FARAPULSE

FARAPULSE Receives FDA Breakthrough Designation for its Endocardial Pulsed Field Ablation System

Menlo Park, California - May 8, 2019 - FARAPULSE Inc. ("FARAPULSE" or "the "Company") today announced it has received Breakthrough Device designation from the Center for Devices and Radiological Health (CDRH) of the U.S. Food and Drug Administration (FDA) for its Endocardial Ablation System. The system is being developed to advance the standard of care for the treatment of drug refractory, recurrent, symptomatic paroxysmal atrial fibrillation. Employing a non-thermal energy source to create durable lesions with the goal of dramatically improving the safety profile of cardiac ablation, FARAPULSE PFA (Pulsed Field Ablation) is being developed to allow physicians to ablate and isolate arrhythmia-causing cells within the heart with greater flexibility and precision.

"A leading cause of stroke, AF is a debilitating condition and the FDA's Breakthrough designation is a welcomed milestone in our progress, allowing us to advance this exciting technology as quickly as possible with the Agency's guidance and collaboration," said Allan Zingeler, President and CEO of FARAPULSE. "We believe FARAPULSE PFA has the very real potential to become the energy source of choice for cardiac ablation, by ultimately facilitating new levels of confidence and safety."

The FDA Breakthrough Device Program is intended to help patients receive more timely access to breakthrough technologies that have the potential to provide more effective treatment or diagnosis for life-threatening or irreversibly debilitating diseases or conditions. Under the program, the FDA will provide FARAPULSE with priority review and interactive communication regarding device development and clinical trial protocols continuing through the premarket review process.

About FARAPULSE

Today, all forms of cardiac ablation to treat arrhythmias are thermal. And while both radiofrequency and cryo-ablation have evolved, they nonetheless carry an inherent risk of indiscriminate thermal damage. Tissue-selective FARAPULSE PFA has emerged to be one of the most promising energy sources for cardiac ablation, including pulmonary vein isolation. Combining speed with safety, FARAPULSE PFA makes durable lesions in a manner of micro-seconds while sparing non-target tissue. FARAPULSE is advancing its PFA tissue-selective therapy on catheter-based and surgical platforms for both endocardial and epicardial approaches.

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