



CryoLife Announces First Clinical Use of BioFoam(R)

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Newly CE Marked Product Used to Stop Bleeding During Liver Resection

ATLANTA and LONDON, Sept. 10 /PRNewswire-FirstCall/ -- CryoLife, Inc., (NYSE: CRY) an implantable biological medical device and cardiovascular tissue processing company, today announced the first clinical implant of its BioFoam(R) Surgical Matrix, which received CE mark approval in August 2009. BioFoam was used in a liver resection procedure following tumor removal as a supplemental measure to promote hemostasis (a complex process that stops bleeding) by sealing vessels.

"Despite advances in surgical technique, bleeding complications continue to be a problem in liver resection surgery and can be life-threatening," said Professor Brian Davidson, MD, FRCS, Professor of Surgery, Department of Surgery, Royal Free Hospital in London who performed the procedure on September 9. "We are very hopeful that BioFoam will reduce the time required to achieve hemostasis during liver resection surgery and will reduce the number of complications following surgery."

CryoLife is conducting a controlled clinical launch of BioFoam at up to six centers in the United Kingdom, Germany, France and Italy. The objectives of this 45-patient controlled launch, in which BioFoam is used as a surgical hemostatic adjunct in the open repair of liver parenchyma following liver resection and/or liver transplant surgery, are to (1) collect additional clinical data supporting the safety and performance of BioFoam and (2) further refine the optimal application technique.

"The clinical availability of BioFoam is another milestone in the company's corporate objective of providing world-class surgical options for the control of intraoperative bleeding," said Steven G. Anderson, CryoLife president and chief executive officer. "We believe the unique adherence and expansion characteristics of this product make it useful for organ sealing and other future surgical applications. It is a wonderful complement to our existing hemostasis products, BioGlue(R) and HemoStase(TM)."

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 and expects to start enrollment in Q4 2009.

During the *European Association of Cardio-Thoracic Surgery (EACTS) annual meeting* in Vienna, Austria Oct. 17-21, booth 43, CryoLife will be soliciting input from the attendees on potential future clinical applications for the use of BioFoam in cardiothoracic surgery.

About BioFoam

BioFoam, a protein hydrogel biomaterial developed 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 can 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. BioFoam received CE mark approval 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.

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(R) SG pulmonary human heart valve, processed using CryoLife's proprietary SynerGraft(R) technology, has FDA 510(k) clearance for the replacement of diseased, damaged, malformed or malfunctioning native or prosthetic pulmonary valves. 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. The Company's BioFoam(R) Surgical Matrix is CE marked 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. 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 hopes that BioFoam will reduce the time required to achieve hemostasis during liver resection surgery and reduce the number of complications following surgery, potential distribution timing and uses and applications for BioFoam and timing of enrollment in the feasibility phase of the Company's BioFoam IDE submission. 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 BioFoam may not prove safe or effective for its intended uses, that BioFoam may not achieve hemostasis in liver resections or reduce complications following surgery due to any number of factors that we will not be able to identify until further procedures are performed, that BioFoam may not be useful in other future surgical applications, that the Company may not start feasibility phase enrollment in quarter 4 of 2009 due to any number of factors, including unanticipated delays in obtaining FDA and U.S. Department of Defense approval, and that BioFoam development may not result in a commercial product on the time table anticipated, or at all, due to factors beyond our control, including potential lack of acceptance by the medical community. 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>

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