FDA Grants CryoLife's BioGlue a Humanitarian Device Exemption for Limited Use in Aortic Dissections

December 13, 1999

ATLANTA--(BW HealthWire)--Dec. 13, 1999--CryoLife, Inc. (NYSE:CRY), the leader in the development and commercialization of living human tissue implantable devices and a manufacturer and distributor of stentless heart valves and surgical adhesives, today announced that it has received notification from the Food and Drug Administration (FDA) of the approval of the Company's BioGlue(R) surgical adhesive for use in aortic dissections under Humanitarian Device Exemption (HDE) regulations. The HDE allows BioGlue surgical adhesive to be used only adjunctively with sutures or staples to facilitate surgical repair of acute thoracic aortic dissections by obliterating the false channels and strengthening the friable diseased aortic tissue for suture placement. This condition affects between 4,000 and 5,000 patients annually.

Steven G. Anderson, President and Chief Executive Officer of CryoLife, said, "With the FDA's approval of the Humanitarian Device Exemption, BioGlue surgical adhesive will now be commercially available for the repair of aortic dissections throughout the U. S. In clinical trials, BioGlue has shown a significant potential to save lives."

BioGlue is a protein-based surgical adhesive which the Company has sold in international markets since March 1998. It is currently in clinical trials in the United States. BioGlue surgical adhesive is "CE" (product certification) marked in Europe for vascular and pulmonary repair applications. The European market for use of BioGlue for vascular and pulmonary repairs is estimated to be $500 million.

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, CE marked in the European Union for use in vascular and pulmonary repair, is distributed throughout Europe. The Company also manufactures CryoLife-O'Brien(R) and CryoLife-Ross(R) stentless porcine heart valves which are distributed only within the European Community.

Statements made in this press release which look forward in time involve risks and uncertainties and are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Such risks and uncertainties include the possibility that humanitarian device exemption for BioGlue surgical adhesive will not lead to increased utilization by surgeons, the possibility that BioGlue surgical adhesive could have currently unforeseen side effects which could render it undesirable for use in aortic dissections, 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 Prospectus dated March 30, 1998 contained in its Registration Statement on Form S-3 (No. 333-46545).

Editor's Note:

CryoLife Customer Service may be accessed by telephone:

1-800-438-8285 (U.S. and Canada)

1-770-419-3355 (International)

1-770-590-3753 (International fax)

E-mail: customerservice@cryolife.com

Explanation of Terms:

Under Humanitarian Device Exemption (HDE) regulations, medical devices that provide treatment for limited populations of patients can be granted approval by the FDA based on more limited clinical experience than that required for a full Pre-Market Approval (PMA).

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

CONTACT: CryoLife Inc., Atlanta
Roy Vogeltanz, 800/438-8285