ARTIVION

NEWS RELEASE

FOR IMMEDIATE RELEASE

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Artivion Announces U.S. FDA Approval of the AMDS Hybrid Prosthesis

ATLANTA, GA – (June 29, 2026) – Artivion, Inc. (NYSE: AORT), a leading cardiac and vascular surgery company focused on aortic disease, today announced that the U.S. Food and Drug Administration (FDA) has approved the premarket approval application (PMA) for the AMDS Hybrid Prosthesis ("AMDS"). The approval covers acute Debakey Type I aortic dissections with either clinical or radiographic malperfusion, which the Company estimates to be approximately 60% of all Debakey Type I aortic dissections. Given this approval, hospitals will no longer be required to obtain institutional review board (IRB) approval in order to implant AMDS in their institutions, a requirement associated with the Humanitarian Device Exemption (HDE). This will reduce administrative burden on hospitals and enabling physicians to treat eligible patients more immediately and broadly across U.S. institutions.

The AMDS is the world's first aortic arch remodeling device for use in the treatment of acute DeBakey Type I aortic dissections and has been shown to significantly reduce the incidence of distal anastomotic new entry (DANE) tears. Used as a complement to hemiarch replacement without adding technical complexity, AMDS is rapidly deployed in the aortic arch during a standard ascending aorta replacement. The device preserves the native arch, enabling minimally invasive re-interventions if needed. The PMA approval is based on data from the PERSEVERE U.S. IDE trial, which at 30 days demonstrated a 72% reduction in all-cause mortality and a 54% reduction in primary major adverse events (MAEs), including stroke, renal failure requiring dialysis, and myocardial infarction, with zero occurrence of distal anastomotic new entry (DANE) tears, compared to the current standard of care hemiarch procedure. Two-year follow-up data from PERSEVERE, presented at the 62nd Annual Meeting of the Society of Thoracic Surgeons in February 2026, further demonstrate the durability of these benefits, showing minimal additional mortality limited to unrelated causes, no additional unanticipated aortic reoperation, continued absence of DANE tears, and stable total aortic diameter with continued mean true lumen diameter expansion across aortic zones 1 to 6.

Each year, approximately 6,000 patients in the U.S. present with an acute DeBakey Type I aortic dissection, an emergent, life-threatening condition requiring immediate surgical repair. Left untreated, mortality is reported to be approximately 1% per hour and up to 50% within the first 48 hours. The current standard of care, ascending replacement or hemiarch repair, can remove the primary entry tear but fails to adequately address the remainder of the diseased aorta, leaving patients at risk for

complications including malperfusion, end-organ ischemia, and aneurysmal growth. Additionally, an estimated 45% of hemiarch repair patients experience DANE leading to increased risk of reoperation.

The PMA approval of AMDS, following its commercial introduction under the HDE, positions Artivion to fully penetrate the estimated $150 million annual U.S. market opportunity.

“We are thrilled to receive AMDS PMA approval, as it not only validates the enduring benefits shown in the PERSEVERE clinical data but also removes a barrier to broader adoption by eliminating the IRB requirement that came with the HDE,” said Pat Mackin, Chairman, President, and Chief Executive Officer of Artivion. “Having already built commercial and clinical infrastructure during our HDE launch, and with strong reordering momentum among accounts already using AMDS, we expect this PMA to help accelerate adoption of this life saving technology.”

Mr. Mackin added, “This approval, following our recent acquisition of the PMA-approved NEXUS system and continued clinical trial enrollment progress for ARCEVO LSA, marks another step forward in our vision of Artivion as the only company globally with a complete portfolio of market leading aortic arch solutions. We are deeply grateful to every PERSEVERE investigator and patient who helped make this possible.”

About the AMDS PERSEVERE Clinical Trial
The PERSEVERE trial is a prospective, multicenter, non-randomized clinical trial designed to evaluate the safety and effectiveness of the AMDS Hybrid Prosthesis in patients with acute DeBakey Type I aortic dissection complicated by malperfusion. The trial consisted of 93 participants in the U.S. and was designed to support the FDA premarket approval application for AMDS. The combined 30-day safety and primary efficacy endpoints assessed the impact of AMDS on DANE, all-cause mortality, new disabling stroke, new onset renal failure requiring dialysis, and myocardial infarction. Two-year follow-up data, presented at the 62nd STS Annual Meeting in February 2026, demonstrated continued clinical and radiographic benefit with no new DANE tears, stable aortic dimensions, and no additional unanticipated aortic reoperations. Each participant will be followed for up to 5 years, with secondary endpoints related to aortic remodeling.

About the AMDS Hybrid Prosthesis and Acute DeBakey Type I Aortic Dissections
The AMDS is the world’s first aortic arch remodeling device for use in the treatment of acute DeBakey Type I aortic dissections. It is used as a complement to, and in conjunction with, hemiarch replacement without adding technical complexity. The design of the AMDS allows for rapid deployment of the graft in the aortic arch during a standard replacement of the ascending aorta, with deployment adding minimal time to the procedure. Deployment of the AMDS preserves the native arch, allowing for minimally invasive re-interventions if needed rather than requiring an invasive arch repair. AMDS has been commercially available in select markets globally, including Europe, Canada, and certain countries in Asia. Aortic dissection occurs when the innermost layer of the aorta tears and blood surges through the tear, separating the layers of the aorta. In acute DeBakey Type I aortic dissections, the dissection flap originates in the ascending aorta and continues into the descending thoracic aorta. Left untreated, aortic dissections lead to death in about half of patients within the first 3 days.

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.

Forward-Looking Statements

Statements made in this press release that look forward in time or that express management's beliefs, expectations, or hopes are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements reflect the views of management at the time such statements are made. These statements include our beliefs regarding the commercial opportunity for AMDS following PMA approval; our expectations regarding the market size for AMDS in the United States and globally; and our expectations regarding the pace of commercial expansion following PMA approval. These forward-looking statements are subject to a number of risks, uncertainties, estimates, and assumptions that may cause actual results to differ materially from current expectations, including but not limited to the risks that the benefits anticipated from the PMA approval of AMDS may not be achieved at all or at the levels anticipated; that commercial uptake of AMDS may be slower than expected; and other risk factors detailed in our Securities and Exchange Commission filings, including our most recent Form 10-K for the year ended December 31, 2025 and the Form 10-Q for the quarter ended March 31, 2026. Artivion does not undertake to update its forward-looking statements, whether as a result of new information, future events, or otherwise.