CryoLife Enters into Worldwide Distribution and Manufacturing Agreements with Starch Medical for Novel Hemostatic Agent

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ATLANTA, Sept 28, 2010 /PRNewswire via COMTEX/ --

CryoLife, Inc. (NYSE: CRY), an implantable biological medical device and cardiovascular tissue processing company, announced today that it has entered into a worldwide distribution agreement and a manufacturing agreement with Starch Medical Inc. (SMI) of San Jose, California for PerClot(R), a novel polysaccharide hemostatic agent used in surgery.

PerClot is a unique, absorbable powder hemostat that has CE Mark designation allowing commercial distribution into the European Community and other markets. It 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.

"PerClot is an exciting technology platform that has already seen significant success in Europe. Its unique formulation allows for full and rapid absorption, while showing excellent hemostatic capabilities. We are very pleased to have secured the rights to this second generation hemostatic agent and its laparoscopic delivery devices via an agreement that will allow us to serve a broader range of medical specialties and leverage the continued opportunities in the large and growing hemostatic agent market," said Steven G. Anderson, president and chief executive officer.

The U.S. hemostatic market is estimated to be $732 million in 2010 growing to approximately $1.1 billion in 2014, while the European market is estimated to be $279 million in 2010 growing to approximately $430 million in 2014.(1)

CryoLife intends to distribute both PerClot and HemoStase(R) until CryoLife can no longer sell HemoStase as a result of Medafor's termination of the parties' distribution agreement for HemoStase. Alternatively, CryoLife believes that in accordance with the terms of the agreement, at its sole discretion, CryoLife can return its inventory of HemoStase to Medafor for reimbursement. CryoLife anticipates that it will commence distribution of PerClot in several international markets in the fourth quarter of 2010 and will obtain U.S. FDA approval by the end of 2013.

"We were restricted by Medafor's continued attempts to terminate our agreement, including interruptions in product shipments. In addition, our agreement with Medafor limited our ability to sell HemoStase in all surgical specialties. Our international and largely unrestricted distribution agreement with SMI for PerClot addresses these issues and allows us to remain active in this important market," said Mr. Anderson.

Transaction Terms

Under the terms of the agreements, CryoLife receives the worldwide rights, excluding China, Taiwan, Hong Kong, Macau, North Korea, Iran and Syria, to commercialize PerClot for all approved surgical indications and a license to manufacture the PerClot product, exclusive of rights to sell PerClot with an endoscope.

As part of the transaction, CryoLife will pay SMI $6.75 million in cash and $1.25 million in restricted CryoLife stock, which includes $1.5 million in prepaid royalties. CryoLife will pay an additional $2.75 million to SMI if certain FDA regulatory and other commercial milestones are achieved, and will also pay royalties on sales of PerClot manufactured by CryoLife.

The PerClot distribution agreement contains certain minimum purchase requirements and has a term of 15 years. CryoLife may begin manufacturing PerClot from plant starch modified by SMI once the technology transfer from SMI has been completed, which is anticipated to occur sometime in 2011 or 2012. Following the technology transfer and U.S. regulatory approval, CryoLife may terminate the distribution agreement. In addition to allowing CryoLife to manufacture PerClot, the license agreement grants CryoLife a three-year option to purchase the remaining technology from SMI.

CryoLife estimates that the costs to develop PerClot and gain U.S. FDA approval will be between $5.0 million and $6.0 million, of which up to $750,000 is expected to be incurred in the fourth quarter of 2010 and the remainder over the next six to eight quarters. Additionally, the Company estimates that it will incur up to $300,000 in product launch and other costs related to PerClot in the fourth quarter of 2010. The Company will update its 2010 financial guidance and issue its initial 2011 financial guidance on its third quarter financial conference call.

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

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 human 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. The Company's BioFoam(R) 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 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 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 plans to file an IDE to begin clinical trials for the purpose of obtaining a PMA to distribute PerClot in the U.S., our belief that the agreements with SMI will allow us to leverage the continued opportunities in the hemostatic agent market, growth expectations regarding the hemostatic market, our intention to distribute both PerClot and HemoStase subsequent to Medafor's termination of our distribution agreement with it, our anticipation that we will commence distribution of PerClot in several international markets in the fourth quarter of 2010 and that we will obtain U.S. FDA approval by the end of 2013, our anticipated timeframe for completing the technology transfer from SMI, CryoLife's estimated cost to acquire and develop PerClot and gain FDA approval, as well as the timing of such incurred costs, and CryoLife's estimated cost in the fourth quarter of 2010 for the product launch and other costs related to PerClot. 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 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. Also, our agreements with SMI may not ultimately lead to significant penetration into a broader range of the market or such penetration may take longer than expected. The 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; and because of confusion regarding CryoLife's position in this market stemming from past difficulties with Medafor and our distribution of HemoStase, 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 and any resultant confusion this may cause, there is no guarantee that we will not experience short-term reductions in our sales in this market as we transition to distributing both HemoStase and PerClot. Additionally, we may not be able to efficiently distribute both PerClot and HemoStase as Medafor has terminated our distribution agreement. Medafor's termination of our distribution agreement with it may exacerbate any confusion in the market regarding our ability to distribute HemoStase and our customers and distributors may lose confidence in our ability to effectively distribute HemoStase and cease purchasing from us; and Medafor is likely to increase its efforts to sell product directly into our exclusive territory and field, which may have a material, adverse impact on our HemoStase sales in the remainder of 2010 and thereafter. In addition, Medafor could attempt to take legal action to inhibit or prevent our sales of HemoStase or otherwise fail to comply with the termination provisions of the distribution agreement with Medafor. Also, pursuant to the terms of the distribution agreement with Medafor, we may choose to return our inventory of HemoStase to Medafor for reimbursement instead of continuing to distribute HemoStase. Our ability to successfully begin distribution of PerClot by the fourth quarter of 2010 is dependent upon our ability to market the product and encourage customers and distributors to purchase the product. There is no guarantee that the FDA will approve PerClot for distribution in the U.S. by the end of 2013, 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. The technology transfer from SMI is subject to delays, human error and technological malfunctions, and may take longer to complete than expected. CryoLife's estimates regarding the costs of the acquisition and development of PerClot and the related FDA approval are only estimates, and given the early stages in the consideration of the FDA approval process for PerClot in which they are made, actual expenses may be significantly higher than expected and may be incurred sooner or later than expected. Also, CryoLife may incur higher costs in the fourth quarter of 2010 for the product launch and other costs related to PerClot, as we are still in the early stages of our experience with SMI and PerClot. 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.

Media Contacts:

D. Ashley Lee

Executive Vice President, Chief Financial Officer and

Chief Operating Officer

Phone: 770-419-3355

Nina Devlin

Edelman

Phone: 212-704-8145

(1) Millennium Research Group (MRG) Report - US Markets for Surgical Hemostats, Internal Tissue Sealants and Adhesion Barriers 2009 RPUS20SA08, page 25. Frost and Sullivan Report - European Tissue Sealants and Topical Hemostats Market M2F8-54 Oct 2008, Page 45.

SOURCE CryoLife, Inc.