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# Artivion Announces Presentation of Late-Breaking Clinical Data at the 38th European Association for Cardio-Thoracic Surgery (EACTS) Annual Meeting

*5-Year Data from the AMDS DARTS Trial Demonstrates Positive Aortic Remodeling with 94% of Patients Free from Unanticipated Reoperation*

*30-Day Data from the AMDS PERSEVERE Trial Shows Cerebral Malperfusion Resolution in 90% of Affected Subjects Post-AMDS Implantation*

*1-Year Data from the NEOS Study Indicate E-vita Open Neo is Safe and Effective in the Treatment of Aortic Arch Pathologies with Low Combined Major Adverse Events Rate*

**ATLANTA, GA – (October 10, 2024) – Artivion, Inc. (NYSE: AORT),** a leading cardiac and vascular surgery company focused on aortic disease, today announced data from its AMDS DARTS and PERSEVERE trials and E-vita Open Neo study presented in Late-Breaking Science presentations at the 38th European Association for Cardio-Thoracic Surgery (EACTS) Annual Meeting in Lisbon, Portugal.

The presentation regarding the AMDS DARTS trial highlighted 5-year aortic remodeling data that demonstrate positive, durable patient outcomes following AMDS implantation. The presentation on the 30-day AMDS PERSEVERE trial data showed cerebral malperfusion resolution for 90% of affected subjects at 30-days post-AMDS implantation. Additionally, the presentation on the 1-year data from the NEOS study showed E-vita Open Neo is safe and effective for the treatment of acute and chronic aortic arch pathologies with a lower combined major adverse event rate compared to the market leading alternative.

“We were thrilled to command such a strong presence at EACTS, with data from our AMDS and E-vita Open Neo clinical trials dominating the aortic focused late-breaking science session,” said Pat Mackin, Chairman, President, and Chief Executive Officer of Artivion. “Artivion remains

committed to driving continued innovation in treating aortic disease, and these data further validate our best-in-class portfolio."

**Late-Breaking 5-Year Data from AMDS DARTS Trial:**
The abstract titled *5-Year Results on Aortic Remodeling in the Dissected Aorta Repair Through Stent (DARTS) Implantation Trial* reports five years of clinical follow-up on the remaining 25 of 46 study participants with acute DeBakey Type I dissection who were treated with a proximal aortic repair and AMDS. The results demonstrate durable benefits out to at least 5 years over the baseline:

- 94% of patients were free from aortic reoperation compared to existing literature on hemiarch-only outcomes which report freedom from late aortic arch reoperation as low as 76%,
- 95% of patients were free from total aortic diameter (TAD) growth >5 mm between the 3-year and 5-year follow up periods at aortic zones 2 and 4; and
- In contrast, existing literature on hemiarch-only outcomes suggest a majority of patients have early TAD growth in the proximal descending aorta. Aortic growth can lead to increased risk of rupture or dissection, and reoperation.

Principal investigator Dr. Michael Moon, Division of Cardiac Surgery, University of Alberta, Edmonton, Canada said, "Significant dilation of the ascending aorta, measured by changes to the TAD, increases the risk of spontaneous rupture or dissection of the aorta, a serious medical emergency. These long-term results from the DARTS study demonstrate a large majority of patients experience a stable or decreased TAD following treatment with AMDS, meaning these patients were successfully treated with AMDS and are at decreased risk for further aortic dissection and reoperation as far out as 5-years post implantation."

**Late-Breaking 30-Day Data from AMDS PERSEVERE Trial:**
The abstract titled *AMDS Hybrid Prosthesis Improves Cerebral Malperfusion in Acute DeBakey Type I Dissection- Early Results of the PERSEVERE Study* focuses on cerebral blood flow across the full 93 study participant IDE cohort at 30-days following AMDS implantation. 20% of patients (19 of 93 patients) presented with symptomatic pre-operative cerebral malperfusion including stroke, transient ischemic attack, delirium or other mental status changes. The 30-day data showed resolution of cerebral malperfusion in the vast majority of patients treated with AMDS. More specifically:

- 90% of patients experienced resolution of their cerebral malperfusion; and
- 63% of those who presented with cerebral malperfusion had complete resolution, while another 26% had no worsening of stroke symptoms

The data compare favorably to hemiarch alone based on data from five articles in the literature, which showed a stroke occurrence rate of 20.9% compared to 10.8% (10 of 93 patients) in the PERSEVERE trial.

Senior author, Dr. William Brinkman, Baylor Scott & White, The Heart Hospital Plano, Plano, Texas said, "Cerebral malperfusion, which often leads to stroke, is a devasting complication of Acute DeBakey Type I aortic dissection. The data from the PERSEVERE trial indicating that

AMDS markedly reduces 30-day malperfusion and new disabling stroke compared to the baseline, is very encouraging."

**Late-Breaking 1-Year Data from E-vita Open Neo NEOS Study:**
The abstract titled *E-vita Open Neo in the treatment of acute or chronic aortic pathologies: 1-year results of the European multicenter NEOS study and sub-group analysis* includes 161 participants treated with E-vita Open Neo in Europe. The 1-year data suggests E-vita Open Neo is safe and effective in the treatment of aortic arch pathologies and compares favorably to the IDE study results of the current market leading device:

- The 1-year mortality rate observed for E-vita Open Neo (9.9%) compared favorably to current market leading device (10.8%); and
- Lower 1 year combined major adverse events rate of mortality, stroke, and paraplegia/ paraparesis occurring after treatment with E-vita Open Neo (17% vs 23.1% for current market leading device).

Professor Martin Grabenwöger, Head, Department of Cardiovascular Surgery, Hietzing Hospital, Vienna, Austria said, "These exciting results from the NEOS study demonstrate the clinical benefits of E-vita Open Neo compare favorably to currently available options for treatment of aortic arch pathologies. This study is a major step forward in improving care for patients suffering from this life-threatening disease."

**About the AMDS DARTS Trial**
The AMDS DARTS (Dissected Aorta Repair Through Stent Implantation) trial is a prospective, multicenter, nonrandomized, single-arm trial of 47 patients evaluating the safety and efficacy of the AMDS Hybrid Prosthesis for the treatment of Acute DeBakey Type I (ADTI) dissection. Trial results supported regulatory approvals for AMDS in Canada, Europe, and other countries around the world.

**About the AMDS PERSEVERE Trial**
The AMDS PERSEVERE trial is a prospective, multicenter, non-randomized clinical trial to determine if patients with ADTI 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 ADTI dissection. Each participant will be followed for up to 5 years. The combined 30-day safety and primary efficacy endpoints were used to 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.

Full 30-day IDE data from the PERSEVERE trial presented at the Society of Thoracic Surgeons in January 2024, demonstrated statistically significant reduction in all-cause mortality and primary major adverse events (MAEs) at 30 days with use of AMDS in ADTI dissections complicated by malperfusion. Data from the trial also demonstrated a 72% reduction in all-cause mortality and 54% reduction in primary major MAEs when compared to the current standard of care hemiarch procedure.

Data presented from the PERSEVERE trial at the 104th American Association for Thoracic Surgery (AATS) Annual Meeting April 2024, showed positive aortic remodeling at 30-days after treatment with AMDS, as well as no occurrence of distal anastomotic new entry (DANE) tears. More specifically, at 30 days, the majority of patients demonstrated favorable remodeling with over 80% showing either stable or decreased total aortic diameter (TAD).

**About the E-vita Open Neo NEOS Study**

The E-vita Open Neo NEOS study is an observational, multicenter study to determine the safety and clinical performance of E-vita Open Neo Stent Graft System in the treatment of acute and chronic aneurysm and dissection in the ascending aorta, aortic arch and descending thoracic aorta. The observational study consists of 161 patients with acute or subacute type A aortic dissection, chronic type A aortic dissection or thoracic aortic aneurysm enrolled at 12 centers in Europe and Asia December 2020 to March 2022. The primary end point was the rate of all-cause mortality at 30 days. The secondary end points included further clinical and safety data that are reported up to 3–6 months postoperatively.

**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.