CryoLife, Inc. Receives 'Ce Mark' Approval for Distribution of Synergraft(R) Tissue-Engineered Pulmonary Heart Valves in Europe

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ATLANTA, Oct. 16 /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 the "CE" (product certification) mark for the commercial distribution in the European Union of its recently introduced SynerGraft tissue-engineered pulmonary heart valves.

SynerGraft technology represents the potential to become a major advancement in replacement heart valve procedures. It incorporates the use of a porcine heart valve which has been depopulated of its porcine heart valve cells providing a collagen matrix that has the normal functionality of a human heart valve, with the potential to recellularize itself with the recipient's own cells. The cell remodeling process has been successful in advanced animal studies that showed that the collagen matrix in SynerGraft pulmonary heart valves repopulated itself with new cells and tissue architecture. It is anticipated that the SynerGraft tissue engineered pulmonary heart valve will be used for right heart reconstruction primarily in children.

Steven G. Anderson, President and Chief Executive Officer, CryoLife, Inc., noted, "I believe the CE Mark approval of the SynerGraft pulmonary heart valve makes CryoLife the technological leader in addressing the $176 million (US$) European heart valve replacement market. Importantly, SynerGraft provides the only heart valve replacement that has the potential to re-populate itself with the patient's own cells. Since the SynerGraft tissue-engineered pulmonary heart valve is not fixed with glutaraldehyde, it should also be of benefit to patients who are prone to exaggerated calcification reaction from other currently available porcine heart valve replacements."

The CE mark for the SynerGraft tissue-engineered pulmonary heart valve, granted by Lloyd's Register Quality Assurance Limited (LRQA) of Cryodon, England, represents the fifth CE mark designation awarded for CryoLife products. CryoLife was awarded CE marks for its stentless porcine aortic and pulmonary heart valves in 1996 and 1998. CryoLife was also awarded CE marks in 1998 and 1999 for its BioGlue(R), a protein-based surgical adhesive for applications in both vascular and pulmonary repairs.

Domestically, CryoLife scientists and regulatory personnel are working on the development of additional SynerGraft information and data relating to an IDE (Investigational Device Exemption) application to the U.S. Food and Drug Administration to use SynerGraft pulmonary heart valves in human clinical trials for pediatric pulmonary heart valve replacement.

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 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 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 SynerGraft test results will not be encouraging or that SynerGraft valves will not repopulate with recipient cells as expected, 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, 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, 1999.

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

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