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Press Release

FlowMedica Announces Completion of the Benephit System Renal Infusion Therapy (Be-RITe) Registry

Results Suggest a 70% Reduction in the Incidence of Contrast-Induced Nephropathy

Fremont, CA (August 29th 2007) – FlowMedica, Inc., a medical device company pioneering Targeted Renal Therapy (TRT[®]), today announced that it has met its objective of enrolling 500 patients in the Be-RITE Registry. This is the first TRT registry data set that contains a significant number of patients with renal insufficiency who are at high risk for contrast induced nephropathy (CIN).

“The Be-RITE Registry is another building block in the clinical foundation supporting TRT,” said Gary Saxton, President and CEO of FlowMedica. “We look forward to seeing these results presented at several major scientific meetings over the next few months, and then published shortly thereafter.”

The Be-RITE Registry is an observational, retrospective registry that is intended to capture “real world” usage patterns, device performance characteristics, clinical outcomes and adverse events data associated with either the *Benephit*[®] CV or *Benephit*[®] PV Infusion System. Both catheter systems have received regulatory clearance for the infusion of physician-specified agents in the peripheral vasculature including but not limited to the renal arteries. The *Benephit* systems have not yet received clearance to treat or prevent CIN or any other condition.

In all, 37 physicians participated in the registry, including interventional cardiologists, interventional radiologists, vascular surgeons and cardiothoracic surgeons. Of all the procedures completed as an adjunct to TRT, 34.6 percent were coronary diagnostic and/or intervention, 54.5 percent peripheral diagnostic and/or intervention, 10.5 percent cardiothoracic or peripheral vascular surgery and 0.4 percent were primary acute kidney injury therapy.

Bilateral renal artery cannulation with the *Benephit* system was successfully achieved with a mean time of 2 minutes in 95.8 percent of patients.

Risk factors among patients enrolled in the registry included chronic kidney disease/renal insufficiency (91.1 percent), diabetes (61.1 percent), anemia (88.0 percent), chronic heart failure (14.6 percent), established acute renal failure (6.2 percent) and advanced age (average age was 72.2 and 49.1 percent of patients were age 75 or older). Baseline patient characteristics for renal function included average serum creatinine of 2.0 mg/dL +/- 0.7 mg/dL and creatinine clearance of 42.9 ml/min +/- 20.9 ml/min (with 61.0 percent of the patients having a creatinine clearance less than 40ml/min).

Physician-specified agents used for TRT within the procedures included fenoldopam mesylate (93.6 percent), sodium bicarbonate (3.5 percent), nesiritide (0.4 percent) and alprostadil (2.5 percent).

Based on a validated model for predicting the incidence of CIN published by Mehran *et al* in the *Journal of the American College of Cardiology*, the expected CIN for all endovascular registry patient population was 27.3 percent, whereas with TRT the actual incidence of CIN was 8.2 percent (p value <0.0001). The registry data by nature is retrospective, observational, and non-adjudicated; therefore, further studies will be needed to support this finding.

“Patients who suffer from diabetes, heart failure, impaired kidney function or are of advanced age are at particularly high risk for CIN. The patients in the registry were at very high risk, with some patients having three or more risk factors as reflected in the high CIN predicted risk score,” said Paul Teirstein, M.D., FACC, Chief of Cardiology and Director of Interventional Cardiology at Scripps Clinic, La Jolla, Calif., and a co-investigator of the study. “CIN can ultimately result in renal failure with need for dialysis, and is associated with increased hospital stays and increased mortality.” A number of strategies have been attempted to prevent or reduce CIN in high-risk patients, including administering medications and other therapeutic agents through systemic intravenous (IV) infusion. Systemic infusion of certain agents can cause serious side effects such as hypotension, the lowering of blood pressure. In addition, researchers believe that with systemic infusion, the amount of medication that reaches the kidneys often does not reach sufficient levels to have a therapeutic effect and therefore, the treatment may not be effective.

TRT is the delivery of physician-specified therapeutic agents directly to the kidneys via the renal arteries through the innovative *Benephit* Infusion Catheter System. TRT may offer significant benefit in direct infusion of therapeutic levels of medications while reducing the side effects that can be encountered with conventional IV delivery.

About FlowMedica

FlowMedica, Inc., a privately held, commercial-stage medical device company located in Fremont, Calif., was founded in 2002, in collaboration with leading cardiologists and surgeons. Investors include: ABN AMRO Capital, De Novo Ventures, Medica Venture partners, Mi3 Venture Partners, Oxford Bioscience Partners and Palo Alto Investors. The company's initial solutions for TRT – the *Benephit* Infusion Systems – have received U.S. 510(k) regulatory clearance and CE Marking for the infusion of physician-specified agents in the peripheral vasculature including, but not limited to, the renal arteries. The company's products have not received FDA clearance to treat contrast-induced nephropathy or any other condition.

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