Direct Flow Medical Completes First Human Use of 18F Percutaneous Aortic Valve System

SANTA ROSA, Calif. - (BUSINESS WIRE - May 20, 2009) - Direct Flow Medical, Inc. a privately held, emerging medical device Company developing a next generation, minimally invasive implant to treat patients with heart valve disease announced today the first human use of their new 18 French Percutaneous Aortic Valve (PAV) System. The 18F system was used to successfully treat two high risk surgical candidates at Dante Hospital in San Paolo, Brazil. The procedures were performed by Dr. Cesar Esteves and assisted by Dr. Reginald Low and Professor Eberhard Grube. In the first patient treated with the 18F PAV system the physicians were able to safely complete the first ever successful retrieval of the device through an 18F sheath before easily positioning and deploying a second device.

The Company's ability to rapidly advance the second generation technology with a true 18F PAV system that can be used to percutaneously treat severely diseased aortic stenosis patients represents a tremendous advancement to the field. The Direct Flow Medical device is a non-metallic, expandable cuff, bovine pericardial tissue valve that allows the physician to assess the hemodynamic outcomes prior to final deployment of the device. The unique and easily repositionable "stentless" valve conforms to the native annulus resulting in tight sealing of the valve in the annulus which minimizes any paravalvular leaks. The reduction of aortic insufficiency is believed to improve clinical status in these high risk patients with significant co-morbidities including coronary heart disease and congestive heart failure.

Stated Prof. Grube from the Helios Heart Center in Siegburg, Germany, "The improvements in the delivery system from the 22F to the 18F system are unparalleled. The system allows for millimeter control of the device placement and is significantly easier and much more intuitive than the prior system. Finally, the changes to the retrieval system made it much quicker to recover a device and the decision to provide the retrieval device as an accessory significantly reduced the complexity of the 18F delivery system."

"The Company also endeavored to increase the radial force of the 'stentless' valve": added Dr. Low. "They have accomplished this through ingenious design improvements. The deployment of the 18F PAV required a maximum of three inflations with a valvuloplasty balloon. The resultant mean gradients in these two patients were 8 and 12 mmHg, respectively and both had effective orifice areas greater than 1.4mm^2 for the 25mm devices implanted."

The Company recently completed a 31 patient Feasibility and Safety Study at 2 sites in Germany with its 22F device in September 2008. Six month data from this study are being presented this month at both the AATS meeting and the EuroPCR meeting by Dr. Hendrik Treede and Professor Joachm Schofer, respectively. These results demonstrate that the Direct Flow Medical PAV device is safe to implant in high risk and non-operative patients with significant aortic stenosis without hemodynamic compromise.

About Direct Flow Medical, Inc.

Founded in 2004, the Company is headquartered in Santa Rosa, California, has a second manufacturing facility in Lake Forest, CA and employs approximately 65 people. The Company's unique implant design is not limited to aortic valve disease but is readily applicable to mitral and other heart valve anatomical sites as its placement and security in an annulus is not dependent on calcium. Direct Flow Medical has raised a total of $35M to date and is funded by EDF Ventures, New Leaf Venture Partners, Spray Venture Partners, Foundation Medical Partners, Johnson & Johnson Development Corporation, VantagePoint Venture Partners and ePlanet Ventures.