CryoLife Announces Enrollment of First Patient in PerClot® IDE Clinical Trial

April 28, 2015

ATLANTA, April 28, 2015 /PRNewswire/ -- CryoLife, Inc. (NYSE: CRY), a leading medical device and tissue processing company focused on cardiac and vascular surgery, announced today the enrollment of the first patient in its PerClot Investigational Device Exemption (IDE) clinical trial, the Company's pivotal clinical trial to gain approval to commercialize PerClot in the U.S.

"The first patient enrolled in the PerClot IDE clinical trial is a positive milestone for the Company and our strategy to expand indications for our products," stated Pat Mackin, CryoLife Chairman, President, and Chief Executive Officer. "We will be working to bring other trial sites online in the coming months, positioning us to complete enrollment in the trial in the first half of 2016. With a three-month follow-up period, we would anticipate obtaining FDA approval for PerClot in the second half of 2017."

"As surgeons, we are continually confronted with controlling surgical bleeding," stated Arthur Coffey, MD, Cardiac Surgeon and PI for the PerClot IDE at Indiana University Health. "We are excited to have the opportunity to evaluate this innovative technology, using a validated bleeding scale, for its ability to control bleeding during cardiac and general surgery." Michael House, MD, General Surgeon at Indiana University Health commented that "this trial is the first of its kind and represents the future for evaluating hemostatic devices desiring market approval. We are excited to announce enrollment of the first patient into this important clinical trial to evaluate PerClot in the U.S."

The PerClot IDE is a multicenter, multidisciplinary, controlled clinical investigation. The study will include 324 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 seven 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 five 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.

About PerClot

PerClot is a medical device composed of 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 are hydrophilic, allowing PerClot to rapidly absorb 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 clean 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 selection of popular surgical hemostatic materials. PerClot has CE Mark designation, and CryoLife began distributing PerClot in several international markets in the fourth quarter of 2010.

About CryoLife, Inc.

Headquartered in suburban Atlanta, Georgia, CryoLife is a leader in the manufacturing, processing, and distribution of implantable living tissues and medical devices used in cardiac and vascular surgical procedures. CryoLife markets and sells products in more than 75 countries worldwide. For additional information about CryoLife, visit our website, www.cryolife.com.

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 anticipated timing and benefits of the PerClot IDE clinical trial and our strategy to gain new indications and regulatory approvals for our products. The risks and uncertainties affecting these statements include that: there is no guarantee that the FDA will approve the surgical version of PerClot for distribution in the U.S. in accordance with our expected timeframe, or at all; clinical trials are subject to a number of risks, including unanticipated reactions or results, delays, and cost overages, and we may ultimately be unsuccessful in our clinical trial; as part of our patent litigation against Medafor, Inc. regarding PerClot (the "Medafor Litigation"), we have been enjoined from selling, marketing, and distributing PerClot in the U.S.; there is no guarantee that we will ultimately prevail in the Medafor Litigation, and if we do not prevail, we will continue to be prohibited from selling PerClot in the U.S., or we may have to pay substantial

royalties to sell PerClot in the U.S., until Medafor's patent expires. These risks and uncertainties include the risk factors detailed in our Securities and Exchange Commission filings, including our Form 10-K for the year ended December 31, 2014 and our subsequent filings with the SEC. CryoLife does not undertake to update its forward-looking statements.

Contacts:

CryoLife	**The Ruth Group**
D. Ashley Lee	Nick Laudico / Zack Kubow
Executive Vice President, Chief Financial Officer and Chief Operating Officer	646-536-7030 / 7020
Phone: 770-419-3355	nlaudico@theruthgroup.com
	zkubow@theruthgroup.com

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