CryoLife Receives FDA Clearance For Next Generation HeRO Device

PR Newswire

ATLANTA, April 4, 2013 /PRNewswire/ -- **CryoLife, Inc. (NYSE: CRY),** a leading tissue processing and medical device company focused on cardiac and vascular surgery, announced today that it has received U.S. Food and Drug Administration (FDA) 510(k) clearance for a next generation HeRO (Hemodialysis Reliable Outflow) device. The HeRO device is the only subcutaneous AV access solution clinically proven to maintain long-term access for end-stage renal disease (ERSD) hemodialysis patients with central venous stenosis. CryoLife anticipates launching the next generation HeRO device during the fourth quarter of 2013 following scale up and validation of the manufacturing process.

The newly cleared version features an adaptor that provides the option to pair the HeRO device's proprietary venous outflow component with certain other available dialysis access grafts, including early access arterial grafts. The current generation includes a standard ePTFE graft, which requires the placement of a temporary dialysis catheter for approximately 2-3 weeks until the graft incorporates into the surrounding tissue and can be used for hemodialysis access. By design, early access grafts allow access in a matter of days, thus eliminating the need for an accompanying dialysis catheter.

"We are pleased to receive FDA clearance for our next generation HeRO device, which will provide our customers with the option of using a standard or early access arterial graft in conjunction with the device's proprietary venous outflow component," noted Steven G. Anderson , chairman, president and CEO of CryoLife. "Early access grafts eliminate the need for temporary dialysis catheters, which are associated with increased risk of infection, further enhancing the clinical benefits of the HeRO device. Over the next several months we will work to optimize and validate the manufacturing processes for this next generation system, which includes scaling up our manufacturing supply chain."

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., certain countries in Europe, and Canada. CryoLife's CryoValve® SG pulmonary heart valve, processed using CryoLife's proprietary SynerGraft® technology, has FDA 510(k) clearance for the replacement of diseased, damaged, malformed, or malfunctioning native or prosthetic pulmonary valves. CryoLife's CryoPatch® SG pulmonary cardiac patch has FDA 510(k) clearance for the repair or reconstruction of congenital heart defects. CryoLife'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. BioGlue is also CE marked in the European Community for use in soft tissue repair and approved in Japan for use in

the repair of aortic dissections. Additional marketing approvals for BioGlue have been granted in several other countries throughout the world. CryoLife, through its subsidiary Cardiogenesis Corporation, specializes in the treatment of coronary artery disease for severe angina using a laser console system and single use, fiber-optic handpieces to perform a surgical procedure known as Transmyocardial Revascularization (TMR). In addition, CryoLife and it's subsidiary Hemosphere, Inc. market the HeRO® device, which is a solution for end-stage renal disease in certain hemodialysis patients. CryoLife distributes PerClot®, an absorbable powder hemostat, in the European Community and other select international countries. CryoLife's BioFoam® Surgical Matrix is CE marked in the European Community for use as an adjunct to hemostasis in cardiovascular surgery and on abdominal parenchymal tissues (liver and spleen) when control of bleeding by ligature or conventional methods is ineffective or impractical.