DIRECT FLOW MEDICAL® RECEIVES CE MARK FOR TRANSCATHETER AORTIC HEART VALVE SYSTEM THAT VIRTUALLY ELIMINATES AORTIC REGURGITATION

Clinicians Can Fully Assess and Optimize Patient Outcomes Before the Valve is Secured in Place, Creating a More Certain and Reproducible Clinical Result

SANTA ROSA, Calif. - January 28, 2013 - Direct Flow Medical®, Inc., a transcatheter heart valve innovator focused on improving patient outcomes, announced that it has received CE Mark (*Conformité Européenne*) for its distinctive transcatheter aortic heart valve with a metal-free frame and low-profile transfemoral delivery system. The Direct Flow Medical Transcatheter Aortic Valve System is designed to virtually eliminate aortic regurgitation by allowing complete assessment of hemodynamic performance, repositioning and retrieval after the valve is fully deployed in the native valve annulus. The unique, double-ring design of the valve creates a tight and durable seal around the annulus. The system is designed to improve the long term survivability of patients by resolving the clinical issues associated with current commercial valves.

Two sizes of valves - 25mm and 27mm – will be commercially available in Europe immediately, both delivered via a flexible, 18 French system.

Post-procedural aortic regurgitation has been shown to be a predictor of long-term mortality[1]. The 30-day, core-lab adjudicated results from the DISCOVER Trial, presented at the 2012 Transcatheter Cardiovascular Therapeutics (TCT) conference, showed that the Direct Flow Medical System achieved 97 percent freedom from all-cause mortality, with 97 percent of patients experiencing no or mild aortic regurgitation[2].

In addition, total average procedure time was 41.8 minutes with no post-dilatations required[2]. The DISCOVER Trial is a prospective multi-center study conducted at seven leading European cardiology centers. Data from Direct Flow's first-in-man study, presented at TCT 2012, showed a four-year survival rate of 54 percent, with 80 percent of patients exhibiting no aortic regurgitation, and 20 percent showing trace amounts[4].

"The Direct Flow Medical System is unique in many ways that combine to virtually eliminate aortic regurgitation, creating greater confidence in the outcome," said Professor Joachim Schofer, MD, of the Medical Care Center, Hamburg, Germany, and co-principal investigator for the DISCOVER Trial.

"Its novel design enables us to fully assess outcomes and adjust or retrieve the valve at any time during the procedure, without creating hemodynamic stress for the patient," Schofer added. "This keeps the procedure calm throughout. Delivery is also easy, as the flexible, low-profile design has enabled me to navigate vessels as small as 5.2 mm without vascular complications."

The Direct Flow Medical System also reduces procedural risk by eliminating the need for rapid pacing during deployment[3] and post-dilitation, which are common with other valves and can compromise hemodynamic stability during deployment and positioning.

To support European commercialization, the company has also announced the appointment of Dan Rose as Vice President, Sales and Marketing. Most recently, Mr. Rose was Vice President of Commercial Operations for Sequana Medical, an emerging Swiss medical device company developing innovative and

proprietary implantable pump systems. Prior to that, Mr. Rose held a number of sales and marketing leadership positions at Medtronic in Europe in both the interventional cardiology and cardiac surgery businesses.

"Dan is an experienced medical device executive who understands how to market novel cardiovascular technologies and commercialize in diverse and competitive international markets," said Bernard Lyons, Chief Executive Officer for Direct Flow Medical. "His experience positioning innovative cardiovascular devices to drive clinical adoption will contribute to our success as we launch 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 and durable seal around the annulus. Three hollow positioning wires allow for the fluid exchange, and also uniquely enable distal, proximal and planar repositioning. The metal-free design enables a low-profile (18 French), fully sheathed delivery system that has been proven to minimize vascular complications and improve hemodynamic outcomes[2].

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 exploring application of its proprietary technology beyond the aortic valve, to the mitral valve and other valve anatomy. Headquartered in Santa Rosa, California, the company also has technology and manufacturing facilities in Lake Forest, California. 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 more information, please visit: 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. Schofer J, Fajadet J, Colombo A, et al. 30-day outcome of the 18F-Direct Flow Medical valve in patients with aortic stenosis – results from the DISCOVER trial. JACC 2012;60(17):B236
3. Schofer J, Schlüter M Treede H, et al. Retrograde transarterial implantation of a nonmetallic aortic valve prosthesis in high-surgical-risk patients with severe aortic stenosis – A first-in-man feasibility and safety study. Circ Cardiovasc Intervent 2008;1:126-133.
4. Bijuklic K, Tuebler T Treede H, et al. Long term performance of a transfemorally implantable nonmetallic, retrievable and repositionable aortic valve in patients with severe aortic stenosis - 4 year follow-up of the 22F-Direct Flow Medical valve. JACC 2012;60(17):B236.

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The Direct Flow Medical® Transcatheter Aortic Valve System is not yet available in the U.S.