Why is the Optimizer® Smart Mini System innovative, what are the broad implications for future research, and how will it improve the human condition?

Impulse Dynamics is a fast-growing global medical device company that pioneered a new form of heart failure (HF) therapy called cardiac contractility modulation. This treatment, provided by the company’s Optimizer® Smart Mini System, which delivers ***CCM***® therapy to the heart, is FDA-approved. CCM is a ﬁrst-of-a-kind, proprietary, life-changing treatment alternative for a vast population of heart failure patients worldwide. We are driven by an unwavering commitment to signiﬁcantly improve heart failure patients’ lives using cardiac contractility modulation.

**CCM Therapy — A Breakthrough Approach**

CCM therapy is delivered by the Optimizer® Smart Mini System, a minimally invasive, implantable device. The innovative treatment is the most recent device generation designed to improve the contraction of the heart, allowing more oxygen-rich blood to reach the body.3 Studies evaluating the FDA-approved therapy have demonstrated the device is safe and is proven to improve the quality of life for suitable patients.3 The Optimizer Smart Mini delivers CCM® therapy, the company’s proprietary technology, to the heart.3

CCM therapy provides precisely timed electrical pulses to the heart during the absolute refractory period of the beating cycle, just after the heart contracts. The approach was proven safe and eﬀective in numerous clinical studies, including several randomized controlled trials. The results have been published in over 80 articles appearing in leading medical journals.4

The Optimizer Smart Mini System is the latest CCM therapy delivery system to be FDA-approved (as of July 30, 2021) for treating heart failure patients in the United States. At the time of this submission, CCM therapy has been used to treat over 9,000 heart failure patients; it is currently available in the United States, Europe, China, Brazil, India, and more than 40 other countries worldwide.

**CCM Therapy — An Effective Option for Millions of HF Patients**

CCM therapy, delivered by the company’s Optimizer® Smart Mini device, is an FDA-approved treatment proven to improve the quality of life for heart failure patients.3 The therapy is a safe and eﬀective minimally invasive treatment option for many heart failure patients who otherwise have few eﬀective options available to them. Additionally, it’s an innovation that can improve the lives of heart failure patients who continue to experience symptoms despite receiving medical therapy.3

CCM therapy provides an option that improves the quality of life for patients who are no longer adequately responding to medications to manage symptoms or slow the progression of heart failure.3 CCM therapy may be an appropriate treatment option for approximately 70 percent of NYHA Class III heart failure patients who remain symptomatic despite guideline-directed medical therapy.3

**How it Works**

The Optimizer® Smart Mini device is similar in size to a pacemaker and is implanted during a minimally invasive procedure while the patient is under light sedation. During the procedure, the device is implanted under the skin of the upper chest, along with electrical leads placed in the heart’s right ventricle through the veins (transcatheter). After the procedure, the physician programs the delivery of CCM therapy for each patient and activates the device.

Following the programming of CCM therapy, the implanted device sends electrical pulses to the heart muscle for a total of ﬁve hours a day, in one-hour treatments separated by regular intervals. From the comfort of their home, the patient charges the device weekly for one hour using an external charger. The Optimizer® Smart Mini System has been rigorously tested, and it is expected to provide CCM therapy for up to 20 years before requiring replacement.