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Impulse Dynamics receives FDA approval for breakthrough Optimizer®

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Designed to address a significant unmet medical need in heart failure, the Optimizer Smart System received Breakthrough Device designation from the FDA in 2015

Impulse Dynamics, developer of the implantable Optimizer® Smart System for delivering CCM™ therapy, announced that it has received approval from the United States Food and Drug Administration for its first-in-class Optimizer Smart System.

Designed to address a significant unmet medical need in heart failure, the Optimizer Smart System received Breakthrough Device designation from the FDA in 2015. It was the first breakthrough device to go before the Circulatory System Devices Panel of the FDA's Medical Devices Advisory Committee, on Dec. 4, 2018, receiving a 12-0 vote on the benefit-to-risk ratio of the device.

Professor William T. Abraham, MD, Professor of Medicine, Physiology, and Cell Biology, and College of Medicine Distinguished Professor at the Ohio State University Wexner Medical Center said, "With the FDA's approval of the Optimizer System for the delivery of CCM, we finally have available in the US an effective device-based therapy for advanced heart failure patients with mildly to moderately reduced left ventricular ejection fractions who are not eligible for CRT. The Optimizer System, along with guideline-directed medical therapies, can improve the lives of many heart failure patients in the US who previously did not have access to this therapy. As such, it represents a real game-changer for these patients."

The Optimizer Smart System is the first and only CCM device approved by the FDA to improve 6-minute hall walk distance, quality of life and functional status of NYHA Class III heart failure patients who remain symptomatic despite guideline directed medical therapy, who are in normal sinus rhythm, are not indicated for CRT, and have an LVEF ranging from 25% to 45%. Only 30 percent of moderate to severe chronic heart failure patients are candidates for CRT, which historically has left 70 percent of patients with few options to help them manage their disease.

Dr. Daniel Burkhoff, Impulse Dynamics' Medical Advisor said, "FDA approval is the culmination of many years of clinical development for this disruptive technology, addressing a significant unmet need in today's heart failure treatment paradigm," commeWe continue to develop the technology with ongoing clinical trials designed to evaluate CCM therapy in additional heart failure populations."

Dr. Simos Kedikoglou, Impulse Dynamics' CEO, announced that the Company will launch the device in the US later this year said, "We are extremely excited that the Optimizer Smart System with CCM therapy is now available in the United States. We

look forward to growing our commercial presence in the US and globally."

CCM is a unique electrical pulse delivered during the absolute refractory period, which is just after the heart contracts. In contrast to a pacemaker or defibrillator, CCM works by modulating the strength of the heart muscle contraction rather than the rhythm.