CardiacAssist Receives FDA IDE Approval for Use of the TandemHeart System in Pivotal Clinical Study

The Associated Press

PITTSBURGH--(BUSINESS WIRE)--Dec 18, 2012--CardiacAssist, Inc., a privately-held medical technology company headquartered in Pittsburgh, Pennsylvania, announced today that it received Investigational Device Exemption (IDE) approval from the Food & Drug Administration (FDA) for a pivotal clinical study of the TandemHeart circulatory support system. The TandemHeart to Reduce Infarct Size (TRIS) Trial will evaluate the effectiveness of ventricular unloading on the reduction of infarct size for patients who have suffered a severe heart attack.

“The approval of the pivotal TRIS Trial represents a major milestone for our company and the industry,” said John Marous, President & CEO of CardiacAssist. “With the completion of our pre-clinical animal studies, which showed a strong correlation between high degrees of ventricular unloading and improved myocardial salvage, we are excited to extend this concept to human trials and hopefully achieve similar clinical benefits.” Patients enrolled in the TRIS Trial will be randomized to receive either conventional therapy or a TandemHeart device to unload the left ventricle along with percutaneous coronary intervention (PCI). The primary efficacy endpoint of the study is improvement in myocardial salvage index (MSI). Additionally, the economic impact of TandemHeart therapy will be studied through secondary endpoints including long term mortality and the rates of repeat hospitalization and implantable cardioverter-defibrillator (ICD) usage. A reduction in these rates could decrease the total cost of treatment for this patient population.

The TRIS Trial is expected to begin enrollment in early 2013 and will include up to 20 hospitals, with leadership from Principle Investigators Biswajit Kar, M.D., Chief of the Center for Advanced Heart Failure at Memorial Hermann Heart and Vascular Institute in Houston, Texas, and David Holmes, M.D., Professor of Medicine at the Mayo Clinic College of Medicine in Rochester, Minnesota, and Immediate Past President of the American College of Cardiology (ACC).

For more information about the TRIS Trial, visit http://www.cardiacassist.com/innovation-research/tris-trial/ [1].

About TandemHeart The FDA-cleared TandemHeart system has provided critical heart support to thousands of patients in the top cardiac centers worldwide. The system's unique left atrial cannulation creates a fully percutaneous extracorporeal blood circuit to bypass the left ventricle, augmenting the flow of blood by up to 5.0 L/min.

About CardiacAssist Headquartered in Pittsburgh, PA, privately-held CardiacAssist is a growing medical technology company that developed the world’s first FDA-cleared

and CE-marked short-term extracorporeal circulatory support system for both cardiologists and cardiac surgeons.

CONTACT: CardiacAssist, Inc.

Travis Deschamps, Director of Marketing, 412-963-7770
tdeschamps@tandemheart.com [2] KEYWORD: UNITED STATES NORTH AMERICA PENNSYLVANIA INDUSTRY KEYWORD: SURGERY HEALTH BIOTECHNOLOGY CARDIOLOGY CLINICAL TRIALS HOSPITALS MEDICAL DEVICES OTHER HEALTH RESEARCH FDA MEDICAL SUPPLIES SCIENCE GENERAL HEALTH SOURCE: CardiacAssist, Inc. Copyright Business Wire 2012 PUB: 12/18/2012 08:00 AM/DISC: 12/18/2012 08:00 AM http://www.businesswire.com/news/home/20121218005105/ [3]

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Links:
[1] http://www.cardiacassist.com/innovation-research/tris-trial/
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