

DIRECT FLOW MEDICAL[®], INC. COMPLETES ENROLLMENT IN U.S. SALUS FEASIBILITY TRIAL OF TRANSCATHETER AORTIC HEART VALVE SYSTEM

SANTA ROSA, Calif., January 9, 2013 – [Direct Flow Medical[®]](#), Inc., a transcatheter heart valve innovator focused on improving patient outcomes, today announced it has completed enrollment in the U.S. SALUS trial of the [Direct Flow Medical Transcatheter Aortic Heart Valve System](#). The SALUS trial is a study to assess the safety of the Direct Flow Medical system to treat patients with severe aortic stenosis who are at extreme risk for surgical aortic valve replacement (SAVR). The Direct Flow Medical valve is the first transcatheter aortic valve designed to meaningfully improve aortic regurgitation outcomes that has been studied in a U.S. clinical trial. Direct Flow Medical is working closely with the Food and Drug Administration (FDA) and plans to initiate a U.S. pivotal trial in 2014.

The fully repositionable and retrievable system includes a distinctive heart valve with a metal-free frame that is delivered transfemorally via a flexible, 18 French delivery system. It is designed to improve the long term survival 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 strong predictor of long-term mortality¹. The Direct Flow Medical Transcatheter Aortic Valve System is designed to address this clinical concern by sealing the annulus and enabling complete assessment of hemodynamic performance with unlimited repositioning of the valve after full deployment. The system avoids rapid pacing of the heart during deployment and post-dilatation following placement, minimizing the risk of hemodynamic instability for patients.

“The Direct Flow Medical system has shown the ability to virtually eliminate aortic regurgitation,” said Murat Tuzcu, MD, Professor of Medicine, Cleveland Clinic and co-principal investigator of the trial. “The completion of the SALUS trial enrollment is an important milestone towards offering this promising new technology to our patients.”

“This is an exciting time for Direct Flow Medical as we are the first company to achieve FDA approval to evaluate a transcatheter aortic heart valve that can solve important issues such as aortic regurgitation,” said Direct Flow Medical Chief Medical Officer Charles Davidson, M.D. “This new technology enables physicians to assess patient outcomes before final valve implantation, so they have the ability to further optimize valve placement through repositioning, if necessary.”

The SALUS Trial is a non-randomized, multi-center, core lab-adjudicated, IDE trial. 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.

Six month data from the DISCOVER CE Mark Trial, recently presented at the 2013 Transcatheter Cardiovascular Therapeutics (TCT) conference, confirm the system’s ability to virtually eliminate significant aortic regurgitation. Through six months, no patient experienced moderate or severe aortic regurgitation and there was a 96 percent overall survival rate, with 90 percent of patients in functional

Class I or II. The system also demonstrated a strong safety profile, with a 97 percent VARC defined Combined Safety rate and no incidence of strokes (major or minor) or myocardial infarction in the evaluable cohort between 30 days and six months.

The DISCOVER Trial is a prospective, multicenter study of the Direct Flow Medical system conducted at nine European sites in 100 patients with severe aortic valve stenosis who required replacement of their native aortic valve but were at extreme risk for open surgical repair.

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.

¹Kodali 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.

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