Positive Mid-Term Results on CryoValve(R) SG Pulmonary Human Heart Valve Presented at Western Thoracic Meeting

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ATLANTA, June 30 /PRNewswire-FirstCall/ -- CryoLife, Inc. (NYSE: CRY), a biomaterials, medical device and tissue processing company, has announced that positive mid-term performance data on the CryoValve(R) SG decellularized pulmonary human heart valve were presented on June 28th at the 34th Annual Western Thoracic Surgical Association Meeting in Kona, Hawaii. The data, used earlier this year to support the marketing clearance for the valve, were presented by John W. Brown, M.D., professor of Cardiothoracic Surgery, Indiana University School of Medicine.

For the study, 342 patients who received a CryoValve SG processed using CryoLife's proprietary SynerGraft(R) technology were compared to 1,246 patients who received a conventionally processed CryoValve pulmonary heart valve. All patients received the valves in conjunction with either a right ventricular outflow tract (RVOT) reconstruction or as part of the Ross Procedure, which is described below. Average follow-up time was 3.9 years for the CryoValve SG RVOT procedure patients, and 4.7 years for the Ross Procedure patients. The average follow-up times were comparable for patients who received the conventionally processed CryoValve.

The results showed that there was a statistically significant reduction in structural valve deterioration -- SVD (71 percent actuarial freedom from SVD at five years for CryoValve SG versus 55 percent for CryoValve) and valvular insufficiency (48 percent of patients with trivial or less valvular insufficiency at last follow-up for CryoValve SG versus 30 percent for CryoValve) in patients who received the CryoValve SG for RVOT reconstruction as compared to the conventionally processed valve. Valvular insufficiency occurs when the valve leaflets do not completely seal when the valve is closed, causing regurgitation, or the backward flow of blood into the heart chamber. The data also indicated that there was a statistically significant reduction in valvular insufficiency in patients who received the CryoValve SG as part of the Ross Procedure as compared to the conventionally processed valve (67 percent of patients with trivial or less valvular insufficiency at last follow-up for CryoValve SG versus 51 percent for CryoValve).

For all other measured mid-term clinical endpoints there was no statistical difference between the CryoValve SG and the CryoValve recipients, including actuarial freedom from SVD at five years in patients undergoing Ross procedures (79 percent for CryoValve SG versus 78 percent for CryoValve), and for all patient groups there was no statistical difference between recipient groups for actuarial freedom from valve related death or explant at five years (Ross patients: 97 percent for CryoValve SG versus 95 percent for CryoValve; RVOT patients: 93 percent for CryoValve SG versus 89 percent for CryoValve), actuarial freedom from endocarditis at five years (Ross patients: 100 percent for CryoValve SG versus 99 percent for CryoValve; RVOT patients: 98 percent for CryoValve SG versus 100 percent for CryoValve) or actuarial freedom from cardiac reoperation at five years (Ross patients: 95 percent for CryoValve SG versus 95 percent for CryoValve; RVOT patients: 93 percent for CryoValve SG versus 90 percent for CryoValve), and transvalvular gradients or pressure change across the valve at last follow-up (Average Peak Gradient in Ross patients: 19.0 millimeters of Mercury for CryoValve SG versus 21.8 millimeters of Mercury for CryoValve; RVOT patients: 22.9 millimeters of Mercury for CryoValve SG versus 22.2 millimeters of Mercury for CryoValve).

About CryoValve SG

CryoLife's proprietary SynerGraft technology is designed to remove allogeneic donor cells and cellular remnants from the valve without compromising the integrity of the underlying collagen matrix.

The CryoValve SG pulmonary human heart valve is indicated for the replacement of diseased, damaged, malformed or malfunctioning native pulmonary valves. The valve can be used in conjunction with right ventricular outflow tract reconstruction procedures (RVOT), commonly performed in children with congenital heart defects. In addition, the valve can be used for pulmonary valve replacement during the Ross Procedure, an operation in which a patient's defective aortic valve is removed and replaced with his own pulmonary valve. The CryoValve SG is then surgically implanted in place of the removed native pulmonary valve.

The CryoValve SG pulmonary human heart valve received market clearance from the FDA in February 2008. The market clearance was supported by documenting the substantial equivalence of the CryoValve SG pulmonary human heart valve to conventionally processed pulmonary human heart valves.

About CryoLife, Inc.

Founded in 1984, CryoLife, Inc. is a leader in the processing and distribution of implantable living human tissues for use in cardiac and vascular surgeries throughout the United States and Canada. The Company recently received FDA clearance for the CryoValve(R) SG pulmonary human heart valve, processed using CryoLife's proprietary SynerGraft(R) Technology. The Company's BioGlue(R) Surgical Adhesive is FDA approved as an adjunct to sutures and staples for use in adult patients in open surgical repair of large vessels. BioGlue is also CE marked in the European Community and approved in Canada and Australia for use in soft tissue repair. CryoLife distributes Hemostase MPH(R), a hemostatic agent, in much of the U.S. for use in cardiac and vascular surgery and in the United Kingdom and Germany for cardiac, vascular, and general surgery, subject to certain exclusions. The Company also distributes the CryoLife-O'Brien(R) stentless porcine heart valve, which is CE marked for distribution within the European Community.

For additional information about the company, visit CryoLife's Web site: www.cryolife.com.

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