

Media Contacts: Brigette Beaudoin  
[bbeaudoin@pci-pr.com](mailto:bbeaudoin@pci-pr.com) or  
Sheena Quinn  
[squinn@pci-pr.com](mailto:squinn@pci-pr.com)  
Public Communications Inc.  
312/558-1770

**FLOWMEDICA'S BENEPHIT™ INFUSION SYSTEM RECEIVES CE MARKING**  
*Company Names Italian Distributor*

**AT A GLANCE**

- The *Benephit*™ Infusion System – a new device designed to deliver medications and other therapeutic agents directly to the kidneys (targeted renal therapy) – has received CE Marking.
- Targeted renal therapy (TRT) with the *Benephit* Infusion System utilizes minimally invasive intravascular systems to administer physician-specified medications and therapeutic agents to treat kidney dysfunction related to certain interventional or surgical procedures and diseases.
- FlowMedica, maker of the system, also announces its first European distributor, N.G.C. Medical S.p.A. of Italy.

ROME (17 February, 2005) – The *Benephit*™ Infusion System, a new device designed to deliver medications and other therapeutic agents directly to the kidneys, has received CE Marking, the system's maker, FlowMedica, Inc., announced today during the Joint Interventional Meeting.

CE Marking enables FlowMedica to make the *Benephit* system available to physicians in all member countries of the European Union.

FlowMedica, a medical device company developing minimally invasive intravascular systems to treat kidney dysfunction related to certain interventional or surgical procedures and diseases, also announced the selection of the first of its European distributors, N.G.C. Medical, S.p.A. of Italy. N.G.C. is a leading distributor of medical devices that focuses on innovative products in the cardiology field.

The *Benephit* Infusion System is an FDA-510(k)-cleared novel, proprietary selective infusion catheter system that delivers medications and other therapeutic agents directly to the kidneys through the renal arteries, a method called *targeted renal therapy* (TRT). TRT is an alternative

to the standard delivery method of systemic intravenous (IV) infusion of medications to treat kidney dysfunction related to cardiovascular disease. Systemic infusion is often associated with serious side effects such as hypotension, the lowering of the blood pressure.

The *Benephit* system is being studied in patients who could benefit from minimally invasive cardiovascular procedures and diagnostic tests, such as stent placement, angioplasty or angiography, but could be at risk for acute kidney failure because their kidneys are unable to withstand the harmful effects of the dye (radiocontrast media) used during the procedure. The condition is called radiocontrast nephropathy (RCN). It is estimated that 20% of patients undergoing coronary interventions could benefit from TRT for RCN.

The system also is being evaluated as a method of delivering medications and therapeutic agents to congestive heart failure patients who develop a kidney dysfunction known as cardiorenal syndrome (CRS). CRS is characterized by excess fluid accumulation in the body, resistance to conventional medical therapy, worsening kidney function and higher mortality. An estimated 25% of hospitalized CHF patients could benefit from TRT for CRS.

“Now that the *Benephit* Infusion System will become available in Europe, physicians in the European Union will be able to conduct post-market studies in patient groups that could benefit from intra-renal infusion,” said Vartan Ghazarossian, Ph.D., president and chief executive officer of FlowMedica. “We will focus our initial efforts in Italy, where our distribution partner has an established market presence among physicians in the interventional cardiology field.”

The *Benephit* system allows for the infusion of medications and other therapeutic agents into both renal arteries simultaneously through a single catheter system, while enabling concurrent cardiovascular procedures through a single-vessel access site in the femoral artery. The system consists of a proprietary bifurcated infusion catheter and a unique introducer sheath.

In a randomized, placebo-controlled, physician-sponsored clinical trial evaluating the intra-renal delivery of a medication using the *Benephit* Infusion System, patients at risk for RCN showed significantly improved kidney function, while standard administration of the same medication via IV did not improve kidney function relative to the placebo. Furthermore, blood levels of the medication and unwanted effects were significantly less with TRT compared to standard IV treatment.

Another trial, a randomized, placebo-controlled physician-sponsored U.S. clinical study, will evaluate treatment with the *Benephit* Infusion System in patients at very high risk for RCN, diabetics with moderate or severe renal dysfunction. The trial is under way and is enrolling 64 patients.

### **About FlowMedica**

FlowMedica is a venture-backed, privately held commercial-stage medical device company founded in 2002 by Accelerated Technologies, Inc., in collaboration with leading cardiologists and surgeons. The company, located in Fremont, Calif., has raised a total of \$15.3 million to date in three rounds of private equity financing.

FlowMedica's initial product, the *Benephit* System, received 510(k) clearance from the U.S. Food and Drug Administration in January 2004 for the infusion of physician-specified agents in the peripheral vasculature including, but not limited to, the renal arteries.

###