ARTIVION

NEWS RELEASE

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Artivion Announces Treatment of First Patient with Arcevo LSA in ARTIZEN Pivotal Trial

ATLANTA, GA – (November 6, 2025) – Artivion, Inc. (NYSE: AORT), a leading cardiac and vascular surgery company focused on aortic disease, today announced the treatment of the first patient in the ARTIZEN pivotal trial, evaluating the safety and effectiveness of the Arcevo™ LSA Hybrid Stent Graft System ("Arcevo LSA") in the treatment of acute and chronic arch pathologies. The trial is designed to support the Company's forthcoming application to the U.S. Food and Drug Administration (FDA) for Premarket Approval (PMA) of Arcevo LSA.

The ARTIZEN trial is a prospective, multicenter, non-randomized clinical trial consisting of 132 participants in the U.S. and Europe at up to 30 centers, who have experienced aortic dissection or aneurysm in the aortic arch. Each participant will be followed for up to five years, with a focus on 1-year outcomes. The combined primary safety and efficacy endpoints will determine the impact of Arcevo LSA on reducing all-cause mortality, new permanent disabling stroke, new permanent paraplegia or paraparesis, unanticipated aortic reoperation in the treated segment, and left subclavian artery (LSA) occlusion.

Dr. Eric Roselli, the ARTIZEN Global Principal Investigator, Chief of Adult Cardiac Surgery at the Cleveland Clinic Department of Thoracic and Cardiovascular Surgery, said "Surgery for aortic arch disease is complex, particularly when connecting to the left subclavian artery because of its anatomic location deep in the chest. The Arcevo device is a major advancement that may streamline the operation, making it faster and potentially safer for the patient."

"We are excited to see the first patient be enrolled in the Arcevo IDE trial which represents a positive milestone for the Company, and we look forward to bringing our next generation frozen elephant trunk to more patients in need through the ARTIZEN pivotal trial," said Pat Mackin,

Chairman, President and Chief Executive Officer of Artivion. “We estimate a PMA for Arcevo would open an incremental $80 million U.S. market opportunity as soon as 2029.”

About the Arcevo LSA ARTIZEN Pivotal Trial

The ARTIZEN trial is a prospective, multicenter, non-randomized clinical trial evaluating the safety and effectiveness of Arcevo LSA in the treatment of acute and chronic aortic arch pathologies. The trial is designed to support the Company’s forthcoming application to the U.S. Food and Drug Administration (FDA) for Premarket Approval (PMA) of Arcevo LSA. The trial consists of 132 participants in the U.S. and Europe, who have experienced aortic dissection or aneurysm. Each participant will be followed for up to five years. The combined primary safety and efficacy endpoints will determine the impact of Arcevo LSA on reducing all-cause mortality, new permanent disabling stroke, new permanent paraplegia or paraparesis, unanticipated aortic reoperation in the treated segment, and LSA occlusion.

About the Arcevo™ LSA Hybrid Stent Graft System

Arcevo LSA comprises of a self-expanding aortic stent graft with an integrated stented left subclavian artery (LSA) branch, preloaded onto a delivery system engineered for controlled and accurate deployment of the implant into the transected aorta and LSA during a Frozen Elephant Trunk (FET) procedure. Arcevo LSA is the Company’s next generation FET device, building on the E-vita® Open Neo Hybrid Stent Graft System, currently available in Europe and Asia.

The FET procedure is a hybrid surgical approach that combines open surgery with an endovascular stented device to treat extensive aortic disease. The stented LSA branch of the Arcevo LSA device is designed to simplify one of the most challenging steps of the procedure by allowing surgeons to perform a more proximal repair with the main anastomosis in zone 2 and eliminating the need for an LSA anastomosis. This innovative design is intended to reduce circulatory arrest time, minimize bleeding and nerve injury, and ultimately improve patient outcomes in complex aortic arch repair[1].

About Artivion, Inc.

Headquartered in suburban Atlanta, Georgia, Artivion, Inc., is a medical device company focused on developing simple, elegant solutions that address cardiac and vascular surgeons’ most difficult challenges in treating patients with aortic diseases. Artivion’s four major groups of products include: aortic stent grafts, surgical sealants, On-X mechanical heart valves, and implantable cardiac and vascular human tissues. Artivion markets and sells products in more than 100 countries worldwide. For additional information about Artivion, visit our website, www.Artivion.com.

References

1. Roselli et al. Branched stented anastomosis frozen elephant trunk repair: Early results from a physician-sponsored investigational device exemption study. JTCVS 2024 September; 168,3:746-756.