CryoLife Receives CE Mark Approval for BioFoam(R) Hemostatic Technology

August 4, 2009

ATLANTA, Aug. 4 /PRNewswire-FirstCall/ -- CryoLife, Inc., (NYSE: CRY) an implantable biological medical device and cardiovascular tissue processing company, today announced it has received CE mark approval for its BioFoam Surgical Matrix (BioFoam). The CE mark allows immediate, unrestricted commercial distribution of BioFoam in the European Community for use as an adjunct in the sealing of abdominal parenchymal tissues (liver and spleen) when cessation of bleeding by ligature or other conventional methods is ineffective or impractical. BioFoam is the second product from the Company's protein hydrogel technology platform to receive a CE mark.

CryoLife plans a controlled clinical launch of BioFoam at up to six centers in the United Kingdom, Germany, France and Italy to support its initial marketing efforts. Based on the number of liver and spleen procedures performed annually in the European Community, CryoLife estimates the annual European market opportunity for BioFoam to be approximately $30 million and more than $100 million on a worldwide basis.

"We are excited about securing our first approval for the use of BioFoam in organ resection surgery and look forward to continuing our development efforts to bring BioFoam into the U.S. market," said Steven G. Anderson, CryoLife president and chief executive officer. "Over the past four fiscal years, the U.S. Department of Defense has allocated approximately $5.4 million to CryoLife for the development of products containing a protein hydrogel, which is the primary component of BioFoam."

In December 2008, CryoLife received conditional approval from the FDA to conduct the feasibility phase of the company's BioFoam IDE submission for liver parenchymal sealing. The feasibility phase will enroll a total of 20 subjects at two investigational sites in the U.S. Before beginning this phase, the Company must receive final approval of the study protocol and related documents from the FDA and an additional approval of the study from the U.S. Department of Defense. CryoLife is in the final stages of this approval process.

About BioFoam

BioFoam, a protein hydrogel biomaterial under development by CryoLife, contains an expansion agent which generates a mixed-cell foam. The foam creates a mechanical barrier to decrease blood flow and pores for the blood to enter, leading to cellular aggregation and enhanced hemostasis. It is easily applied and could potentially be used intraoperatively to control internal organ hemorrhage, limit blood loss, and reduce the need for future reoperations in liver resections. BioFoam is based on the same protein hydrogel technology platform from which BioGlue Surgical Adhesive was developed. BioGlue is approved by the U.S. Food and Drug Administration to control bleeding as an adjunct to sutures and staples 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.

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's CryoValve SG pulmonary heart valve, processed using CryoLife's proprietary SynerGraft technology, has FDA 510(k) clearance for the replacement of diseased, damaged, malformed, or malfunctioning native pulmonary valves. 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. BioGlue is also CE marked in the European Community and approved in Canada and Australia for use in soft tissue repair. BIOGLUE Aesthetic(TM) Medical Adhesive is CE marked in the European Community for periosteal fixation following endoscopic browplasty (brow lift) in reconstructive plastic surgery and is distributed by a third party for this indication. CryoLife distributes HemoStase(TM), a hemostatic agent, in much of the U.S. for use in cardiac and vascular surgery and in the European Community 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, including statements regarding the receipt and application of DOD funds and potential distribution timing and uses and applications for BioFoam. These future events may not occur as and when expected, if at all, and, together with the Company's business, are subject to various risks and uncertainties. These risks and uncertainties include that the Company may not receive all or any funds allocated under the DoD Appropriation, that BioFoam may not prove safe or effective for its intended uses, and that BioFoam development may not result in a commercial product on the time table anticipated, or at all. For additional risks impacting the Company's business, see the Risk Factors section of the Company's Annual Report on Form-10-K for the year ended December 31, 2008 and the Company's subsequent Form 10-Q filings. 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.

SOURCE: CryoLife, Inc. - 08/04/2009

CONTACT: D. Ashley Lee, Executive Vice President, Chief Financial
Officer and Chief Operating Officer, +1-770-419-3355; or Katie Brazel,
Fleishman Hillard, +1-404-739-0150
Web Site: http://www.cryolife.com
(CRY)