Company's Proprietary Approach Expected To Further Advance The Practical Application and Clinical Benefits Of Therapeutic Hypothermia

The Associated Press

MENLO PARK, Calif.--(BUSINESS WIRE)--Feb 14, 2012-- Velomedix, Inc., a clinical stage medical device company advancing the field of therapeutic hypothermia, announced it has received Investigational Device Exemption (IDE) approval from the U.S. Food and Drug Administration (FDA) to evaluate the use of rapid therapeutic hypothermia for the treatment of patients suffering an acute myocardial infarction (AMI or heart attack). The conditional approval allows the company to initiate a clinical trial at select sites in the United States.

Therapeutic hypothermia has been shown to significantly improve outcomes for several acute events such as cardiac arrest, heart attack, and acute ischemic stroke. It has also been used with great success for spinal cord injury. While there are several technologies currently being marketed for hypothermia management, Velomedix's proprietary technology delivers unparalleled cooling speed and procedural efficiency that is expected to result in enhanced clinical outcomes and enable more widespread clinical adoption of this promising therapy. "While current technologies can reach a therapeutic target temperature of 33C in 1-2 hours, the Velomedix system has shown the ability to achieve 33C in less than 15 minutes," commented Jeff Gold, President and CEO of Velomedix. "For AMI patients requiring an intervention to open a blocked artery, the ability to deliver rapid cooling is crucial to optimizing the protective benefits of therapeutic hypothermia while still complying with mandated hospital 'time-to-treatment' standards," added Griff Tully, MD, Velomedix's Vice-President & Chief Medical Officer.

The recently approved IDE study will build upon limited, yet significant, data developed over the last 8 years for the use of therapeutic hypothermia for heart attack victims. Though the early randomized studies clearly pointed to the potential benefits of therapeutic hypothermia in this patient population, the effectiveness of the therapy was limited by the slow cooling times of the technologies employed and, as such, failed to meet the primary clinical endpoints. More recent studies have shown that rapid cooling, as enabled by Velomedix's proprietary system, can result in clinical results that rival the best data extracted from earlier studies. Study patients who were rapidly and effectively treated with therapeutic hypothermia showed up to a 50% reduction in the amount of heart muscle lost during a major heart attack. This reduction is expected to correlate with improved survival rates and enhanced quality of life post-infarct.

It is anticipated the Velomedix IDE study will begin enrolling patients in the second half of 2012.

About Velomedix, Inc.

Velomedix is a venture capital backed clinical stage company located in Menlo Park, CA. Founded in 2007, the company has completed an initial human trial in the European Union (EU) that showed improved survival rates and neurological outcomes for patients suffering a cardiac arrest. In both the EU and the United States, awareness of the benefits of therapeutic hypothermia is growing and, in 2010, the American Heart Association (AHA) elevated the recommendation for therapeutic hypothermia for out-of-hospital cardiac arrest to a Class I. Yet clinical adoption of the therapy continues to be burdened by the insufficiencies of current approaches. Velomedix feels its rapid cooling approach has the potential to expand the clinical application and practical adoption of therapeutic hypothermia for the management of cardiac arrest patients as well as those suffering from a heart attack, stroke, traumatic brain injury, or spinal cord injury.

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