**Direct Flow Medical® Transcatheter Aortic Valve System Shown To Virtually Eliminate Aortic Regurgitation With No Vascular Complications In DISCOVER CE Mark Trial**

SANTA ROSA, California, October 23, 2012 - Direct Flow Medical, Inc., a transcatheter heart valve innovator focused on improving patient outcomes, announced that its DISCOVER CE Mark Trial met its primary mortality endpoint. The study also demonstrated that greater than 95 percent of patients had mild or less aortic regurgitation, and no patients experienced vascular complications. The DISCOVER Trial results were presented yesterday at the Transcatheter Cardiovascular Therapeutics (TCT) Conference in Miami, Florida.

The DISCOVER Trial is a prospective, multicenter study of up to 100 patients conducted at 10 European sites of patients with severe aortic valve stenosis who require replacement of their native aortic valve but are at extreme risk for open surgical repair. The device studied was the Direct Flow Medical Transcatheter Aortic Valve System, which is endovascularly delivered via an 18F introducer sheath. The trial was initiated in November 2011 and the first patient was treated at the L'Institut Jacques Cartier in Massy, France by Co-Principal Investigator Thierry Lefevre, MD.

In the presentation of 30 day results for the pre-specified CE Cohort of 33 patients reported by Co-Principal Investigator Joachim Schofer, MD from the Medical Care Center, Hamburg, Germany, all patients were successfully treated via a transfemoral approach using the low profile, flexible Direct Flow Delivery System. The primary endpoint, freedom from all-cause mortality from procedure to 30 days, was met at 97 percent. Freedom from all cause cardiovascular mortality at 30 days was 100 percent.

Importantly, the Direct Flow Valve resulted in 97 percent mild or less aortic regurgitation, with 81 percent of patients experiencing none/trace aortic regurgitation as reported by the study Corelab. There were no major vascular complications in any patients post-procedure through 30 days even though the minimum vessel diameter treated in the study was 5.2 mm. The mean gradient pre-procedure to discharge and out to 30 days of 46.0, 13.6 and 12.9 mmHg, respectively, demonstrated the ability to significantly reduce gradients over time. All hemodynamic results were analyzed by an independent imaging core laboratory.

Secondary endpoints (VARC defined Safety) had a combined Safety Rate of 9 percent. In the study, there were 2 strokes (major or minor) and one patient had a mild myocardial infarction. The device success rate was 97 percent. The average age of patients in the CE Mark Cohort was 83 years, with logistic euroSCORE/STS Scores of 27.0 percent and 11.0 percent, respectively.

"We are pleased to report the positive initial results for the Direct Flow Valve, as it resolves one of the most important clinical issues in the TAVR market today – aortic regurgitation," said Professor Schofer. "In the trial, we also found that the device was easy to use, offered maximum control and resulted in precise placement. This novel device has the potential to improve clinical outcomes globally and better serve the needs of a growing patient population."

"We designed the Direct Flow Medical System specifically to address complications that were problematic with earlier generations of transcatheter aortic heart valves," said Dr. Charles Davidson, the Company's Chief Medical Officer, Professor of Medicine at Northwestern University Feinberg School of Medicine and Clinical Chief of Cardiology at Northwestern Memorial Hospital, Chicago, Illinois. " Our proprietary design takes a very different approach to restoring valvular flow, while being fully repositionable and retrievable."

The Direct Flow Medical Transcatheter Aortic Valve System is a novel system utilizing an inflatable cuff with a conforming polymer support structure. Inflatable rings at the top and bottom of the valve are designed to conform and seal above and below the native valve to virtually eliminate aortic regurgitation. The lack of a metallic frame allows for a low profile, flexible, fully-sheathed system with the potential to reduce bleeding and vascular complications, particularly in patients with tortuous and variable anatomy. Full-thickness bovine pericardial leaflets are incorporated in the valve design for durability. The valve can be repositioned even after the implant is fully expanded to its final configuration, providing a unique ability to assess clinical outcomes before final deployment.

**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.

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The Direct Flow Medical® Transcatheter Aortic Valve System is an investigation device, limited by applicable law to investigational use and not available for sale.