Velomedix Receives Health Canada Approval for VELOCITY Pilot Study and Bolsters Leadership Team

The Associated Press

MENLO PARK, Calif.--(BUSINESS WIRE)--Jan 9, 2013--Velomedix, a venture-backed medical device company advancing the field of therapeutic hypothermia, today announced it has received Health Canada Approval for its VELOCITY pilot study in addition to the previously announced US IDE approval. The study is a prospective, randomized, multi-center study designed to further evaluate the safety and feasibility of the Velomedix rapid therapeutic hypothermia system in patients with acute myocardial infarctions (AMIs or heart attacks). The study will enroll 60 awake patients with anterior ST segment elevation myocardial infarctions (STEMIs) at up to three Canadian sites in addition to US sites. Patients will be randomized to either primary percutaneous coronary intervention (PCI) or a combination of primary PCI and cooling to therapeutic temperatures before reperfusion.

“We are excited by the positive response from Health Canada,” said Griff Tully, M.D., Chief Medical Officer of Velomedix. “The expansion of the VELOCITY study into Canada will provide broader physician and patient experience on the use of therapeutic hypothermia in STEMI patients. We are working with very experienced STEMI centers across Canada to obtain hospital approval and begin enrollment. Once active, we expect these sites will enroll a good percentage of the sixty patients.” 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, left ventricular volumes, and left ventricular ejection fraction, assessed by cardiac magnetic resonance imaging (MRI). Thus, while primarily a safety trial, the study will also gather initial efficacy information.

Previous studies of therapeutic hypothermia in AMI patients have shown that cooling can significantly reduce the severity of STEMIs only if patients are cooled to temperatures of less than 35°C prior to PCI. The Velomedix approach may be unique in its ability to cool patients to this desired temperature in less than 15 minutes.

Concurrent with initiating the VELOCITY trial, Velomedix strengthened its leadership team with the addition of Vicki Bebeau as Vice President of Clinical Affairs. Ms. Bebeau has more than 18 years of experience in the planning and execution of drug and medical device trials across multiple geographies.

From 2005 to 2012, Ms. Bebeau served as Senior Clinical Director for the St Jude Medical cardiovascular and international divisions where she was responsible for several IDEs, PMAs, and post market programs supporting regulatory approvals and physician adoption in the U.S., Canada, Europe, Australia, and Japan. Prior to her

tenure at St. Jude Medical, Ms. Bebeau served in various clinical leadership roles at Boston Scientific and Medtronic. Ms. Bebeau holds a BSN from Bethel College and is a licensed registered nurse.

About Acute Myocardial Infarction (AMI) AMI affects 1,255,000 people in the US yearly 1, reducing the heart's ability to pump the needed amount of blood throughout the body. The most severe form of AMI, called ST segment elevation myocardial infarction (STEMI), often leads to heart failure, a substantially debilitating disease and one of the most costly conditions for our healthcare system.

While it is extremely important to restore blood flow to the heart as early as possible, the process (called reperfusion) may cause coincidental damage, known as reperfusion injury. Thus, (it is hypothesized that) an approach that not only restores blood flow quickly, but also minimizes reperfusion injury, could further improve AMI patient outcomes and substantially reduce overall healthcare costs.

About the Velomedix mild therapeutic hypothermia system The Velomedix mild therapeutic hypothermia system incorporates a peritoneal-based approach to rapidly cool patients from their core. Using tools and techniques similar to those for peritoneal dialysis, the physician first accesses the peritoneal cavity and then uses the Velomedix system to circulate cold fluid in the peritoneal cavity. This cavity provides a unique means of very rapidly removing heat (cooling) from the patient due to the fact that the cavity is in contact with a large part of the body's core and a high percentage of blood flows past it at any one time. This efficient "heat exchanger" enables the system to cool patients to less than 35 degrees C in fewer than 15 minutes on average.

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

Note: The Velomedix Automated Peritoneal Lavage System is limited by federal (United States) law to investigational use only and is not available for sale.

References 1. Véronique R. Heart Disease and Stroke Statistics--2012 Update: A Report From the American Heart Association. Circulation. 2012;125:e2-e220.

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