



CryoLife Begins Distribution of Blood-Clotting Agent PerClot(R) in Europe

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European Distribution Comes on Heels of Worldwide Distribution and Manufacturing Agreement with Starch Medical, Inc.

ATLANTA, Oct 25, 2010 /PRNewswire via COMTEX/ -- CryoLife, Inc. (NYSE: CRY), an implantable biological medical device and cardiovascular tissue processing company, announced today that it has begun European distribution of PerClot(R), a novel polysaccharide hemostatic agent used to control bleeding during surgical procedures or following traumatic injuries.

"PerClot is an exciting technology platform that has seen success in Europe already, and we are pleased to begin offering this product in France," stated Steven G. Anderson, CryoLife president and chief executive officer. "Our international and largely unrestricted distribution agreement allows us to address a very broad range of medical specialties in the growing hemostatic agent market. We look forward to expanding distribution within the European Union and many other markets around the world in the coming months."

The European hemostatic market is estimated to be \$279 million in 2010 growing to approximately \$430 million in 2014.(1)

On September 28, 2010, CryoLife entered into a worldwide distribution agreement and a manufacturing agreement with Starch Medical Inc. (SMI) of San Jose, California for PerClot, a unique, absorbable powder hemostat that has CE Mark designation allowing commercial distribution into the European Community and other markets. PerClot is indicated for use in surgical procedures, including cardiac, vascular, orthopedic, spinal, neurological, gynecological, ENT and trauma surgery as an adjunct hemostat when control of bleeding from capillary, venous, or arteriolar vessels by pressure, ligature, and other conventional means is either ineffective or impractical.

CryoLife plans to file an Investigational Device Exemption (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.

About PerClot

PerClot is a medical device composed of absorbable modified polymer (AMP(R)) particles and delivery applicators. AMP 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 rapid absorption. PerClot particles are readily dissolved by saline irrigation and are degraded rapidly by human enzymes, primarily amylase, 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. CryoLife currently distributes HemoStase(R), a hemostatic agent, in much of the U.S. for use in cardiac and vascular surgery and in many international markets for cardiac, vascular, and general surgery, subject to certain exclusions, although CryoLife has received notice from Medafor, Inc. that it has terminated its HemoStase distribution agreement with CryoLife.

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 European hemostatic market by 2014, and CryoLife's plans to file an IDE with the FDA to begin clinical trials for the purpose of obtaining a PMA to distribute PerClot in the U.S. 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. These risks and uncertainties include that we may not ultimately be successful in our attempts to expand our distribution into other markets or such expansion may take longer than expected. Depending on the market, we may still need to obtain regulatory approvals prior to distribution and there is no guarantee that such approvals and/or market acceptance of PerClot will be obtained within our expected timeframe, if at all. Also, some degree of confusion regarding our position in various markets may exist because of our past difficulties with Medafor and our distribution of HemoStase, and our ability to leverage opportunities related to PerClot may take longer than expected and require more resources from us in order to educate the market. Given the addition of PerClot to our product mix and any resultant confusion this may cause, there is no guarantee that we will not experience short-term difficulties in our efforts to successfully expand into other markets. The European hemostatic market may not continue to grow as expected due to any number of economic or regulatory factors or as the result of the advantages of or pricing competition from competitive products. 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. 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-Q filing for the quarter ended June 30, 2010, our Form 10-Q filing for the quarter ended March 31, 2010 and our Form 10-K filing for the year ended December 31, 2009, 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) Frost and Sullivan Report - European Tissue Sealants and Topical Hemostats Market M2F8-54 Oct 2008, Page 45.

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