

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**  
WASHINGTON, D.C. 20549

**FORM 8-K**

**CURRENT REPORT**

**Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

Date of Report (Date of Earliest Event Reported): **November 14, 2011**

**Aastrom Biosciences, Inc.**

(Exact name of registrant as specified in its charter)

**Michigan**  
(State or other jurisdiction  
of incorporation)

**000-22025**  
(Commission  
File Number)

**94-3096597**  
(I.R.S. Employer  
Identification No.)

**24 Frank Lloyd Wright Drive, P.O. Box**  
**376, Ann Arbor, Michigan**  
(Address of principal executive offices)

**48106**  
(Zip Code)

Registrant's telephone number, including area code: **(734) 418-4400**

**Not Applicable**

Former name or former address, if changed since last report

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

**Item 7.01. Regulation FD Disclosure.**

On November 14, 2011, Aastrom Biosciences, Inc. (the "Company") presented 12-month final data from the RESTORE-CLI Phase 2 clinical trial of ixmyelocel-T in the treatment of critical limb ischemia patients with no revascularization options. The results were presented by William Marston, M.D., chief, Division of Vascular Surgery, and professor, Department of Surgery, University of North Carolina, in an oral presentation at the 2011 American Heart Association Scientific Sessions in Orlando, FL, a copy of which is furnished herewith as Exhibit 99.1.

**Item 8.01. Other Events..**

On November 14, 2011, the Company issued a press release, a copy of which is attached hereto as Exhibit 99.2 and is incorporated herein by reference.

**Item 9.01. Financial Statements and Exhibits.**

Exhibit 99.1. Slide presentation dated November 14, 2011

Exhibit 99.2. Press release dated November 14, 2011

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Aastrom Biosciences, Inc.

Date: November 14, 2011

By: /s/ TIMOTHY M. MAYLEBEN

Name: Timothy M. Mayleben

Title: Chief Executive Officer and President

**Exhibit Index**

99.1 Slide presentation dated November 14, 2011

99.2 Press release dated November 14, 2011

# Patient-Specific Cellular Therapy (Ixmyelocel-T) is Safe and Improves Time to Treatment Failure in Patients with Critical Limb Ischemia and No Revascularization Options

American Heart Assoc Scientific Sessions 2011

William Marston MD

For the RESTORE-CLI Clinical Investigators

Orlando, FL

November 14, 2011

# RESTORE-CLI Investigators

- Scott Berceci
- W Todd Bohannon
- Anthony Comerota
- Carlo Dall'Olmo
- Raul Guzman
- Brian Halloran
- Peter Henke
- Timothy Henry
- Colleen Johnson
- William Marston
- Jeff Martinez
- Farrell Mendelsohn
- Richard Powell
- Jorge Saucedo
- Patrick Stiff
- Edith Tzeng
- Omaid Velazquez

## Disclosures

William Marston, MD

### TITLE:

Chief, Division of Vascular Surgery  
Professor, Department of Surgery  
University of North Carolina

### FINANCIAL DISCLOSURE:

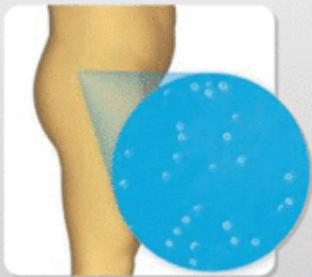
Aastrom (Consultant/Advisory Board)

# Ixmyelocel-T: Description

- Autologous (patient-specific), expanded multicellular therapy
- Target population: CLI patients with no options for revascularization
- Cell source: Bone marrow
- Cell delivery: Twenty intramuscular injections in lower extremity

# Ixmyelocel-T Production

## Extract Bone Marrow



**Day 1**

- Bone marrow (approx. 50ml / 3 tablespoons) is taken from patient's hip
- 15 minute outpatient procedure

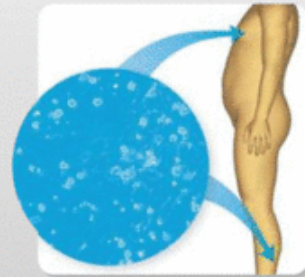
## Expand Cell Population



**Days 2-13**

- automated system expands key beneficial cell types

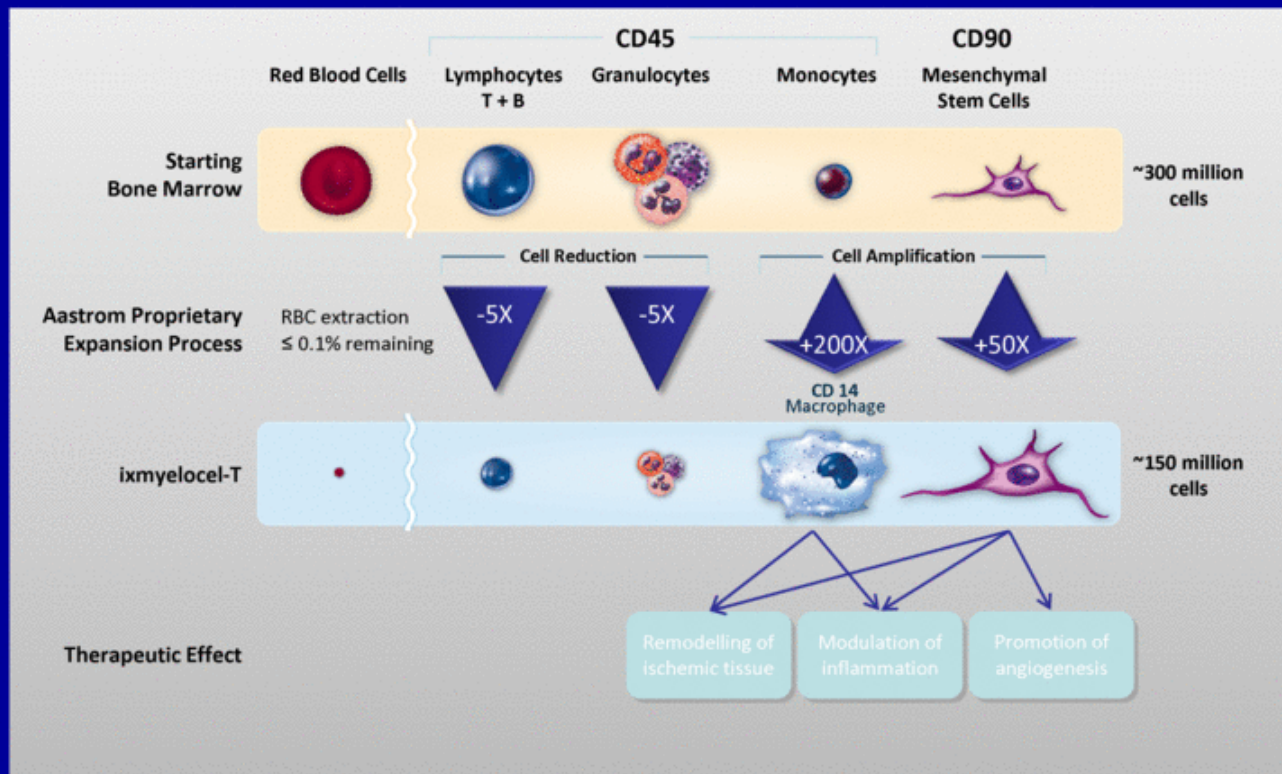
## Administer to Patient



**Day 14**

- Expanded multicellular therapy is administered to the same patient
- 20 minute in-office procedure for CLI patients

# Ixmyelocel-T Cell Expansion



# Ixmyelocel-T Has Multiple Biological Activities

- Remodeling of tissues
  - Secretion of MMPs
  - Phagocytosis and efferocytosis
  - Contraction of ECM
- Promotion of angiogenesis
  - Secretion of angiogenic cytokines
  - Activation of eNOS
- Resolution of inflammation
  - Secretion of anti-inflammatory cytokines
  - Alternatively activated macrophages

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## Phase 2b RESTORE-CLI Study Design

- Randomized, placebo controlled
- Double-blind
- Powered as Phase 2 safety study
- 150 patients
- 18 active centers
- No-option CLI patients who had rest pain with or without baseline wounds

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## Key Inclusion Criteria

- Age 18-90
- Diagnosed CLI
  - Ischemic rest pain  $\geq$  2 weeks duration
  - Ulceration or gangrene of toe or foot
  - Toe systolic pressure  $\leq$  50 mmHg
  - Ankle systolic pressure  $\leq$  70 mmHg
- Infrainguinal occlusive arterial disease judged not amenable to revascularization

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## Key Exclusion Criteria

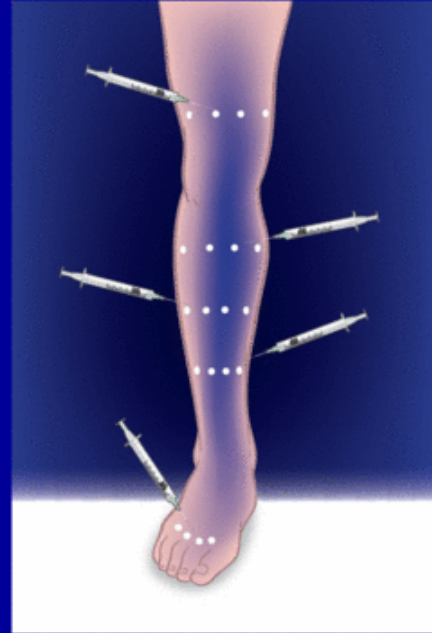
- Previous amputation at talus or above
- Failed ipsilateral revascularization within 2 weeks of randomization
- Active infection of target extremity
- HbA<sub>1c</sub>  $>$  10%
- Untreated aorto-iliac occlusive disease
- Exposed tendon or bone in wound

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# Study Protocol

- 2:1 randomization
  - ixmyelocel-T
  - placebo injection (acellular vehicle)
- One-time set of 20 intramuscular injections 0.5 ml each
  - Lower thigh
  - Calf
  - Foot
- 12 month follow-up



# Defined Study Outcomes

- Safety population: all pts randomized and aspirated
- Efficacy population: all pts randomized, aspirated and treated
- Primary (safety): All adverse events
- Primary efficacy: Time to first occurrence of treatment failure (TTF)
  - Major amputation of treated leg
  - All-cause mortality
  - Doubling of wound total surface area from baseline
  - *De novo* gangrene
- Secondary: Amputation-free survival (AFS)
  - Major amputation of treated leg
  - All-cause mortality

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## RESTORE-CLI Results: Patient Flow

- Based on interim analysis, randomization stopped at 86 patients
- 9 withdrew prior to aspiration
- 77 aspirated
- 72 received treatment injections
  - 48 ixmyelocel-T
  - 24 placebo control

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## Patient Disposition – All Treated Patients (n=72)

	Ixmyelocel-T N = 48	Control N = 24
Completed	39 (81)	21 (88)
Died	3 (6)	2 (8)
Withdrew	6 (13)	1 (4)
-w/endpoint*	3 (6)	0 (0)
-w/o endpoint	3 (6)	1 (4)

\* All 3 patients had a major amputation prior to withdrawing from the study.

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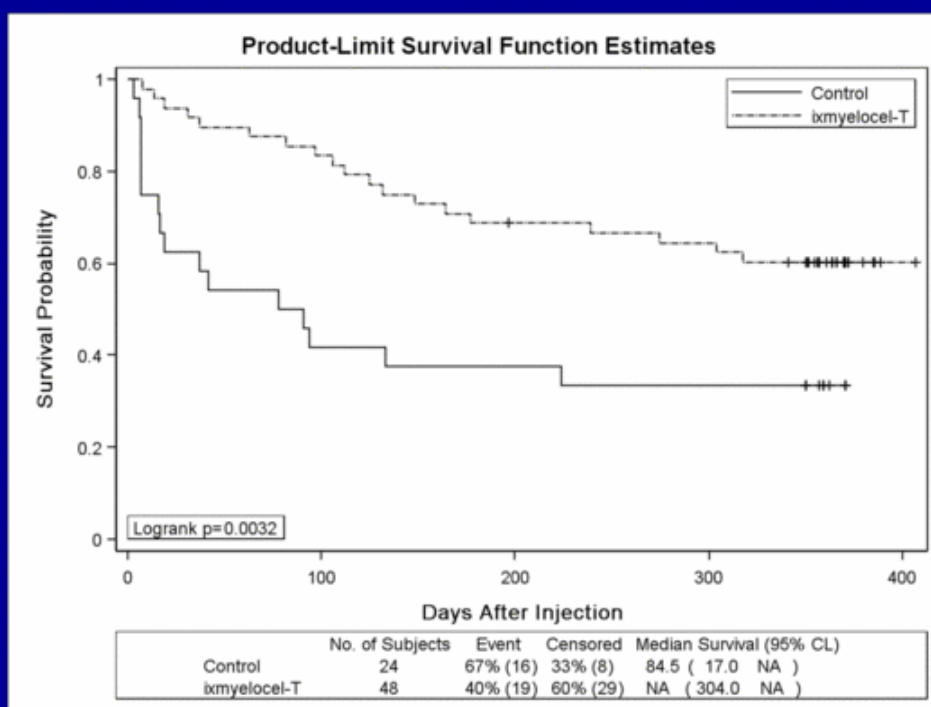
## Patient Demographics– All Treated Patients (n=72)

Parameter* (Mean values)	Ixmyelocel-T N = 48	Control N = 24
% Male	71	58
Age	69	67
% Current, % Past smokers	17, 67	38, 46
% Current, % Past alcohol	44, 23	29, 33
BMI	27	28
Creatinine mg/dL	1.2	1.1
N (%) with known Diabetes	21 (44)	15 (63)

\*No significant differences

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# Time to First Occurrence of Treatment Failure – All Treated Patients (N=72)



62% risk reduction: HR 0.38, 95%CI = (0.20-0.74)

# First Event Contributed to Treatment Failure – All Treated Patients (N=72)

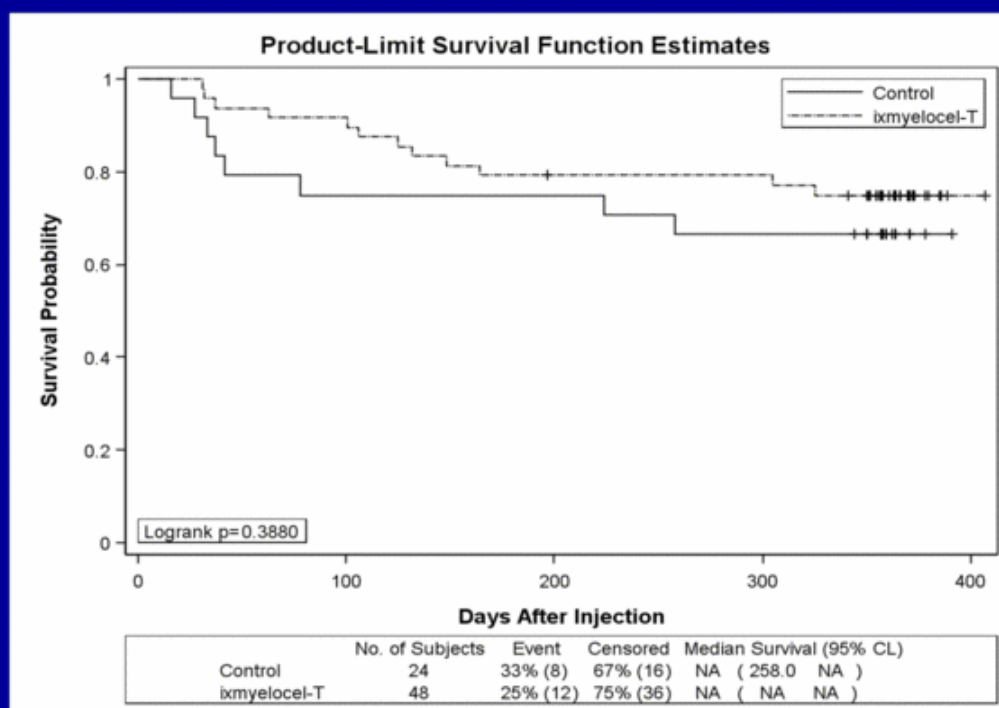
	Ixmyelocel-T N = 48	Control N = 24
Endpoint (n)		
Major amputation	6	4
All-cause mortality	2	1
Doubling in total wound surface area*	5	7
De novo gangrene	6	4
Total n(%)	19 (39.6%)**	16 (66.7%)**

\*For wound size doubling: patient must have come into the study with a wound to be eligible to contribute to this event.

\*\* p = 0.0451, Fisher's exact test.

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# Amputation-Free Survival – All Treated Patients (N=72)



32% risk reduction: HR 0.68, 95%CI = (0.28-1.65)

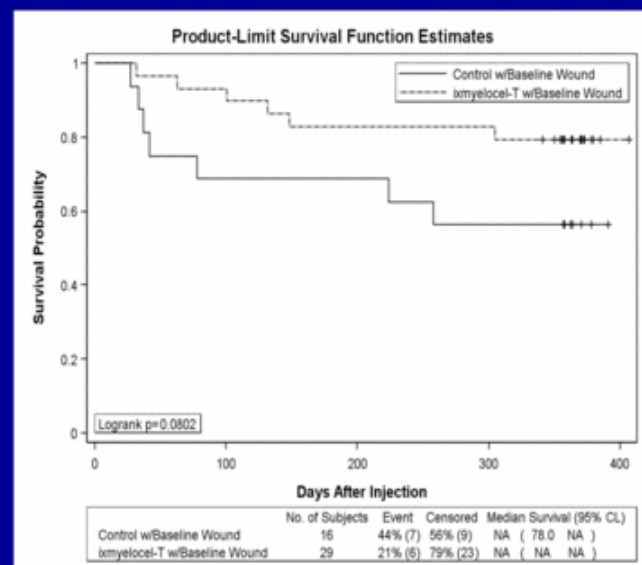
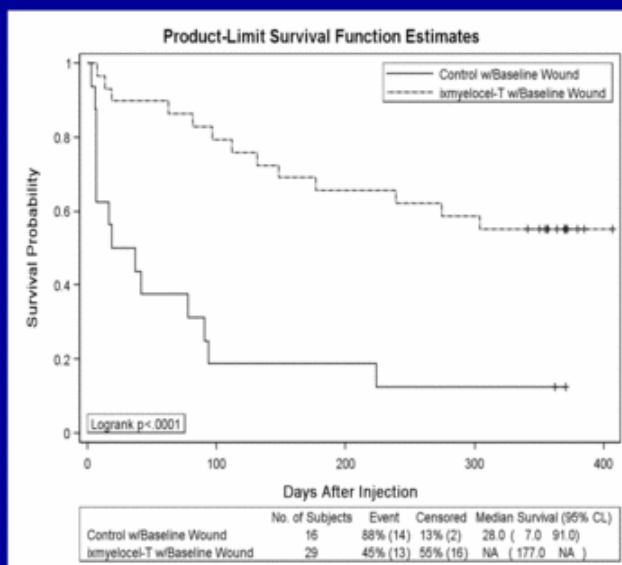
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# Post Hoc Analysis – Patients with Baseline Wounds

- Patients with Baseline Wounds – 45 of 72 treated patients
  - Ixmyelocel-T: 29 / 48 patients (60.4%)
  - Control: 16 / 24 patients (66.7%)
- Repeat analysis for only those patients with baseline wounds
  - TTF
  - AFS

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## TTF and AFS – Baseline Wound Patients (N=45)



77% risk reduction: HR = 0.225  
 95% CI = (0.103, 0.490)  
 Cox PH p-value for treatment = 0.0002

61% risk reduction: HR = 0.391  
 95% CI = (0.131, 1.164)  
 Cox PH p-value for treatment = 0.0915

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## Safety Overview: All Aspirated Patients (N=77)

Safety Parameter	Ixmyelocel-T N = 53	Control N = 24	P-value**
N (%) with Adverse Events	47 (89)	23 (96)	0.424
N (%) Serious Adverse Event	23 (43)	12 (50)	0.628
N (%) withdrawal due to AE	2 (4)	0 (0)	1.000
N (%) Deaths *	3 (6)	2 (8)	1.000

\* An additional ixmyelocel-T patient died ~100 days after completing study.

\*\* Based on Fisher's Exact Test.

# Safety Overview: AEs in $\geq 10\%$ of Aspirated Patients

Preferred Term n (%)	Ixmyelocel-T N = 53	Control N = 24	P-value**
Pain in extremity	17 (32)	4 (17)	0.181
Gangrene	7 (13)	6 (25)	0.209
Cellulitis	5 (9)	6 (25)	0.087
Skin Ulcer	6 (11)	5 (21)	0.303
Hypertension	6 (11)	2 (8)	1.000
Nausea	5 (9)	3 (13)	0.699

\*\* Based on Fisher's Exact Test.

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## Summary: RESTORE-CLI

- Safety profile for aspiration, injection and treatment with ixmyelocel-T favorable
  - No increased adverse events compared to placebo
- TTF primary endpoint positive
  - Significantly fewer adverse limb events
- 32% reduction in AFS in all treated patients
  - Not significant difference
  - Study not powered for AFS outcome
- Patients with baseline wounds had more pronounced treatment effect

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# Ixmyelocel-T Development Plan: Phase 3 REVIVE – CLI

- 594 no-option CLI patients with tissue loss followed for 18 months
- Primary Efficacy Endpoint: AFS at 12 months
- 80 sites (site selection ongoing); US only
- 1:1 randomization to ixmyelocel-T or placebo
- Special Protocol Assessment (SPA) concurrence with FDA on trial design, endpoints, and statistical analysis plan
- Screening/enrollment initiation expected 4Q 2011

## REVIVE – CLI



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**FOR IMMEDIATE DISTRIBUTION**

Aastrom Reports Positive 12-Month Results from the RESTORE-CLI Phase 2  
 Clinical Trial for Ixmyelocel-T in Patients with Critical Limb Ischemia

*Results presented today at the American Heart Association Scientific Sessions show  
 ixmyelocel-T met primary safety and efficacy endpoints in CLI patients with no  
 revascularization options.*

**ANN ARBOR, Mich., [November 14, 2011]** - Aastrom Biosciences, Inc. (Nasdaq: ASTM), the leading developer of patient-specific, expanded multicellular therapies for the treatment of severe, chronic cardiovascular diseases, today reported positive 12-month final results from the RESTORE-CLI Phase 2 clinical trial of ixmyelocel-T in the treatment of critical limb ischemia (CLI) patients with no revascularization options. The results were presented today by William Marston, M.D., chief, Division of Vascular Surgery, and professor, Department of Surgery, University of North Carolina, in an oral presentation at the 2011 American Heart Association Scientific Sessions in Orlando, FL.

The randomized, double-blind, placebo-controlled, multicenter study assessed the safety and efficacy of ixmyelocel-T, a patient-specific, expanded multicellular therapy for the treatment of CLI, in a group of 72 patients at one year after treatment. 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 ( $p = .0032$ ). Treatment failure was defined as the first occurrence of any one of the following: major amputation of the treated leg, all-cause mortality, doubling of wound total surface area from baseline, or *de novo* gangrene. While the study was not powered to show statistical significance in the secondary endpoint of amputation-free survival (AFS; major amputation of the treated leg or all-cause mortality), results from a subgroup of 45 patients with wounds at baseline showed a positive trend in this measure (21% ixmyelocel-T treated vs 44% control event rate;  $p = 0.0802$ ). The study also met the primary safety endpoint with no differences between the treated and control groups.

"These results provide substantial additional evidence that treatment with ixmyelocel-T significantly reduces the risk of disease progression for CLI patients with no options for

– more –

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revascularization. Importantly, the efficacy results demonstrate concordance across all of the defined measures of treatment failure in the trial," said Dr. Marston. "In addition, the results related to AFS in the subgroup of patients with tissue loss similar to those who will be studied in the upcoming pivotal Phase 3 clinical trial show a strong and clinically relevant positive trend for such a small number of patients. These results are especially encouraging since the primary endpoint for the planned REVIVE-CLI pivotal Phase 3 clinical trial for ixmyelocel-T in no-option CLI patients will be amputation-free survival."

The RESTORE-CLI Phase 2 clinical trial involved 72 CLI patients treated at 18 active centers in the United States. Patients were randomized 2:1 treatment versus placebo. Patients were treated with a one-time course of 20 intra-muscular injections in the lower thigh, calf and foot and were then followed for 12 months.

Forty percent of patients treated with ixmyelocel-T in this study had a treatment failure event compared to 67% of patients in the placebo group (a statistically significant risk reduction of 62%,  $p = .0032$ ). In addition, 29% of the placebo group in the trial experienced their first event to be a doubling in total wound surface area from baseline in comparison to 10% of patients treated with ixmyelocel-T. Among patients whose first treatment failure event was *de novo* gangrene, the median time that patients treated with ixmyelocel-T reported the event was day 205 of the study, while the median time that patients in the placebo group reported the event was day 19 of the study (a difference of 186 days).

Aastrom will initiate the REVIVE-CLI Phase 3 clinical trial for ixmyelocel-T this quarter. The study will include 594 CLI patients with no option for revascularization and existing tissue loss. The primary endpoint of this study will be amputation-free survival at 12 months. Patients will be followed for a total of 18 months from the time of treatment.

"The 12-month results from our RESTORE-CLI Phase 2 clinical trial provide compelling clinical evidence that ixmyelocel-T could represent a major advance in the treatment of patients with CLI who have no option for revascularization. We look forward to initiating our pivotal Phase 3 clinical trial for ixmyelocel-T this quarter," said Tim Mayleben, Aastrom's president and chief executive officer.

The presentation slides will be available on the Aastrom web site today at <http://investors.aastrom.com/events.cfm>.

**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.

– more –

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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 planned 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](http://www.aastrom.com).

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*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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