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BENEPHIT™ DELTA INFUSION SYSTEM RECEIVES 510(k) CLEARANCE
*Device Enables Targeted Therapy to Kidneys for
Congestive Heart Failure Patients and Others*

AT A GLANCE

- New *Benephit* Delta Infusion System is designed to provide targeted renal therapy (TRT) for patients with kidney dysfunction due to congestive heart failure (CHF) and other conditions.
- TRT is the delivery of physician-specified medications and agents directly to the kidneys.
- One million CHF patients are hospitalized annually and a large percentage of them develop cardiorenal syndrome (CS), which is characterized by excess fluid accumulation in the body (fluid overload), resistance to conventional medical therapy, worsening kidney function and higher mortality.
- Physicians are assessing the premise that the therapeutic effect of drugs on the kidneys will be maximized and side effects minimized with TRT.

FREMONT, CA (March 16, 2005) – The *Benephit*™ Delta Infusion System, a new device that provides administration of physician-specified medications and other therapeutic agents directly to the renal arteries, has received 510(k) clearance from the U.S. Food and Drug Administration (FDA), FlowMedica, Inc. announced today. The *Benephit* Delta system is designed for patients with kidney dysfunction who may benefit from targeted renal therapy (TRT), including those with congestive heart failure (CHF).

TRT is an alternative to the standard delivery method of systemic intravenous (IV) infusion of medications to treat kidney dysfunction that is related to a number of conditions, including cardiovascular disease, kidney failure and congestive heart failure.

The FDA previously granted 510(k) clearance to the *Benephit* Infusion System, which

typically is used to provide TRT in conjunction with minimally invasive interventional procedures for the diagnosis or treatment of cardiovascular disease. TRT with the original *Benephit* system was usually limited to the interventional laboratory, where a single catheter is placed in a femoral artery access site in the patient's groin enabling interventional procedures to take place concurrently with TRT.

The reduced profile, increased flexibility, and longer lengths of the *Benephit* Delta system allow for access through arterial sites such as the arm. The system is designed to allow greater patient mobility and ease in providing therapy once the patient leaves the interventional laboratory. Patients who may benefit from this approach to TRT include CHF patients who develop kidney dysfunction and patients with acute renal failure who might benefit from targeted delivery of medications or therapeutic agents.

Both the original *Benephit* and new *Benephit* Delta systems are designed to provide TRT into both renal arteries simultaneously, using a single catheter.

“The *Benephit* Delta system is specially designed for patients who are experiencing kidney dysfunction and may need dedicated renal treatment,” said Paul Teirstein, M.D., FACC, director of interventional cardiology, Division of Cardiovascular Diseases, Scripps Clinic, La Jolla, Calif. “In addition to congestive heart failure patients who develop cardiorenal syndrome, the Delta system might also be used to provide therapy to patients who develop acute kidney failure while in the intensive care unit, or during or after surgery.”

Cardiorenal syndrome (CS) is a dysfunction of the kidneys that occurs in a large percentage of patients hospitalized with CHF. It is characterized by excess fluid accumulation in the body (fluid overload), resistance to conventional medical therapy, worsening kidney function and higher mortality.

Because the heart pumps ineffectively in patients with CHF, the kidneys don’t get enough blood to enable them to properly do their job, which includes filtering the blood, ridding the body of wastes and maintaining the proper volume of water in the body. When the kidneys aren’t able to rid the body of extra water and sodium (salt), the heart has to work harder to pump a greater volume of fluid, which in turn decreases the heart function even more. Symptoms of fluid overload include swelling, fatigue and shortness of breath.

Approximately 1 million hospitalizations a year are due to CHF and an estimated 25 percent of those patients could benefit from TRT for CS.

There are no proven therapies to treat CS and, in the worst cases, the condition requires dialysis, a process that mechanically removes waste products from the blood. A number of strategies have been tried to prevent CS in at-risk patients, including

administering medications and other therapeutic agents through systemic IV infusion. However, systemic infusion often is associated with serious side effects such as hypotension, the lowering of blood pressure. Researchers believe that the amount of medication that reaches the kidneys often does not attain sufficient levels to be therapeutic and, therefore, the treatment may not be effective.

Physicians are assessing the premise that drug benefits to the kidneys will be maximized with TRT because the drug is delivered in a therapeutic dose directly to the kidneys. Furthermore, since medications and other therapeutic agents used for TRT are excreted by the kidneys, physicians believe the side effects will be minimized because the kidneys will eliminate most of the drug immediately and, therefore, limit the amount of drug going to the rest of the body.

In addition to assessing the premise that TRT may benefit people with CS, physicians also are assessing the premise that TRT may prevent kidney dysfunction in people with diabetes mellitus and others whose kidneys may be unable to withstand the harmful effects of the dye (radiocontrast media) used during minimally invasive procedures and diagnostic tests, such as stent placement, angioplasty or angiography. The condition is called radiocontrast nephropathy (RCN).

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* Infusion System, received 510(k) clearance from the FDA in January 2004, and CE marking in February 2005, for the infusion of physician-specified agents in the peripheral vasculature including, but not limited to, the renal arteries.

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