

## **Patient Enrollment Completed in FIX-HF-5 Clinical Trial**

### **-Largest Study to Date Evaluating Cardiac Contractility Modulation Therapy-**

**Orangeburg, NY – June 7, 2007** – Impulse Dynamics, a medical device company, announced today that it has completed patient enrollment for the FIX-HF-5 congestive heart failure (CHF) study. The FIX-HF-5 study is the company's largest randomized clinical trial to date and is designed to evaluate the safety and efficacy of the Optimizer™ System, which delivers cardiac contractility modulation (CCM) non-excitatory impulses to treat patients with moderate to severe heart failure.

“We are pleased to have reached this important milestone in the FIX-HF-5 study. The dedication of our clinical investigators and coordinators in their support of the study and the therapy has been outstanding,” said Dr. Yuval Mika, chief operating officer of Impulse Dynamics. “In contrast to other device-based therapies for heart failure, such as cardiac resynchronization therapy (CRT), this study is focused on those patients without evidence of ventricular dyssynchrony. Patients with symptomatic heart failure without dyssynchrony currently have few treatment options.”

Over 50 investigational sites across the U.S. are participating in the FIX-HF-5 study. These sites consented over 760 patients and randomized nearly 430 patients in just a two-year period. “We have been very active in this trial and are committed to offering our patients the newest treatment options available,” said Dr. Steven Krueger, director of the Heart Improvement Program, Bryan LGH Heart Institute in Lincoln, Nebraska and a lead FIX-HF-5 enroller. “We believe that CCM therapy has an effect on the cellular level. This is a novel approach with the potential to help many patients without alternative treatments.”

Functional assessments made at baseline and throughout the follow-up period include cardiopulmonary treadmill exercise testing, six minute walk test, NYHA classification, and quality-of-life scoring. Safety variables such as the rate and cause of hospitalizations and deaths are also being monitored by an independent Data and Safety Monitoring Board.

“The Optimizer System with CCM Therapy is an exciting approach with the potential to treat those patients with Class III or Class IV heart failure, despite treatment with standard drug therapies, who presently have no other options,” said Dr. William Abraham, chief, Division of Cardiovascular Medicine, Ohio State University and FIX-HF-5 co-principal investigator. “The primary value here lies in the fact that the device is intended to improve the strength of the heart beat without adding to its overall workload. The combination of improved strength and increased efficiency of the heart makes us very optimistic about this particular therapy,” he added.

In a separate European trial evaluating CCM called FIX-4, initial results were presented at the late-breaking clinical trials session at the Heart Failure Society of America's annual meeting in 2006. The FIX-4 investigators reported that the data demonstrated that the Optimizer enhances exercise tolerance and improves the quality of life (indexed by Minnesota Living with Heart Failure Questionnaire) in heart failure patients.

“The completion of the FIX-HF-5 trial enrollment will substantially add to the growing body of evidence evaluating CCM therapy,” said Dr. Alan Kadish, professor, Division of Cardiology, Northwestern University and FIX-HF-5 co-principal investigator. “Unlike other cardiac devices for heart failure like pacemakers and defibrillators, the Optimizer System is designed to modulate the strength of contraction of the heart muscle rather than its rhythm. It is always important to consider and evaluate new heart failure therapies in order to do everything possible to potentially improve the lives of patients with this debilitating disease.”

### **About Heart Failure**

Heart failure is a disease caused by a weak or damaged heart muscle that is unable to pump enough blood throughout the body. Nearly five million Americans are living with the disease, and 550,000 new cases are diagnosed each year.<sup>1</sup>[1] It is one of the most common causes of hospitalization and a growing and costly burden to the healthcare system. It is estimated that the U.S. healthcare system will spend over twenty billion dollars in related costs for the treatment of heart failure patients in 2007.<sup>2</sup>[2]

### **About the Optimizer System & Cardiac Contractility Modulation (CCM) Therapy**

The Optimizer System is CE-Marked in Europe and investigational in the U.S. The pulse generator looks similar to a pacemaker and uses conventional pacing leads to sense electrical activity and deliver the cardiac contractility modulation (CCM) therapy to the cardiac tissue. The device is implanted in a manner similar to other implantable cardiac device procedures such as defibrillators and pacemakers. Unlike conventional pacing methods, however, the Optimizer System utilizes CCM therapy in which electrical impulses are delivered to the heart after the heart has already initiated its contraction and is intended to increase the forcefulness of the heart’s pumping action rather than initiating a new contraction.

### **About Impulse Dynamics**

Impulse Dynamics is focused on the development of electrical therapies for the treatment of heart failure. The company’s proprietary technology stems from a scientific discovery regarding the electrical control of tissue function. Optimizer is a trademark of Impulse Dynamics. For more information, please visit [www.impulse-dynamics.com](http://www.impulse-dynamics.com).

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