CryoLife Receives FDA Approval to Begin U.S. Clinical Trial for BioFoam(R)

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ATLANTA, Oct. 27 /PRNewswire-FirstCall/ -- *CryoLife, Inc.*, (NYSE: CRY), an implantable biological medical device and cardiovascular tissue processing company, today announced that the U.S. Food and Drug Administration (FDA) has granted approval for the company's Investigational Device Exemption (IDE) to conduct a human clinical trial for its *BioFoam® Surgical Matrix* protein hydrogel technology. BioFoam will be used to help seal liver parenchymal tissue when cessation of bleeding by ligature or other conventional methods is ineffective or impractical.

The approved IDE is for a prospective, multicenter, randomized feasibility study evaluating safety outcomes of BioFoam as compared to a standard topical hemostatic agent. The feasibility investigation will be conducted at two investigational sites and will enroll 20 eligible subjects with 10 subjects in each treatment group. CryoLife now will seek approval from the U.S. Department of Defense (DoD), which will be the final step necessary to begin this trial.

"Following our July 2009 CE Mark approval to distribute BioFoam in the EU, we now have approval to begin a clinical trial, a critical step forward in the process to gain FDA approval of BioFoam in the U.S.," said Steven G. Anderson, CryoLife president and chief executive officer. He added, "We believe that BioFoam may hold tremendous promise for surgeons around the world and are excited by the early data published thus far."

CryoLife is currently conducting a 60-patient controlled clinical launch of BioFoam at up to six centers in the United Kingdom, Germany, France and Italy. 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 worldwide.

Upon successful completion of the feasibility study, and subsequent FDA and DoD approvals, a follow-on prospective, multicenter, randomized, controlled pivotal study will be conducted. It is currently anticipated that the pivotal investigation will enroll a total of 164 eligible subjects, 82 subjects in each treatment group across a maximum of 10 investigational sites.

The primary objective of the pivotal investigation will be to demonstrate a decrease in the time to achieve intraoperative hemostasis (a complex process that causes bleeding to stop) following open liver resection surgery in subjects receiving an application of BioFoam compared to a standard topical hemostatic agent. The secondary objectives of this investigation will be to compare time to hemostasis and the achievement of immediate hemostasis between the BioFoam group and the control group (a standard topical hemostatic agent) to demonstrate that BioFoam is at least equivalent in performance to the control group.

About BioFoam

BioFoam, a protein hydrogel biomaterial developed by CryoLife, contains an expansion agent that 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® 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 or prosthetic pulmonary valves. The Company's CryoPatch® SG pulmonary cardiac patch has FDA 510(k) clearance for the repair or reconstruction of the right ventricular outflow tract (RVOT), which is a surgery commonly performed in children with congenital heart defects, such as Tetralogy of Fallot, Truncus Arteriosus, and Pulmonary Atresia. CryoPatch SG is distributed in three anatomic configurations: pulmonary hemi-artery, pulmonary trunk and pulmonary branch. 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. The Company's BioFoam® 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, timing of enrollment in the feasibility phase of the Company's BioFoam IDE submission and the ability to conduct and details of the follow-on study after the feasibility phase has been completed. 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 early data regarding BioFoam may be more positive than final data, 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 a timely fashion or may not be able to conduct the follow-on study as planned due to any number of factors, including

unanticipated delays or difficulty 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 Dec. 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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