CryoLife Receives FDA Approval to Begin Clinical Trials for PerClot® in the U.S.

April 2, 2014

ATLANTA, April 2, 2014 /PRNewswire/ -- CryoLife, Inc. (NYSE: CRY), a leading medical device and tissue processing company focused on cardiac and vascular surgery, announced today that it has received approval of its Investigational Device Exemption (IDE) for PerClot from the United States Food and Drug Administration (FDA). This approval allows CryoLife to begin its pivotal clinical trial to gain approval to commercialize PerClot in the U.S. The Company plans to begin enrollment in the trial in the second quarter of 2014, and could potentially receive pre-market approval from the FDA by the end of 2015.

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.

The PerClot IDE is a prospective, multicenter, multidisciplinary, controlled clinical investigation. The study will include 320 patients across cardiac, general and urological surgical specialties. The primary objective of this investigation will be to collect clinical data concerning the safety and efficacy of PerClot versus C.R. Bard's Arista MPH Hemostat 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 five 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 two 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 at three months.

"We're pleased to have received this approval, which will allow us to begin our U.S. clinical trial for PerClot," stated Steven G. Anderson, CryoLife president and chief executive officer. "Based on the anticipated enrollment and follow up timeline, we could potentially receive pre-market approval for PerClot by the end of 2015."

The U.S. hemostatic market is estimated to have been $780 million in 2013 growing to approximately $915 million by 2016, while the European market is estimated to have been $395 million in 2013 growing to approximately $468 million by 2016.[1]

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. 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.

About CryoLife, Inc.

CryoLife, Inc. is a leader in medical device manufacturing and distribution and in the processing and distribution of implantable living human tissues for use in cardiac and vascular surgeries. It operates throughout the U.S. and internationally. CryoLife manufactures and distributes BioGlue® Surgical Adhesive, an FDA-approved adjunct to sutures and staples for use in adult patients in open surgical repair of large vessels. BioGlue is also CE marked in Europe for use in soft tissue repair and has received additional marketing approvals in several other countries throughout the world. CryoLife's BioFoam® Surgical Matrix is CE marked in Europe 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 powdered hemostat, in Europe and other select international countries. 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). CryoLife and its subsidiary Hemosphere, Inc. market the HeRO® Graft, which is a solution for end-stage renal disease in certain hemodialysis patients. 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.

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 the timing, plans and expectations related to the clinical testing and pre-market approval of PerClot, as well as the estimated growth of the U.S. and European hemostatic markets by 2016. Risks potentially impacting these statements include the following: 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. Clinical trials are subject to a number of risks, including unanticipated reactions or results, and we may ultimately be unsuccessful in our clinical trials and/or may be unable to obtain FDA approval to market PerClot in the U.S. Our approval efforts,

including clinical testing and regulatory submissions, for PerClot in the U.S. are subject to delays and cost overages, and management plans with respect to clinical testing, regulatory submissions and regulatory approvals are subject to change at any time based on the overall needs of the Company. Even if we receive approval, we may be unsuccessful in our attempts to sell PerClot in the U.S. as other competing products may have penetrated the market by that time. In addition, if we ultimately sell PerClot in the U.S., we will likely end up in a patent infringement lawsuit with C.R. Bard's Medafor, Inc. subsidiary, which will be expensive. If we lose, we may be prohibited from selling PerClot in the U.S. or may have to pay substantial royalties or damages when we sell PerClot in the U.S. Our ability to fully realize our investment in Starch Medical, Inc. is dependent on our ability to sell PerClot in the U.S. at a reasonable rate of return, which may be materially negatively impacted by any royalty that we might be required to pay. Growth of U.S. and European hemostatic markets is subject to a number of factors, including economic conditions, government regulations, patient and physician acceptance, technology advances and competition from other products. Our estimates regarding the growth of the hemostatic markets may be incorrect, and the markets may shrink, or fail to grow as expected, due to factors beyond our control, including general economic conditions. To the degree that our estimates regarding the growth of the hemostatic markets are correct, there is no guarantee that we will successfully grow sales within these markets. 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, 2013 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 2013 RPUS20SA13, page 47. Frost and Sullivan Report – European Tissue Sealants and Topical Hemostats Market M2F8-54 Oct 2008, Page 95.

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.