CryoLife to Respond to Recent FDA Inspection Observation

October 20, 2003

ATLANTA, Oct. 20 /PRNewswire-FirstCall/ -- CryoLife, Inc. (NYSE: CRY), announced today its commitment to promptly respond to an observation made in a recent FDA inspection report (Form 483). The observation requires CryoLife to complete the validation of its processing operations and procedures for decontaminating tissues, written procedures for the prevention of infectious disease contamination during processing, and its anti-microbial solution.

"CryoLife is committed to ensuring the quality and safety of our tissues, making continual improvements to our tissue processing, and fulfilling all FDA requirements and expectations," stated Tom Lynch, VP Regulatory Affairs and Quality Assurance. "The Company will begin its validation study on October 21st and plans to have it completed by year-end. The Company also plans to apply appropriate corrective actions to all processes, procedures and quality systems."

Founded in 1984, CryoLife, Inc. is a leader in the processing and distribution of implantable living human tissues for use in cardiovascular 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, and is CE marked in the European Community and approved in Canada for use in soft tissue repair, and approved in Australia for use in vascular and pulmonary sealing and repair. The Company also manufactures the SynerGraft(R) Vascular Graft, 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 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 revenues may not meet expectations, that demand for CryoLife preserved tissues may not return to prior levels, the possibility that the FDA could impose additional restrictions on the Company's distribution of tissues, require a recall, or prevent the Company from distributing tissues, as could occur if the Company is unable to satisfactorily address the concerns raised in the FDA's most recent Form 483, that FDA regulation of the Company's CryoValve SG and CryoVein SG may require significant time and expense, that the Company may not have sufficient borrowing or other capital availability to fund its business, that present and future litigation may be resolved only by substantial payments by the Company in excess of available insurance coverage since the outcomes of products liability, securities class action, and derivative cases are inherently uncertain, that pending litigation cannot be settled on terms acceptable to the Company, that the Company may not have sufficient resources to pay punitive damages which are not covered by insurance or liabilities in excess of available insurance, the possibility of severe decreases in the Company's revenues and working capital, the possibility that CryoLife will not satisfactorily address the observations contained in the most recent Form 483s issued by the FDA, changes in laws and governmental regulations applicable to CryoLife 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, 2002, 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

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