Direct Flow Medical Transcatheter Aortic Valve System Demonstrates Excellent Six-Month Outcomes in DISCOVER Trial

The Associated Press

SAN FRANCISCO--(BUSINESS WIRE)--Mar 12, 2013--Direct Flow Medical®, Inc., a transcatheter heart valve innovator focused on improving patient outcomes, announced that the DISCOVER Trial results presented Sunday at the American College of Cardiology (ACC) Annual Meeting showed that patients treated with the Direct Flow Medical ® Transcatheter Aortic Valve System achieved excellent survivability and sustained hemodynamic improvements with minimal occurrence of aortic regurgitation at six months. Also presented was a larger cohort of 54 patients at 30 days that continued to demonstrate excellent outcomes.

The DISCOVER Trial 30-day and six-month outcomes were presented by trial investigator Azeem Latib, MD, from San Raffaele Scientific Institute in Milan, Italy in a podium presentation. In 54 patients, there was 98 percent freedom from all-cause mortality at 30 days. The six-month results comprised from the pre-specified CE Mark Cohort demonstrated 92 percent freedom from all-cause mortality. The average age of patients was 84 years, with a Logistic EuroSCORE of 23.5 percent.

One hundred percent of patients experienced mild or less aortic regurgitation at six months, with 74 percent of patients experiencing none/trace aortic regurgitation. The mean gradient (mmHg) pre-procedure to discharge as measured by transthoracic echo improved from 47.1 mmHg to 13.8 mmHg, and sustained these results at six months (13.7 mmHg). The hemodynamic outcomes were assessed and reported by an independent imaging core laboratory.

Secondary endpoints (VARC defined Safety) had a combined Safety Rate of 89 and 85 percent, respectively, at 30 days and six months. Within 30 days, there were two strokes and one patient experienced a myocardial infarction (MI); however, there were no additional strokes or MIs after 30 days. There was only one major vascular complication in the 54 patient cohort. The VARC Combined Device Success was 96.3 percent. No patient required rapid pacing or post-dilatation, minimizing the risk of hemodynamic stress for patients.

The DISCOVER Trial is a prospective, multicenter study of up to 100 patients conducted at up to 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 includes a distinctive heart valve with a metal-free frame that was delivered transfemorally via a flexible, 18 French delivery system.

“The Direct Flow Medical system is demonstrating very low mortality, sustained improvement in hemodynamics and minimal aortic regurgitation at six months,”

said Dr. Latib. “It is also continuing to demonstrate excellent results in a larger patient cohort. The system enables us to optimize outcomes for our patients by allowing full hemodynamic assessment and the flexibility of repeated repositioning, as well as retrieval, improving the TAVR procedure and minimizing risk.” 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.

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