Cardialen Receives FDA Approval to Conduct Clinical Trial of Low-Energy Atrial Fibrillation Treatment

U.S. Food and Drug Administration approval of a clinical trial of Cardialen's low-energy defibrillation and cardioversion therapy expands the number of leading clinical institutions evaluating its promising MultiPulse™ Therapy.

Minneapolis, Nov. 17, 2021 – **Cardialen, Inc.,** has received approval from the U.S. Food and Drug Administration (FDA) for an Investigational Device Exemption (IDE) to begin a clinical trial of its MultiPulse™ Therapy (MPT™) to treat paroxysmal and persistent atrial fibrillation (AF).

MPT is delivered as a sequence of low-energy electrical pulses designed to restore abnormally rapid heart rates, such as AF, to a normal rhythm in a manner potentially less painful to the patient. This FDA-approved trial, "A Clinical Feasibility Study to Evaluate the Safety and Performance of Low-Energy Therapy in Patients with Atrial Fibrillation," builds on a previous study conducted by Cardialen,[1] as well as its companion study that is currently enrolling patients at seven medical centers in Australia.

Dr. John Hummel, a leading clinical researcher at The Ohio State University Wexner Medical Center and the principal investigator (PI) of this study, added, "We are excited to be contributing to Cardialen's ongoing development of this AF therapy. I believe MPT has the potential to improve heart failure outcomes in patients suffering from AF and receiving a CRT-D implant."

Also commenting on the IDE approval, Igor Efimov, PhD, Cardialen founder and professor at The George Washington University, said, “I am pleased with Cardialen’s progress. This will build on the approximately 100 patients already treated. MPT has the potential to offer patients an option of pain-tolerable cardioversion.”

Atrial fibrillation, commonly known as A-fib, is an irregular and rapid heart rate that can lead to patient discomfort and increased risk of stroke. Approximately 34 million patients suffer from this condition worldwide.[2] Approximately 26% of ICD patients,[3] and 36% of CRT-D patients,[4] receiving an implantable cardiac defibrillator have, or will likely experience, atrial fibrillation. Cardialen seeks to provide a therapy for those patients already receiving an implantable cardiac resynchronization therapy defibrillator device.

About Cardialen

Cardialen, Inc., is a Minneapolis-based medical device company developing a low-energy defibrillation and cardioversion therapy designed to treat dangerously fast heart rhythms, including atrial fibrillation and ventricular tachycardia. Cardialen’s MultiPulse Therapy uses a patented sequence of low-energy pulses to restore normal heart rhythm more gently than high-energy, often painful, shocks used for atrial fibrillation and ventricular fibrillation. Learn more at **www.cardialen.com.**

MultiPulse Therapy is currently an investigational device only and is not currently commercially available for use in any market.

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