FIRST PATIENT ENROLLS IN U.S. SALUS TRIAL EVALUATING DIRECT FLOW MEDICAL® TRANSCATHETER AORTIC HEART VALVE SYSTEM

SANTA ROSA, Calif., September 10, 2013 - Direct Flow Medical®, Inc., a transcatheter heart valve company focused on improving patient outcomes, today announced the first patient enrollment in the U.S. SALUS clinical trial. The trial will study the Direct Flow Medical Transcatheter Aortic Heart Valve System, which encompasses a distinctive transcatheter aortic heart valve with a metal-free frame and flexible, low-profile delivery system designed to eliminate aortic regurgitation. The device is intended to improve the long term survivability of aortic stenosis patients by resolving the clinical issues associated with current commercial valves.

The SALUS Trial is a non-randomized, multi-center, core lab-adjudicated, IDE trial of 30 patients being conducted at six U.S. clinical sites. Principal investigators for the SALUS Trial are Murat Tuzcu, M.D., Vice Chairman of the Department of Cardiology, Cleveland Clinic, and Patrick McCarthy, M.D., Director of the Bluhm Cardiovascular Institute and Chief of Cardiac Surgery, Northwestern Memorial Hospital.

William O'Neill, M.D., Medical Director of the Center for Structural Heart Disease at Henry Ford Hospital performed the first Direct Flow Medical case in the United States.

"The team at Henry Ford Hospital is pleased to be the first in the U.S. to implant the Direct Flow Medical heart valve," said Dr. O'Neill. "A device that is repositionable and able to pass through smaller diameter blood vessels is an important advance in the next generation of transcatheter aortic valve replacement (TAVR) systems. This could help patients who have not been good candidates for earlier TAVR devices."

Post-procedural aortic regurgitation following TAVR has been shown to be a predictor of long-term mortality[1]. The Direct Flow Medical Transcatheter Aortic Valve System is designed to achieve optimal outcomes by enabling in-situ hemodynamic assessment after the valve is fully deployed in the native valve annulus, as well as repositioning with full distal, proximal and planar control, or retrieval, if required. The system avoids rapid pacing of the heart during deployment, and does not require post-dilatation following placement, minimizing the risk of hemodynamic stress for patients.

"After surgical aortic valve replacement, aortic regurgitation is rare. We need that same level of assurance after a transcatheter procedure, and we look forward to matching those results in this study of the Direct Flow Medical System," said Dr. McCarthy.

Direct Flow Medical will be participating in the PCR London Valves scientific programme, including a symposium entitled "Direct Flow Medical Transcatheter Aortic Valve" on Tuesday, September 17 from 13:00 to 14:00 in Room 2 (Whittle), as well as a live case performed from St. Thomas Hospital, London on Monday, September 16 from 11:30 to 12:30 in the Main Arena.

The Direct Flow Medical System received the CE Mark in January 2013 and is currently available commercially in Europe.

About The Direct Flow Medical System

The benefits of the Direct Flow Medical Transcatheter Aortic Valve System are enabled by its design, which features a distinctive, metal-free frame. Rather than a metal stent, the Direct Flow Medical System incorporates a polymer frame, which is expanded using pressurized saline and contrast for placement, assessment and repositioning. The saline/contrast solution is exchanged for a quick-curing polymer that solidifies and secures the valve in place once optimal positioning is reached. The unique conformable-ring design of the valve creates a tight seal around the annulus. The system is fully repositionable and retrievable until polymer exchange. The metal-free design enables a low-profile (18 French), fully sheathed delivery system for all valve sizes that minimizes vascular complications and improves hemodynamic outcomes.

About Direct Flow Medical, Inc.

Founded in 2004, Direct Flow Medical, Inc. is focused on developing novel transcatheter heart valve technologies that improve patient outcomes while reducing patient complications. The company is headquartered in Santa Rosa, California, with technology and manufacturing facilities in Lake Forest, California. The Company's proprietary technology is applicable to aortic and mitral valve disease, and other heart valve anatomical sites. Direct Flow Medical investors include EDF Ventures, New Leaf Venture Partners, Spray Venture Partners, Foundation Medical Partners, VantagePoint Venture Partners, ePlanet Venture Partners and strategic corporate investors. For further information, please visit the Web site at www.directflowmedical.com.

[1]Kodali S, Williams M Smith C, et al. Two-year outcomes after transcatheter or surgical aortic-valve replacement. N Engl J Med 2012;366(18):1686-1695.

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The Direct Flow Medical Transcatheter Aortic Valve System has not been approved for sale in the USA, Canada, or Japan.