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Aastrom Biosciences Announces First Patient Enrolled in REVIVE Phase 3 Clinical Trial of Ixmyelocel-T

ANN ARBOR, Mich., May 9, 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, today announced that the first patient has been enrolled in the REVIVE Phase 3 clinical trial of ixmyelocel-T. The REVIVE study is currently underway in the United States to assess the efficacy and safety of ixmyelocel-T in the treatment of no option patients with critical limb ischemia (CLI).

The REVIVE trial is the largest randomized, double-blind, placebo-controlled, multicenter study ever conducted in patients with CLI. The Phase 3 trial has 80 treatment centers qualified to enroll patients 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 primary endpoint of the trial will be amputation-free survival at 12 months.

"The enrollment of the first patient in the REVIVE clinical trial represents another important milestone in our effort to advance the development program for ixmyelocel-T through the final stages of clinical development. We are grateful to our investigators for their commitment to enrolling patients as quickly as possible in this important trial," said Tim Mayleben, president and chief executive officer at Aastrom Biosciences.

For more information about the REVIVE trial, please visit www.revivecli.com.

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.

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