

Morning Note – January 25, 2012

- **NeoStem Begins Enrolling Phase II Trial of AMR-001 for AMI (Heart Attack)**
- **Market Weakness Provides Solid Buying Opportunity for NeoStem Shares**

Please See Last 2 Pages For Important Disclosures And Analyst Certification

Company	Ticker	Price	Mkt. Cap.	Daily Volume	Rating	Target	Analysts
NeoStem	NBS	\$0.71	\$76M	3-month 364,665 10-day 768,220	Strong Buy	\$4.00	Stephen M. Dunn Sr. Managing Director Research sdunn@LifeTechCapital.com (954) 240-9968

Summary

NeoStem announced the first patient enrollment in their Amorcyte PreSERVE Phase II trial for Acute Myocardial Infarction (AMI). The study is a 160-patient, multicenter, randomized, double-blind, placebo-controlled clinical trial to evaluate the safety and efficacy of intra-coronary infusion of AMR-001, an autologous bone marrow derived cell therapy enriched for CD34+ cells, in patient with AMI. AMR-001 is being developed initially for the preservation of heart muscle function for approximately 160,000 American patients who sustain a heart muscle damaging STEMI annually.

Enrollment of the 160 patients is expected to take approximately 12-18 months with top-line data expected after the 6 month follow-up of the last patient treated.

Design Summary: The study will assess the safety and efficacy AMR-001 administered 5 to 11 days post-stent placement in patients diagnosed with an ST segment elevation myocardial infarction (STEMI) with ejection fraction less than or equal to 48% as determined by cardiac magnetic resonance imaging (MRI) measured after recovery from myocardial stunning (reversible ischemic damage). Efficacy will be assessed by evaluating and comparing the autologous stem cell treatment group to the placebo control group via change in myocardial perfusion (RTSS) measured quantitatively by gated single photon emission computed tomography myocardial perfusion imaging (gated SPECT MPI) among other secondary endpoints measured by cardiac MRI in addition to clinical endpoints.

More information on the trial design can be found at: <http://www.clinicaltrials.gov/ct2/show/NCT01495364>

PHASE II HUMAN CLINICAL TRIAL PROTOCOL

Title	A Prospective Randomized Double Blind Placebo Controlled Phase II Trial of Intra-coronary Infusion of AMR-001, a Bone Marrow Derived Autologous CD34+ Selected Cell Product, in Patients With Acute Myocardial Infarction.
# of Patients	160 (male and female)
Ages	18 Years and Older
Trial Design	Randomized, Double-Blind, Placebo-Controlled Phase II Trial
Arm 1:	AMR-001 dosage = 10 or more million CD34+ cells via intracoronary infusion
Arm 2:	Matching Placebo
Primary Endpoints	Safety and efficacy of intracoronary infusion of AMR-001 on myocardial perfusion (RTSS) measured by gated SPECT MPI at baseline and 6 months in subjects post-STEMI.

	<p><u>Safety:</u> safety of bone marrow procurement (measured by adverse events) and AMR-001 cell infusion (including incidence of re-stenosis and stent thrombosis in addition to other adverse events)</p> <p><u>Efficacy:</u> measured by quantitative by gated SPECT MPI specifically looking at resting total severity score) at 6 months</p> <p><u>Follow-Up:</u> Clinical endpoints and safety will be measured through 36 months</p>
Inclusion Criteria	<ul style="list-style-type: none"> • Acute ST elevation myocardial infarction meeting ACC/AHA criteria, with symptoms of chest pain within 3 days of admission. Criteria include (ST elevation > 1mm in limb leads or 2 mm in two or more precordial leads, and increased levels of troponin, CPK MB or both). • Successful stent placement and reperfusion within 3 days of chest pain onset and with TIMI Flow score of 2 or 3 and infarct related artery (IRA) with < 20% stenosis after revascularization. • Wall motion abnormality associated with the target lesion • NYHA heart failure class I, II or III. • Study entry LVEF ≤ 48% determined by CMR no sooner than 96 hours from stent placement. • Subjects must have a Hgb ≥ 10 grams/dL, WBC ≥ 3500 cells/mm³, a platelet count ≥ 100,000 cells/mm³ and INR ≤ 2.0 1-2 days before the bone marrow collection or by the end of screening phase. • Subjects must have a serum creatinine ≤ 2.5 mg/dL, total bilirubin ≤ 2.0 mg/dL within 7 days of the bone marrow collection or by the end of screening phase.
Exclusion Criteria	<ul style="list-style-type: none"> • History of sustained chest pain unrelieved by nitrates, occurring 4 or more days before stent placement. • Subjects presenting with cardiogenic shock (systolic pressure < 80mm/Hg, on vasopressors or intra-aortic counterpulsation). • Subjects unable to receive aspirin, clopidogrel or ticlopidine. • Subjects receiving warfarin who have an INR > 2 or with major bleeding requiring active transfusion support. • Subjects with severe aortic stenosis. • Cirrhosis requiring active medical management. • Malignancy requiring active treatment (except basal cell skin cancer). • Subjects with documented active alcohol and/or other substance abuse. • Females of child bearing potential unless a pregnancy test is negative within 7 days of the bone marrow harvest. • Re-occlusion of the infarct related artery (IRA) prior to the infusion procedure. • Planned revascularization intervention during the next 6 months. • Active or suspected bacterial infection requiring systemic intravenous antibiotics.
Centers	The Carl and Edyth Lindner Center for Research and Education at the Christ Hospital, Cincinnati, Ohio, United States, 45219
Investigators	<p>Study Director: Tom Moss, MD Amorocyte/NeoStem</p> <p>Principal Investigator: Arshed Quyyumi, MD Emory University</p>

Source: ClinicalTrials.gov NCT01495364

AMR-001 Background

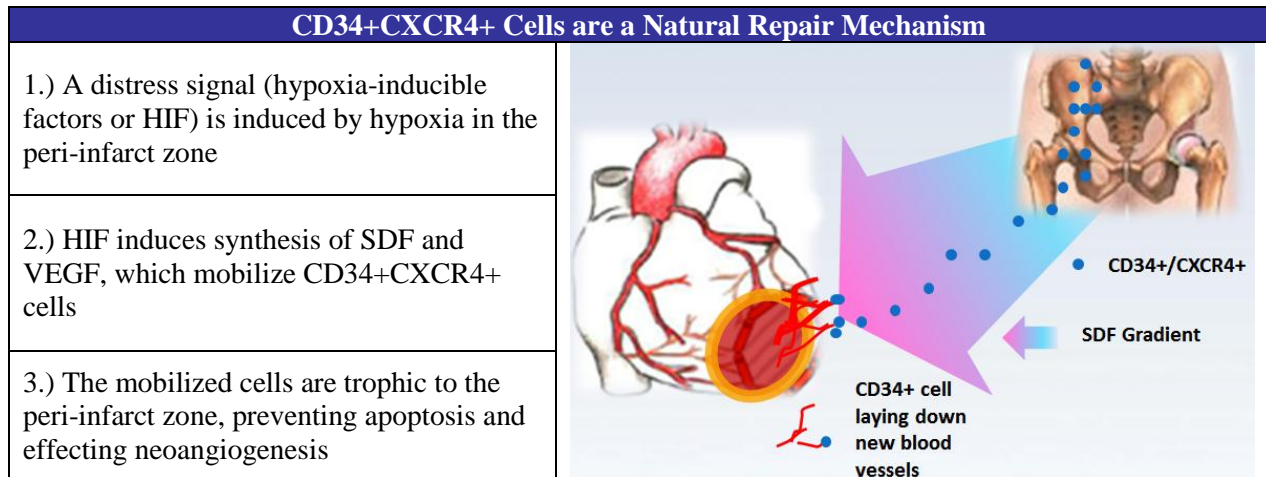
About AMR-001

AMR-001 is an autologous, bone marrow derived, pharmaceutical grade cell-based product that uses a CD34+CXCR4+ enriched cell population and is thought to limit the damage of heart muscle that develops following AMI.

Mechanism of Action

AMR-001 works by increasing microvascular blood flow in the myocardium via neoangiogenesis, thereby reversing post-infarct ischemia and rescuing tissue from hibernation and preventing eventual death (apoptosis):

- CD34+CXCR4+ cells are harvested from the patient's own bone marrow and isolated to increase potency
- The selected cells are infused via the infarct-related artery 6-10 days following the ST-Elevation MI (STEMI) – the optimal time frame for cellular intervention, after the pro-inflammatory “hot phase” and prior to permanent scar formation
- The infused CD34+CXCR4+ cells home to the at-risk tissue via the SDF-1 (Stromal Cell-Derived Factor-1) gradient, inducing neoangiogenesis and a resultant functional benefit



Source: NeoStem Inc.

Phase I Clinical Trial Results

The Phase I clinical trial results of AMR-001 for Acute Myocardial Infarction (AMI) were published in the January 2011 issue of the *American Heart Journal* in a paper titled “CD34+ cell infusion after ST elevation myocardial infarction is associated with improved perfusion and is dose dependent” which is summarized below:

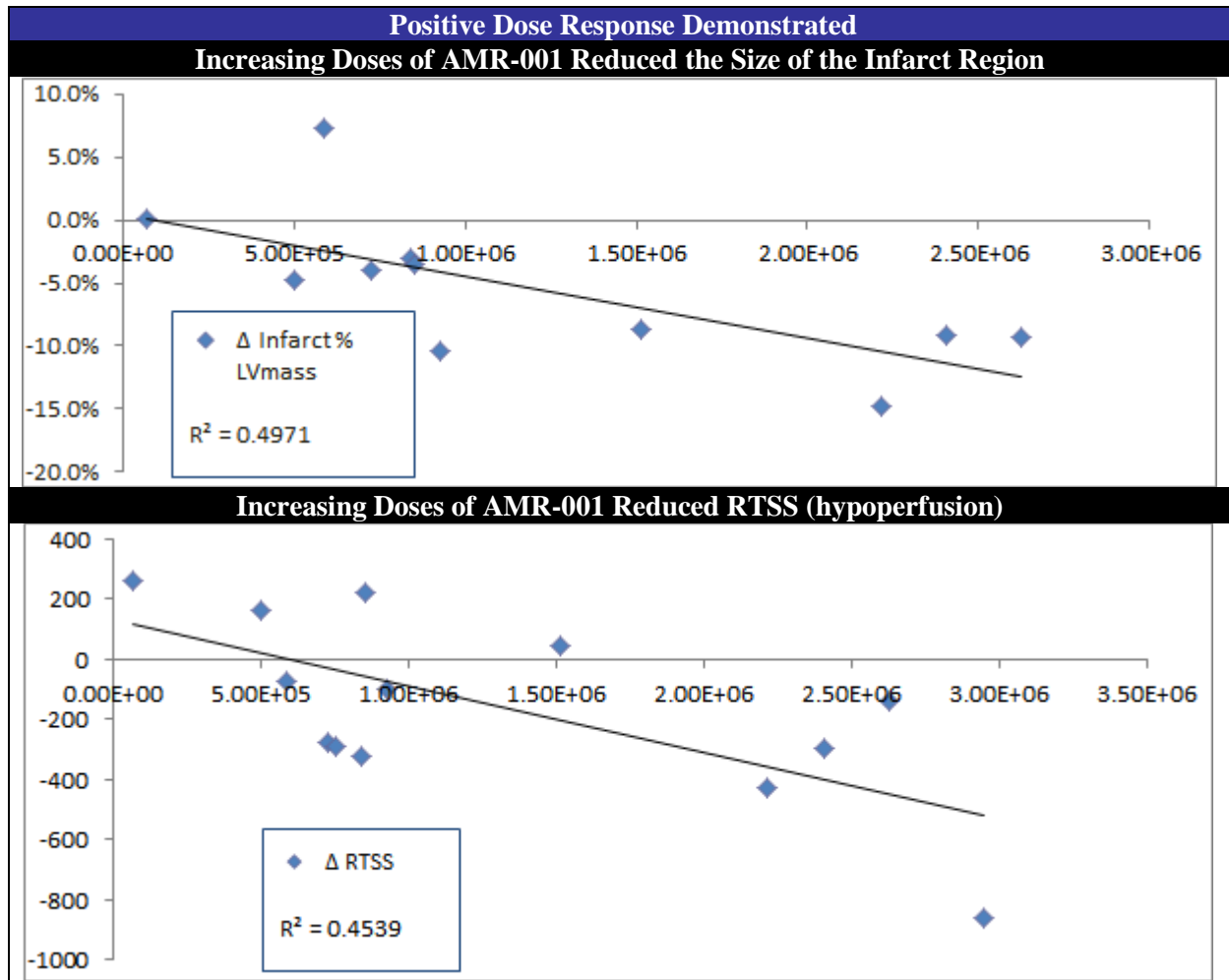
Background: The objective of the study was to determine whether the effects of infarct-related artery (IRA) infusion of autologous bone marrow–derived CD34+ cells after ST elevation myocardial infarction (STEMI) are dependent on the dose (quantity and mobility) of the cells infused. Beneficial effects of IRA infusion of mononuclear cells after STEMI have been inconsistent, possibly because of differences in timing, cell type, quantity, and mobility of infused cells.

Methods: Patients were randomized to bone marrow harvest (n = 16) or control (n = 15). At a median of 8.3 days after coronary stenting for STEMI, CD34+ cells were infused via the IRA at 3 dose levels (5, 10, and 15 × 10⁶) in cohorts of 5 patients each. Baseline and follow-up imaging and ex vivo CD34+ cell mobility were performed.

Results: Cell harvest and infusion were safe. Quantitative rest hypoperfusion score measured by single-photon emission computed tomography improved at 6 months in the ≥10 million cohorts compared with controls (−256 vs +14, P = .02). There was a trend toward improved ejection fraction at 6 months (+4.5%) in the ≥10 million cohorts compared with no change in the controls and 5 million cohort (+0.7%). Improved perfusion and infarct size reduction correlated with the quantity and mobility of the infused CD34+ cells.

Conclusions: The effects of CD34+ cell IRA infusion during the repair phase after STEMI are dose dependent and, at a threshold dose of 10 million CD34+ cells, associated with a significant improvement in perfusion that may limit deterioration in cardiac function.

Note: for the complete clinical trial design see <http://clinicaltrials.gov/ct2/show/NCT00313339>



Source: Quyyumi AA et al "CD34+ cell infusion after ST elevation myocardial infarction is associated with improved perfusion and is dose dependent" 2011, American Heart Journal; 161(1) 98-105 [http://www.ahjonline.com/article/S0002-8703\(10\)00894-X/abstract](http://www.ahjonline.com/article/S0002-8703(10)00894-X/abstract)

Threshold Dose of 10 Million Cells Shows Significant Improvement in Perfusion				
RTSS Cohort	Baseline	6 Months	Change	% Change
Control	259.0	273.5	+14.5	+5.6%
5M Cells	714.2	722.0	+7.8	+1.1%
10M Cells	998.6	635.8	-362.8	-36.4%
15M Cells	584.0	462.0	-122.0	-20.9%

Source: Quyyumi AA et al "CD34+ cell infusion after ST elevation myocardial infarction is associated with improved perfusion and is dose dependent" 2011, American Heart Journal; 161(1) 98-105 [http://www.ahjonline.com/article/S0002-8703\(10\)00894-X/abstract](http://www.ahjonline.com/article/S0002-8703(10)00894-X/abstract)

Subgroup Analysis of ≥10 Million Cell Threshold on Additional Cardiac Functions				
	RTSS % Change	Ejection Fraction % Change	End Systolic Volume % Change	Drop in Ejection Fraction % Change
Control & 5M Cells	+3.3%	+1.3%	+4.6%	30%-40%
10M & 15M Cells	-31.4%*	+9.4	-6.1%	0%

* Statistically Significant p=0.01

Source: Quyyumi AA et al "CD34+ cell infusion after ST elevation myocardial infarction is associated with improved perfusion and is dose dependent" 2011, American Heart Journal; 161(1) 98-105 [http://www.ahjonline.com/article/S0002-8703\(10\)00894-X/abstract](http://www.ahjonline.com/article/S0002-8703(10)00894-X/abstract)

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Ratings and Price Target Changes over Past 3 Years
 Initiated September 10, 2010 – Strong Buy - Price Target \$3.75
 Updated January 21, 2011 – Strong Buy - Price Target \$4.00

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Strong Speculative Buy	58%	43%	Hold/Neutral	8%	100%
Buy	0%	0%	Sell	17%	0%
Speculative Buy	0%	0%	Total	100%	33%
Neutral	8%	100%			
Avoid/Sell	17%	0%			
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Not Rated	0%	0%			
Restricted	0%	0%			
Total	100%	33%			

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