CryoLife Ships BioGlue Surgical Adhesive to U.S. Hospitals; HDE Approval Opens Door for Hospitals in the U.S. to Use BioGlue in Aortic Dissections

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ATLANTA--(BW HealthWire)--Jan. 4, 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 received Institutional Review Board (IRB) approval from four United States hospitals and shipped its first commercial shipments of BioGlue(R) surgical adhesive for use in aortic dissections. BioGlue was recently approved by the Food & Drug Administration (FDA) for commercial distribution in the treatment and repair of aortic dissections under a Humanitarian Device Exemption (HDE). The Company has targeted 180 hospitals for initial use of BioGlue in aortic dissections. The Company estimates the U.S. market for BioGlue in aortic dissections to be about $12 million.

Steven G. Anderson, President and Chief Executive Officer of CryoLife, said, "We believe that the speed with which the Institutional Review Boards of these four hospitals acted, following the FDA's commercial approval of BioGlue for use in aortic dissections, is an indication of the enthusiastic acceptance of BioGlue by the U.S. medical community and an indication of the sales potential of BioGlue in the U.S. We expect BioGlue usage in the U.S. will meet analyst expectations.

"BioGlue is CE marked and has been available for vascular and pulmonary repair in international markets since March 1998. BioGlue's international revenues increased by almost 100 percent in 1999 over 1998 figures. We estimate that the international market potential for the use of BioGlue in all vascular and pulmonary procedures approaches $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 is approved for aortic dissections 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 surgeons may not accept BioGlue surgical adhesive, the possibility 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).

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

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