CryoLife Submits IDE Supplement to Expand Indications Of BioGlue in U.S.

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ATLANTA--(BW HealthWire)--Jan. 6, 2000--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 had submitted an Investigational Device Exemption (IDE) supplement with the Food & Drug Administration (FDA) for an expanded clinical study of the Company's BioGlue(R) surgical adhesive. The supplement requests that the application for the IDE be expanded to include the use of BioGlue in vascular and certain cardiac repairs in addition to the commercially approved usage as an adjunct in acute thoracic aortic dissections cited in the original application.

The original IDE application for the use of BioGlue surgical adhesive in the treatment of acute thoracic aortic dissections was filed with the FDA on June 9, 1998. The FDA approved the use of BioGlue for the repair of acute thoracic aortic dissections under Humanitarian Device Exemption (HDE) regulations on December 13, 1999. Shipments of BioGlue to U.S. hospitals began on January 3, 2000.

Steven G. Anderson, President and Chief Executive Officer of CryoLife, said, "We are very pleased with the progress we have made in bringing our BioGlue surgical adhesive to market throughout the world. We began marketing BioGlue in European markets in March 1998. BioGlue surgical adhesive is "CE" (product certification) marked in Europe, a market which is estimated at $500 million, for vascular and pulmonary repair applications. BioGlue surgical adhesive is approved under HDE regulations as an adjunct in the treatment of acute thoracic aortic dissections in the United States. The approval of this IDE supplement would allow CryoLife to expand human clinical trials in the U. S. to include all vascular repairs. The market for these aortic dissections and vascular and cardiac repairs is estimated to be approximately $500 million in the United States."

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 is approved as an adjunct for acute thoracic aortic dissections under HDE regulations in the United States and is CE marked in the European Union for use in vascular and pulmonary repair. 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 the Food and Drug Administration (FDA) may not approve the Company's Investigational Device Exemption supplement, that surgeons may not accept BioGlue surgical adhesive, that BioGlue surgical adhesive could have currently unforeseen side effects which could render it undesirable for use in vascular repairs, 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).

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

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