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NEWS RELEASE

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Artivion Granted FDA Humanitarian Device Exemption for the AMDS Hybrid Prosthesis

ATLANTA, GA – (December 9, 2024) – 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 granted a Humanitarian Device Exemption (HDE) for use of the AMDS Hybrid Prosthesis ("AMDS") in acute DeBakey Type I dissections in the presence of malperfusion. The AMDS is the world's first aortic arch remodeling device for use in the treatment of acute DeBakey Type I aortic dissections.

An HDE is a marketing application for a product that has been designated a Humanitarian Use Device (HUD). AMDS received both HUD and Breakthrough Designation, due to its intended benefit for patients in the treatment or diagnosis of a rare disease or condition in which no other comparable options currently exist. The HDE allows for commercial distribution of AMDS in the United States prior to anticipated approval of a Premarket Approval ("PMA") Application. Under the HDE, AMDS will be available as a treatment for acute DeBakey Type I dissections in the presence of malperfusion, which represent approximately 40% of all acute DeBakey Type I dissections in the U.S. The PMA, if approved, is expected to cover all acute DeBakey Type I dissections with and without malperfusion, representing an estimated $150 million annual US market opportunity.

Each year, approximately 6,000 patients in the U.S. present with an acute DeBakey Type I dissection, an emergent, life-threatening medical condition that requires immediate surgical repair. Left untreated, mortality from such a dissection is reported to be approximately 1% per hour and up to 50% in the first 48 hours. Today the standard of care is an ascending replacement or hemiarch repair. While this procedure can successfully remove the primary entry tear, it fails to adequately address the remainder of the diseased aorta, resulting in complications in both the acute and long-term phases.

The HDE for AMDS was granted following the availability of full cohort data from the PERSEVERE US IDE trial for AMDS. The trial consisted of 93 participants in the U.S. and met its primary endpoints demonstrating significant reduction of major adverse events (MAEs), including all-cause mortality, stroke, renal failure requiring dialysis, and myocardial infarction at 30-days following AMDS implantation. More specifically, data showed, from the use of AMDS, a 72 % reduction in all-cause mortality and a 54% reduction in primary MAEs, with zero occurrence of distal anastomotic new entry

(DANE), when compared to the current standard of care hemiarch procedure. Dr. Wilson Szeto, Chief of Cardiovascular Surgery at Perelman School of Medicine at the University of Pennsylvania, recently presented the data from the PERSEVERE US IDE trial as a late-breaking abstract at the STS Annual meeting (primary endpoint results reported below).

	PERSEVERE (%)	Historical Reference[1] (%)
Primary major adverse events (≥1 MAE)	26.9	58.0
All-cause mortality	9.7	34.6
New disabling stroke	10.8	20.9
New onset renal failure requiring dialysis	19.4	24.1
Myocardial infarction	0.0	10.5
Distal anastomotic new entry (DANE)	0.0	45.0

Dr. Szeto said, "The fact that the FDA has recognized the AMDS device through the HDE pathway is very encouraging and speaks to the unique aspects of the device to treat a rare and emergent condition. The compelling results from the PERSEVERE study paired with the ease of use and approachability of the AMDS device will undoubtedly expand the ability of *all* cardiac surgeons to offer a more comprehensive treatment for patients."

"This HDE from the FDA validates the groundbreaking nature of AMDS, a device with no comparable clinical alternative," said Pat Mackin, Chairman, President, and Chief Executive Officer of Artivion. "We will now work diligently with facilities and physicians in the U.S. to expand access to this life saving device as we continue to work towards PMA approval, which we still expect in late 2025. We thank every PERSEVERE investigator and study participant for helping to advance this revolutionary technology."

Mr. Mackin added, "We are excited to start laying the groundwork for this launch over the coming weeks and months by obtaining hospital IRB approvals, a requirement of the HDE, submitting to hospital value analysis committees ("VAC") and training surgeons. This will position us to begin penetrating the $150 million US market opportunity available upon PMA approval as we move through 2025."

About the AMDS PERSEVERE Clinical Trial

The PERSEVERE trial is a prospective, multicenter, non-randomized clinical trial to determine if patients with acute DeBakey Type I aortic dissection can be treated safely and effectively using the AMDS Hybrid Prosthesis. The trial is designed to support the Company's forthcoming application to the U.S. Food and Drug Administration (FDA) for premarket approval of the AMDS. The trial consists of 93 participants in the U.S., who have experienced an acute DeBakey Type I aortic dissection. Each participant will be followed for up to 5 years. The combined 30-day safety and primary efficacy endpoints will determine the impact of the AMDS Hybrid Prosthesis on DANE prevention, reducing mortality, new disabling stroke, new onset renal failure requiring dialysis, and myocardial infarction. The secondary endpoint relates to remodeling of the aorta.

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. The deployment of the AMDS preserves the native arch, allowing for minimally invasive re-interventions if needed, rather than an invasive arch repair. AMDS is available in select markets around the world including Europe, Canada and certain countries in Asia. The PERSEVERE clinical trial underpinning the AMDS PMA met its primary endpoints and demonstrated a 72% reduction in all-cause mortality and a 54% reduction in primary major adverse events (MAEs), with zero occurrence of distal anastomotic new entry, or DANE, when compared to the current standard of care hemiarch procedure at 30-days following AMDS implantation. In the clinical trial (DARTS) supporting the CE Mark and Health Canada approvals, the AMDS was shown to reduce complications and reoperations in comparison to published rates with the standard of care, thereby improving the care of patients and offering potential cost savings for the health care system.

Globally, approximately 48,000 patients suffer annually from acute DeBakey Type I aortic dissections, representing an estimated $150 million market opportunity in the United States and $540 million market opportunity globally, pending regulatory approvals. 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 down into the descending thoracic aorta. Left untreated, aortic dissections lead to death in about half of patients within the first 3 days. The current standard of care for repairing acute DeBakey Type I aortic dissections with a primary entry tear in the ascending aorta is a hemiarch repair which involves open chest surgery during which the ascending thoracic aorta is replaced. Though this typically addresses the most critical and pressing issues resulting from acute DeBakey Type I dissections, it is often not enough. Hemiarch repair alone does not address downstream true lumen expansion or treat the false lumen beyond the ascending aorta, which could lead to costly and fatal complications such as malperfusion with subsequent end-organ ischemia resulting from a lack of blood-flow and continued pulsatile blood flow in the false lumen leading to aneurysmal growth of the aorta.

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 that we will secure PMA approval for AMDS in late 2025; that our launch efforts for AMDS will position us to begin penetrating the $150M market in the US after PMA approval for AMDS as we move through 2025; and regarding our estimates of the number of patients who suffer annually from acute DeBakey Type I aortic dissections and of the annual U.S. and global market opportunities for AMDS. 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 benefits anticipated from the

Ascyrus Medical LLC transaction may not be achieved at all or at the levels we had originally anticipated; the benefits anticipated from our clinical trials, including the PERSEVERE trial, may not be achieved or achieved on our anticipated timelines and the financial and operational impact from the November 21, 2024 cybersecurity event may be more severe than currently anticipated. These risks and uncertainties also include the risk factors detailed in our Securities and Exchange Commission filings, including our Form 10-K for the year ended December 31, 2023. Artivion does not undertake to update its forward-looking statements, whether as a result of new information, future events, or otherwise.

References

1. Zindovic I et al. J Thorac Cardiovasc Surg 2019; Pacini D et al. Eur J Cardiothorac Surg 2013; Girdauskas E. et al. J Thorac Cardiovasc Surg 2009; Geirsson A. et al J Thorac Cardiovasc Surg 2007; Bossone E. et al Am J Cardiol 2002