AMR-001 Background

http://www.amorcyte.com/

About Amorcyte

Company Overview

- Incorporated in 2005 and headquartered in Allendale, New Jersey, Amorcyte, Inc. is a clinical stage company developing cell therapeutics for cardiovascular disease
- The Company is focused on its first product, AMR–001, a bone marrow-derived, CD34 positive selected stem cell product for the preservation of heart muscle function following Acute Myocardial Infarction (AMI)
- Amorcyte partners with Progenitor Cell Therapy (PCT), a cGMP cell manufacturer accredited by the Foundation for the Accreditation of Cell Therapies for all product manufacturing. Amorcyte expects PCT's significant expertise in cell therapy and core process development to provide a cost advantage for AMR-001 manufacturing
- Amorcyte is lead by clinicians, scientists, and business executives with significant accomplishments in both the general field of health care and specifically within the field of cell-based therapeutics. Key management members include:
  - Andrew Pecora, M.D. FACP, Founder and CSO of Amorcyte, Chairman of HUMC Cancer Center, Chairman and Founder of Progenitor Cell Therapy
  - Hans Mueller, Ph.D., Chairman of Amorcyte
  - Paul Schmitt, CEO of Amorcyte, Managing Director of Novitas Capital

AMR-001

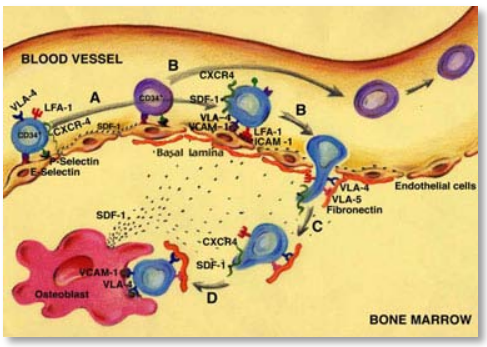
Overview

- Amorcyte's therapeutic strategy focuses on preventing subsequent major adverse cardiac events following a significant AMI by preserving heart muscle tissue
- AMR-001, Amorcyte's lead product candidate, is an autologous bone marrow derived, CD34 positive selected stem cell product, that limits progressive cardiomyocyte loss following AMI and, thus, has the potential to maintain cardiac muscle function and prevent further adverse cardiac events
- The target population for AMR-001 is the segment of cardiac patients who are at significant risk for downstream major adverse events including premature death, recurrent myocardial infarction, congestive heart failure, significant arrhythmias, acute coronary syndrome and poor quality of life. These patients represent a large cost segment and are the largest financial burden in many managed care programs. We expect this burden to increase as the baby boomer population ages. AMR-001 is expected to have a significant pharmacoeconomic benefit by preventing downstream adverse events
- AMR-001 fits seamlessly into physicians' standard treatment practices. Administered in the catheterization laboratory as an out-patient procedure, AMR-001 is a simple addition to the standard of care

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 using Amorcyte's patented technology
  - The selected cells are infused via the infarct-related artery 7-10 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 gradient, inducing neoangiogenesis and a resultant functional benefit
  - Amorcyte has recently verified the mechanism of action (CD34+CXCR4+ cell induced neoangiogenesis resulting in a functional benefit) of AMR–001 in animal models and in humans in a phase I trial. Publication is in process.

AMR-001 Exploits Natural Mechanism



Market Opportunity

- There are approximately 160,000 patients per year who have a STEMI resulting in a reduced left ventricular ejection fraction of less than 50%
- These patients are at significant risk of downstream adverse events including congestive heart failure, recurrent MI, significant arrhythmias, premature death or acute coronary syndrome, and are the target population for AMR-001
- The AMR-001 target population represents an accessible market of over $1.4 billion annually

AMR-001 (Cont.)

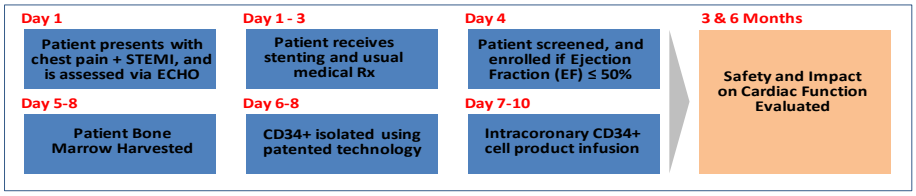
Intellectual Property Position

- Amorcyte has a dominant IP position having been granted United States Patent number 7,794,705 titled "Compositions and Methods of Vascular Injury Repair." The patent contains both composition of matter and method claims surrounding therapeutic chemotactic hematopoietic stem cell products used in treating or repairing a vascular injury following an acute myocardial infarction (AMI), and delivery of the cell therapy
- This is the first instance of a U.S. patent being issued for a chemotactic hematopoietic stem cell product, its delivery and the cell potency and stability needed to treat the consequences of a vascular injury
- 38 claims cover composition of matter and methods:
  - Composition of matter claims for CD34+ stem cells having CXCR-4+ receptors that have achieved neoangiogenisis (formation of new blood vessels) in heart muscle damaged from an AMI
  - Process/methods claims for enriching the cells and maintaining potency, stability, purity and shelf life
  - Claims covering most catheters that would be used by an Interventional Cardiologist to administer the cells to patients
- Patent expires in May 2028 (plus any patent term adjustments or extensions)
- Amorcyte has obtained a freedom to operate opinion and patentability analysis for AMR-001
- Amorcyte is pursuing patent rights outside the U.S. and additional patent rights in the U.S. directed to related aspects of its technology

Clinical Trials

- In a recently completed Phase I study of 31 patients presented at the 2009 American College of Cardiology Annual Scientific Session, AMR–001 showed a dose–related significant improvement in myocardial perfusion (RTSS)

Overview of AMR-001 Phase I Trial



- Study results demonstrated that patients receiving 10 million (n=5) or 15 cells (n=4) showed significant improvement in resting perfusion rates at six months as compared to patients receiving 5 million cells (n=6) or control (n=15), as measured by the SPECT total severity score, (–256 versus +13, p=0.01)
- The data also showed that patients receiving 10 or more million cells showed a trend towards improvement in ejection fraction, end systolic volume, and reduction in infarct size
- In 2011, Amorcyte expects to commence a Phase II multicenter, blinded, prospective, randomized, controlled clinical trial to evaluate the efficacy and safety of intra-coronary infusion of AMR-001 after STEMI in subjects with ejection fraction ≤50%, as determined by screening gated SPECT MPI 96 hours post stenting
  - Goal of phase II study is to determine the effect of infusion of a potent dose of CD34+/CXCR4+ cells on cardiac function and outcomes of patients after significant STEMI
  - Primary assessment for effect of AMR-001on cardiac function is improvement in cardiac perfusion as measured by SPECT scan
  - Amorcyte will also evaluate impact of AMR-001 on adverse events post MI as defined by premature death, recurrent MI, congestive heart failure, significant arrhythmias, and acute coronary syndrome

Contacts

Torreya Partners is assisting Amorcyte in a potential transaction for AMR-001 and invites indications of interest. The next step for interested parties would be to sign a CDA with Amorcyte and receive a detailed product dossier and then enter due diligence discussions

Questions regarding the product should be directed to:

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