



CryoLife, Inc. Updates Actions of FDA

June 24, 2002

Letter Relating to April 2002 Inspection Received; No Actions Expected on Current Inventory

ATLANTA, Jun 24, 2002 /PRNewswire-FirstCall 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 orthopaedic grafts, and surgical adhesives, announced that it has received a warning letter from the Food and Drug Administration related to an inspection of the Company's human tissue processing laboratories completed on April 12, 2002. The Company also said that, since its inception, it has never before received a warning letter. Based on the information currently available, the Company believes that neither the FDA's recommendations and observations nor the Company's anticipated corrective actions will affect the distribution of the current tissue inventory.

CryoLife was first inspected by the FDA in 1986 and is also licensed and inspected separately by the States of Georgia, California, Florida, and New York. The Company has been ISO 9001-certified since 1995.

The FDA inspected the Company's operations in December 2001, and in March- April 2002. The FDA inspection in December 2001 followed publicity surrounding the unfortunate and untimely death of a knee surgery patient in Minnesota who in November 2001 had received a transplant of connective tissue. The Centers for Disease Control conducted a separate, exhaustive investigation. The patient apparently died of an infection attributed to the rare bacterium *Clostridium sordellii*. The FDA made no observations or recommendations as a result of its December 2001 inspection. All samples taken during the December 2001 inspection tested negative for microorganisms.

The second FDA inspection at CryoLife, completed in April 2002, followed a report of two allograft heart valve infections. Subsequently, CryoLife received pathology data from the implanting hospitals' own laboratories that clearly demonstrated that there was no evidence of infection in either valve. As part of its March-April investigation, the FDA did make a number of observations, the majority of which are reflected in the warning letter. CryoLife is implementing measures in an attempt to resolve the FDA's comments, such as demonstrating that its practices and equipment in place are better documented and validated.

The FDA letter reiterated observations from the inspection. The Company has either corrected the observations or will work closely with the FDA to correct them as soon as possible. The Company intends to meet with the FDA shortly to discuss the remaining issues. While there are costs associated with these corrections and related studies, the Company does not believe that such costs will be significant. Additionally, the Company believes the majority of these changes have the potential to benefit CryoLife by upgrading its processing in anticipation of future Good Tissue Practice requirements expected to be issued by the FDA.

Steven G. Anderson, CryoLife's President and Chief Executive Officer, noted, "Patient safety is of paramount concern to us. We carefully considered the CDC's report of March 15, 2002, and adopted those recommendations which were scientifically useful and technically feasible. CryoLife is responding to the FDA's observations, many of which have already been implemented, although some studies are expected to require additional time."

Mr. Anderson also commented "It is important to point out that although cryopreserved, soft tissue orthopaedic allografts cannot presently be sterilized without compromising clinical performance; we note that the reported incidence of infection in orthopaedic surgeries involving the use of allografts processed by CryoLife is approximately 0.2%, which compares well to the overall reported incidence rate of infection in general U.S. orthopaedic surgeries of between 0.6% and 2.2%. Notwithstanding our more-than- satisfactory overall record, we continue to evaluate our procedures, available processes and technologies, with a view to continuously improving our own processes and patient safety." For further details, see the updates on our website at www.cryolife.com/newsevent.htm .

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(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 and Australia for use in vascular and pulmonary sealing and repair. The Company also manufactures the SynerGraft(R) heart valve and the SynerGraft vascular graft, the world's first tissue-engineered heart valve and vascular replacement, respectively, 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.

Forward-Looking Statements. Statements made in this press release that look forward in time or that express management's beliefs, expectations or hopes regarding the FDA warning letter, improvements in processes and related matters are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Future developments and events may differ materially from management's expectations, may not occur when expected, if at all, and are subject to various risks and uncertainties. Such risks and uncertainties include the Company's ability to adequately address the concerns raised by FDA on a timely, cost-effective basis, if at all, the risk that other Company initiatives are delayed pending FDA compliance, that the FDA may take actions adversely affecting the Company's operations, the risk of negative impacts on tissue inventory or cryopreservation processes as a result of resolution of the FDA observations, the Company's dependence on revenues from cryopreservation of human tissue, that allograft tissue revenues could be adversely impacted due to the recent CDC report and the issuance of the FDA warning letter, potential loss of relationships with tissue providers, the possibility of rapid technological change, uncertainties regarding products in development, uncertainties related to patents and protection of proprietary technology, 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 Form 10-K filing for the year ended December 31, 2001.

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

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