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Protembis announces successful first-in-human use of its ProtEmbo[®] Cerebral Protection System in European trial

Click [here](#) for the video animation of the ProtEmbo[®] System

AACHEN, Germany, Sept. 5, 2017 — [Protembis GmbH](#), a privately held medical device company, announced today the first clinical applications of its ProtEmbo[®] Cerebral Protection System to complement a transcatheter aortic valve replacement (TAVR) procedure. The ProtEmbo[®] System is an intra-aortic filter device that deflects embolic material arising during TAVR away from the brain.

Darren Mylotte, M.D., and his team at Galway University Hospital, Ireland, performed the first-in-human procedure with the ProtEmbo[®] System. He commented: “Over the next 10 years, TAVR procedures are expected to increase fourfold. With TAVR shifting to younger and lower-risk patients, cerebral protection becomes even more important. Clinical data from two recent studies of intermediate-risk patients undergoing TAVR suggest 30-day stroke risk as high as 5.5%. It is therefore critically important that we have a cerebral-focused protection device that will reduce the frequency of embolic events. The ProtEmbo[®] System shows tremendous promise in reaching this clinical objective – first-in-human use of the device was safe and feasible.”

The objective of the current ongoing European trial is to demonstrate the safety and feasibility of the ProtEmbo[®] System when used to provide embolic protection during TAVR. The ProtEmbo[®] System was successfully deployed via the left radial artery across all three branches of the aortic arch for the duration of the TAVR procedures. The procedures were conducted under conscious sedation. On completion of the valve implant, the ProtEmbo[®] System was safely withdrawn without difficulty. None of the patients experienced a stroke event and there were no other device-related adverse events.

Protembis has developed the ProtEmbo[®] Cerebral Protection System, the next-generation cerebral-focused embolic protection device (EPD), that not only minimizes the risk of cerebrovascular events related to transcatheter aortic valve replacement (TAVR) but also many other interventional and surgical procedures. Features and benefits of the ProtEmbo[®] include:

- Low-profile access via left radial artery (6Fr guiding sheath)
- Best access route: no interference with TAVR catheter or accessories
- Simple, quick, and reliable deployment
- Complete coverage of all three aortic side branches
- Deflection of micro particles, as tiny as 60 microns
- Suitable for a wide variety of aortic arch anatomies
- Heparin coating for optimal biocompatibility

Renu Virmani, M.D., President and Medical Director at CVPPath Institute, U.S., commented: “Our preclinical work with the ProtEmbo[®] System prior to this clinical trial resulted in no safety or biocompatibility concerns. These initial findings from Europe now confirm our previous results. Despite the small pore size of the ProtEmbo[®] System, there is no thrombus formation on the filter. This is promising because it may enable physicians to deflect even smaller particles away from the brain.”

Conrad Rasmus, who heads Protembis together with **Karl von Mangoldt**, explained: "Clinically detectable strokes are just a tiny fraction of embolic events that occur in TAVR, and even small infarcts and micro emboli may have adverse long-term effects on brain function. Certainly, we need a simple yet effective way to protect the brain during TAVR, and the ProtEmbo® System is designed to be this solution." **Karl von Mangoldt** added: "The low-profile access of the ProtEmbo® System by way of the left radial artery is the optimal access route because it offers a simple, quick and easy way to protect the brain while not interfering with the valve replacement procedure. We look forward to expanding our clinical successes in Europe with the ProtEmbo® System."

About Protembis

Founded in 2013, Protembis is a medical device start-up company with its R&D base in the engineering and technology city of Aachen, Germany. The company's vision is to bring the ProtEmbo® System into every interventional procedure which bears a risk of neurologic injury, thereby radically improving patient safety. Protembis is sponsored by Germany's Federal Ministry of Education and Research (BMBF) and by the Federal Ministry for Economic Affairs and Energy (BMWi).

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