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Artivion Announces Presentation of New Clinical Data for On-X Aortic Heart Valve and AMDS at the 104th American Association for Thoracic Surgery (AATS) Annual Meeting

5-Year Real-World Safety and Efficacy Data from On-X Aortic Heart Valve Low INR Post-Market Study Demonstrate Even Better Patient Outcomes Than Predicted by the PROACT IDE Study

Late-Breaking 30-Day Data from AMDS PERSEVERE Trial Demonstrate Positive Aortic Remodeling Outcomes and Zero DANE Tears

ATLANTA, GA – (April 29, 2024) – Artivion, Inc. (NYSE: AORT), a leading cardiac and vascular surgery company focused on aortic disease, today announced the presentation of new clinical data from the On-X Low INR post-market study and AMDS PERSEVERE Trial at the 104th American Association for Thoracic Surgery (AATS) Annual Meeting in Toronto, Canada.

Presentations highlighted 5-year real-world safety and efficacy data from the On-X Aortic Heart Valve Low INR post-market study that demonstrate even better patient outcomes than predicted by the On-X Aortic Heart Valve PROACT IDE Study, as well as Late-Breaking data from the AMDS PERSEVERE Trial demonstrating, at 30-days post-AMDS implantation, positive aortic remodeling outcomes and zero distal anastomotic new entry (DANE) tears.

5-Year Real-World Safety and Efficacy Data from On-X Aortic Heart Valve Low INR Post-Market Study:

Dr. Marc Gerdisch, Chief of Cardiothoracic Surgery at Franciscan St. Francis Health in Indianapolis, IN, presented an abstract titled, *Low-Dose Warfarin with a Novel Mechanical Aortic Valve: Interim Registry Results at 5-Year Follow-up.* The abstract reported five years of clinical follow-up on 229 study participants with a target INR of 1.8 (range 1.5-2.0). Results show a significantly lower composite primary endpoint of thromboembolism, valve thrombosis, and major bleeding (linearized occurrence rate (LOR) of 1.83% compared to the pre-defined historic control rate of 5.39% ($p<0.0001$)), driven by an 87% reduction in major bleeding and no increase in thromboembolism compared to historic control group of standard dose warfarin (2.0-3.0).

These real-world interim results confirm that the On-X Aortic Valve remains safe and effective with low-dose warfarin and reflect even better patient outcomes compared to those in the On-X Aortic Heart Valve Low INR Post-Market Study 1-year results presented in 2023[1], and the On-X Aortic Low INR IDE Study first published in 2014[2]. A key aspect of this post market study is the real-world representation of patient INR monitoring, where the majority (84%) of On-X recipients underwent INR monitoring at a clinic rather than at home, whereas 100% patients in the PROACT IDE study were managed using home INR monitoring.

	Post-Market Study		
	Test group (%/pt-yr) 1.5-2.0 INR	**Control group (%/pt-yr)** 2.0-3.0 INR	***P* value**
N	229	292	-
Major Events**	1.83	5.39	<0.0001
Thromboembolism	1.32	1.41	0.749
Valve thrombosis	0.00	0.18	0.573
Major bleeding events	0.51	3.80	<0.0001
All bleeding events	2.04	7.07	<0.001

**Composite of Thromboembolism, Valve Thrombosis, & Major bleeding

Dr. Gerdisch said, “The primary concern for patients who would like the opportunity of a single aortic valve replacement for life is the risk of bleeding related to anticoagulation with warfarin. This real-world data, in a predominantly clinic monitored setting shows a bleeding risk reduction of 87% and should certainly be part of the decision-making conversation for patients with expected longevity.”

“The long-term data continue to validate the safety of managing On-X aortic valve patients at a lower INR in the range of 1.5 to 2.0 and our confidence in our ability to gain further market share with On-X globally,” said Pat Mackin, Chairman, President, and Chief Executive Officer of Artivion.

Late-Breaking 30-Day Data from AMDS PERSEVERE Trial:

Dr. Shinichi Fukuhara, MD from University of Michigan, presented data from the PERSEVERE US IDE trial as a late-breaking abstract titled, *Aortic Arch Remodeling following Implantation of a Novel Aortic Arch Hybrid Prosthesis in Acute DeBakey Type I Dissection- Early Results of the PERSEVERE Study.* The data at 30-days following AMDS implantation suggest positive aortic remodeling after treatment with the AMDS Hybrid Prosthesis, as well as no occurrence of distal anastomotic new entry (DANE) tears. These are key clinical outcomes, given the frequency of complications and the need for reintervention in the common standard of care with a hemiarch procedure [3,4]. By eliminating DANE tears, AMDS prevents flow in the false lumen, and its stented section further supports the true lumen in the arch, thereby, inducing positive aortic remodeling.

More specifically, at 30 days, AMDS induced positive aortic remodeling in over 80% of patients across the aortic arch demonstrated by three main attributes – total aortic diameter (TAD) stabilization, True Lumen (TL) diameter increase, and False Lumen (FL) thrombosis.

Dr. Fukuhara said, “The early aortic remodeling results with AMDS are very promising. Post-repair aortic remodeling data is scarce in the literature, and the PERSEVERE study offers us an excellent dataset to understand this better. Future studies will assess the relationships between aortic remodeling, presence of secondary entry tears, and need for additional aortic procedures.”

"We are excited to continue to see positive results from the PERSEVERE study as they reinforce the unrivaled clinical benefit and life-saving nature of AMDS. The significant reduction in MAEs paired with the prevention of DANE and positive remodeling outcomes offer a major benefit to these patients without adding any technical complexity to the lifesaving operation," 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 to the FDA for AMDS."

About the On-X Aortic Low INR Post-Market Study

The On-X Aortic Low INR post-market study is a prospective, international, multi-center, observational study to assess the occurrence of bleeding, valve-related thromboembolism and valve thrombosis with the On-X Aortic Prosthetic Valve when targeted at an International Normalized Ratio (INR), level of 1.8 (1.5-2.0 range) during a 5-year follow-up period. The trial is designed to compare adverse event rates for patients with target INR range of 1.5 to 2.0 per On-X instructions for use, to rates from the previous IDE trial. The trial consisted of 510 participants who have only an On-X aortic prosthetic heart valve implant. The combined primary efficacy and safety endpoints determine the impact of the On-X Aortic Prosthetic Valve on reducing thrombotic events, major bleeding events, and mortality.

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 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 set from the PERSEVERE trial presented at the Society of Thoracic Surgeons in January 2024, demonstrated 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. Data from the trial demonstrated 72% reduction in all-cause mortality and 52% reduction in primary major MAEs when compared to current standard of care hemiarch procedure.

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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