



CryoLife Receives Japanese Regulatory Approval for BioGlue Surgical Adhesive

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ATLANTA, Oct 07, 2010 /PRNewswire via COMTEX/ -- CryoLife, Inc. (NYSE: CRY), an implantable biological medical device and cardiovascular tissue processing company, today announced that its BioGlue Surgical Adhesive has received Shonin approval from the Japanese Ministry of Health, Labor and Welfare (MHLW) for use in the repair of aortic dissections.

CryoLife's partner Century Medical, Inc. (CMI) will distribute BioGlue in Japan for use in this subset of cardiac surgery. Prior to distribution, MHLW will need to complete certain additional steps, most notably an on-site inspection of CryoLife pursuant to Japanese Quality Management System requirements and required product reimbursement paperwork for Japanese authorities. As a result, management estimates that distribution in Japan will begin in the first half of 2011. CryoLife will remain the exclusive supplier of BioGlue to CMI.

"We are pleased to have received Japanese approval for the use of BioGlue in the repair of aortic dissections, a potentially life-threatening condition if not properly repaired," stated Mr. Akira Hoshino, president and chief executive officer of CMI. "We believe that BioGlue is a valuable tool that will address many issues facing cardiac surgeons in Japan."

"We are pleased that BioGlue is approved for this initial use in Japan. We estimate Japan to be the second largest market in the world for surgical hemostats and sealants," said Steven G. Anderson, president and chief executive officer, CryoLife, Inc. "Estimated to have been used in more than 600,000 procedures worldwide, BioGlue has proven to be a safe, efficacious product, and we look forward to continuing to expand both its applications and availability worldwide."

The company estimates that the annual Japanese market for the use of surgical adhesives in the repair of aortic dissection is approximately \$10 million, and the total annual market for the use of adhesives and sealants in Japan is approximately \$150 million.

About BioGlue

BioGlue is a two-component adhesive that creates a flexible, mechanical seal, independent of the body's clotting mechanism, within 20 to 30 seconds, and reaches its maximum bonding strength in two to three minutes.

The Company's BioGlue Surgical Adhesive is FDA approved as an adjunct to sutures and staples for use in adult patients in open surgical repair of large vessels, and is CE-marked in the European Community. In addition, BioGlue is approved in Canada for use in soft tissue repair and in Australia for use in vascular and pulmonary sealing and repair.

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. 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. In late September, CryoLife entered into a distribution agreement for PerClot(R), an absorbable powder hemostat that has CE Mark designation allowing commercial distribution into the European Community. CryoLife currently distributes HemoStase(TM), 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. For additional information about the company, visit CryoLife's Web site: <http://www.cryolife.com/>.

About Century Medical

Century Medical, Inc. (CMI) is one of the largest independent medical device distributors in Japan. With over 30 years experience marketing medical devices in Japan, CMI has been a pioneering force successfully introducing many new technologies to the Japanese healthcare community. CMI maintains six regional sales offices and employs over 200 highly trained field sales and marketing people throughout Japan providing direct nation-wide sales coverage.

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 management's estimate that distribution of BioGlue in Japan will begin in the first half of 2011, the belief that BioGlue is a valuable tool that will address many issues facing cardiac surgeons in Japan, and CryoLife's anticipated continuing expansion of BioGlue's applications and availability worldwide. 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 distribution of BioGlue in Japan is subject to additional steps, including an on-site inspection, and the on-site inspection and other regulatory procedures may not be completed as soon as expected and authorities may withhold final approval based on the findings of their inspection, all of which may delay commencement of the distribution of BioGlue in Japan beyond the first half of 2011. Also, CryoLife may be unsuccessful in its attempts to expand BioGlue's applications and availability worldwide, as such expansion is subject to regulatory approval

and market acceptance in various jurisdictions and countries, and Japanese approval of BioGlue for use in a specific subset of cardiac surgery does not guarantee that requisite approvals and/or market acceptance will be obtained for the product in other jurisdictions or for other applications in Japan, and it is unlikely that BioGlue will address any significant issues facing cardiac surgeons in Japan outside of aortic dissections unless and until additional approvals are obtained. Additional Japanese approvals could be extremely costly and/or time consuming, as was the aortic dissection approval, which took over ten years to obtain. Even if the required cost and time are invested, there is no guarantee that any additional approvals can be obtained. 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.

Media Contacts:

D. Ashley Lee

Phone: 770-419-3355

Executive Vice President, Chief Financial

Officer and Chief Operating Officer.

Dana Hartline

Vice President, Edelman

Phone: 404-262-3000

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