Arteriocyte Receives FDA Approval to Initiate Cellular Therapy Trial for Treatment of Thermal Burn Wounds in Wounded Warriors

The Associated Press

Arteriocyte, a leading biotechnology company with offices in Cleveland, Ohio and Hopkinton, Massachusetts announced today approval from the Food and Drug Administration (FDA) to initiate a Phase I clinical trial using its Magellan@ System technology in the treatment of thermal burn wounds.

The FDA Investigational Device Exemption (IDE-15140) allows Arteriocyte and its clinical partners to initiate evaluation of autologous platelet gel (APG) (using the Magellan@ Autologous Platelet Separator technology) as an adjunctive therapy for autologous skin grafting in patients with thermal injuries. This treatment has been developed in partnership with the United States Telemedicine and Advanced Technology Research Center (TATRC), and the University of Utah Health Science Center and Intermountain Burn Center. Arteriocyte is initiating a series of investigations employing Arteriocyte's Magellan@ Autologous Platelet Rich Plasma and Bone Marrow Derived Stem Cell Based Therapies for Burn Wounds as part of Arteriocyte's Cellular Therapies for Battlefield Wounds Program.

The Magellan@ System is an FDA 510(k) cleared medical device for the rapid production of Platelet Rich Plasma from blood and bone marrow that can be applied to a surgical site as surgeons deem necessary for their clinical use requirements. Magellan@ MAR01a technology enables the rapid Operating Room based "closed system" concentration of aspirated bone marrow, yielding an injectable tissue rich in platelets, hematopoietic stem cells and mesenchymal stem cells in as little as fifteen minutes. The self-contained Magellan@ Unit provides critical ease-of-use and operator-independent consistency necessary for deployment in military medical operations. Arteriocyte has partnered with the U.S Military to develop Magellan@ MAR01a in clinical use across three trauma platforms: Extremity Trauma, Burn Wounds and Infection Prevention.

The current clinical protocol will evaluate the Magellan@ Autologous Platelet Gel as an adjunctive therapy to improving skin graft acceptance and integration in thermally injured patients. Autologous Platelet Gel is used to improve adherence of the autologous skin graft, while providing beneficial growth factors and antimicrobial protection ensuring graft survival.

"We're thrilled to see that industry continues to pursue the development of point-of-care cellular therapies to advance military medicine," said COL Lee Cancio, MD, a surgeon at the U. S. Army Institute of Surgical Research Burn Center at the San Antonio Military Medical Center. "Programs like this are examples of efforts to improve stabilization, retention and readiness for thousands of our Wounded Warriors." Enrollment into the Burn clinical trial is anticipated to begin in early 2013

and will be conducted at The University of Utah's Health Science Center and Burn Center, led by Drs. Amit Patel, MD and Amalia Cochran, MD.

Arteriocyte CEO Don Brown said, "We are and will continue to be committed to improving care delivery for our men and women in uniform and to do our best to help those that serve and protect our country.

The extraordinary vision and commitment of our partners at TATRC and SAMMC to develop and deliver the best care possible for our combat wounded Soldiers is to be lauded." About Arteriocyte Arteriocyte, a leading clinical stage biotechnology company, is dedicated in developing novel stem cell products and medical devices to help patients heal faster. 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. Arteriocyte Medical Systems manufactures and distributes the Magellan@ Autologous Platelet Separator System SOURCE Arteriocyte -0- 01/31/2013 /CONTACT: For Media Relations and General Inquiries about Arteriocyte: Deborah Faucher, +1-508-497-8950, dfaucher@arteriocyte.com CO: Arteriocyte; U.S Military ST: Ohio Massachusetts IN: BIO MEQ HEA SU: FDA TRI PRN -- CL50667 -- 0000 01/31/2013 15:37:35 EDT http://www.prnewswire.c

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