# CryoLife Receives Humanitarian Use Device Designation for SynerGraft(R) Processed Human Aortic Heart Valves

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ATLANTA, Oct. 6 /PRNewswire-FirstCall/ -- *CryoLife, Inc.,* (NYSE: CRY) an implantable biological medical device and cardiovascular tissue processing company, today announced that it has received a Humanitarian Use Device (HUD) designation from the Food and Drug Administration (FDA) for its CryoValve® SG aortic human heart valve. The HUD designation is the first step in obtaining a Humanitarian Device Exemption (HDE) for the CryoValve SG aortic human heart valve, which is processed with the Company's proprietary *SynerGraft® technology*. An approved HDE would allow the Company to market the CryoValve SG aortic human heart valve. The patented SynerGraft technology serves as the foundation for the next generation of implantable biological tissues and is designed to remove allogeneic donor cells and cellular remnants from the valve without compromising the integrity of the underlying collagen matrix.

An HUD is a medical device intended to benefit patients in the treatment or diagnosis of a disease or condition that affects or is manifested in fewer than 4,000 individuals in the United States (U.S.) per year. An HUD can be granted when no comparable device with the same intended use is marketed through the premarket approval (PMA) process or the premarket notification (510(k)) process.

The CryoValve SG aortic human heart valve is intended to be used for the replacement of diseased, damaged, malformed or malfunctioning native or prosthetic aortic valves in children from 0 to 21 years of age. The Company estimates that up to 1,500 children per year could benefit from this technology if the Company is successful in obtaining an HDE, which is the next step in making these valves commercially available in the U.S.

"The CryoValve SG aortic human heart valve may offer an attractive valve replacement option for many children with aortic valve disease. We plan to immediately begin conducting the bench and animal studies, as well as collecting the human clinical data necessary to apply for the HDE," said Steven G. Anderson, CryoLife's president and chief executive officer. "This HUD designation is an important first step toward expanding the use of our SynerGraft technology platform, which we believe is the foundation for the next generation of implantable biological tissues."

In February 2008, the Company received a 510(k) clearance from the FDA for its CryoValve® SG pulmonary human heart valve. The CryoValve SG pulmonary human heart valve is indicated for the replacement of diseased, damaged, malformed, or malfunctioning native or prosthetic 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 pulmonary human heart valve is then surgically implanted in place of the removed native pulmonary valve.

In August 2009, the Company received a 510(k) clearance from the FDA for its CryoPatch® SG pulmonary human cardiac patch. CryoPatch SG is indicated for the repair or reconstruction of the right ventricular outflow tract (RVOT), which is a surgery commonly performed in children with congenital heart defects, such as Tetralogy of Fallot, Truncus Arteriosus, and Pulmonary Atresia. CryoPatch SG is distributed in three anatomic configurations: pulmonary hemi-artery, pulmonary trunk, and pulmonary branch.

*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 U.S. and Canada. The Company's CryoValve® SG pulmonary human heart valve, processed using CryoLife's proprietary SynerGraft® technology, has FDA 510(k) clearance for the replacement of diseased, damaged, malformed or malfunctioning native or prosthetic pulmonary valves. The Company's BioGlue® 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. The Company's BioFoam® Surgical Matrix is CE marked in the European Community for use as an adjunct in the sealing of abdominal parenchymal tissues (liver and spleen) when cessation of bleeding by ligature or other conventional methods is ineffective or impractical. BIOGLUE *Aesthetic(TM)* Medical Adhesive is CE marked in the European Community for periosteal fixation following endoscopic browplasty (brow lift) in reconstructive plastic surgery and is distributed by a third party for this indication. CryoLife distributes HemoStase(TM), a hemostatic agent, in much of the U.S. for use in cardiac and vascular surgery and in the European Community and Canada for cardiac, vascular, and general surgery, subject to certain exclusions.

*Statements made in this press release that look forward in time or that express management's beliefs, expectations or hopes are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These statements include those regarding the belief that SynerGraft technology serves as the foundation for the next generation of implantable biological tissues, the expected benefits of the CryoValve SG aortic human heart valve and its potential impact on patients, the estimated U.S. market it would address, and the Company's plans and timing for applying and obtaining an HDE. These forward looking statements may not occur as, when or to the extent expected, and are subject to a number of risks, including the following: CryoValve SG aortic human heart valve continues to undergo testing, and additional test results may not yield the anticipated benefits. Many factors impact the suitability of patients for transplants, and there can be no guarantee that CryoLife will receive an HDE designation. Doctors may not continue to accept SynerGraft products for use in treating their patients, and additional SynerGraft products in development may not achieve anticipated benefits or approvals. The Company does not undertake to update its forward-looking statements. Additional risks and uncertainties impacting CryoLife's business are detailed in CryoLife's Securities and Exchange Commission filings, including CryoLife's Form 10-K filing for the year ended December 31, 2008, our Form 10-Q for the quarter ended March 31, 2009, our Form 10-Q for the quarter ended June 30, 2009, and the Company's other SEC filings. The Company does not undertake to update its forward-looking statements.*

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

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