CryoLife, Inc. Files Application With FDA for SynerGraft: World's First Tissue-Engineered Heart Valve

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ATLANTA, Aug. 1 /PRNewswire/ -- CryoLife, Inc. (NYSE: CRY), a diversified biological implantable device company, announced today that it has submitted an application to the U.S. Food and Drug Administration (FDA) for an Investigational Device Exemption (IDE) to conduct human clinical trials for its SynerGraft tissue-engineered replacement heart valves.

If successful, SynerGraft technology will represent a major advancement in heart valve replacement. 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 be repopulated with the recipient's own cells. The valve repopulation process has been proven successful in advanced animal studies that showed that the heart valve's collagen matrix was repopulated with new cells and tissue architecture from the valve recipient.

The FDA application is for approval of human trials for the use of SynerGraft heart valves in heart reconstruction surgery for children requiring replacement of the pulmonary heart valve.

"If these trials are successful, clinical use of the SynerGraft heart valve will provide cardiovascular surgeons with a revolutionary heart valve replacement option in pediatric applications," noted Steven G. Anderson, President and Chief Executive Officer, CryoLife, Inc. "In advanced animal studies it has been shown that SynerGraft heart valves repopulate themselves with the recipient's own cells, thus offering the possibility of providing a permanent heart valve replacement. SynerGraft heart valves should eliminate the necessity of a series of heart valve replacement surgeries that are normally required during a child's growth and development." If the FDA approves CryoLife's application for human trials, it is anticipated that the SynerGraft trials would involve 10-12 pediatric heart surgery centers and up to 150 patients.

In August of 1999, the noted surgeon Mark F. O'Brien, F.R.A.C.S., F.R.C.S., Senior Cardiac Surgeon, The Prince Charles Hospital, Brisbane, Australia, and a member of CryoLife's International Cardiovascular Medical Advisory Board, began a series of SynerGraft heart valve human clinical trials in adults. There are now six SynerGraft implants in Australia. All adult patients continue to do well and the valves are functioning properly. SynerGraft heart valves are currently under review by European regulatory authorities for CE Mark (product certification) for general distribution in the European Union.

The SynerGraft heart valve is the first in a series of tissue-engineered living implantable biological products being developed by CryoLife scientists, utilizing animal tissue structures that are depopulated of animal cells and that have the potential to be repopulated by the recipient's own cells. The SynerGraft anterior cruciate ligament (ACL) and the SynerGraft vascular graft projects are presently completing advanced animal studies.

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, CE marked in the European Union for use in vascular and pulmonary sealing and repair, is distributed throughout Europe. 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 .

SOURCE CryoLife, Inc.

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