



Protembis Initiates Collaboration with German Accelerator Life Sciences for Planned U.S. Expansion

Company Set to Initiate European First-in-Human Trial with its Novel Cerebral Protection System

Aachen, Germany and Cambridge, MA, July 25, 2017

Protembis, a medical device company headquartered in the engineering and technology city of Aachen, Germany, announced today its collaboration with the German Accelerator Life Sciences (GALS) program, an initiative supported by the German Federal Ministry for Economic Affairs and Energy (BMWi), to facilitate its U.S. expansion and accelerate its clinical development plans. Protembis is sponsored by the German Federal Ministry of Education and Research (BMBF) as well as by a consortium of experienced institutional and private investors.

Protembis is developing a novel technological approach to minimize the risk of embolic cerebral lesions during minimally invasive cardiovascular interventions, a significant side-effect of these procedures. Protembis' ProtEmbo[®] System consists of a filter device which can be introduced into the aortic arch during minimally invasive procedures and prevent the migration of embolic particles via all three major branch vessels into the brain by deflecting the debris. The company has completed the pre-clinical testing of the device and has recently obtained regulatory approval by the Health Products Regulatory Authority (HPRA) in Ireland to evaluate the safety and feasibility of the ProtEmbo[®] Cerebral Protection System in a first-in-human study in patients undergoing transcatheter aortic valve implantations (TAVI/ TAVR).

“Being accepted into the GALS program is very exciting and a testament to the ProtEmbo[®] System and our development strategy,” said Conrad Rasmus, Co-CEO and Co-Founder of Protembis. “The broad network and expertise of GALS represents a significant opportunity for the company and will accelerate our expansion into the U.S. market as well as help us establish further partnerships with U.S. companies and investors.”



“The plan is to establish a presence in Cambridge, MA and to conduct a pivotal trial including U.S. sites to make our technology available to patients and providers in the very important North American markets as well,” stated Karl von Mangoldt, Co-CEO and Co-Founder of Protembis, adding “With the first comparable product recently approved by the FDA, there is now a validated regulatory pathway to market in the U.S.”

Earlier this year, the FDA approved the use of the Sentinel™ by Claret Medical. Like the ProtEmbo® System, the Sentinel™ device is designed to protect the brain from debris that may be dislodged during minimally invasive cardiovascular interventions. Other CE-marked competitor products include TriGuard™ (Keystone Heart) and Embrella™ (Edwards Lifesciences), however these are not FDA approved.

“We look forward to working with Protembis. The company’s intra-aortic deflection technology has enormous potential to make the growing number of TAVI/ TAVR procedures safer for patients worldwide. We are confident that GALS can add to Protembis’ success by assisting in the continued development of the company’s U.S. strategy,” commented Christoph Lengauer, CEO of the German Accelerator Life Sciences.

Protembis’ U.S. expansion will be guided by a team of GALS mentors with profound expertise in the medical device industry. “We look forward to kicking off the first work streams with Protembis,” says strategic project lead and GALS mentor Michael Bogenstaetter, adding “we will work on strategic questions such as the regulatory pathway for the ProtEmbo® Cerebral Protection System and reimbursement for the product.” Additional support through GALS includes access to the vast GALS network of medical device industry leaders, investors, and top-notch service providers.

About Protembis

Founded in 2013, Protembis is a medical device start-up company with its headquarters in the 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.

www.protembis.com



About the German Accelerator Life Sciences

The German Accelerator Life Sciences (GALS) is an initiative of the German Federal Ministry for Economic Affairs and Energy (BMWi), with the goal of helping German startups and young companies succeed in the global marketplace. GALS offers support in multiple areas, from free office space in the world's leading life science innovation hub, to mentoring and advising from industry experts and experienced leaders. GALS opened its doors in October 2015 and has its headquarters in Cambridge, Massachusetts.

For more information, visit: www.GermanAccelerator.com/Life-Sciences

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