FOR IMMEDIATE RELEASE

DIRECT FLOW MEDICAL® RECEIVES IDE APPROVAL FOR U.S. SALUS TRIAL OF TRANSCATHETER AORTIC HEART VALVE SYSTEM

SANTA ROSA, Calif., May 16, 2013 - Direct Flow Medical®, Inc., a transcatheter heart valve company focused on improving patient outcomes, today announced that it has received approval from the United States Food and Drug Administration (FDA) for an Investigational Device Exemption (IDE) to begin the SALUS feasibility trial of the Direct Flow Medical Transcatheter Aortic Heart Valve System. The device encompasses a distinctive transcatheter aortic heart valve with a metal-free frame and flexible, low-profile delivery system that virtually eliminates aortic regurgitation. It is designed to improve the long term survivability of patients by resolving the clinical issues associated with current commercial valves.

Post-procedural aortic regurgitation following transcatheter aortic heart valve replacement (TAVR) has been shown to be a predictor of long-term mortality[1]. The Direct Flow Medical Transcatheter Aortic Valve System is designed to address this clinical concern by enabling in-situ hemodynamic assessment after the valve is fully deployed in the native valve annulus, as well as limitless repositioning with full distal, proximal and planar control, or retrieval, if required. The system avoids rapid pacing of the heart during deployment, and post-dilatation following placement, minimizing the risk of hemodynamic stress for patients.

"Paravalvular leak leading to aortic regurgitation continues to be a clinical complication of TAVR and has been correlated to long term unfavorable outcomes," said Murat Tuczu, MD, Professor of Medicine, Cleveland Clinic and co-principal investigator of the trial. "The Direct Flow Medical system has shown the ability to virtually eliminate this problem, and I look forward to studying this promising new treatment in this U.S. feasibility trial."

With receipt of IDE approval, Direct Flow Medical plans to commence its U.S. clinical study evaluating the use of the Direct Flow Medical Transcatheter Aortic Heart Valve System. The system includes a distinctive heart valve with a metal-free frame that will be delivered transfemorally via a flexible, 18 French delivery system. The SALUS Trial is a 30-patient feasibility trial that will be conducted at up to six U.S. clinical sites, led by co-principal investigators Dr. Tuczu and Vinod Thourani, MD, Associate Professor of Surgery, Division of Cardiothoracic Surgery, Department of Surgery, Emory University School of Medicine and the Emory Clinic.

"It is a major milestone for our company to bring our rigorous clinical research to the U.S. in order to improve outcomes for patients," said Direct Flow Medical Chief Executive Officer Bernard Lyons. "Our device has shown the ability to achieve excellent outcomes while minimizing the risk of aortic regurgitation in our European trials, and we expect to demonstrate the same in our U.S. study."

Six-month results from the company's DISCOVER CE Mark Trial presented at the American College of Cardiology (ACC) 2013 Annual Meeting, which studied the Direct Flow Medical system, demonstrated excellent survivability, sustained hemodynamic improvements and few adverse events, with minimal occurrence of aortic regurgitation[2].

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 easily exchanged for a quick-curing polymer that solidifies and secures the valve in place once optimal positioning is reached. The unique double-ring design of the valve creates a tight seal around the annulus. The system is fully repositionable and retrievable up 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 not limited to aortic valve disease, and is readily applicable to mitral 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.
[2]Colombo A, De Marco F, Fadajet J, et al. The DISCOVER CE trial: 6-month outcomes of the Direct Flow Medical transcatheter aortic valve. JACC 2013;61(10):E1983

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