CryoLife, Inc. Receives Approval to Expand IDE Indications for BioGlue Under Conditions Specified by FDA

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ATLANTA, March 30 /PRNewswire/ -- 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, announced today that it has received notification from the Food and Drug Administration (FDA) that it may expand its Investigational Device Exemption (IDE) application on the Company's BioGlue(R) surgical adhesive human clinical study to include the use of BioGlue in vascular and selected cardiac repairs. CryoLife, Inc. has agreed to the FDA's conditions and is proceeding to initiate the expanded clinical study. Previously, CryoLife's BioGlue had been approved for use in an IDE clinical study as a surgical adjunct in the repair of Type A aortic dissections.

The expanded BioGlue IDE study will assess the safety and effectiveness of BioGlue as a hemostatic adjunct (to stop bleeding) in connection with cardiac and vascular repairs. The clinical study, anticipated to be completed by the end of 2000, will be conducted at six to eight investigational sites and involve approximately 160 patients.

BioGlue has demonstrated in the laboratory, its ability to withstand vascular pressures three times a normal blood pressure within two minutes of the glue's application to a wound site. In December 1999, CryoLife announced that the FDA approved the Company's application for a Humanitarian Device Exemption (HDE), allowing the commercial distribution of BioGlue for use as an adjunct in the repair of acute thoracic aortic dissections, a life-threatening condition.

Steven G. Anderson, President and Chief Executive Officer, CryoLife, Inc., noted, "I believe the expanded IDE application for cardiac and vascular repair will enable us to broaden the experience base for BioGlue and will hopefully lead to our future ability to provide surgeons in the U.S. with new surgical protocols that will benefit a wide range of patients."

BioGlue is currently in commercial distribution in 35 countries outside the U.S. for application in vascular and pulmonary repair, addressing an annual market potential that CryoLife estimates in excess of $500 million (USD). If the expanded IDE clinical study is successful, use of BioGlue in vascular applications in the U.S. would address an estimated annual market in excess of $350 million (USD).

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 in the repair of acute thoracic aortic dissections under HDE regulations in the United States and is CE marked in the European Union and approved in Canada for use in vascular and pulmonary sealing and repair. The Company also manufactures CryoLife-O'Brien(R) and CryoLife-Ross(R) stentless porcine heart valves, which are distributed 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 future human clinical results will prove less encouraging or that BioGlue surgical adhesive will not be found to be effective in reducing bleeding in humans, 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 Form 10-K for the year ended December 31, 1998.

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

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