Press Release

FARAPULSE's Pivotal Trial to Assess Its Leading Pulsed Field Ablation System for The Treatment of Atrial Fibrillation Receives FDA Conditional Approval

- Large, Randomized Controlled ADVENT Trial Designed to Establish New Gold Standard for AF Ablation -

Menlo Park, California – December 17, 2020 - FARAPULSE Inc. ("FARAPULSE" or "the Company") today announced the U.S. Food and Drug Administration (FDA) conditionally approved the Company's Investigational Device Exemption (IDE) application to initiate its U.S. pivotal ADVENT trial to evaluate the safety and effectiveness of its Pulsed Field Ablation (PFA) system for the treatment of paroxysmal Atrial Fibrillation (AF). AF affects one in four adults during their lifetime and is a leading cause of stroke.

"By committing to a randomized and demanding trial design with a well-defined and cogent endpoint of single-procedure freedom from AF, the ADVENT study will ultimately provide a comprehensive, data-driven rationale that establishes FARAPULSE PFA as the gold standard approach to safe and effective AF ablation," said Allan Zingeler, President and CEO of FARAPULSE. "With more than 170 cases already performed around the world, FARAPULSE PFA has raised expectations for the safe and effective treatment of AF. The ADVENT trial is the next step towards revolutionizing the therapeutic approach for treating AF in the U.S."

Jeremy Ruskin, MD, Founder and Director Emeritus of the Cardiac Arrhythmia Service at Massachusetts General Hospital and Chair of FARAPULSE's Scientific Advisory Board, commented on the trial design, "The design of the randomized ADVENT Study, which uses a novel control arm of both contact force RF and cryoballoon treatments, will generate robust clinical data to assess the performance and potential advantages of the FARAPULSE PFA System against currently used technologies."

Since 2013 FARAPULSE has led the development of cardiac PFA, championing this innovative energy source's potential to more safely and effectively ablate all arrhythmias, including AF. Having developed the first cardiac PFA system ever put into human use, FARAPULSE has now established an unrivaled library of advanced preclinical and clinical data. This clinical data stems from more than 170 treated AF patients performed by six physicians across multiple centers in Europe. Over 100 patients have completed 1 year of follow-up. Of note, more than 130 patients underwent prospective reassessment (remapping) 3 months after their procedures to confirm the durability of FARAPULSE PFA therapy to isolate the pulmonary veins. Top line safety results from the Company's clinical studies showed that the severe complications of PV stenosis and both esophageal and phrenic nerve injury were absent in all patients.

The FDA's conditional approval of the IDE allows FARAPULSE to finalize trial arrangements with the participating hospitals prior to patient enrollment, including Institutional Review Board (IRB) approvals.

About the ADVENT Trial
The ADVENT Trial is a randomized controlled trial, enrolling at least 350 randomized patients across more than 30 U.S. centers. Patients will be randomized between PFA, radiofrequency and cryo ablation in a 2:1:1 ratio. The primary endpoint will be freedom from AF for twelve months after a single ablation procedure. Dr. Vivek Reddy, Director of Cardiac Arrhythmia Services for The Mount Sinai Hospital and the Mount Sinai Health System, is the trial's Principal Investigator.

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 (FARAPOINT) and a proprietary deflectable delivery sheath (FARADRIVE).

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Contact:
Allan Zingeler
azingeler@farapulse.com