

## **DIRECT FLOW MEDICAL<sup>®</sup>, INC. RECEIVES CE MARK FOR FIRST FULLY REPOSITIONABLE 29 MM TRANSCATHETER AORTIC VALVE SYSTEM**

SANTA ROSA, Calif., January 9, 2013 - [Direct Flow Medical<sup>®</sup>](#), Inc., a transcatheter heart valve innovator focused on improving patient outcomes, announced today it has received CE Mark for the first fully repositionable 29mm transcatheter aortic heart valve, delivered through its flexible, 18 French transfemoral delivery system. The Direct Flow Medical valve is designed to virtually eliminate aortic regurgitation in all sizes of annulus by allowing complete assessment of hemodynamic performance and unlimited repositioning of the valve after full deployment in the native valve annulus. The approval expands the population of patients who can be treated using the Direct Flow Medical valve to patients with annulus sizes ranging from 21mm to 28mm.

“As with the smaller sizes of the Direct Flow Medical valve, the implantation of the 29mm valve is precise and fully controllable,” said Christoph Naber, M.D., from the Contilia Heart and Vascular Center, Essen, Germany. “With this new valve size, a broader patient population will be able to benefit from the unique advantages of the Direct Flow Medical system.”

“Until now, patients with large annulus sizes who could not undergo surgical valve replacement had limited options, as other commercially available valves often leave significant aortic regurgitation at larger sizes and are not repositionable or retrievable,” said Bernard Lyons, President and CEO of Direct Flow Medical. “With the addition of the 29mm valve to our portfolio, we can now greatly improve outcomes for this group of patients, as well.”

The unique, double-ring design of the Direct Flow Medical valve conforms to the anatomy and creates a tight and durable seal around the annulus. The system is designed to improve long term survival of patients by resolving the clinical issues associated with current commercial valves. The system avoids rapid pacing of the heart during deployment, and does not require post-dilatation following placement, minimizing the risk of hemodynamic instability for patients. The [Direct Flow Medical Transcatheter Aortic Valve System](#) is indicated for the treatment of patients with severe aortic stenosis who are at extreme risk for surgical aortic valve replacement (SAVR).

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 portfolio now includes 25mm, 27mm and 29mm transcatheter aortic valves, all delivered through its flexible, 18 French delivery system, which have received the CE Mark and are currently commercially available 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](http://www.directflowmedical.com).

###

#### **MEDIA CONTACT:**

Michelle McAdam  
Chronic Communications  
michelle@chronic-comm.com  
(310) 902-1274

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

Direct Flow Medical and the Direct Flow logo are trademarks of Direct Flow Medical, Inc.