



## CryoLife Receives FDA 510(k) Clearance for SynerGraft(R) Processed Human Cardiac Patch Material

August 12, 2009

ATLANTA, Aug. 12 /PRNewswire-FirstCall/ -- CryoLife, Inc., (NYSE: CRY) an implantable biological medical device and cardiovascular tissue processing company, today announced that it has received 510(k) clearance from the U.S. Food and Drug Administration (FDA) for its CryoPatch SG pulmonary human cardiac patch. CryoPatch SG is processed with the Company's proprietary SynerGraft technology designed to remove allogeneic donor cells and cellular remnants from tissue without compromising the integrity of the underlying collagen matrix.

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.

Implantation of the CryoPatch SG reduces the risk for induction of HLA class I and class II alloantibodies, based on Panel Reactive Antibody (PRA) measured at up to one year, compared to standard processed pulmonary cardiac tissues. Data have not been provided to evaluate the effect of reduced alloantibodies on the long-term durability, or long-term resistance to rejection by the patient, of the CryoPatch SG.

Avoiding elevated PRA is important for patients receiving CryoPatch SG as some may ultimately require a heart transplant. While the link between immune response and allograft tissue performance is still being debated, there is evidence that an elevated PRA poses a significant risk to future organ transplant patients. In these patients, an increased PRA can decrease the number of possible donors for subsequent organ transplants, and increase time on transplant waiting lists.

"The introduction of CryoPatch SG represents another step in the broadening applications of the SynerGraft technology to patients and surgeons," said Steven G. Anderson, CryoLife's president and chief executive officer. "CryoPatch SG may offer an attractive tissue reconstruction option for many children born with heart defects."

Management estimates that the U.S. market for CryoPatch SG and other tissues and products for the indications listed above is \$15 million. CryoLife anticipates that the first CryoPatch SG will be available for shipment late in the third quarter of 2009.

In February 2008, the Company received a 510(k) clearance from the FDA for its CryoValve SG pulmonary human heart valve. CryoValve SG 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 is then surgically implanted in place of the removed native pulmonary valve.

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. 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. 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. 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 anticipated effectiveness, benefits and indications for use of CryoPatch SG and the anticipated U.S. market it would address, as well as the timing of use of the SynerGraft technology. These future events may not occur as and when expected, if at all, and, together with the Company's business, are subject to various risks and uncertainties. These risks and uncertainties include that CryoPatch SG may not perform as well as expected or provide all of the benefits anticipated, nor may the first shipments of CryoPatch SG occur as expected, that the CryoPatch SG has a one year shelf life, and other risk factors 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:

SOURCE: CryoLife, Inc. - 08/12/2009

CONTACT:

D. Ashley Lee, Executive Vice President, Chief Financial Officer and Chief Operating Officer, +1-770-419-3355;

Katie Brazel, Fleishman Hillard, +1-404-739-0150

Web Site: <http://www.cryolife.com>

(CRY)