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Press Release

Benephit[®] Renal Infusion Therapy (Be-RITe) Registry Results Presented at American Society of Nephrology Meeting

Multicenter Registry Results Suggest a 1% Incidence of Contrast-Induced Nephropathy Among High-Risk Patients

San Francisco (Nov. 4, 2007) -- Data from a multicenter registry of *targeted renal therapy* (TRT[®]) in patients at high risk for acute kidney injury – a common complication of hospitalized patients and one that is associated with increased short and long-term mortality -- was presented Sunday at the American Society of Nephrology's Renal Week 2007 by James A. Tumlin, M.D., nephrologist, Clinical Research Division, Southeast Renal Associates, Charlotte, N.C.

TRT is the delivery of physician-specified therapeutic agents directly to the kidneys via the renal arteries through the innovative *Benephit* Infusion Systems from FlowMedica, Inc. TRT may offer significant benefit in direct infusion of therapeutic levels of medications without the side effects that can be encountered with conventional IV delivery.

Dr. Tumlin's presentation, "Intra-Renal Infusion with Fenoldopam Mesylate Reduces Acute Kidney Injury Following Cardiothoracic Surgery or Exposure to Iodinated Contrast Agents: Results from the Be-RITe Registry," included the analysis of 501 patients enrolled in the Be-RITe Registry. The presentation of the registry results was the first time the data has been presented at the ASN meetings.

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 associated with the *Benephit* Infusion Systems. The catheter systems have received regulatory clearance in the United States and Europe for the infusion of physician-specified agents in the peripheral vasculature including, but not limited to, the renal arteries. The *Benephit* systems have not received clearance to treat or prevent contrast-induced nephropathy (CIN) or any other condition.

In all, 37 physicians participated in the registry, including interventional cardiologists, interventional radiologists, vascular surgeons and cardiothoracic surgeons. Of the 501 TRT procedures reported in the Registry, 48.4 percent were adjunctive to peripheral diagnostic and/or intervention, 40.5 percent coronary diagnostic and/or intervention, 10.3 percent cardiothoracic or peripheral vascular surgery, and 0.4 percent represented TRT as a stand-alone procedure for primary acute kidney injury therapy.

The registry participants reported that bilateral cannulation of the renal arteries with the *Benephit* catheter was completed in a mean time of 2 minutes with successful bilateral cannulation achieved in 95.8 percent of patients. There were a total of 5 (1.0 percent) reported complications, none as a serious adverse event, which were all resolved without lasting adverse effects.

Dr. Tumlin reported that the intra-renal delivery of fenoldopam mesylate (a potent renal vasodilator) using the *Benephit* catheter allows for higher doses to be delivered directly to the renal vascular bed, significantly increasing glomerular filtration rates (measurement of kidney function), without the development of systemic hypotension (the lowering of blood pressure).

Of the 248 patients receiving intra-renal fenoldopam, 212 received TRT for prophylaxis for contrast-induced nephropathy (CIN), while an additional 34 patients received TRT for the

prophylaxis of acute kidney injury (AKI) following cardiothoracic surgery. Based on a validated model for predicting the incidence of AKI requiring dialysis published by Thakar *et al* in the *Journal of American Society of Nephrology*, the expected incidence of AKI requiring dialysis for the 34 patients was 7.1 percent, whereas with TRT the actual incidence of AKI requiring dialysis was 2.9 percent.

CIN is an increasingly recognized syndrome that occurs in patients whose kidneys are unable to withstand side effects that can be caused by the dye (radiocontrast media) used during minimally invasive cardiovascular and endovascular intervention procedures such as diagnostic angiography, angioplasty, atherectomy, and stent and stent graft placement. "In patients with impaired renal function, it has been recognized that the development of acute kidney injury after the administration of contrast media is associated with increased hospital stay, dialysis, morbidity and mortality," said Dr. Tumlin.

A sub-set analysis of the registry population was completed on 210 patients who received intra-renal infusion of fenoldopam mesylate at 0.4 mcg/kg/min for 1 hour or greater during coronary or peripheral interventions and/or diagnostic procedures, and for whom appropriate follow-up data within 48 hours was reported for analysis. Based on a validated model using easily-identifiable risk factors for predicting the incidence of CIN published by Mehran *et al* in the *Journal of the American College of Cardiology*, the expected CIN incidence for these 210 patients was 28.1 percent, whereas with TRT the actual incidence of CIN was 1.0 percent (p value <0.00001). The registry data by nature is retrospective, observational, and non-adjudicated; therefore, further studies will be needed to support this finding.

Major risk factors for the group of patients evaluated in the sub-set analysis included: diabetes mellitus (76.2 percent), low creatinine clearance (average 35.0 ml/min), anemia (97.1 percent), advanced age (63.8 percent older than 75 years), and a high average volume of contrast dye (139.0 ml). "These patients represent a very high-risk group, with more co-morbidities and more severely depressed kidney function than has been presented and published in any prior CIN clinical trials, and yet the reported incidence of CIN was extremely low," said Dr. Tumlin.

"The results of the registry demonstrate that targeted renal therapy is safe, and may provide a new approach for the prophylaxis of contrast-induced nephropathy," said Dr. Tumlin. "In addition, intra-renal drug delivery may find an application in the treatment of established AKI."

About FlowMedica

FlowMedica, Inc., a venture-backed, privately held, commercial-stage medical device company, located in Fremont, Calif., was founded in 2002, in collaboration with leading cardiologists and surgeons. Investors include: De Novo Ventures, Forbion Capital Partners, 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 bear the 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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