



Final Results from RESTORE-CLI Phase 2b Clinical Trial for Ixmyelocel-T in Treatment of Critical Limb Ischemia Published in the Peer-Reviewed Journal *Molecular Therapy*

Results Confirm Improvement in Time to Treatment Failure and no Major Safety Issues

ANN ARBOR, Mich., April 5, 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 final results from the company's RESTORE-CLI Phase 2b clinical trial for ixmyelocel-T were published in the peer-reviewed journal *Molecular Therapy*. The Phase 2b clinical results demonstrated that treatment with ixmyelocel-T improved time to treatment failure in patients with critical limb ischemia (CLI) compared to the control group, and in the subgroup of patients with wounds at baseline demonstrated an improvement in amputation free survival.

The RESTORE-CLI study was a randomized double blind Phase 2b clinical trial comparing the efficacy and safety of ixmyelocel-T to placebo. Patients received a one-time treatment of ixmyelocel-T of 20 intramuscular injections in the treated leg and were followed for 12 months. The results also showed no major safety issues associated with treatment with ixmyelocel-T.

"These results clearly suggest that ixmyelocel-T has the potential to be a promising treatment option in patients with CLI who are not eligible for revascularization. This study represents an important advance in research related to regenerative medicine and the treatment of CLI patients," said Richard J. Powell, M.D., section chief of vascular surgery at the Dartmouth-Hitchcock Medical Center in Lebanon, NH, and a co-principal investigator of the RESTORE-CLI clinical trial.

CLI is the most severe form of peripheral arterial disease (PAD) caused by chronic inflammatory processes associated with atherosclerosis that result in markedly reduced blood flow to the legs, feet and hands. Patients are considered "no option" because they are unable to have revascularization surgery to treat their CLI disease. Major amputation may be necessary for these patients.

In the study, efficacy assessments included time to first occurrence of treatment failure, defined as major amputation, all-cause mortality, doubling of total wound surface area from baseline, or de novo gangrene. A total of 48 patients were treated with ixmyelocel-T and 24 received a placebo. Adverse event rates in both groups were similar. Patients in the treatment arm showed a 62% reduction in risk relative to placebo in the primary efficacy endpoint of time to first occurrence of treatment failure ($p=0.0032$). A post hoc analysis of the subgroup of 45 patients with wounds at baseline resulted in a 77% risk reduction in time to first occurrence of treatment failure ($p=0.0002$) and a positive trend in the Phase 3 endpoint of amputation-free survival (61% risk reduction, $p=0.0915$).

"Based on the results of our RESTORE-CLI study, we recently initiated the Phase 3 REVIVE clinical trial at 80 treatment centers across the U.S. We continue to see very strong promise resulting from our development efforts, and are working aggressively to complete the Phase 3 trial and position ixmyelocel-T for the final phase of regulatory review," said Tim Mayleben, Aastrom president and chief executive officer.

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 two Phase 2 clinical trials in patients with 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

Bill Berry

Berry & Company

bberry@berrypr.com

(212) 253-8881

Investor contact

Danielle Spangler

The Trout Group

dspangler@troutgroup.com

(646) 378-2924