Artivion Announces Publication of On-X® Mitral Heart Valve PROACT Study Results in The Annals of Thoracic Surgery

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Results Presented at the 2022 Annual Meeting for The Society of Thoracic Surgeons

ATLANTA, Jan. 31, 2022 /PRNewswire/ -- Artivion, Inc. (NYSE: AORT), a leading cardiac and vascular surgery company focused on aortic disease, today announced the publication of PROACT clinical trial results in *The Annals of Thoracic Surgery,* the official journal of The Society of Thoracic Surgeons. The publication, titled *Low-Dose Versus Standard Warfarin After Mechanical Mitral Valve Replacement: A Randomized Controlled Trial, https://www.annalsthoracicsurgery.org/article/S0003-4975(22)00138-2/fulltext,* highlighted outcomes from the multicenter, non-inferiority, two-arm study which assessed whether, after an On-X mechanical mitral valve replacement (MVR), patients could be safely managed with lower-intensity warfarin plus aspirin. The results were published online on January 29, 2022. In tandem with the publication, the study results were presented at the 2022 Annual Meeting for *The Society of Thoracic Surgeons* on January 30, 2022.

"The PROACT Mitral results add to the data from clinical trials we have sponsored showing that patients with our On-X heart valves can be safely maintained with lower anticoagulation levels than required for competitors' mechanical valves. We continue investing in scientific studies to improve and simplify the lives of prosthetic heart valve patients. In addition, the ongoing PROACT Xa trial aims to prove that patients with the On-X aortic valve can be safely maintained on apixaban, without the need for routine anticoagulation blood tests," said Pat Mackin, Chairman, President and CEO of Artivion, Inc.

Michael W. A. Chu, M.D., FRCSC, Chair/Chief of Cardiac Surgery at London Health Sciences Centre, Western University, London, ON, Canada, and lead author for the PROACT mitral clinical trial, said, "this randomized trial has very important and reassuring findings for patients with unrepairable mitral valve disease. Patients with an On-X mechanical mitral valve can be reassured that a lower INR target is safe, without any increased risk of blood clots or stroke, which may help to alleviate some of the concerns with anticoagulation management with a mechanical valve. We believe this research represents one of the most important advances in the clinical management of mechanical mitral valves over the past 2 decades and will potentially have important practice and guideline changing implications. We are proud to have presented it at the Society of Thoracic Surgeons' Annual Meeting along with simultaneous publication in *The Annals of Thoracic Surgery*."

About the On-X Mechanical Heart Valve PROACT Trial
The On-X Mechanical Heart Valve PROACT clinical trial was a two-armed, multicenter, non-inferiority trial to determine if patients with an On-X mechanical mitral valve replacement (MVR) can be safely managed with lower-intensity warfarin plus aspirin. After On-X mechanical mitral valve replacement followed by at least 3 months of standard anticoagulation, 401 patients at 44 North American centers were randomized to low-dose warfarin (target INR 2.0 to 2.5) or standard-dose warfarin (target INR 2.5 to 3.5). All patients were prescribed aspirin 81 mg daily and encouraged to use home INR testing. Mean patient follow-up was 4.1 years with a maximum follow-up of 8 years. No differences in bleeding, valve thrombosis, or thromboembolism rates were observed between patient groups treated with low-dose vs standard-dose warfarin. This study demonstrates that a lower target INR is safe and feasible for patients with an On-X mechanical valve in the mitral position. The U. S. Food and Drug Administration (FDA) is currently reviewing the labeling change recommendation for the On-X mechanical mitral valve based on this clinical trial.

About the On-X Mechanical Heart Valve
On-X mechanical heart valves are made with the most advanced design and materials in the industry including length-to-diameter ratio similar to a native valve, an inlet flared orifice, a leaflet opening up to 90 degrees, an actuated pivot, and pure pyrolytic carbon. These key features translate into laminar flow, low gradients, and reduced thrombogenicity making it the most clinically beneficial lifelong heart valve replacement option available for patients today.

About Artivion
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. This multinational company's four major groups of products include: aortic stents and stent grafts, prosthetic heart valves, cryopreserved cardiac and vascular allografts, and surgical sealants. 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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