



CLEAN-TAVI TRIAL SHOWS CLARET MEDICAL CEREBRAL PROTECTION SYSTEM DRAMATICALLY REDUCES BRAIN LESIONS AND NEUROLOGICAL EVENTS FOLLOWING TRANSCATHETER AORTIC VALVE REPLACEMENT (TAVR)

Clinical Trial is First to Definitively Demonstrate That Removing Embolic Debris from Cerebral Circulation Can Significantly Shield the Brain

WASHINGTON, DC — September 13, 2014 — [Claret Medical](#)[™], Inc. today announced that the CLEAN-TAVI Trial met its primary endpoint by demonstrating that the company's cerebral protection system significantly reduced the quantity and volume of brain lesions detected by a serial review of magnetic resonance imaging (MRI) following transcatheter aortic valve replacement (TAVR). The trial results showed a 53 percent reduction in the total volume of new brain lesions and a 60 percent reduction in the number of new brain lesions two days after the procedure. The results were reported today by Professor Axel Linke, MD in a Late Breaking Clinical Trial session at the 26th Transcatheter Cardiovascular Therapeutics (TCT) meeting, the annual scientific symposium of the Cardiovascular Research Foundation.

At two days post-TAVR in the "Intent to Treat" analysis, a neurological deficit was observed in 28 percent of all control patients when evaluated by a NIHSS (National Institute of Health Stroke Scale) trained specialist, demonstrating that prospective assessment pre- and post-procedure can identify more neurological effects than has been reported to date. However, importantly, the "Per Protocol" analysis at two days showed a statistically significantly lower ataxia rate of 24 percent versus nine percent in favor of the treatment group protected with the Claret Medical technology.

"The results seen with the Claret Medical system are striking," said Professor Axel Linke, MD, of the University of Leipzig, principal investigator for CLEAN-TAVI. "They clearly show that by removing embolic debris from cerebral circulation when performing TAVR we can dramatically reduce both the quantity and volume of brain lesions."

"The CLEAN-TAVI outcomes validate our expectations that filter-based cerebral protection has the potential to improve neurological outcomes and enable a safer TAVR procedure, which will be necessary for the procedure to expand to lower risk populations," said Claret Medical Chief Executive Officer and President Azin Parhizgar, PhD.

CLEAN-TAVI is a prospective, double blinded, 1:1 randomized controlled trial enrolling 100 patients indicated for transfemoral aortic valve implantation with the Medtronic CoreValve[®], where the Claret system was used for cerebral protection. The study was conducted using a 3-Tesla MRI system, which provides higher sensitivity in visualizing lesions, and the data was

analyzed blindly by the independent Buffalo Neuroimaging Analysis Center MRI core lab. The trial was conducted at the University of Leipzig, Germany, and evaluates mechanistic and clinical outcomes at two, seven, 30 and 365 days post-procedure.

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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