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Contacts:

Artivion
Lance Berry
Executive Vice President &
Chief Financial Officer
Phone: 770-419-3355

Gilmartin Group LLC
Brian Johnston / Laine Morgan
Phone: 332-895-3222
investors@artivion.com

Artivion Announces Presentation of Late-Breaking Data from AMDS PERSEVERE Trial at the 60th Society of Thoracic Surgery Annual Meeting

Full IDE Data Set Demonstrates Statistically Significant Reduction of All-Cause Mortality and Primary Major Adverse Events (MAEs) at 30 days with use of AMDS in Acute DeBakey Type I (ADTI) Dissections Complicated by Malperfusion

72% Reduction in All-Cause Mortality and 52% Reduction in Primary Major MAEs when Compared to Current Standard of Care Hemi-arch Procedure

ATLANTA, GA – (January 29, 2024) – Artivion, Inc. (NYSE: AORT), a leading cardiac and vascular surgery company focused on aortic disease, today announced the presentation of results from the AMDS PERSEVERE clinical trial in a Late-Breaking Science presentation at the 60th Annual Meeting of the Society of Thoracic Surgeons in San Antonio, Texas. The data presented analyzed clinical outcomes across the full 93 study participant IDE cohort at 30-days following AMDS implantation.

Dr. Wilson Szeto, Chief of Cardiovascular Surgery at Penn Presbyterian Medical Center, presented the data from the PERSEVERE US IDE trial as a late-breaking abstract titled, *Results of a Novel Aortic Arch Hybrid Prosthesis for Open Repair of Acute DeBakey Type I Dissection with Malperfusion: 30-day Results from the PERSEVERE Study*.

Data from the trial demonstrate statistically significant reduction of all-cause mortality and primary major adverse events (MAEs), as well as no occurrence of distal anastomotic new entry (DANE):

	PERSERVERE (%)	Historical Reference[1] (%)
Primary major adverse events (≥1 MAE)	28.0	58.0
All-cause mortality	9.7	34.6
New disabling stroke	11.8	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

The data also demonstrate excellent results for secondary endpoints:

	PERSEVERE (%)
Technical Success	98.9
Unanticipated aortic reoperations	3.2
Distal stent-induced new entry (d-SINE)	1.1
Occlusion of Supra-aortic vessels	0.0
New Post-op Paraplegia or Paraparesis[1]	0.0

[1]One event remains in adjudication

The data compares very favorably with 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.[2,3] 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 3 years of follow up of AMDS-treated patients.[4]

Dr. Szeto said, "Acute DeBakey Type I (ADTI) dissections remain one of the most life-threatening emergencies that cardiac surgeons address. Despite the seriousness of the condition, there have been limited surgical advancements in the last several decades, demonstrating an unequivocal need for innovation to better treat these patients. I am extremely encouraged by the results of the PERSEVERE study which indicate that AMDS significantly reduces 30-day MAE's in ADTI patients complicated by malperfusion and helps prevent DANE. The ease of use and approachability of the AMDS device will expand the ability of cardiac surgeons to offer a more comprehensive treatment for these patients amidst a life-threatening emergency."

"We are extremely excited to share these overwhelmingly positive results from the PERSEVERE study as they reinforce the unrivaled clinical benefit and life-saving nature of AMDS. Notably, these results show an even greater improvement in all-cause mortality compared to interim data presented in October," said Pat Mackin, Chairman, President, and Chief Executive Officer of Artivion. "We now look forward to quickly completing patient follow up and our PMA submission for AMDS to the FDA and to delivering this revolutionary technology to patients with no comparable alternatives as soon as possible."

About the AMDS PERSERVE 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; as well as remodeling of the aorta.

About the AMDS Hybrid Prosthesis and DeBakey Type I Aortic Dissections

The AMDS is the world's first aortic arch remodeling device for use in the treatment of acute 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. 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 from acute Stanford Type A aortic dissections annually, an estimated $540 million market opportunity 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, a subset of Type A 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 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 treating 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.

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