



CryoLife, Inc. Files Premarket Approval Application With FDA for BioGlue Surgical Adhesive for Vascular and Cardiac Repair

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ATLANTA, Feb. 1 /PRNewswire/ -- CryoLife, Inc. (NYSE: CRY), the leader in the development and commercialization of living tissue implantable devices and a manufacturer and distributor of stentless heart valves and surgical adhesives, today announced that it has filed a Premarket Approval (PMA) application with the U. S. Food and Drug Administration (FDA) for the use of its BioGlue surgical adhesive in vascular and cardiac repair.

The application is based upon results of FDA approved Investigational Device Exemption (IDE) studies conducted at six U.S. medical centers over the last ten months. BioGlue is currently approved for vascular and pulmonary repair in 41 foreign countries and is commercially available in the U.S. under an FDA approved Humanitarian Device Exemption (HDE) for use as an adjunct in the repair of acute thoracic aortic dissections, a life-threatening condition. For this indication, BioGlue is currently being distributed to over 500 hospitals in the United States.

Steven G. Anderson, President and Chief Executive Officer, CryoLife, Inc., noted, "BioGlue surgical adhesive for use in vascular and cardiac repair addresses an annual U.S. market of approximately \$500 million and world market of US \$1 billion, according to industry sources."

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 is approved as an adjunct for acute thoracic aortic dissections under HDE regulations in the United States and is CE marked in the European Union and approved in Canada for use in vascular and pulmonary sealing and repair. The Company also manufactures the SynerGraft heart valve, the world's first tissue-engineered heart valve replacement and the CryoLife-O'Brien(R) and CryoLife-Ross(R) stentless porcine heart valves, which are CE marked for distribution within the European Community. The human heart valves and vascular grafts processed by CryoLife using the SynerGraft technology are distributed in the U.S. under the trade names of CryoValve(R) SG and CryoVein(R) SG, respectively.

Statements made in this press release that look forward in time or that express management's beliefs, expectations or hopes regarding future occurrences are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These future events may not occur when expected, if at all, and are subject to various risks and uncertainties. Such risks and uncertainties include the possibility that the FDA will not approve the Company's PMA for use of BioGlue in vascular and cardiac repair or that such an approval will be delayed, that results from the use of BioGlue will not meet expectations, that other BioGlue regulatory submissions will not be ready when planned or that anticipated regulatory approvals will not be obtained on a timely basis, if at all, the possibility that there will not be an adequate supply of human tissue for cryopreservation, the possibility of rapid technological change, uncertainties regarding products in development, 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 Form 10-K for the year ended December 31, 1999.

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

Contact: Roy Vogeltanz

Vice President, Corporate Communications

(800) 438-8285

SOURCE CryoLife, Inc.

CONTACT: Roy Vogeltanz, Vice President, Corporate Communications of CryoLife, Inc., 800-438-8285/