

## FOR IMMEDIATE RELEASE

Contact: Brigette Beaudoin  
Public Communications Inc.  
312/558-1770

### **FLOWMEDICA ANNOUNCES NEW PHYSICIAN-SPONSORED STUDY OF ITS BENEPHIT™ INFUSION SYSTEM IN PATIENTS WITH RENAL INSUFFICIENCY Study to Focus on Benefits of Intra-Renal Drug Delivery**

FREMONT, Calif.(January 31, 2005) – FlowMedica, Inc., a medical device company developing intravascular systems for treating renal dysfunction related to cardiovascular diseases, today announced Scripps Clinic’s initiation of a physician-directed clinical study of its FlowMedica *Benephit* Infusion System in patients with compromised kidney function who are undergoing coronary procedures. The *Benephit* Infusion System is a proprietary catheter-based infusion system for *Targeted Renal Therapy* – direct delivery of therapeutic agents to the kidneys via the renal arteries.

The physician-sponsored, multi-center, randomized, placebo-controlled study is being coordinated by Scripps Clinic, La Jolla, Calif., under the direction of principal investigator Paul Teirstein, M.D., FACC, director of interventional cardiology at Scripps Clinic. Eight to 10 centers will participate, enrolling 64 diabetic patients with compromised kidney function. These patients are at high risk of developing acute kidney failure due to their inability to process the contrast agents used during coronary interventional or diagnostic procedures – a condition known as radiocontrast nephropathy (RCN).

RCN is a growing problem among hospitalized patients as the number of contrast-enhanced examinations and interventions performed annually in the U.S. is increasing rapidly. It is estimated that about half a million patients in the U.S. each year have known risk factors for this life-threatening condition.

The study will evaluate the ability of the *Benephit* Infusion System to deliver fenoldopam selectively to the kidneys to preserve renal function as measured by serum creatinine levels – a direct indication of kidney function. Although fenoldopam can increase blood flow to the kidneys and improve kidney function, its systemic use to prevent RCN is limited since doses high enough to be effective are associated with significant lowering of blood pressure, or hypotension. The study is designed to assess the effectiveness of escalating doses of fenoldopam delivered intrarenally by the *Benephit* System.

“This study builds on the success of an initial trial of the *Benephit* System in patients at a lesser risk for developing RCN,” said Dr. Teirstein. “In this case we will be evaluating high-risk patients to confirm that targeted intra-renal drug delivery can maximize the beneficial kidney effects of drugs while minimizing systemic side effects.”

According to a previous study conducted at Scripps Clinic and St. Joseph’s Medical Center in Stockton, Calif., the intra-renal delivery of fenoldopam via the *Benephit* Infusion System improved kidney function significantly; the intravenous administration of fenoldopam at the same dose improved kidney function only minimally. The study also showed that systemic drug levels were significantly less following intra-renal delivery of fenoldopam vs. intravenous treatment, leading to less blood pressure reduction. The results were reported in September 2004 at the Cardiovascular Research Foundation’s (CRF) Sixteenth Annual Scientific Symposium, Transcatheter Cardiovascular Therapeutics (TCT2004).

The FlowMedica *Benephit* Infusion System is a proprietary, selective infusion catheter system capable of delivering therapeutic agents directly to the renal arteries through a dedicated infusion catheter while enabling concurrent cardiovascular procedures through a single-vessel access site. The system consists of a proprietary Bifurcated Infusion Catheter and a unique Introducer Sheath. In January 2004, the system received 510(k) clearance from the U.S. Food and Drug Administration (FDA) for the infusion of physician-specified agents to the renal arteries.

#### **About FlowMedica**

FlowMedica is a venture-backed, privately held medical device company developing intravascular systems to treat renal dysfunction related to cardiovascular diseases using *Targeted Renal Therapy* – the direct delivery of therapeutic agents to the kidneys via the renal arteries. The company’s initial product is the *Benephit* Infusion System, a proprietary site-specific therapeutic agent infusion catheter system. Physicians are evaluating the system’s ability to treat and prevent acute renal failure related to cardiovascular procedures, congestive heart failure, and other sources. Founded in 2002 by Accelerated Technologies, Inc., FlowMedica has raised a total of \$15.3 million to date in three rounds of private equity financing.

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