## News Release

# Protembis announces completion of 20 cases in European CE mark study with the ProtEmbo® Cerebral Protection System

## Enrollment with advanced generation device for complete cerebral protection nearing halfway mark in clinical study in Germany and Poland

**Aachen, Germany, February 25, 2021**

Protembis GmbH, a privately held emerging medical device company, announced today the successful completion of 20 clinical cases in its European regulatory study of the ProtEmbo® Cerebral Protection System. The ProtEmbo® System is an intra-aortic filter device that deflects embolic material away from the brain during transcatheter aortic valve replacement (TAVR). The device is a low profile system which is delivered through the left radial artery, an ideal access site enabling physicians to avoid interference with TAVR equipment, typically delivered through the femoral artery.

**Nikos Werner, M.D.**, Professor of Medicine, Head of Cardiology at the Heart Center Trier, Germany, and Principal Investigator in Germany commented: “Embolic protection in TAVR procedures has been shown to be effective in reducing the ischemic burden in the brain, but physicians look forward to next generation devices that are easy to use, cover all three potential access arteries to the brain, and can be simply and rapidly deployed without interfering with the TAVR procedure. The initial procedures with the ProtEmbo® System are very promising in this regard and show that the device can fulfil all of these criteria, with even smaller pores allowing effective protection of the brain.”

This new generation of the ProtEmbo® System has an improved frame shape and a dedicated ergonomic handle to facilitate push-pull and torque of the device during deployment and retrieval. The filter, using 60 micron pores, is self-positioning in the aortic arch across all three major cerebral arteries, maintaining blood flow to the brain. The filter surface is heparin-coated to avoid clot formation.

**Dariusz Jagielak, M.D.**, Professor of Medicine, and his team at Medical University of Gdansk, Poland, have performed more than ten procedures with the device. He commented: “Recently, we presented the very first-in-human case at the PCR Valves e-Course in which the ProtEmbo® System was able to protect all three cerebral

vessels from debris migration in a challenging TAVR procedure. Using the ProtEmbo® System is very intuitive because it is self-positioning across all three cerebral vessels and does not interfere with TAVR devices and accessories used during the procedure."

**Eberhard Grube, M.D.**, Professor of Medicine, Head of Center of Innovative Interventions in Cardiology at University Hospital Bonn, Germany, Consulting Professor at Stanford University School of Medicine and Clinical Advisor to Protembis, commented: "The ProtEmbo® System has shown to be intuitively designed for seamless integration into the TAVR workflow. I am excited about this device because it offers a simple and elegant solution for reducing the risk of stroke during TAVR."

Co-CEOs of Protembis, **Conrad Rasmus** and **Karl von Mangoldt,** are pleased with the progress of the study and commented: "We believe that the full coverage cerebral protection of the ProtEmbo® System from even extremely small particles in combination with outstanding simplicity enabling rapid and easy deployment will offer physicians significant advantages over existing technologies."

The objective of the European trial (PROTEMBO C Trial, NCT04618718) is to assess the safety and performance of the ProtEmbo® System used for embolic protection during TAVR compared to historical data. The trial is designed as a multi-center, single-arm study in 60 patients with severe symptomatic native aortic valve stenosis indicated for TAVR. Patients will undergo MRI assessments to evaluate the efficacy of the ProtEmbo® System.

## About Protembis

Protembis is a privately-held, emerging medical device company that has developed the ProtEmbo® Cerebral Protection System. The company strives to offer a simple and reliable solution to protect patients from brain injury during left-sided heart procedures, improving patient quality of life and reducing overall healthcare costs associated with brain injury during those procedures. The ProtEmbo® System is available for investigational use only and is not approved for sale.

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