CryoLife Files for FDA Clearance to Distribute BioGlue Surgical Patch in U.S.

May 6, 1999

ATLANTA--(BW HealthWire)--May 6, 1999--CryoLife, Inc. (NYSE:CRY), the leader in the development and commercialization of living human tissue implantable devices and a manufacturer and distributor of stentless heart valves and surgical adhesives, today announced that it has filed a 510(k) premarket notification submission with the U. S. Food and Drug Administration (FDA) requesting clearance to market its BioGlue(R) Surgical Patch in the United States. There is a statutory 90-day review period for a 510(k) premarket notification submission.

The BioGlue Surgical Patch has been developed to reinforce and seal the soft tissues of the lung and bronchi to reduce air leaks and to provide sealing during reconstructive surgery. A prefilled cartridge of BioGlue Patch Adhesive and a BioGlue Adhesive Delivery Device will be included with the BioGlue Surgical Patch. If the 510(k) application is cleared by the FDA, the BioGlue Patch Adhesive will be used to attach the BioGlue Surgical Patch to pulmonary tissues.

Steven G. Anderson, President and Chief Executive Officer of CryoLife, said, "The 510(k) filing for BioGlue Surgical Patch represents a major milestone in the Company's history, paving the way for the Company's potential introduction in the United States of a product from the BioGlue family. Approximately 250,000 pulmonary procedures are done annually in the United States, and we believe the BioGlue Surgical Patch could address a significant percentage of those procedures. In addition, we are pleased that our newly expanded BioGlue manufacturing facilities are completely operational and will enable us to meet our anticipated BioGlue production needs."

Founded in 1984, CryoLife, Inc. is the leader in the development and commercialization of implantable living human tissues for use in cardiovascular, vascular, and orthopaedic surgeries throughout the United States and Canada. The Company's BioGlue surgical adhesive, CE marked in the European Union for use in vascular and pulmonary sealing and repair, is distributed throughout Europe. The Company also manufactures CryoLife-O'Brien(R) and CryoLife-Ross(TM) stentless porcine heart valves which are distributed within the European Community.

Statements made in this press release which look forward in time involve risks and uncertainties and are "forward-looking" statements within the meaning of the Private Securities Litigation Reform Act of 1995. Such risks and uncertainties include the possibility that the FDA will not clear the BioGlue Surgical Patch 510(k) application in a timely manner, if at all, or if cleared, that surgeons may choose not to utilize BioGlue Surgical Patch, the possibility that BioGlue Surgical Patch could have currently unforeseen side effects which could render it undesirable for use in pulmonary sealing, the possibility that the Company's BioGlue manufacturing facility may not have sufficient capacity to handle actual BioGlue production needs, changes in economic cycles, competition from other companies, changes in laws and governmental regulations applicable to the Company and other risk factors detailed in the Company's Securities and Exchange Commission filings, including the Company's Prospectus dated March 30, 1998, contained in its Registration Statement on Form S-3 (No. 333-46545).

Editor's Note: CryoLife Customer Service may be accessed by telephone: 1-800-438-8285 (U.S. and Canada) 1-770-419-3355 (International) 1-770-590-3753 (International fax) E-mail: customerservice@cryolife.com

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

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