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Aastrom Biosciences Announces Strategic Change in Research and Development Programs to Focus on Dilated Cardiomyopathy and Other Rare Disease Indications

- Focus shifted to Phase 2b ixCELL-DCM clinical study and the development of ixmyelocel-T for dilated cardiomyopathy, an orphan drug indication.
- Company to stop enrollment and end Phase 3 REVIVE CLI study following strategic program review.
- Corporate restructuring will significantly reduce operating expenses and capital requirements.

ANN ARBOR, Mich., March 27, 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 a strategic change in its research and development programs to focus on the clinical development of its lead product, ixmyelocel-T, for the treatment of dilated cardiomyopathy (DCM). Aastrom, which recently initiated the Phase 2b ixCELL-DCM clinical trial, previously received a U.S. orphan drug designation for the use of ixmyelocel-T in the treatment of DCM. As a result of the strategic change, Aastrom will stop enrollment and end the Phase 3 REVIVE clinical trial in patients with critical limb ischemia (CLI). In addition, the company is executing a corporate restructuring that will reduce staff and operating expenses by approximately 50 percent.

Nick Colangelo, president and chief executive officer of Aastrom, stated: "We completed our strategic review of the CLI program, including an evaluation of the challenges in enrolling patients in the REVIVE study and a recent determination that the CLI program would not be supported by a partner in a timeframe that would impact the pace of enrollment of the study. Based on this review, we have decided that the best path to commercialization of ixmyelocel-T is to focus aggressively on the DCM program. We will begin treating patients in the Phase 2b ixCELL-DCM clinical study within the next few weeks. In our earlier Phase 2a DCM clinical trials, ixmyelocel-T was well-tolerated and efficacy observations were consistent with improved function of impaired myocardium in patients with DCM. In addition, preclinical results demonstrated that ixmyelocel-T was protective of ischemic heart tissue in a murine model of heart failure. These findings strongly support the decision to focus our resources on the development of ixmyelocel-T for the DCM orphan indication."

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

Mr. Colangelo added: "We appreciate the contributions of all of the participants in the REVIVE clinical program and continue to believe that ixmyelocel-T has great therapeutic potential to treat patients with CLI. Our Phase 2b results demonstrated that ixmyelocel-T was efficacious and well-tolerated in patients with CLI. However, we have determined that the optimal use of our resources at this time is to focus on the development of ixmyelocel-T for DCM and other rare disease indications where clinical development may require smaller studies with lower costs and a shorter path to regulatory approval. We also plan to continue to explore the use of our proprietary Aastrom Replicell system to develop new cell therapy products for other areas of unmet medical need."

He further stated: "This was a difficult but necessary decision, and I appreciate the diligence and support of my colleagues in our effort to define the best path forward for Aastrom. Based on all of these considerations, I believe this is the right course of action for our company and the best way to create sustainable long-term value for our shareholders."

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>.

Forward-Looking Statements

This document contains forward-looking statements, including, without limitation, statements concerning clinical trial plans and progress, objectives and expectations, clinical activity timing, including the timing and expenses associated with winding down the CLI trial, intended product development, restructuring plans, 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, the ability to execute on our restructuring plans and successfully reduce expenses, the unproven nature of our proprietary Aastrom Replicell system 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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