CryoLife Receives FDA 510(k) Clearance for PerClot® Topical Hemostatic Powder in the U.S.

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Requests Court Confirmation that PerClot Does Not Infringe Bard Patent

ATLANTA, April 29, 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 510(k) clearance for PerClot Topical hemostatic powder from the U.S. Food and Drug Administration (FDA). This clearance allows CryoLife to begin commercialization of PerClot Topical hemostatic powder in the U.S. The Company plans to begin shipping PerClot Topical hemostatic powder in June of this year.

"We are pleased to have received 510(k) clearance for PerClot Topical in the U.S.," stated Steven G. Anderson, CryoLife president and chief executive officer. "We expect to begin commercialization efforts in June and to focus on the ENT specialty through a combination of our existing sales force and distributors experienced with a competitive product. Many of our existing hospital customers also have large ENT practices, providing a natural opportunity for PerClot Topical. Longer term, we believe we will be able to expand PerClot Topical to additional markets such as the emergency room."

PerClot Topical is a unique hemostat composed of polysaccharide granules and is intended for use as a topical dressing for the temporary treatment of mildly bleeding wounds such as surgical wounds (post-operative, donor sites, dermatological, etc.), cuts and lacerations and for the treatment of mild bleeding from topical ENT surgical wounds and nosebleeds. It is also indicated for control of bleeding from the skin at percutaneous needle access, vascular access and percutaneous catheter access sites.

PerClot Topical is ready to use, requiring no mixing and/or other components and does not need special handling or storage conditions. Preclinical evaluations have shown the effectiveness of PerClot Topical to be comparable to the current popular choice of surgical hemostatic materials.

PerClot Topical is the same product as PerClot, which has received an Investigational Device Exemption (IDE) from the FDA for a pivotal clinical trial 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. The Company plans to begin enrollment in the pivotal clinical trial for PerClot in the second quarter of 2014, and could potentially receive pre-market approval from the FDA by the end of 2015.

Management estimates the U.S. hemostatic market for PerClot Topical in procedures included in the 510(k) clearance to be in excess of $100 million, while the U.S. hemostatic market for all procedures is estimated to have been $780 million in 2013, growing to approximately $915 million by 2016 and the European market is estimated to have been $395 million in 2013, growing to approximately $468 million by 2016.[1]

Declaratory Judgment Action

CryoLife also announced today that it has filed a declaratory judgment action against C.R. Bard, Inc. and certain of its subsidiaries (collectively, Bard) in federal court, requesting that the court confirm that CryoLife's anticipated sales of PerClot (once it has received final FDA approval) and certain of its derivative products (including PerClot Topical) will not infringe upon patents held by Bard. CryoLife filed the declaratory judgment action in the U.S. District Court for the District of Delaware.

Mr. Anderson noted, "We believe that our sales of PerClot Topical and PerClot (once approved by the FDA) will not infringe the Bard patent, and we are optimistic that the court will affirm our position."

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®, a powdered hemostat, in Europe and other select international countries. CryoLife has received FDA 510(k) clearance for a topical version of PerClot and is conducting a pivotal clinical trial in the U.S. for potential FDA approval of the surgical version of PerClot that is currently distributed outside of the U.S. 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 commercialization and distribution of, and expanded indication opportunities for, PerClot Topical in the U.S.; expectations regarding the timing of the clinical testing and pre-market approval of PerClot; estimates regarding the U.S. and European hemostatic market size; and the anticipated outcome of our declaratory judgment action filed against Bard. Risks potentially impacting these statements include the following: There is no guarantee that we will complete our PerClot Topical commercialization and distribution efforts in accordance with our expected timeframes. Even if we complete our commercialization and distribution efforts timely, we may be unsuccessful in our attempts to sell PerClot Topical in the U.S. or for specific markets, such as ENT and emergency room procedures, as other competing products may have penetrated the market by that time. There is also 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. The estimated U.S. and European topical and total hemostatic markets may ultimately be smaller and/or more difficult, time-consuming, and/or expensive to penetrate than the Company anticipates. Our declaratory judgment action against Bard will be expensive; it may continue for longer and be costlier than we anticipate; we may incur costs associated with the action earlier or later than we anticipate; and there is no guarantee that we will ultimately prevail. If we do not prevail in such action, or if Bard obtains an injunction, we may be prohibited from selling PerClot and PerClot Topical in the U.S., or we may have to pay substantial royalties or damages when we sell PerClot or PerClot Topical in the U.S. Our ability to fully realize our investment in Starch Medical, Inc. is dependent on our ability to sell PerClot and PerClot Topical 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. 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.

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