CryoLife Files Investigational Device Exemption (IDE) to Begin Clinical Trials for PerClot(R) in the U.S.

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CryoLife, Inc. (NYSE: CRY), an implantable biological medical device and cardiovascular tissue processing company, announced today thatit has filed an IDE with the United States Food and Drug Administration (FDA) to begin clinical trials for the purpose of obtaining Pre-Market Approval (PMA) to distribute PerClot in the U.S. to control bleeding during surgical procedures or following traumatic injuries.

PerClot is a unique, absorbable powder hemostat and is intended for use in surgical procedures when control of bleeding by pressure, ligature, and other conventional means is either ineffective or impractical. The therapeutic areas in which PerClot will be used consist of cardiac, general, urological, orthopedic, and neurosurgical procedures. PerClot has CE Mark designation and CryoLife began distributing PerClot in several international markets in the fourth quarter of 2010.

"We're pleased to reach this milestone in the commercialization of PerClot in the U.S.," stated Steven G. Anderson, CryoLife president and chief executive officer. "We plan to begin enrollment in the pivotal trial later this year and hope to have pre-market approval no later than 2013."

The U.S. hemostatic market is estimated to be $732 million in 2010 growing to approximately $1.1 billion in 2014, while the European market is estimated to be $279 million in 2010 growing to approximately $430 million in 2014.(1)

CryoLife's proposed IDE study would include a total of approximately 330 patients in a randomized, prospective, multicenter trial. The primary objective would be to evaluate the hemostatic effectiveness of PerClot versus control hemostatic devices (Gelfoam(R) and Surgicel(R)) at 5 minutes. Efficacy would be assessed by comparing intraoperative time to hemostasis (primary endpoint). The secondary objectives would be to evaluate the proportion of subjects with hemostasis at 1, 3, 7, and 10 minutes after trial treatment. Safety endpoints would include but are not limited to the incidence of reoperation due to bleeding, total hospitalization time, and the incidence of procedure complications and/or adverse events through final patient follow-up.

About PerClot

PerClot is a medical device composed of absorbable polysaccharide particles and delivery applicators. The particles are derived from purified plant starch. PerClot contains no human or animal components. It is intended for use as an absorbable hemostatic system to control bleeding during surgical procedures or following traumatic injuries.

PerClot is ready to use, requiring no mixing and/or other components and does not need special handling or storage conditions. Pre-clinical evaluations, clinical studies and surgical use have shown the efficacy of PerClot to be comparable to the current popular choice of surgical hemostatic materials while its unique formulation allows for superior rapid absorption. PerClot particles are degraded by human enzymes, alpha-amylase and glucoamylase, and by macrophages typically within several days.

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 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 CryoPatch(R) 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(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 and was recently approved in Japan for use in the repair of aortic dissections. The Company'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(R), an absorbable powder hemostat, in the European Community.

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 CryoLife's expanding distribution of PerClot within the European Union and many other markets around the world in the coming months, the estimated growth of the U.S. and European hemostatic market by 2014, and expectations of obtaining FDA approval no later than 2014. 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. There is no guarantee that the FDA will approve PerClot for distribution in the U.S. in accordance with our expected timeframe, if at all. FDA approvals are dependent upon a number of factors, many of which are outside CryoLife's control, including successful clinical trial results, and discretionary decisions made by the FDA personnel. Any number of factors could delay clinical trial conduct and analysis and result in delays in the approval process. CryoLife's IDE application could be denied by the FDA, and if the application is approved, the clinical trials that follow may not be successful in leading to approval for our distribution of PerClot in the U.S. Growth of U.S. and European hemostatic markets is subject to a number of factors, including economic conditions, technology advances and competition from other products. CryoLife's business is also subject to a number of risks and uncertainties, including the risk factors detailed in our Securities and Exchange Commission filings, including our Form 10-K filing for the year ended December 31, 2010, and the Company's other SEC 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.

(1) Millennium Research Group (MRG) Report - US Markets for Surgical Hemostats, Internal Tissue Sealants and Adhesion Barriers 2009 RPUS20SA08, page 25. Frost and Sullivan Report - European Tissue Sealants and Topical Hemostats Market M2F8-54 Oct 2008, Page 45.

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