CryoLife, Inc. Reports FDA Approval for BioGlue(R) Surgical Adhesive Use in Vascular Repair for Hemostasis

December 4, 2001

ATLANTA, Dec 4, 2001 /PRNewswire via COMTEX/ -- CryoLife, Inc. (NYSE: CRY), a life-science company involved in the development and commercialization of cryopreserved and tissue-engineered implantable heart valves, vascular, and orthopedic reconstruction grafts and surgical adhesives, today announced that the U.S. Food and Drug Administration (FDA) has approved the Company's Premarket Approval (PMA) application for use of BioGlue surgical adhesive. This device is indicated for use as an adjunct to standard methods of achieving hemostasis (such as sutures and staples) in adult patients in open surgical repair of large vessels (such as aorta, femoral and carotid arteries).

From 1999 to present, BioGlue has been available in the United States under an FDA-approved Humanitarian Device Exemption (HDE) for use as an adjunct to sutures and staples in the repair of acute thoracic aortic dissections, a life-threatening condition. Approximately 600 U.S. hospitals are currently using BioGlue under the FDA's HDE.

Steven G. Anderson, President and Chief Executive Officer, CryoLife, Inc., said, "BioGlue represents a major advancement in surgical technology because of its ability to control bleeding at the surgical site. BioGlue's vascular surgery approval by the FDA significantly increases the number of procedures in which BioGlue can be used."

Anderson also noted, "BioGlue surgical adhesive employs a unique delivery system, incorporating a single pre-filled cartridge and applicator device, providing the surgeon complete control of the adhesive at the surgical site."

According to industry estimates, surgical adhesives address an annual worldwide market of $2 billion. BioGlue is the easiest to use surgical adhesive, capable of being utilized by the operating room staff in less than a minute.

To accommodate commercial rollout of BioGlue in both domestic and overseas markets, CryoLife recently completed a build-out of a new 7,500 square foot BioGlue manufacturing facility at its headquarters and laboratories located in suburban Atlanta, Georgia. When fully operational, the new BioGlue facility will have the capacity to manufacture two million BioGlue cartridges annually.

Founded in 1984, CryoLife, Inc. is the leader in the development and commercialization of implantable living human tissues for use in cardiovascular, vascular, and orthopedic surgeries throughout the United States and Canada. The Company's BioGlue surgical adhesive is approved as an adjunct for use in acute thoracic aortic dissections under HDE regulations in the United States, is CE Marked in the European Community, and is approved in Canada and Australia for use in vascular and pulmonary sealing and repair. The Company also manufactures the SynerGraft(R) heart valve, the SynerGraft vascular graft, the world's first tissue-engineered heart valve and vascular replacements, 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 future BioGlue performance, including the performance of gel and foam formulations will prove less encouraging than current results, that surgeons will not continue to accept and use BioGlue, competition from other wound closure products 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, 2000.

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