Clinical Trial Finds CorMatrix ECM® Technology Does Not Increase Incidence of Postoperative Cardiac Tamponade or Graft Closure

The Associated Press

ATLANTA--(BUSINESS WIRE)--Jan 18, 2013--CorMatrix ® Cardiovascular, Inc., (www.cormatrix.com) a leading medical device developer, today announced preliminary results of its New Onset Post-Operative Atrial Fibrillation Clinical Trial. The randomized, prospective trial evaluated the use of CorMatrix ECM ® to close the pericardium of patients undergoing first-time CABG (coronary artery bypass grafting) at 15 U.S. clinical sites by examining post-operative clinical outcomes and the incidence of selected complications. More than 400 patients participated in the study and were randomly assigned either to have their pericardium closed with CorMatrix ECM or to have their pericardium left open following CABG surgery.

CorMatrix ECM (Photo: Business Wire) The study met its primary and secondary safety endpoints related to the use of CorMatrix ECM to close the pericardium. In addition, the study demonstrated that the ECM technology does not increase the incidence of cardiac tamponade and does not cause bypass grafts to ‘kink’ and close postoperatively. Results regarding new onset of postoperative atrial fibrillation, the primary effectiveness endpoint of the trial, did not show a statistically significant difference between the treatment and control groups. Statisticians and physician consultants will continue to study the extensive data to identify any patient or surgical technique factors that may impact patient outcomes.

Although cardiac surgeons understand the benefit of closing the pericardium to avoid injury of the heart when they are required to perform second operations, which currently represents one in five cardiac surgical procedures, many surgeons are hesitant to close the pericardium for fear that immediate postoperative cardiac bleeding might compress the heart (cardiac tamponade). The study found there was no significant difference in the incidence of cardiac tamponade when using CorMatrix ECM to form a water-tight seal of the pericardium following cardiac surgery.

Moreover, concerns that closing the pericardium could cause coronary bypass grafts to ‘kink’ and close postoperatively were also found to be unwarranted. The study found there was no significant difference in the incidence of graft occlusion when using CorMatrix ECM technology, providing another important safety assurance for surgeons.

“We are highly encouraged by the study’s excellent safety results and by the growing acceptance of this regenerative technology in the marketplace,” said David B. Camp, chairman and CEO of CorMatrix. “We will continue to evaluate the clinical trial data to better understand the factors that may affect postoperative atrial fibrillation.” CorMatrix ECM is a naturally-occurring extracellular matrix biomaterial

that supports native tissue repair by enabling a patient's own cells to repopulate and repair damaged tissues. CorMatrix ECM has been used at more than 720 hospitals across the U.S. and implanted in patients during nearly 70,000 cardiac procedures. The CorMatrix ECM technology is increasingly recognized as a leading option for pericardial reconstruction and the trial results provide additional assurances to physicians seeking evidence of the safety of the biomaterial.

This clinical study is an important milestone that confirms the strong safety profile for ongoing development of CorMatrix ECM technology to treat a variety of cardiovascular conditions. In addition to use in repair of the pericardium, cardiac tissue and carotid artery, CorMatrix is developing a platform of other applications for the biomaterial including the repair of heart valves, replacement of heart valves and an injectable form of ECM for the treatment of congestive heart failure.

About CorMatrix CorMatrix ® Cardiovascular, Inc. was founded in 2001 as a privately held medical device company dedicated to developing and delivering innovative biomaterial devices that harness the body’s own innate ability to repair damaged heart tissue. Headquartered in Atlanta, Georgia, the company is currently researching, developing and commercializing a platform technology known as CorMatrix ECM ® for a variety of cardiovascular indications, and has U.S. clearance and European approval (with a CE Mark) for its ECM technology as an implant for pericardial closure and for use in cardiac tissue repair, as well as U.S. clearance for carotid repair. With significant patent protection, CorMatrix is poised to successfully expand its current line of products. For more information, visit www.cormatrix.com.

About Extracellular Matrix (ECM) Biomaterial The unique properties of extracellular matrix biomaterials were discovered at Purdue University. The decellularized matrix material serves as a scaffold to allow adjacent tissues to deliver cells and nutrients to the matrix, which then differentiate into tissue-specific cells. The ECM material is gradually replaced as the patient’s own body reinforces and rebuilds the weakened site. During repair, the matrix is naturally degraded and resorbed, leaving remodeled functional tissue where scar tissue or injured tissue would normally be expected. The safety of extracellular matrices has been well established in a number of different clinical applications and more than 500 published papers. Since 1999, an estimated one million patients worldwide have received an extracellular matrix implant.

Photos/Multimedia Gallery Available:http://www.businesswire.com/multimedia/home/20130118005628/en/
CONTACT: For CorMatrix®Cardiovascular, Inc.

Cookerly Public Relations Mike Mullet, 404-816-2037 mike@cookerly.com
KEYWORD: UNITED STATES NORTH AMERICA GEORGIA INDUSTRY KEYWORD: SURGERY HEALTH CARDIOLOGY CLINICAL TRIALS MEDICAL DEVICES SOURCE: CorMatrix Cardiovascular, Inc. Copyright Business Wire 2013 PUB: 01/18/2013 11:43 AM/DISC: 01/18/2013 11:43 AM
http://www.businesswire.com/news/home/20130118005628/

Source URL (retrieved on *07/29/2014 - 12:15am*):
http://www.mdtmag.com/news/2013/01/clinical-trial-finds-cormatrix-ecm%C2%AE-technology-does-not-increase-incidence-postoperative-cardiac-tamponade-or-graft-closure