CryoLife Initiates Enrollment in U.S. Clinical Trial for BioFoam®

October 24, 2011

ATLANTA, Oct. 24, 2011 /PRNewswire via COMTEX/ -- CryoLife, Inc., (NYSE: CRY), a leading tissue processing and medical device Company focused on cardiac and vascular surgery, today announced that it has enrolled the first patient in its U.S. Investigational Device Exemption (IDE) clinical trial for its BioFoam® Surgical Matrix protein hydrogel technology. In connection with the trial, BioFoam will be used as an adjunct to conservative measures of achieving hemostasis on newly resected liver parenchyma.

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 up to three investigational sites and will enroll 20 eligible subjects with 10 subjects in each treatment group.

"We are pleased to begin enrolling patients in our IDE study, which is a milestone in our efforts to obtain BioFoam approval for distribution in the U.S.," said Steven G. Anderson, CryoLife president and chief executive officer. "We have worked with FDA on two recent protocol amendments which we think should help speed enrollment into the pilot study. Once it is completed, assuming that the data is positive, we will begin planning for a larger pivotal study to support a PMA application for BioFoam with the FDA. We believe that BioFoam may hold promise for surgeons around the world and are encouraged by the early clinical experience in Europe."

Upon successful completion of the feasibility study in the U.S., and subsequent FDA and Department of Defense approvals, a follow-on prospective, multicenter, randomized, controlled pivotal study is planned. It is currently anticipated that the pivotal investigation would enroll a total of 164 eligible subjects, 82 subjects in each treatment group across a maximum of 10 investigational sites. This data would then be used to support a U.S. Premarket Approval application to allow commercialization of BioFoam in the U.S.

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 control group (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 control group to demonstrate that BioFoam is at least equivalent in performance.

In Europe, CryoLife has completed a 55-patient prospective, multicenter, single-arm study of BioFoam at three centers in the United Kingdom, Germany, and France. The results from this study were presented at the Association of Surgeons of Great Britain and Ireland (ASGBI) Congress in May 2011. The efficacy results show that the time to obtain hemostasis after an application of BioFoam compares favorably to results reported for related products. Analysis of the safety endpoints defined for this study and the collection of adverse events were also consistent with data reported within historical literature. 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 USD and more than $100 million USD worldwide.

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 has 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. CryoLife'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. CryoLife'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. CryoLife'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 and was recently approved in Japan for use in the repair of aortic dissections. CryoLife's BioFoam(TM) 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. CryoLife distributes PerClot®, an absorbable powder hemostat, in the European Community. CryoLife, through its subsidiary Cardiogenesis Corporation, specializes in the treatment of cardiovascular disease and devices that treat severe angina. Its market leading FDA-approved Holmium: YAG laser system and single use fiber-optic delivery systems are used to perform a surgical procedure known as Transmyocardial Revascularization (TMR).

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. Such forward-looking statements reflect the views of management at the time such statements are made and are subject to a number of risks, uncertainties, estimates, and assumptions that may cause actual results to differ materially from current expectations. These statements include those regarding our ability to enroll patients in the pilot study and the speed of such enrollment, our plans for a larger pivotal study to support a PMA application for BioFoam with the FDA, our belief that BioFoam may hold promise for surgeons around the world, our plans for a follow-on prospective, multicenter, randomized, controlled pivotal study subsequent to

FDA and Department of Defense approvals, the anticipated number of eligible subjects that would enroll in the pivotal investigation, plans to use the data from the pivotal investigation to support a U.S. Premarket Approval application to allow commercialization of BioFoam in the U.S., and our estimates regarding the annual European and worldwide market opportunity 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 regulatory approval process and related studies can be time consuming and costly, and our ability to market and distribute BioFoam in the desired jurisdictions may be delayed or denied based on the results of these studies. Studies may also be delayed if we are unable to successfully enroll the requisite number of patients in each respective study in a timely manner. Based on changing conditions in our Company and in the economy generally, management may decide to terminate its pursuit of regulatory approval for BioFoam at any stage in the approval process, and our current plans and timeline for regulatory approval may be altered. Also, BioFoam may not provide the anticipated medical benefits, may not ultimately be accepted by physicians and patients, and competing products and solutions may be developed that adversely impact future BioFoam sales. Our estimates regarding the European and worldwide market for BioFoam may be incorrect and we may not be successful in our attempts to market BioFoam in Europe or in other parts of the world. The potential market for BioFoam could be impacted by a number of factors, including the effectiveness and relative cost of competing products, the impact of future surgical innovations and medical breakthroughs and the perceptions of surgeons and other medical professionals regarding the treatment of liver disease. 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, 2010, 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/.

Contacts:
CryoLife
D. Ashley Lee
Executive Vice President, Chief Financial Officer and
Chief Operating Officer
Phone: 770-419-3355

The Ruth Group
Nick Laudico / Zack Kubow
646-536-7030 / 7020
nlaudico@theruthgroup.com
zkubow@theruthgroup.com

SOURCE CryoLife, Inc.