CLARET MEDICAL ANNOUNCES SENTINEL PIVOTAL IDE TRIAL TO BE FEATURED IN LATE-BREAKING TRIAL SESSION AT TRANSCATHETER CARDIOVASCULAR THERAPEUTICS (TCT) CONFERENCE

SANTA ROSA, Calif. – September 14, 2016 – Claret Medical®, an innovator in filter-based cerebral embolic protection technologies, today announced that data from its SENTINEL pivotal IDE trial has been accepted for the Late-Breaking Clinical Trial session at the 28th Transcatheter Cardiovascular Therapeutics (TCT), the annual scientific symposium of the Cardiovascular Research Foundation, being held October 29 to November 2 in Washington, DC. The SENTINEL trial evaluated the company's Sentinel® Cerebral Protection System (CPS), the only device designed to protect the brain by capturing and removing embolic debris dislodged during transcatheter aortic valve replacement (TAVR).

The SENTINEL results will be presented by co-principal investigator Susheel Kodali, MD, of Columbia University Medical Center/New York-Presbyterian Hospital on Tuesday November 1 at 9:00 a.m. in the Main Arena, on behalf of the other study co-PIs Samir Kapadia, MD, of the Cleveland Clinic, and Axel Linke, MD, of the University of Leipzig Heart Center.

The SENTINEL trial is a prospective, randomized, controlled, blinded study of 363 TAVR patients at 19 centers in the US and Germany. Trial endpoints included reduction in new ischemic cerebral infarcts, major adverse cardiac or cerebrovascular events, neurocognitive outcomes, and quantitative and qualitative histopathological findings. The SENTINEL trial allowed inclusion of all TAVR platforms commercially available in the US.

"The importance of this landmark trial in highlighting the impact of TAVR on the unprotected brain of patients is acknowledged by its acceptance as part of the TCT Late-Breaking Clinical Trial session," said Claret Medical President and Chief Executive Officer Azin Parhizgar, PhD. "We look forward to sharing new scientific insights from this rigorous trial, as we develop a large collection of clinical evidence on the impact of ischemic cerebral infarcts and the protective benefits that the Sentinel CPS may provide."

The Sentinel CPS will be featured in several other presentations at the TCT conference:

- **Cerebral Embolic Protection I: The Sentinel Filter – Design Features and Updates from CLEAN-TAVI, SENTINEL RCT and Others**, presented by Axel Linke, MD – Tuesday, November 1, 5:45 p.m., Room 152, Level 1.
- **Is Cerebral Embolic Protection Needed for TAVR? The Evidence from DEFLECT 3, CLEAN-TAVI, and the SENTINEL Clinical Trials**, presented by Samir Kapadia, MD – Monday, October 31, 2:00 p.m., Room 152, Level 1.

- **FDA Town Hall Session – Spectrum and Assessment of TAVR Accessory Devices**, presented by Martin Leon, MD – Tuesday, November 1, 3:25 p.m., Room 202, Level 2.
- **Claret Medical Symposium – SENTINEL Science: Compelling New Evidence for Cerebral Protection in TAVR**. Tuesday, November 1, 1:00-2:00 p.m., Presentation Theater 5. Symposium co-chairpersons include Martin Leon, MD, Axel Linke, MD, and Adnan Siddiqui, MD, PhD.

Stroke continues to be a devastating complication of TAVR and other endovascular procedures. New ischemic brain infarcts have been associated with adverse neurologic and cognitive consequences, including dementia. In population-based studies, they have also been shown to increase the risk of future stroke two- to four-fold.

The Sentinel CPS received the CE Mark in 2013. More than 3,000 patients have been protected by a Claret Medical cerebral protection system.

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 TAVR, a significant unmet clinical need. For more information: www.claretmedical.com.

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