CryoLife Announces Clarification of Interim Agreement With FDA

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ATLANTA, Jan. 6 /PRNewswire-FirstCall/ -- CryoLife Inc. (NYSE: CRY), a leading tissue processing and medical device company, announced that the U.S. Food and Drug Administration has provided clarifying interpretations of the September 5, 2002 Interim Agreement that will expedite processing and distribution of the Company's life-saving and limb-saving non-valved cardiac and vascular tissues.

For non-valved cardiac and vascular tissues processed since September 5, 2002, the Company is not required to obtain physician prescriptions, label the tissue as subject to a recall, or require special steps regarding procurement agency records of donor screening and testing beyond those required for all processors of human tissue. The Company's human heart valves were never subject to the original FDA Order.

"We remain confident in the safety of our processed tissues and continue to cooperate fully with the FDA," said CryoLife's CEO, Steven G. Anderson. "This interpretation clarifies that non-valved cardiac and vascular tissues processed since September 5 may be shipped without extraordinary restrictions."

Since 1984, nearly 100,000 CryoLife preserved allograft tissues have been implanted. For more than 18 years, CryoLife has actively tracked and published patient outcome and tissue safety data respecting its processed tissues. CryoLife's data shows its tissues to be as safe as synthetic, sterile implantable devices.

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 are subject to various risks and uncertainties. Such risks and uncertainties include the risk that the clarifications may not expedite processing and distribution of the company's non-valved cardiac and vascular tissues covered by the Interim Agreement, the Interim Agreement may not be renewed, that CryoLife may not be able to establish a corrective plan that is satisfactory to the FDA, in a timely manner or at all, that surgeons will not continue to accept and use tissues preserved by the Company, that the FDA may require the recall of heart valve tissue processed by CryoLife, and that CryoLife may be forced to discontinue its tissue processing business due to the FDA Order or subsequent FDA actions.

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

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