

For Immediate Release

Arterioocyte Receives FDA Approval to Move Forward with Critical Limb Ischemia Trial

Cleveland, OH, January 27th, 2011

Arterioocyte®, a leading clinical stage biotechnology company with offices in Cleveland, Ohio and Hopkinton, Massachusetts that develops proprietary stem cell and tissue engineering based therapies announced today approval from the Food and Drug Administration (FDA) to initiate a Phase I clinical trial using its Magellan MAR01™ technology in the treatment of Critical Limb Ischemia (CLI). The FDA Investigational Device Exemption (IDE 14522) allows Arterioocyte and its clinical partners to initiate evaluation of concentrated marrow injections (using the Magellan MAR01™ technology) in improving perfusion in ischemic tissue in affected limbs of patients with CLI who are not eligible for revascularization surgery.

The Magellan technology combines a rapid bedside tissue concentration device and sterile surgical disposables that produce platelet rich plasma from blood and bone marrow aspirations in approximately 15 minutes and was FDA approved through the 510(k) process for use as deemed appropriate by surgeons. The Magellan MAR01™ technology enables the rapid “closed system” concentration of aspirated bone marrow, yielding an injectable tissue rich in platelets, hematopoietic stem cells and mesenchymal stem cells, commonly viewed as key components in tissue repair. The company is developing MAR01™ for use as a clinical treatment for Critical Limb Ischemia, and plans to initiate additional clinical trials evaluating MAR01™ in cardiovascular disease, and the clinical setting of orthopedics and tissue repair during 2011.

Patient enrollment for the phase I safety study will begin immediately at The Ohio State University Medical Center (as the first clinical site), under the direction of Dr. Michael Go, Assistant Professor of Surgery in the Division of Vascular Diseases and Surgery. “This clinical trial represents a unique opportunity to evaluate a novel biologic treatment for ‘no-option’ CLI patients and reinforces Ohio State Medical Center’s leadership role in the clinical evaluation of these important technologies to improve the delivery of care for our patients.”

Ultimately, Arterioocyte expects this technology to benefit many of the 750,000 individuals suffering from Critical Limb Ischemia in the United States. CLI is caused by a severe blockage of peripheral arteries that significantly impairs blood flow to the extremities, causing chronic tissue degeneration and necrosis. It is estimated that 150,000 individuals lose a limb due to this disease each year. ¹

Arterioocyte’s Chief Executive Officer, Don Brown shared. “We’re thrilled to have the green light to initiate this next important step in the clinical development program for the Magellan MAR01™ technology. It represents yet another achievement in our public-private partnership with Ohio’s Third Frontier Program, and their support of our development of Magellan based cellular therapies for the treatment of cardiovascular and critical limb ischemia patients.”

About Arterioocyte

ARTERIOCYTE

CELLULAR THERAPIES
MEDICAL SYSTEMS

Arteriocyte, a leading clinical stage biotechnology company, is dedicated in developing novel stem cell products and medical devices for unmet research and clinical needs. Arteriocyte leverages its expertise in stem cell and tissue engineering in order to develop a broad portfolio of cell based therapeutics to improve patient outcomes. In October of 2007, Arteriocyte partnered with DW Healthcare Partners and Comerica to create Arteriocyte Medical Systems Inc., in order to commercialize and distribute novel medical devices and point of care surgical solutions to address serious unmet medical needs in cardiac, orthopedic and vascular surgeries. Today, Arteriocyte Medical Systems manufactures and distributes the Magellan[®] Autologous Platelet Separator System worldwide.

Contact Information

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Reference

1. Ramsey SD NK, Blough D, et al. : Incidence, outcomes, and cost of foot ulcers in patients with diabetes. **Diabetes Care** 22:382-387, 1999