CryoLife, Inc. Advances Development Of An Injectable Spinal Disc Replacement Device

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ATLANTA, May 30 /PRNewswire/ -- CryoLife, Inc. (NYSE: CRY), a life-science company involved in the development and commercialization of cryopreserved and tissue-engineered implantable heart valves, vascular and orthopedic grafts, and surgical adhesives, presented the results of a biomechanical study on the use of CryoLife's protein hydrogel device (PHD) technology in the repair of denucleated intervertebral discs at the 14th Annual Meeting for the International Intradiscal Therapy Society, Phoenix, Arizona, May 25-27, 2001. The study was presented by Steven P. Walsh, Ph.D., Director of Biomaterials Technology, CryoLife, Inc.

Denucleation of intervertebral discs is a common treatment for lower back pain that involves the surgical removal of damaged or diseased disc materials resulting in motion destabilization and progressive reduction in disc height. The CryoLife research proposed the use of protein hydrogel (BioDisc(TM)) injected in fluid form into the denucleated disc space that sets up as a pliable support solid to restore disc height and stability while preserving motion. BioDisc employs a unique, minimally invasive delivery system incorporating a dual chamber applicator allowing the surgeon to inject the biomaterial into the void created by the removal of disc materials.

Phase I of the biomechanical study concluded that the application of PHD technology can restore a denucleated interdiscal void to normal height and compressibility, restoring normal spine function and potentially eliminating lower back pain. Phase II animal studies on CryoLife's BioDisc are currently underway and are expected to be completed by the end of the third quarter of 2001. The results of animal studies of BioDisc will be included in CryoLife's application for an Investigational Device Exemption (IDE) for human studies expected to be filed in the fourth quarter of 2001.

Steven G. Anderson, President and Chief Executive Officer, CryoLife, Inc., noted, "The commercial introduction of BioDisc would represent a major advancement in spinal disc surgical technology and offer orthopedic surgeons, and the more than 320,000 patients in the U.S. that annually undergo spinal disc repair, a potentially more efficient and cost-effective alternative to current disc repair methods." Industry estimates indicate the spinal disc repair market worldwide to be US $1.20 billion in revenues annually.

Founded in 1984, CryoLife, Inc. is the leader in the development and commercialization of implantable living human tissues for use in cardiovascular, vascular, and orthopedic 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 Community and approved in Canada and Australia 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. The human heart valves and vascular grafts processed by CryoLife using the SynerGraft technology are distributed in the U.S. under the trade names of CryoValve(R)SG and CryoVein(R)SG, respectively.

This press release includes statements that look forward in time or that express management's beliefs, expectations or hopes regarding future occurrences. Such statements 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 PHD technology regulatory submissions will not be ready when planned or that anticipated regulatory approvals will not be obtained on a timely basis, if at all; or that future animal or other studies utilizing the PHD technology will prove less encouraging than current biomechanical study results. The Company's business is also subject to other risk factors, as detailed in the Company's Securities and Exchange Commission filings, including the Company's Form 10-K for the year ended December 31, 2000.

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

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