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Artivion Announces Presentation of Real World Data from Post Market Study of On-X® Aortic Heart Valve Replacement Patients Treated with Low Dose Warfarin

Late-Breaking Science Presented at the 37th European Association for Cardio-Thoracic Surgery Annual Meeting

ATLANTA, GA – (October 5, 2023) – Artivion, Inc. (NYSE: AORT), a leading cardiac and vascular surgery company focused on aortic disease, today announced data from its On-X Aortic Heart Valve Low INR post-market study presented in a Late-Breaking Science session at the 37th European Association for Cardio-Thoracic Surgery (EACTS) Annual Meeting in Vienna, Austria. Real world interim results for all patients confirm that the On-X Aortic Valve remains safe and effective with low-dose warfarin.

Professor Aung Oo, Clinical Lead for Aortovascular Surgery at Barts Heart Centre, London, England, presented an abstract titled, *Real World Experience of 510 On-X Aortic Valve Replacement Patients Treated with Low Dose Warfarin.* The abstract included at least 1-year and up to 5 years of clinical data on study participants, with median follow up time of 3.4 years. Results show a significantly lower composite primary endpoint of thromboembolism, valve thrombosis, and major bleeding (linearized occurrence rate (LOR) of 2.31% compared to the pre-defined historic control rate of 5.39%, p<0.0001), driven by an 85% reduction in major bleeding and a 73% reduction in all bleeding. Notably, the data reflected an improvement in outcomes compared to the On-X Aortic Low INR IDE Study (IDE Study) data first published in 2014.

	Post-Market Study			**IDE Study[1]**		
	Test group (%/pt-yr)	**Control group (%/pt-yr)**	***P* value**	**Test group (%/pt-yr)**	**Control group (%/pt-yr)**	***P* value**
Major events	2.31	5.39	<0.0001	4.44	5.16	0.539
Thromboembolism	1.73	1.41	0.64	2.96	1.85	0.178
Valve thrombosis	0.00	0.18	0.35			
Major bleeding events	0.58	3.8	<0.0001	1.48	3.31	0.032
All bleeding events	1.92	7.07	<0.0001	2.67	6.62	<0.001

Prof. Oo said, "Heart valve replacement therapy presents several post-operative challenges for patients, especially the need for blood thinners and the related risk of bleeding and thrombotic events. These long-term data demonstrate the clinical benefits of a lower-dose post-operative warfarin regimen, further validating the use-case for On-X valves with low-dose warfarin."

"The data presented by Professor Oo validate the safety and benefit of physicians managing On-X aortic valve patients at a lower INR compared to other mechanical valves and reinforce our conviction in On-X as a key component of our product portfolio," said Pat Mackin, Chairman, President, and Chief Executive Officer of Artivion. "With these data, we are increasingly confident in our ability to gain further market share globally with On-X, the only mechanical aortic heart valve that can be maintained at an INR of 1.5 to 2.0 backed by that recommendation in the American College of Cardiology / American Heart Association Guideline for the Management of Patients With Valvular Heart Disease.[2]"

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 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.

References

1. Puskas J, Gerdisch M, Nichols D, Quinn R, Anderson C, Rhenman B, Fermin L, McGrath M, Kong B, Hughes C, Sethi G, Wait M, Martin T, Graeve A, Investigators P. Reduced anticoagulation after mechanical aortic valve replacement: interim results from the prospective randomized on-X valve anticoagulation clinical trial randomized Food and Drug Administration investigational device exemption trial. J Thorac Cardiovasc Surg. 2014;147:1202–1210. discussion 1210-1201.
2. J Am Coll Cardiol. 2021 Feb, 77 (4) e25–e197