CryoLife Receives Conditional IDE Approval to Begin Clinical Trials for PerClot@ in the U.S.

The Associated Press

CryoLife, Inc. (NYSE: CRY), a leading tissue processing and medical device Company focused on cardiac and vascular surgery, announced today that it has received conditional approval of its Investigational Device Exemption (IDE) for PerClot from the United States Food and Drug Administration (FDA).

PerClot is a unique hemostat composed of absorbable polysaccharide granules and is intended for use in surgical procedures as an adjunctive hemostatic device when control of capillary, venular, and arteriolar bleeding by pressure, ligature, and other conventional means is ineffective or impractical. PerClot has CE Mark designation and CryoLife began distributing PerClot in several international markets in the fourth quarter of 2010. PerClot international sales were up 34 percent in the first quarter of 2013 compared to the first quarter of 2012.

"We're pleased to reach this initial milestone toward the commercialization of PerClot in the U.S.," stated Steven G. Anderson, CryoLife president and chief executive officer. "Subject to satisfaction of the FDA's conditions, we plan to begin enrollment in the pivotal trial in the third quarter of 2013, and hope to have pre-market approval in 2015." The U.S. hemostatic market is estimated to be $889 million in 2012 growing to approximately $1.1 billion in 2014, while the European market is estimated to be $361 million in 2012 growing to approximately $430 million in 2014.[1] The PerClot IDE is a prospective, multicenter, multidisciplinary, controlled clinical investigation. The primary objective of this investigation will be to collect clinical data concerning the safety and efficacy of PerClot versus a similar marketed hemostatic device in multiple surgical disciplines when used as an adjunct to conventional means of achieving hemostasis such as pressure or ligature. The primary efficacy endpoint of this investigation will be achievement of hemostasis at the site of application at 5 minutes following application of the prescribed hemostatic agent. The secondary efficacy endpoint for this investigation will be hemostasis at the site of application evaluated at 2 minutes. Safety endpoints will include, but are not limited to, the incidence of reoperation due to bleeding, total hospitalization and procedure time, and the incidence of procedure complications and/or adverse events through final patient follow-up.

As part of the conditional approval for the PerClot IDE, CryoLife must make certain revisions to the investigational study protocol, clinical product labeling and Patient Informed Consent forms. The Company anticipates refiling the IDE submission in July. The Company expects to begin enrollment in the general and urological surgical cohorts during the third quarter. The Company will have further discussions with the FDA to clarify the requirements prior to enrollment in the cardiac and orthopedic indications.

About PerClot PerClot is a medical device composed of absorbable polysaccharide granules and delivery applicators. The granules are biocompatible, non-pyrogenic, and derived from purified plant starch. The granules do not contain any human or animal components. PerClot granules have a molecular structure that rapidly absorbs water, forming a gelled adhesive matrix that provides a mechanical barrier to further bleeding and results in the accumulation of platelets, red blood cells, and coagulation proteins (thrombin, fibrinogen, etc.) at the site of application. One gram of PerClot absorbs at least 19 mL of water.

The gelled adhesive matrix thus promotes the normal physiological clotting cascade. PerClot granulaes are enzymatically degraded by alpha-amylase and glucoamylase and by macrophages. Based on preclinical studies, absorption normally requires several days and is dependent on the amount of material applied on the wound and the site of use.

PerClot is intended for use in surgical procedures as an adjunctive hemostatic device when control of capillary, venular, and arteriolar bleeding by pressure, ligature, and other conventional procedures is ineffective or impractical.

PerClot is ready to use, requiring no mixing and/or other components and does not need special handling or storage conditions. Preclinical 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.

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., certain countries in Europe, 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 congenital heart defects. 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 for use in soft tissue repair and approved in Japan for use in the repair of aortic dissections. Additional marketing approvals for BioGlue have been granted in several other countries throughout the world.

CryoLife, through its subsidiary Cardiogenesis Corporation, specializes in the treatment of coronary artery disease for severe angina using a laser console system and single use, fiber-optic handpieces to perform a surgical procedure known as Transmyocardial Revascularization (TMR). In addition, CryoLife and its subsidiary Hemosphere, Inc. market the HeRO@ Graft, which is a solution for end-stage renal disease in certain hemodialysis patients. CryoLife distributes PerClot@, an absorbable powdered hemostat, in the European Community and other select international countries. CryoLife's BioFoam@ Surgical Matrix is CE marked in the European Community for use as an adjunct to hemostasis in cardiovascular surgery

and on abdominal parenchymal tissues (liver and spleen) when control of bleeding by ligature or conventional methods is ineffective or impractical.

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 22. Frost and Sullivan Report - European Tissue Sealants and Topical Hemostats Market M2F8-54 Oct 2008, Page 95.

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