CryoLife Receives FDA 510(k) Clearance for SynerGraft(R) Processed Human Pulmonary Heart Valves

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ATLANTA, Feb. 7 /PRNewswire-FirstCall/ -- CryoLife, Inc., (NYSE: CRY) a biomaterials, medical device and tissue processing company, today announced that it has received 510(k) clearance from the Food and Drug Administration (FDA) for its CryoValve(R) SG pulmonary human heart valve processed with the Company's proprietary SynerGraft technology. 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.

"CryoValve SG may offer an attractive valve replacement option for many children born with heart defects," said Steven G. Anderson, CryoLife's president and chief executive officer. "CryoValve SG may also be a good option for patients who have undergone valve replacement surgery as young children, but may require another valve replacement as they've grown into adulthood."

"Children born with heart defects often face frequent and challenging surgeries," stated John W. Brown, M.D., professor of Cardiothoracic Surgery, Indiana University School of Medicine, Indianapolis, Ind. "For certain heart defects, CryoValve SG may give these kids a great opportunity to live active, normal lives. As a surgeon, I'm very excited to be able to offer them and their families this treatment option."

At FDA's request, CryoLife is planning a post-clearance study to seek evidence for the potential and implied long-term benefits of the SynerGraft process. Data to be collected is expected to include long-term safety and hemodynamic function, immune response, and explant analysis. CryoLife believes that this information may help it ascertain whether the SynerGraft process reduces the immunogenicity of the transplanted heart valve and recellularizes with the recipients own cells.

CryoLife will be using the SynerGraft technology for the majority of its pulmonary valve processing and anticipates that the first CryoValve SG may be available for shipment late in the first quarter of 2008.

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'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. The Company also distributes the CryoLife-O'Brien(R) stentless porcine heart valve, which is CE marked for distribution within the European Community.

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 CryoValve SG 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 CryoValve SG may not perform as well as expected or provide all of the benefits anticipated, the Company may not be able to begin processing the majority of its pulmonary valves by the anticipated time, nor may the first shipments of CryoValve SG occur as expected, 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, 2006, its most recent Form 10-Q, 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

Media Contacts: D. Ashley Lee Executive Vice President, Chief Financial Officer and Chief Operating Officer Phone: 770-419-3355 Katie Brazel Fleishman Hillard Phone: 404-739-0150 SOURCE: CryoLife, Inc. 02/07/2008 CONTACT: D. Ashley Lee, Executive Vice President, Chief Financial Officer and Chief Operating Officer of CryoLife, Inc., +1-770-419-3355; or
Katie Brazel of Fleishman Hillard, +1-404-739-0150
Web site: http://www.cryolife.com
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