

FOR IMMEDIATE RELEASE

FDA ADVISORY COMMITTEE STRONGLY SUPPORTS GRANTING DE NOVO APPLICATION FOR THE FIRST CEREBRAL PROTECTION SYSTEM FOR TRANSCATHETER AORTIC VALVE REPLACEMENT (TAVR)

SANTA ROSA, Calif. – February 27, 2017 – [Claret Medical](#)[®] today announced that in an open public hearing of the FDA’s Circulatory System Devices Panel last week, virtually all panel members recommended the *de novo* application of the Sentinel[®] Cerebral Protection System (CPS) be granted, which would enable US commercialization of the device. The American Association of Neurological Surgeons (AANS) and the Society of NeuroInterventional Surgery (SNIS) also endorsed the need for embolic protection in transcatheter aortic valve replacement (TAVR), and were represented in the open public hearing by Adnan Siddiqui, MD, PhD., professor of neurological surgery at the University of Buffalo and chief medical officer at the Jacobs Institute.

The Sentinel CPS is the only device designed to protect the brain by capturing and removing debris dislodged during TAVR that would otherwise enter the cerebral circulation and increase the potential for stroke. A formal vote was not taken as the Sentinel CPS is a medium risk accessory device reviewed as a *de novo* application.

“The Sentinel device has shown its potential, across multiple trials, to filter and remove brain-borne debris safely, with very few vascular complications,” said Martin Leon, MD, of Columbia University Medical Center/New York-Presbyterian Hospital, and chairman of the SENTINEL Clinical Steering Committee. “When we see the size and heterogeneity of the material captured, it is reassuring for me as a practicing TAVR implanter to know that it can be removed from the patient’s vasculature before it reaches the brain.”

In the landmark SENTINEL pivotal trial, the primary safety endpoint of MACCE at 30 days was met, with reported MACCE in the protected Sentinel group at 7.3 percent, significantly lower than the pre-specified historical performance goal of 18.3 percent and the rate of 9.9 percent seen in the control arm. The stroke rate for Sentinel-protected patients was 5.6 percent versus 9.1 percent for unprotected patients. Importantly, the observed peri-procedural stroke rate – encompassing 72 hours’ post-procedure – was reduced by 63 percent, from 8.2 percent for unprotected patients to 3.0 percent for protected patients.

In the trial, device delivery and retrieval were accomplished safely and successfully in 99.6 percent of cases. The Sentinel access site complication rate was only 0.4 percent. The device captured and removed embolic debris in 99 percent of patients in the study, with one in four patients having more than 25 pieces of debris with a size greater than, or equal to, 0.5 millimeters captured in the filters.

A meta-analysis of five randomized controlled clinical trials examining cerebral protection in valve repair and replacement procedures across more than 625 patients was published in the

Journal of the American College of Cardiology (JACC) in January. More than 80 percent of the patients (510 subjects) came from three of the five cited studies where Claret Medical's dual-filter cerebral protection systems were used. These data demonstrate that the use of cerebral protection is associated with a greater than 40 percent lower risk of death or stroke after TAVR. The data corresponded to a rate of one death or stroke potentially being averted for every 22 patients treated with cerebral protection.

"We were extremely pleased with the near unanimous recommendation of the committee based on consideration of the totality of the clinical evidence that we have generated over the past six years. This strong support was based on the excellent safety profile and ability of the Sentinel CPS to reduce cerebral insults," said Claret Medical President and Chief Executive Officer Azin Parhizgar, PhD. "The panel provided valuable feedback that will help define future study success criteria in the field of cerebral protection. We look forward to working collaboratively and diligently with the US FDA in the coming weeks to ensure that we can bring the Sentinel technology to American physicians and their patients."

The Sentinel CPS is the most-studied device in the field of TAVR cerebral protection, having been systematically evaluated in three randomized controlled trials involving more than 600 patients. More than 3,250 patients worldwide have been protected with the device to-date.

About Claret Medical

A privately-held company, Claret Medical is the leader in the field of cerebral protection and the first to have filed an FDA application for entering the US market. The company develops 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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