 3 study. CPC Clinical Research provides quality control services for the collection of endpoint data for the REVIVE clinical trial.

About Aastrom Biosciences

Aastrom Biosciences is the leader in developing patient-specific, expanded multicellular therapies for use in the treatment of patients with 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 Phase 3 clinical program to study patients with critical limb ischemia and a planned Phase 2b clinical trial in patients with ischemic dilated cardiomyopathy. For more information, please visit Aastrom's website at www.aastrom.com. For more information on the pivotal REVIVE Phase 3 clinical trial, please visit the trial website at www.revivecli.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

CONTACT: Media contact

Andrea Coan

Berry & Company

acoan@berrypr.com

(212) 253-8881

Investor contact

Danielle Spangler

The Trout Group

dspangler@troutgroup.com

(646) 378-2924