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Aastrom Biosciences Announces First Patients Treated in ixCELL-DCM Clinical Study of ixmyelocel-T

ANN ARBOR, Mich., April 19, 2013 (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 patients were treated in the ixCELL-DCM Phase 2b clinical trial. This study is evaluating the safety and efficacy of ixmyelocel-T compared to placebo in patients with advanced heart failure due to ischemic dilated cardiomyopathy (ischemic DCM). Aastrom has received U.S. orphan drug designation for the use of ixmyelocel-T in patients with DCM.

"There is an unmet need for additional treatment options for DCM as this condition significantly reduces quality of life and places patients at high risk of multiple hospitalizations and increased mortality. The survival rate for DCM drops to just 30% after five years. Ixmyelocel-T has been shown to promote tissue repair in the heart, which can potentially improve outcomes for the hundreds of thousands of people who suffer from advanced heart failure," said Dr. Safwan Kassas, interventional cardiologist, director of the stem cell and regenerative medicine program at the Michigan CardioVascular Institute/Covenant Medical Center and principal investigator in the ixCELL-DCM trial.

The ixCELL-DCM trial is a randomized, double-blind, placebo-controlled phase 2b study with a planned enrollment of 108 patients at approximately 30 sites in the U.S. In the study, ixmyelocel-T will be administered via catheter-based injections to patients with advanced heart failure due to ischemic DCM. The primary endpoint of the trial will be the average number of events per patient, which include all-cause mortality, all-cause hospitalizations or unplanned hospital visits to treat worsening heart failure over 12 months.

"We are very enthusiastic about evaluating the therapeutic potential of ixmyelocel-T to treat patients with DCM, and grateful to our study coordinators and investigators for their progress in moving this important clinical program forward," said Nick Colangelo, president and chief executive officer at Aastrom Biosciences.

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 2b clinical trial in patients with ischemic 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 Report on Form 10-K, Quarterly Reports on Form 10-Q and other filings with the Securities and Exchange Commission. 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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