CryoLife Announces Peer Review Publication of On-X® Aortic Heart Valve PROACT Study

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ATLANTA, June 11, 2018 /PRNewswire/ -- **CryoLife, Inc. (NYSE: CRY),** a leading cardiac and vascular surgery company focused on aortic disease, today announces the publication of our clinical study entitled *"Anticoagulation and Antiplatelet Strategies After On-X Mechanical Aortic Valve Replacement"* in a peer-reviewed medical journal, the *Journal of the American College of Cardiology*. The publication reports outcomes from a multicenter, non-inferiority, two-arm study (the PROACT clinical trial) testing whether, after an On-X mechanical aortic valve replacement (AVR), patients in a High Risk Arm could be safely managed with lower-intensity warfarin plus aspirin or in a Low Risk Arm could be safely managed with dual antiplatelet therapy (DAPT).

High Risk Arm - Patients with one or more thromboembolic (TE) risk factors were randomized to a High Risk study group with lower-intensity warfarin plus aspirin (international normalized ratio [INR] 1.5-2.0) compared to standard warfarin plus aspirin (INR 2.0-3.0). Patients randomized to the lower-intensity warfarin plus aspirin group experienced a greater than 60% reduction in bleeding, at up to 8.7 years follow-up, with no differences in TE and all-cause mortality. Based on the results of this study, the U. S. Food and Drug Administration (FDA) approved a labeling recommendation for the On-X mechanical aortic valve with an INR of 1.5-2.0 plus aspirin (81 mg/day), beginning 3 months after surgery.

John D. Puskas, M.D., Professor of Cardiovascular Surgery at the Icahn School of Medicine at Mount Sinai in New York, Chairman of the Department of Cardiovascular Surgery at Mount Sinai Saint Luke's Hospital, and International Principal Investigator for the PROACT clinical trial, said, "We are honored that the *Journal of the American College of Cardiology* has recognized our clinical work in their publication. Our findings support an important lower warfarin threshold advantage specifically for the On-X valve, which decreases the risks and health concerns associated with long-term anticoagulation. These findings led the FDA and other professional societies to support an Indication for Use related only to On-X. We consider the On-X valve to be state-of-the-art for aortic valve replacement as it offers a one-time surgical solution with proven low gradients, resistance to pannus formation, and outstanding durability."

Low Risk Arm - Patients without TE risk factors undergoing AVR were randomized to a Low Risk study group with DAPT (aspirin 325mg and clopidogrel 75mg) compared to standard warfarin plus aspirin. In the Low Risk study group, patients randomized to DAPT experienced significantly more TE events and a statistically similar rate of bleeding events compared to patients maintained on standard warfarin plus aspirin. As a result, the study was terminated early. Since antiplatelet strategies were unsuccessful in this study group, warfarin is still required with mechanical valves, but with a lower-intensity INR for the On-X mechanical aortic valve as shown by the results for the High Risk study group.

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 CryoLife

Headquartered in suburban Atlanta, Georgia, CryoLife is a leader in the manufacturing, processing, and distribution of medical devices and implantable tissues used in cardiac and vascular surgical procedures focused on aortic repair. CryoLife markets and sells products in more than 90 countries worldwide. For additional information about CryoLife, visit our website, www.cryolife.com.

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