CryoLife, Inc. Files Premarket Approval Application (PMA) With FDA for CryoLife-O'Brien(R) Aortic Heart Valve

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ATLANTA, Aug. 16 /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 orthopaedic reconstruction grafts, and surgical adhesives, today announced that it had filed a Premarket Approval Application (PMA) with the U.S. Food and Drug Administration (FDA) for the CryoLife-O'Brien stentless porcine heart valve. The CryoLife-O'Brien heart valve is directed toward the adult aortic valve replacement market, currently estimated at over $250 million in the United States and complements the estimated $60 million per year pulmonary heart valve replacement market, which CryoLife is the leading provider.

The PMA is based upon the results of several hundred human implants performed in the European Union and Australia. The O'Brien stentless heart valve has been implanted in Europe since 1991. CryoLife, Inc. has distributed the CryoLife-O'Brien heart valve in Europe since 1996 after the company was awarded a CE (product certification) Mark. The CryoLife-O'Brien stentless aortic heart valve was designed by Mark F. O'Brien, M.D., F.R.A.C.S., F.R.C.S., Senior Cardiac Surgeon, The Prince Charles Hospital, Brisbane, Queensland, Australia.

The proposed medical indication for use of the CryoLife-O'Brien valve is in surgeries for patients diagnosed with narrowing of the aortic valve (aortic stenosis). When the degree of narrowing becomes significant enough to impede the flow of blood from the left ventricle to the arteries, heart valve problems develop. Aortic stenosis is a result of several diseases, including calcification in older patients, wear and tear of the valve and congenital disease during childhood. The CryoLife-O'Brien stentless heart valve is targeted for patients over the age of 55 who wish to avoid long-term anticoagulant drug therapy that is required with a mechanical valve implant.

Steven G. Anderson, President and Chief Executive Officer, CryoLife, Inc., noted, "Upon approval of the PMA, the addition of the CryoLife-O'Brien stentless aortic heart valve to the company's US product and services offering will enable the company to compete in the US adult tissue heart valve replacement market and complements the company's heart valve product offering which now will serve the entire heart valve replacement marketplace."

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 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.

Statements made in this news release which look forward in time or that express management's beliefs, expectations or hopes regarding future occurrences 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 possibilities that the FDA will not approve the company's PMA and that, if the PMA is approved, American surgeons will not accept the CryoLife-O'Brien valve or utilize it in aortic valve surgeries or competing products will be deemed more effective or expedient than the CryoLife-O'Brien valve.

For additional information about the company, visit CryoLife's web site:

http://www.cryolife.com

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