PATIENT ENROLLMENT COMPLETED IN LANDMARK CLEAN-TAVI CLINICAL TRIAL STUDYING THE ROLE OF CEREBRAL PROTECTION IN REDUCING CEREBROVASCULAR EVENTS

Claret Medical’s Cerebral Protection System For Capture and Removal of Embolic Debris During Transcatheter Aortic Valve Implantation (TAVI) Being Evaluated in Trial

SANTA ROSA, Calif. — September 4, 2014 — Claret Medical™, Inc., developer of innovative solutions for cerebral protection during structural heart, vascular and cardiac surgery procedures, today announced completion of enrollment in the CLEAN-TAVI clinical trial studying its filter-based cerebral protection system (CPS). The trial was designed as a first-of-its-kind, randomized controlled trial powered to definitively demonstrate the importance of cerebral protection in reducing the number and volume of new cerebral lesions created by debris lodged in the brain as a result of transcatheter aortic valve implantation (TAVI).

The Claret Medical system is the only filter-based device on the market that both captures and removes embolic debris released during TAVI procedures that could otherwise be a source of acute stroke. The system has been safely used in more than 800 procedures worldwide to date.

CLEAN-TAVI is a prospective, single blind, randomized controlled trial of 100 patients treated with the Medtronic CoreValve®, where the Claret Medical filter-based system was used for cerebral protection. The trial was conducted at the University of Leipzig, with Professor Axel Linke, MD, as the lead investigator.

The efficacy outcomes reported will be the difference in the volume and number of embolic lesions detected in the brain pre- and post-TAVI procedure, with or without the use of cerebral protection, through a serial review of magnetic resonance imaging (MRI) performed over time. The MRI scans will be assessed blindly by an independent core lab overseen by Robert Zivadinov, MD, PhD, of the Buffalo Neuroimaging Analysis Center in Buffalo, New York. Evaluation of patients’ neurological and neurocognitive functions will also be performed, as well as blinded histopathological review of the captured debris by Renu Virmani, MD, at CVPath Institute of Pathology in Gaithersburg, Maryland. The trial will evaluate outcomes at two, seven and 30 days post-procedure, and at one year.

Stroke continues to be a devastating complication of TAVI procedures, occurring in approximately two to eight percent of procedures. In addition, new ischemic brain lesions, or “silent” infarcts, have been shown to occur in more than 70 percent of TAVI patients. These lesions have been associated with adverse neurologic and cognitive consequences, and can increase the risk of cerebral infarction by two to four times in future years, according to
population-based studies published in the 2013 American Stroke Association/American Heart Association consensus guidelines.

“CLEAN-TAVI is a landmark clinical trial, and we expect it to be the first to show a reduction in brain lesions associated with TAVI when cerebral protection is used,” said Professor Linke. “As TAVI patients get younger and healthier, it will be unacceptable for the stroke rate to remain where it is today or for us to ignore the resulting neurocognitive decline associated with these lesions in the brain. This study may have significant implications for the expansion of TAVI into new patient populations in the years to come.”

In addition, the company announced that it has initiated the SENTINEL-H post-market observational study evaluating its latest generation cerebral protection system, the Sentinel CPS. SENTINEL-H is a pan-European, core-lab adjudicated study enrolling up to 250 patients at 10 to 15 centers. The study is designed to evaluate the effectiveness of the Sentinel CPS in capturing debris during TAVI procedures. The primary endpoint of the study is the rate of capture and histomorphometric analysis of the embolic debris, including total and per-filter embolic debris volume lodged in the right and left carotid arteries, as well as characterization of the embolic material. The first patient was treated by Peter Frambach, MD in the Centre Hospitalier de Luxembourg. Associate Professor Christoph Naber, MD from Elisabeth-Krankenhaus, Essen Germany, is the principal investigator for the SENTINEL-H study.

Earlier this year, the company received Investigational Device Exemption (IDE) approval from the U.S. Food and Drug Administration (FDA) to begin a U.S. pivotal trial of the Sentinel CPS. The trial is expected to begin patient enrollment shortly.

About Claret Medical
Claret Medical is a privately-held company focused on innovative solutions for cerebral protection during structural heart interventions, vascular interventions, and cardiac surgery procedures. The company is currently focusing product development and clinical research on addressing the problem of stroke during TAVI, a significant unmet clinical need. For more information: www.claretmedical.com.

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