FDA Renews Interim Agreement With CryoLife; Company Continues Tissue Processing and Distribution Under Agreement

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ATLANTA, Jan. 13 /PRNewswire-FirstCall/ -- CryoLife, Inc. (NYSE: CRY), a leading tissue processing and medical device company, announced that the U.S. Food and Drug Administration (FDA) has renewed its September 5, 2002 Interim Agreement with the Company. The renewal allows CryoLife to distribute non- valved cardiac and vascular tissue processed prior to September 5, 2002, under the terms of the original agreement for an additional 45 working days, ending March 20, 2003. 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 believe the renewal demonstrates that CryoLife is in compliance with the Interim Agreement and continues to make progress under the corrective action plan," said CryoLife's President and CEO, Steven G. Anderson. "We continue to cooperate with the FDA and other agencies to work toward a full resolution."

Throughout its history, CryoLife has actively tracked and published patient outcome and tissue safety data respecting the tissues it has processed. This data demonstrates the safety and efficacy of the nearly 100,000 tissues CryoLife has processed and CryoLife's continuing commitment to quality.

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 Interim Agreement may not be renewed again, that a reinspection by the FDA may not demonstrate progress satisfactory to the FDA, that CryoLife may not be able to meet FDA requirements in a timely manner or at all, that the recent clarifications may not expedite processing and distribution of the Company's non-valved cardiac and vascular tissues covered by the Interim Agreement to the extent anticipated by the Company, 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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