



FARAPULSE

FARAPULSE Receives European Approval To Commercialize Its Leading Pulsed Field Ablation System To Treat Paroxysmal Atrial Fibrillation

- FARAPULSE becomes first company in the world to commercialize a cardiac PFA system -

Menlo Park, California – January 29, 2021 - FARAPULSE Inc. ("FARAPULSE" or "the Company") today announced that it has received the Conformité Européene (CE) Mark for its FARAPULSE Pulsed Field Ablation (PFA) system for the treatment of Paroxysmal Atrial Fibrillation (AF). The approval makes FARAPULSE the first company in the world to commercialize a cardiac PFA system and permits marketing of the system across the European Union and other CE Mark geographies. AF affects one in four adults during their lifetime and is a leading cause of stroke.

"FARAPULSE PFA has garnered a high level of interest at scientific symposia in the past several years, making it abundantly clear that the medical community is primed to adopt our technology into routine use. The clinical results and unparalleled volume of data chronicled through investigator-authored abstracts and manuscripts have been exceedingly well received," said Allan Zingeler, President and CEO of FARAPULSE. "Europe's modern and progressive electrophysiology market represents a unique opportunity for FARAPULSE to showcase our PFA system's powerful yet incredibly safe ability to lead in the treatment of AF."

"Based on my own multi-year experience with the FARAPULSE system and the compelling results from the Company's comprehensive clinical program, I believe PFA will define a new era in the ablation of AF and possibly other arrhythmias," said Pierre Jaïs, Bordeaux University Hospital, Electrophysiology and Heart Modeling Institute (LIRYC), France. "In more than 160 procedures performed across Europe, the system has surpassed all expectations with respect to safety, effectiveness, efficiency and ease-of-use. It will be exciting to welcome this ground-breaking technology into our clinic, especially as the potential for fatal esophageal fistula has been in the back of our minds for decades, and now this risk is significantly mitigated with FARAPULSE's technology."

The CE Mark confirms that the FARAPULSE PFA system meets all requisite quality standards for safety, design, manufacture and final inspection. Through a thoughtful European launch catalyzed by high demand, FARAPULSE will partner with a select number of physicians prior to a broader rollout. In September 2020, Boston Scientific announced an expanded investment in FARAPULSE and secured an exclusive option to acquire the Company.

The Company's PFA technology will feature prominently in the scientific sessions of the 2021 AF Symposium beginning today and broadcasted online at www.afsymposium.com.

About FARAPULSE and PFA

Today, all forms of cardiac ablation to treat arrhythmias are thermal. 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 to treat Atrial Fibrillation. Leading with safety, FARAPULSE PFA makes durable cardiac lesions in seconds while sparing non-target tissue. FARAPULSE is pioneering tissue-selective PFA therapy through development and commercialization of its dedicated generator (FARASTAR), PVI-focused catheter (FARAWAVE), large-area focal catheter (FARAFLEX), precision focal catheter (FARAPPOINT) and a proprietary deflectable delivery sheath (FARADRIVE).

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