



CryoLife, Inc. Files Investigational Device Exemption With FDA for BioGlue Surgical Adhesive for Use in Pulmonary Repair

November 28, 2000

ATLANTA, Nov. 28 /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 that it has filed an Investigational Device Exemption (IDE) application with the U.S. Food and Drug Administration (FDA) for use of its BioGlue Surgical Adhesive in all pulmonary surgical repairs. The BioGlue clinical study is expected to be conducted at up to ten (10) medical centers and involve about 100 patients.

BioGlue is currently approved for vascular and pulmonary repair in 41 foreign countries and is commercially available in the U.S. under a FDA-approved Humanitarian Device Exemption (HDE) for use as an adjunct in the repair of acute thoracic aortic dissections, a life-threatening condition. For this use, BioGlue is being distributed to 424 hospitals in the U.S.

As previously announced, CryoLife also received approval from the FDA to expand human clinical trials under an IDE, for use of BioGlue for all vascular and cardiac repairs, in May of this year. The enrollment of patients for the BioGlue vascular and cardiac repair study was completed in September and the Pre-Market Approval (PMA) for vascular and cardiac repair is scheduled to be submitted to the FDA in early 2001.

Steven G. Anderson, President and Chief Executive Office, CryoLife, Inc., noted, "We had previously announced that we planned to file the IDE for the use of BioGlue in all pulmonary repairs during the first quarter of 2001. The earlier than anticipated filing was prompted by the excellent results we are seeing in other clinical studies of BioGlue."

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 the SynerGraft(R) heart valve, the world's first tissue-engineered heart valve replacement and the CryoLife-O'Brien(R) and CryoLife-Ross(R) stentless porcine heart valves, which are CE marked for distribution within the European Community.

Statements made in this press release that look forward in time or that express management's beliefs, expectations or hopes regarding future occurrences are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These future events may not occur when expected, if at all, and are subject to various risks and uncertainties. Such risks and uncertainties include the possibility that future clinical BioGlue test results will prove less encouraging than current results, and that BioGlue regulatory submissions will not be ready when planned or that anticipated regulatory approvals will not be obtained on a timely basis, if at all.

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

CONTACT: Roy Vogeltanz, Vice President, Corporate Communications of
CryoLife, Inc., 800-438-8285

SOURCE CryoLife, Inc.

CONTACT: Roy Vogeltanz, Vice President, Corporate Communications of CryoLife, Inc., 800-438-8285/