FDA Clears New Immune Response Claim for the CryoValve(R) SG Pulmonary Human Heart Valve

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ATLANTA, Feb 17, 2009 /PRNewswire-FirstCall via COMTEX/ -- CryoLife, Inc. (NYSE: CRY), a biomaterials, medical device and tissue processing company, announced today that the U.S. Food and Drug Administration (FDA) has cleared a new claim for the CryoValve(R) SG pulmonary human heart valve. The new labeling claim relates to reducing a component of the immune response in recipients of the CryoValve SG.

CryoValve SG pulmonary human heart valve is processed with the Company's proprietary SynerGraft(R) technology, which is designed to remove allogeneic donor cells and cellular remnants from the valve without compromising the integrity of the underlying collagen matrix.

The new claim relates to the fact that data from three company-sponsored clinical studies and a comprehensive review of the scientific literature on allograft heart valves shows that implantation of the CryoValve SG reduces the risk of inducing HLA class I and class II alloantibodies, based on Panel Reactive Antibody (PRA) measured at up to one year, compared to the standard- processed pulmonary human heart valve. The effect of reduced alloantibodies, however, on the long-term durability, or long-term resistance to rejection by the patient, of the CryoValve SG has not yet been clinically proven. The company has documented the implantation of more than 1,800 CryoValve SG pulmonary human heart valves.

The CryoValve SG pulmonary human heart valve is indicated for the replacement of diseased, damaged, malformed or malfunctioning native or prosthetic pulmonary valves. The valve can be used in conjunction with right ventricular outflow tract reconstruction procedures (RVOT), commonly performed in children with congenital heart defects. In addition, the valve can be used for pulmonary valve replacement during the Ross Procedure, an operation in which a patient's defective aortic valve is removed and replaced with his or her own pulmonary valve. The CryoValve SG is then surgically implanted in place of the removed native pulmonary valve.

A PRA screen is used to identify allosensitized patients prior to organ transplantation. An elevated PRA level, indicating pretransplant alloantibodies, increases the risk of organ transplant rejection and patient mortality. In addition, high and prolonged PRA levels may prevent or delay transplantation until a suitable crossmatch-compatible donor is identified.

"A major objective of our research and development is to reduce and ultimately eliminate the risk of an immune response for patients, and we are making great strides toward achieving that goal," said Steven G. Anderson, president and chief executive officer of CryoLife. "This new claim is important because a subset of patients receiving an allograft heart valve is likely to eventually require an organ transplant. Demonstration of reduced alloantibody levels with the CryoValve SG can be a key consideration for cardiac surgeons when replacing the pulmonary valve. Working with the FDA, we will monitor the long-term clinical outcomes over the coming years to assess what impact the SynerGraft process has on valve durability."

About CryoLife, Inc.

Founded in 1984, CryoLife, Inc. is a leader in the processing and distribution of implantable living human tissues for use in cardiac and vascular surgeries throughout the U.S. and Canada. The Company received FDA clearance for the CryoValve(R) SG pulmonary human heart valve, processed using CryoLife's proprietary SynerGraft(R) Technology in early 2008. The Company's BioGlue(R) Surgical Adhesive is FDA approved as an adjunct to sutures and staples for use in adult patients in open surgical repair of large vessels. BioGlue is also CE marked in the European Community and approved in Canada and Australia for use in soft tissue repair. CryoLife distributes Hemostase MPH(R), a hemostatic agent, in much of the U.S. for use in cardiac and vascular surgery and in the United Kingdom, Germany, France, and Canada for cardiac, vascular, and general surgery, subject to certain exclusions.

Statements made in this press release that look forward in time or that express management's beliefs, expectations or hopes are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These statements include those regarding the expected benefits of the CryoValve SG and its potential impact on patients as well as the factors considered by surgeons when replacing a pulmonary valve. These forward looking statements may not occur as, when or to the extent expected, and are subject to a number of risk, including the following: CryoValve SG continues to undergo testing, and additional test results may not yield the anticipated benefits. Many factors impact the suitability of patients for transplants, and there can be no guaranty that patients who receive the CryoValve SG will be more likely to be considered suitable for transplants or have better results following a transplant. In addition, the factors considered by surgeons in weighing transplant options may vary and may change over time. The Company does not undertake to update its forward-looking statements.

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

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