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Contacts:

Artivion
D. Ashley Lee
Executive Vice President &
Chief Financial Officer
Phone: 770-419-3355

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

Artivion Announces Presentation of Late-Breaking Interim Data from AMDS PERSEVERE Trial at the 37th European Association for Cardio-Thoracic Surgery Annual Meeting

Interim Data Demonstrate Meaningful Reduction of All-Cause Mortality with AMDS

ATLANTA, GA – (October 05, 2023) – Artivion, Inc. (NYSE: AORT), a leading cardiac and vascular surgery company focused on aortic disease, today presented interim results from the AMDS PERSEVERE clinical trial in a Late-Breaking Science presentation at the 37th European Association for Cardio-Thoracic Surgery (EACTS) Annual Meeting in Vienna, Austria.

Dr. Fernando Fleischman, Associate Professor of Clinical Surgery at Keck Hospital of the University of Southern California, presented data from the PERSEVERE US IDE trial as a late-breaking abstract titled, *Interim results of AMDS Hybrid Prosthesis in Acute DeBakey Type I Dissection with Malperfusion (Persevere Investigational Device Exemption Study)* which includes interim data on 52 study participants at 30-days post-implantation and an additional 8 participants in total follow up (60 total participants).

Interim data demonstrate clinically meaningful reduction of all-cause mortality and primary major adverse events (MAEs), with 79% of participants experiencing no target MAEs at 30-days (41 of 52 patients):

	PERSERVERE (%)	**Historical Reference[1] (%)**
All-cause mortality	13.5	29-44
New disabling stroke	9.6	12-35
New onset renal failure requiring dialysis	7.7	12-43
Myocardial infarction	0.0	7-15

Interim data also demonstrate excellent results for additional endpoints:

	PERSEVERE (%)
Technical Success	98.3
Unanticipated aortic reoperations	1.7
Distal anastomotic new entry (DANE) tears	0.0
Distal stent-induced new entry (d-SINE)	0.0
Occlusion of Supra-aortic vessels	0.0
New Post-op Paraplegia or Paraparesis	0.0

The interim data compares favorably with expected rates of early reintervention and DANE tears in this patient population. DANE occurs in 25-70% of patients following hemiarch repair without AMDS and allows 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. Through this interim analysis, DANE has not been detected in any patients in the PERSEVERE study, nor was it reported in the DARTS study through 3 years of follow up of AMDS-treated patients.[4]

Dr. Fleischman said, "The current standard of care to manage acute Type I aortic dissections is technically meticulous and often leads to distal anastomotic new entry tears, or DANE tears, which are associated with increased risk for re-intervention and mortality. I am encouraged by the interim results of the PERSEVERE study which indicate that the use of AMDS offers substantial clinical benefit, notably the absence of DANE tears and an improved all-cause mortality rate, for patients presenting with malperfusion and ADTI dissection at 30-days, while adding minimal time and complexity to the procedure."

"We are incredibly pleased with the overwhelmingly positive interim results of the PERSEVERE trial which have demonstrated the lifesaving nature of AMDS, including reduction of stroke, new onset renal failure requiring dialysis and myocardial infraction," said Pat Mackin, Chairman, President, and Chief Executive Officer of Artivion. "Given there is no alternative solution on the market today, we are excited to complete this trial and submit our PMA to FDA as expeditiously 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 will consist 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 reducing mortality, new disabling stroke, myocardial infarction, and new onset renal failure requiring dialysis, and 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 time. The deployment of the AMDS preserves the native arch, potentially allowing for minimally invasive re-interventions, including the repair of additional entry tears, 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 supporting the CE Mark and Health Canada approvals, the AMDS was shown to reduce mortality, complications and reoperations in comparison to published rates with the standard of care, thereby improving the care of patients and offering potentially significant 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 often fatal complications such as continued blood flow in the false lumen, an aneurysmal aorta, and malperfusion with subsequent end-organ ischemia resulting from a lack of blood-flow.

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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