Velomedix Receives IDE Approval for Randomized Pilot Trial to Evaluate Rapid Therapeutic Hypothermia in the Management of Acute Myocardial Infarction Patients

The Associated Press

MENLO PARK, Calif.--(BUSINESS WIRE)--Nov 28, 2012--Velomedix, Inc., a venture-backed 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 expand the design of its VELOCITY pilot clinical trial. This North American trial will evaluate the use of rapid therapeutic hypothermia in the treatment of patients suffering an acute myocardial infarction (AMI or heart attack). Positive discussions with the FDA resulted in approval to include a control arm for a randomized comparison, thus doubling the number of patients, and to increase the number of U.S. trial sites.

Mild therapeutic hypothermia has been shown to substantially improve outcomes for acute events, such as heart attack and cardiac arrest *. While several technologies are currently being used clinically for hypothermia management, Velomedix's proprietary technology delivers unparalleled cooling speed, as demonstrated in previous clinical trials *. This form of rapid cooling may enhance clinical outcomes and enable widespread clinical adoption of this promising therapy. "More rapid cooling may be critical to reduce infarct size in patients with heart attacks undergoing angioplasty," commented Gregg Stone, MD, Columbia University Medical Center / New York-Presbyterian Hospital and co-principal investigator of the VELOCITY trial.

The VELOCITY trial is a 60-patient randomized trial at up to nine U.S. investigational sites to evaluate the Velomedix Automated Peritoneal Lavage System in patients with ST segment elevation myocardial infarction, presenting within six hours of symptom onset. The study will investigate the safety and feasibility of augmenting today's standard of care (primary PCI) with mild therapeutic hypothermia delivered by the Velomedix system. "We are very excited that collaboration with the FDA resulted in a randomized trial which will likely provide much more clinically useful information than a comparison to historical control," said Jeff Gold, President and CEO of Velomedix.

The study's primary endpoint is a composite of specific new-onset, serious adverse events during the first thirty days following treatment. Several secondary endpoints will also be collected, including infarct size, myocardial salvage, and left ventricular ejection fraction. Thus, while primarily a safety trial, it will also gather meaningful efficacy information.

Graham Nichol, MD, University of Washington - Harborview Center for Pre-Hospital

Emergency Care, will be working with Dr. Stone as the other co-principal investigator for this study. The trial is set to begin enrollment before the end of 2012. More information on this trial can be found at www.clinicaltrials.gov, study NCT01655433.

About Velomedix, Inc. Velomedix is a private medical device company in Menlo Park, CA created to realize the clinical potential of mild therapeutic hypothermia in patients suffering from acute vascular insults. These include heart attack, cardiac arrest, and ischemic stroke. Therapeutic hypothermia (TH) has been shown to reduce the ischemic and reperfusion effects in these costly and debilitating conditions.

Unlike other cooling approaches, Velomedix's unique technology can rapidly reduce patient temperatures to therapeutic levels. In clinical studies outside the U.S., the system has achieved therapeutic temperatures in less than 15 minutes on average *. This rapid cooling rate may therefore make TH an effective enhancement to the time-sensitive treatments of these patients.

For additional information, please visit www.velomedix.com.

Note: The Velomedix Automated Peritoneal Lavage System Investigational Device is limited by Federal (United States) Law to Investigational Use.

* References available upon request
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