CryoLife, Inc. Receives 'CE Mark' Approval for Distribution of Model 700 Synergraft Tissue-Engineered Pulmonary Heart Valves in Europe

April 18, 2001

ATLANTA, April 18 /PRNewswire/ -- CryoLife, Inc. (NYSE: CRY), a life- science company involved in the development and commercialization of tissue-engineered implantable heart valves, vascular and orthopaedic grafts and surgical adhesives, today announced that it has received a "CE" (product certification) Mark allowing for the commercial distribution of its Model 700 SynerGraft tissue-engineered pulmonary heart valves within the European Community.

CryoLife's Model 700 SynerGraft pulmonary heart valve represents a major development in tissue-engineered replacement biologic devices for repair of damaged or diseased human tissues. The technology incorporates the use of a porcine pulmonary heart valve that has been depopulated of its porcine cells, leaving a collagen matrix that has the potential to repopulate with the recipient's own cells, providing a bioengineered human heart valve with structure and biodynamics similar to the recipient's own heart valve. It is anticipated that the tissue-engineered valve will have the capability to grow with the maturing of a child, thus potentially avoiding a series of heart valve replacement procedures.

Steven G. Anderson, President and Chief Executive Officer, CryoLife, Inc., said, "The addition of the Model 700 SynerGraft pulmonary heart valve demonstrates the potential for expansion of the SynerGraft technology platform. CryoLife now provides two tissue-engineered heart valves for patients requiring heart valve replacement, the SynerGraft Model 500 aortic valve and the Model 700 pulmonary valve, thus making CryoLife a technology leader in tissue-engineered products. In advanced animal studies, both of these valves have been repopulated with the recipient's own cells."

The CE Mark for the SynerGraft Model 700 tissue-engineered pulmonary heart valve, granted by Lloyd's Register Quality Assurance Limited (LRQA) of Coventry, England, represents the sixth CE Mark designation awarded for CryoLife products. CryoLife was awarded its CE Mark for the SynerGraft Model 500 heart valve last year. CryoLife was awarded CE Marks for its stentless porcine aortic and pulmonary heart valves in 1996 and 1998, respectively. CryoLife was also awarded CE Marks in 1998 and 1999 for its BioGlue(R) surgical adhesive for applications in both vascular and pulmonary repairs.

Domestically, CryoLife scientists and regulatory personnel are working on the development of additional SynerGraft Model 500 and 700 clinical data relating to an IDE (Investigational Device Exemption) application to the U.S. Food and Drug Administration to use SynerGraft Model 500 and 700 pulmonary heart valves in human clinical trials. These IDE applications are expected to be made in the fourth quarter of 2001.

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 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 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.

Statements made in this 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 SynerGraft heart valves will not repopulate with human recipient cells, or if repopulation does occur, that it will not have the anticipated effects, including without limitation, growing with a maturing child; that future clinical SynerGraft test results will prove less encouraging than current results; that SynerGraft regulatory submissions will not be ready when planned or that anticipated regulatory approvals will not be obtained on a timely basis, if at all; that SynerGraft and SynerGraft SG heart valves will not be accepted by surgeons 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, 2000.

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

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