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Artivion Announces Presentation of Late-Breaking Data from AMDS PERSEVERE Trial at the 61st Society of Thoracic Surgery Annual Meeting

Full IDE Data Set Demonstrates Sustained Benefit at One Year with Use of AMDS in Acute DeBakey Type I (ADTI) Dissections Complicated by Malperfusion

ATLANTA, GA – (January 27, 2025) – Artivion, Inc. (NYSE: AORT), a leading cardiac and vascular surgery company focused on aortic disease, today announced data from the AMDS PERSEVERE clinical trial (the "IDE") was presented in a Late-Breaking Science presentation at the 61st Annual Meeting of the Society of Thoracic Surgeons in Los Angeles, California. The data presented analyzed clinical outcomes across the full 93 study participant IDE cohort at one year following AMDS implantation.

Dr. Shinichi Fukuhara, Division of Cardiac Surgery, University of Michigan, presented the data from the PERSEVERE US IDE trial (NCT05174767) as a late-breaking abstract titled, *One-Year Results of a Novel Aortic Arch Hybrid Prosthesis for Open Repair of Acute DeBakey Type I Dissection with Malperfusion in the PERSEVERE Study.*

Data from the trial demonstrate sustained benefit of AMDS out to one year showing minimal new occurrence of stroke, renal failure requiring dialysis, or myocardial infarction. 80% of patients survived through 1-year with mortality after 30-days attributed to comorbidities and dissection-related complications.

Primary Endpoints	**PERSEVERE (N=93)**		**Historical Controls[1]**	
	30-Days (%)	**1-Year (%)**	**30-Days (%)**	**1-Year (%)**
All-Cause Mortality	9.7	20.4	34.6	42.7
New Disabling Stroke	10.8	11.8	20.9	NR
New Renal Failure/Dialysis	19.4	20.4	24.1	NR
Myocardial Infarction	0	2.2	10.5	NR
Total # with ≥ 1 MAE	**26.9**	**30.1**	**58.0**	**NR**
DANE	0	0	45.0	NR

[1]NR = Not Reported

Further, core lab analysis of follow up CT scans suggests AMDS prevents the occurrence of distal anastomotic new entry (DANE) tears which compares favorably to expected rates of early reintervention and DANE tears in this patient population. DANE tears occur in up to 70% of patients following hemiarch repair without AMDS, allowing continued blood flow into the false lumen created by the dissection.[1,2] The presence of DANE is associated with enlargement of the aorta, reoperation, and increased mortality. In contrast, DANE has not been detected in any patients in the PERSEVERE study and it was not reported in the DARTS study through 5 years of follow up of AMDS-treated patients.[3] The need for unanticipated aortic reoperations was low at 4.3%[4].

Dr. Fukuhara commented, "Patient outcomes following AMDS treatment of acute DeBakey Type I aortic dissection with malperfusion remain impressive through one year after operation. AMDS is an important tool for cardiovascular surgeons in treating this devasting disease."

"We are very pleased to see such clinically meaningful one year data for AMDS, particularly the complete avoidance of DANE tears. These data build on the positive findings from the 30-day readout and validate with the groundbreaking, lifesaving nature of AMDS," said Pat Mackin, Chairman, President, and Chief Executive Officer of Artivion. "We look forward to bringing AMDS to more patients through our recently received Humanitarian Device Exemption (HDE) while continuing our work with FDA towards PMA approval, which we still expect to receive in late 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 complicated by malperfusion. Each participant will be followed for up to 5 years. 30-day trial data met combined safety and primary efficacy endpoints demonstrating significant reduction of major adverse events (MAEs), including all-cause mortality, stroke, renal failure requiring dialysis, and myocardial infarction following AMDS implantation. 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 the United States under an HDE and 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.

References

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