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Artivion Announces Completion of Enrollment in PERSEVERE Trial

ATLANTA, GA – (November 9, 2023) – Artivion, Inc. (NYSE: AORT), a leading cardiac and vascular surgery company focused on aortic disease, today announced that it has completed enrollment in the 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 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.

Dr. Wilson Szeto, the PERSEVERE National Principal Investigator, Chair of the Steering Committee and Chief of Cardiovascular Surgery at Penn Presbyterian Medical Center, said, "Congratulations to all the investigators and the entire Artivion team for the completion of the PERSEVERE trial. AMDS represents a practice-changing advancement for all cardiothoracic surgeons in the surgical treatment of patients with acute DeBakey type I aortic dissection presenting with malperfusion. Completion of this important trial is an exciting milestone in the field of thoracic aortic surgery. We are hopeful that the study will be positive and demonstrate AMDS as a transformative innovation that will improve the lives of our patients with this devastating clinical scenario."

"We are incredibly pleased to have completed enrollment in the PERSEVERE clinical trial. We recently presented overwhelmingly positive interim results of the PERSEVERE trial at the European Association of Cardiothoracic Surgery Meeting in Vienna that 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. "The completion of the enrollment of the study keeps us on track to achieve PMA approval in the second half of 2025."

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.