



FDA Panel Recommends Approval of CryoLife's BioGlue(R) Surgical Adhesive for Use in Vascular and Cardiac Repair

September 17, 2001

ATLANTA, Sept. 17 /PRNewswire/ -- CryoLife, Inc. (NYSE: CRY), a life-science company involved in the development and commercialization of cryopreserved and tissue-engineered implantable heart valves, vascular and orthopaedic reconstruction grafts, and surgical adhesives, today announced that the U.S. Food and Drug Administration's (FDA) Circulatory System Devices Panel has unanimously recommended to approve the Company's BioGlue Surgical Adhesive as an adjunct to the use of sutures and staples in vascular and cardiac repair to achieve hemostasis. The Panel's recommendation will be reviewed by the FDA, which is ultimately responsible for market approval decisions.

In December 1999, BioGlue was made available in the U.S. under an FDA approved Humanitarian Device Exemption (HDE) for use as an adjunct in the repair of acute thoracic dissections, a life-threatening condition. For this indication, BioGlue is currently being distributed to over 600 hospitals in the United States.

Internationally, BioGlue is currently approved in 36 foreign countries for use in vascular and pulmonary repair and to provide more effective hemostasis control.

Steven G. Anderson, President and Chief Executive Officer, CryoLife, Inc., noted, "BioGlue surgical adhesive is currently being used as an adjunct in the repair of acute thoracic aortic dissections. The Panel's recommendation is an important step forward in extending BioGlue's use in vascular and cardiac surgical repair."

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 Community and approved in Canada and Australia for use in vascular and pulmonary sealing and repair. The Company also manufactures the SynerGraft(R) 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 final FDA approval will not be obtained, that future BioGlue performance with respect to wound closure 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> .

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