CryoLife, Inc. Receives FDA Order

August 14, 2002

ATLANTA, Aug 14, 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 orthopedic grafts, and surgical adhesives, announced that it received an order from the Atlanta District Office of the U.S. Food and Drug Administration respecting the vascular, non-valved cardiac and orthopedic tissue processed by the Company since at least October 3, 2001. The order provides for the affected tissue to be retained "until it is recalled, destroyed, the safety of the tissue is confirmed, or an agreement is reached with the FDA for its proper disposition under the supervision of an authorized official of the FDA." The order does not apply to allograft heart valves.

CryoLife is exercising its right to appeal the order and requesting a hearing with the FDA. Initiating this appeal and request will place the destruction order in abeyance pending resolution of the hearing request. The Company has placed all vascular, non-valved cardiac and orthopedic tissue on quality assurance quarantine and will recall all vascular, non-valved cardiac and orthopedic tissue that has been distributed but not implanted.

The order follows FDA inspections of CryoLife facilities on March 25 and April 12, 2002, and states that the Company "may be in violation" of 21 CFR 1270 with respect to the noted tissue by reason of "not having validated" infectious disease prevention procedures. The order notes that the Center for Devices and Radiological Health is evaluating whether there are similar risks that may be posed by CryoLife processed heart valves and will take further regulatory action if appropriate.

CryoLife provided the FDA with its current process validations and is responding to the FDA's concerns respecting those validations. The Centers for Disease Control made several recommendations to CryoLife, many of which were already included in the Company's procedures. Others were adopted well in advance of the FDA's order, including recommended refrigeration protocols, preprocessing microbiological cultures and tissue discard criteria. CryoLife will continue to cooperate with the FDA and will endeavor to assure the FDA that the Company's tissue processing methods effectively address the issue of infectious disease prevention.

Steven G. Anderson, CryoLife's President and Chief Executive Officer, noted, "We are confident about the quality and safety of CryoLife processed tissue. We plan to continue our cooperation with the agency." Mr. Anderson also stated, "We have always operated CryoLife with the highest concern for patient safety. As we noted in earlier press releases, the reported incidence of infection involving CryoLife processed tissues is and continues to be low, especially when compared to general rates of infection from other implantable devices. Over the years, CryoLife processed tissues have enhanced thousands of patient lives."

In light of these developments, CryoLife is withdrawing its guidance for 2002 results and evaluating the present situation to determine its expected impact on the Company's business and operations.

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 risk that the Company will be unable to develop cost-effective procedures for the prevention of infectious disease contamination or cross-contamination by tissue, that compliance with the FDA's requirements could reduce the Company's supply of orthopedic and vascular tissue available for transplant or that compliance will significantly reduce the Company's revenues or operating income or negatively impact its financial position.

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

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