Cryolife, Inc. Cooperates With Health Agencies on Rare Bacterial Infection

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ATLANTA, Dec 7, 2001 /PRNewswire via COMTEX/ -- 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 reconstruction grafts, and surgical adhesives, today said that it is cooperating with the Minnesota Department of Public Health, The Centers for Disease Control and Prevention (CDC), and the U.S. Food and Drug Administration (FDA) in an investigation into causal factors resulting in the death of knee surgery patients who presented similar symptoms in Minnesota.

The investigation centers upon the coincidence of three knee surgery patient deaths in Minnesota over a relatively short period of time. The Minnesota Department of Public Health initiated a causal factor study to assure that a single causal factor was not involved in the three incidents.

Two deaths involved patients undergoing knee replacement surgery that did not involve a human tissue transplant. The third fatality was a patient who received a CryoLife-processed human donor condyle tissue to repair articular cartilage in the knee. The investigation focused on the possibility of the death being related to a Clostridium sordellii infection, a rare bacterial infection caused by a spore-forming bacterium that is normally found in soil.

Based upon our recent conversations with state and federal public health agencies, they are unable at this time to tell us how the Clostridium sordellii bacterium was introduced into the knee patient's body, and they have revealed no conclusion regarding the source of the infection in the patient. The CDC is testing a similar tissue from the same donor, but the final results are not known at this time.

James C. VanderWyk, Ph.D., Vice President, Regulatory Affairs and Quality Assurance, CryoLife, Inc., noted, "Tissues from the same donor processed by CryoLife, Inc. have been implanted in eight other patients. Physician follow- ups on these patients have indicated they are all doing well. There were twelve separate cultures on tissue recovered from the donor, none of these cultures were positive for Clostridium sordellii. CryoLife's processing protocols in its clean-room environment assure the highest standard of quality control. In the past 17 years CryoLife has processed some 250,000+ pieces of human tissue from more than 60,000+ donors, without a single known incidence of Clostridium sordellii bacterial infection."

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 surgical adhesive is FDA approved as an adjunct to sutures and staples for use in adult patients in open surgical repair of large vessels 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 SynerGraft vascular graft, the world's first tissue-engineered heart valve and vascular replacements, 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.

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

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