



CryoLife Launches BioGlue(R) Surgical Adhesive in Japan

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CryoLife, Inc. (NYSE: CRY), an implantable biological medical device and cardiovascular tissue processing company, today announced that its [BioGlue Surgical Adhesive](#) has launched in Japan and is expected to be available in hospitals by late May 2011.

[BioGlue received Shonin approval from the Japanese Ministry of Health, Labor and Welfare \(MHLW\)](#) for use in the repair of aortic dissections in September 2010. Prior to distribution, MHLW completed a remote inspection of CryoLife pursuant to Japanese Quality Management System requirements and required product reimbursement paperwork for Japanese authorities.

CryoLife's partner, Century Medical, Inc. (CMI) will distribute BioGlue in Japan for use in this subset of cardiac surgery. 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 615,000 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. The initial order is expected to be shipped in late April or early May and the Company estimates approximately \$600,000 in sales for the first 12 months to CMI, our exclusive distribution partner in Japan. As a part of its product launch, CMI and the Company provided an introduction of BioGlue to approximately 110 physicians during [The Japanese Society of Cardiovascular Surgery conference in Tokyo in February](#), and renowned cardiac surgeon, Dr. John W. Fehrenbacher provided clinical data related to BioGlue usage at [The Japanese Society for Vascular Surgery](#) in Okinawa in April.

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 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. In late September 2010, 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 and other markets. 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 CryoLife's or CMI's management's beliefs, expectations or hopes are forward-looking statements. These statements include those regarding the expectation that BioGlue will be available in hospitals in Japan by late May 2011, the belief that BioGlue will address many issues facing cardiac surgeons in Japan, the expectation that CryoLife will continue to expand BioGlue's applications and availability worldwide, and estimated BioGlue sales for the first 12 months in Japan. These future events may not occur as and when expected, if at all, and, together with CryoLife's business, are subject to various risks and uncertainties. These risks and uncertainties

include that the availability of BioGlue in hospitals in Japan by late May 2011 may be delayed by various factors beyond the control of CryoLife, including regulatory and logistical issues, the belief that BioGlue will address many issues facing cardiac surgeons in Japan will ultimately be determined by surgeons and regulators in Japan, and approvals for additional uses may not be approved and, even if approved, Japanese surgeons may choose other methods and products for meeting the needs of their patients, CryoLife's ability to expand BioGlue's applications and availability worldwide may be delayed or prohibited altogether by market forces, including the development of competing products and the changing demands of consumers and surgeons, and government regulators in various jurisdictions, estimated BioGlue sales for the first 12 months in Japan may be lower than expected, particularly as sales in a new market are difficult to predict and will be subject to the ability of CMI and its salespeople to successfully market the product and compete with competing products. CryoLife's business is also subject to a number of risks and uncertainties, including the risk factors detailed in CryoLife's Securities and Exchange Commission filings, including its Form 10-K filing for the year ended December 31, 2010, and CryoLife's other SEC filings. CryoLife does not undertake to update its forward-looking statements.

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