CryoLife Reaches Agreement With FDA to Resume Limited Tissue Processing And Distribution

September 6, 2002

ATLANTA, Sep 6, 2002 /PRNewswire-FirstCall via COMTEX/ -- CryoLife Inc. (NYSE: CRY), a tissue processing and medical device company, reached an agreement with the U.S. Food and Drug Administration permitting the company to immediately resume processing and limited distribution of its life-saving and limb-saving non-valved cardiac and vascular tissues.

The agreement allows CryoLife to distribute existing and newly processed non-valved cardiac conduits and patches, saphenous veins, femoral veins and arteries, and aorto-iliac arteries for specified medically urgent uses when alternative treatments have been exhausted or are unavailable. The Company estimates that most of the covered tissue under its control is used by surgeons under the conditions permitted by the agreement.

"We remain confident in the safety of our processed tissues and continue to cooperate fully with the FDA," said CryoLife CEO Steve Anderson. "In many cases, our processed tissues offer treatments for conditions that could not be otherwise treated, such as certain repairs to a child's diseased heart," he added.

Since 1984, more than 90,000 CryoLife preserved allograft tissues have been implanted. The overall infection rates in surgeries involving CryoLife tissues are comparable to or below published infection rates in surgeries involving sterile synthetic implant devices.

"I applaud the fact that CryoLife tissues are once again available, as these tissues, which are often in short supply, are essential to modern medical care, especially for infants and small children," said John Lamberti, M.D., Director, Pediatric Cardiac Surgery, New York Weill Cornell Medical Center. "I have been implanting these valves and tissues for more than 15 years without incidence of infection."

"This is good news for patients to have the nation's largest tissue processor once again able to handle what is surely the most precious gift one human can give to another," said John Lee, Executive Director Tissue Services of DCI Donor Services.

The agreement allows the tissue to be released for distribution after CryoLife completes steps to assure that the tissue is used for approved purposes and that patients will be notified of risks associated with tissue use. Specifically, CryoLife must obtain physician prescriptions, and tissue packaging must contain appropriate warning labels. The agreement also calls for CryoLife to undertake to identify third-party records of donor tissue testing, and to destroy tissue from donors in whom micro-organisms associated with an infection are found.

In addition, the agreement, which has a forty-five working-day term, specifies interim operating procedures to permit CryoLife to distribute tissues processed during the term of the agreement. CryoLife also agreed to establish a corrective action plan within 30 days with steps to validate processing procedures. A copy of the agreement is available as an Exhibit to the Company's Form 8-K filed September 6, 2002, and on the Company's Web site, http://www.cryolife.com.

Forward-Looking Statements. 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 business, are subject to various risks and uncertainties. Such risks and uncertainties include the risk that the interim procedures will prove insufficient, that CryoLife may not be able to establish a satisfactory corrective plan within 30 days, CryoLife's dependence on cryopreservation of human tissue, the possibility that anticipated decreases in the Company's revenues and working capital may be severe, the possibility that SynerGraft-treated heart valves will not have the expected long-term functionality, repopulate with human recipient cells or reduce immune response, that future clinical SynerGraft or BioGlue test results will prove less encouraging than current results, the possibility that the SEC investigation could be concluded in a manner adverse to the Company, that SynerGraft, BioGlue, or other regulatory submissions will not be ready when planned or that anticipated regulatory approvals will not be obtained when expected, if at all, that surgeons will not continue to accept and use tissues preserved by the Company or its other products such as BioGlue, competition from other wound closure products, that CryoLife will be unable to find an investor in its proprietary light activated drug delivery systems or that such systems will prove ineffective in oncology applications, that pending government and legal proceedings against CryoLife will not be resolved in its favor, that the FDA may require the recall of heart valve tissue processed by CryoLife, that CryoLife may be forced to discontinue its tissue processing business due to the FDA Order or subsequent FDA actions, 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 CryoLife and other risk factors detailed in CryoLife's Securities and Exchange Commission filings, including CryoLife's Form 10-Q Filing for the quarter ended June 30, 2002, and the Company's other SEC filings.

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

Contact: D. Ashley Lee
Vice President, Chief Financial Officer
(800) 438-8285

John Deaver
Senior Vice President
Fleishman Hillard
(404) 739-0111