



CryoLife Announces Enrollment of First Patients in BioGlue® Clinical Trial in China

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ATLANTA, Nov. 6, 2017 /PRNewswire/ -- **CryoLife, Inc. (NYSE: CRY)**, a leading medical device and tissue processing company focused on cardiac and vascular surgery, announced today that enrollment has started in the Company's BioGlue clinical trial in China. The results from the trial will serve as the basis of the Company's regulatory submission to the Chinese Food and Drug Administration (CFDA) to gain approval to commercialize BioGlue in China. Patients are currently being enrolled at multiple heart centers in China.



"The initiation of patient enrollment in our BioGlue China clinical trial is a positive milestone that supports our effort to expand our global presence in key markets," stated Pat Mackin, CryoLife Chairman, President, and Chief Executive Officer. "We estimate there are more than 40,000 aortic surgeries in China each year, which represents a significant growth opportunity for BioGlue. We anticipate trial enrollment and follow up will take about one year, which would put us on track for potential CFDA approval of BioGlue by the end of 2019."

Li-Zhong Sun, MD, Cardiac Surgeon at Anzhen Hospital in Beijing and primary investigator for the BioGlue clinical trial in China, said, "BioGlue has been used for many years in the U.S., Europe and other Asian countries to successfully treat patients with aortic dissections and in other cardiac surgery procedures. We are pleased to begin the BioGlue clinical trial in China in order to bring this important product to Chinese patients."

The BioGlue clinical trial in China is a prospective, multicenter, randomized, controlled clinical investigation. The study will enroll 195 patients across seven sites. The trial will assess treatment of Chinese patients with acute type A aortic dissections with standard-of-care procedures with and without BioGlue as an adjunct for structural repair and hemostasis. The primary efficacy endpoint of the study will be successful closure of the false lumen as determined by intraoperative transesophageal echocardiography (TEE). The closure will also be measured at the time of patient discharge by computed tomography angiography (CTA).

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.

Headquartered in suburban Atlanta, Georgia, CryoLife is a leader in the manufacturing, processing, and distribution of medical devices and implantable living tissues used in cardiac and vascular surgical procedures. CryoLife markets and sells products in more than 80 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 our estimates of the number of aortic surgeries in China each year, that such surgeries represent a significant growth opportunity for BioGlue, the anticipated pace of and timing for enrollment and follow up in our China BioGlue clinical trial, and the timing of potential approval by CFDA of BioGlue. These risks and uncertainties affecting these statements include that: our estimates of the number of aortic surgeries in China each year and our belief that they represent a significant growth opportunity for BioGlue may be incorrect, CFDA clinical trials are subject to a number of risks and uncertainties, including unanticipated reactions or results, delays, including in enrollment and follow up, and cost overages, we may be unsuccessful in our clinical trial and there is no guarantee that the CFDA will approve BioGlue for distribution in China in our expected timeframe or at all. 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, 2016, and our subsequent filings with the SEC. CryoLife does not undertake to update its forward-looking statements.

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