



Adagio Medical Announces Initiation and First Patient Enrollment in PARALELL Trial To Investigate Safety and Performance of CryoPulse™ Catheter System for Pulsed Field Ablation and Pulsed Field Cryoablation of Persistent Atrial Fibrillation

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LAGUNA HILLS, Calif., October 24, 2022 /PRNewswire/ -- Adagio Medical, Inc., a leading innovator in catheter ablation technologies for atrial fibrillation (AF) and ventricular tachycardia (VT), announced its first pulsed field cryoablation (PFCA) procedure performed using the Adagio CryoPulse™ catheter system as part of the PARALELL Pulsed Field Ablation and Pulsed Field CRyoAbLation in PErsistent AtriaL Fibrillation) clinical trial, NCT #05408754. The procedure was performed at St. Antonius Hospital Nieuwegein, Netherlands by Lucas Boersma, MD, PhD, Professor at Amsterdam UMC, and a co-principal investigator of the trial.

"PFCA is a unique ablation modality consisting of a 30-second ultra-low temperature cryoablation (ULTC) cycle with pulsed field ablation (PFA) delivered at the very end of the cycle using a single catheter system," said Dr. Boersma. "The recent trial of ULTC established a new benchmark of ablation effectiveness in persistent AF with reported 85% freedom from AF after a single procedure, and the PARALELL trial will test the performance of PFCA against that benchmark, with additional benefit of shorter ablation times. In addition, the trial design allows for randomization of patients to PFCA or PFA, delivered by the same catheter to create identical sets of lesions with similar characteristics."

"PFA has recently captured the attention of the EP community with the expectation of achieving safer and faster procedures based on the selective effect on the myocardium as compared to currently dominant point-by-point RF ablations, and multiple PFA systems are currently undergoing clinical evaluations," said Dr. Atul Verma, MD, Associate Professor and Director, Division of Cardiology McGill University Health Centre, PARALELL co-principal investigator and a world-renowned expert in PFA. "Physiologically, PFCA builds on the tissue selectivity of PFA by focusing electrical fields into a target myocardial tissue, pre-treated by short-duration ULTC to increase lesion depth and ensure transmural, and by forming the isolating layer of ice between the electrodes and the blood. As a result, microbubble showers, phrenic nerve capture and muscle contractions observed in traditional PFA are effectively eliminated. So, in effect, we are taking advantage of the benefits of ULTC and PFA collectively, while minimizing their individual disadvantages."

The ablation procedures in the PARALELL trial will be performed using the first generation of Adagio's CryoPulse™ PFCA catheter in combination with proprietary PFA and iCLAS™ cryoablation consoles. The iCLAS cryoablation system for treatment of paroxysmal and persistent AF as well as atrial flutter received CE Mark and is commercial in Europe. The safety and effectiveness of the iCLAS system for the treatment of persistent AF are being evaluated in an FDA IDE trial in the US (NCT # 04061603). The Adagio Medical clinical trials portfolio also includes the Cryocure-VT trial (NCT #04893317) which is evaluating safety and performance of the vCLAS™ ULTC catheter system for treatment of monomorphic ventricular tachycardias.

"The initiation of the PARALELL trial is another step towards Adagio's goal to advance the field of clinical EP and to improve the outcomes of arrhythmia patients with catheter technologies of uncompromising durability, versatility and safety," said Olav Bergheim, President and CEO of Adagio Medical. "Our immediate goal is to use the results of the PARALELL study to obtain CE Mark for the first-generation CryoPulse™ catheter system, thus putting all three ablation modalities, ULTC, PFA, and PFCA at the fingertips of every electrophysiologist, first in Europe and eventually worldwide."

About Adagio Medical

Adagio Medical, Inc. (www.adagiomedical.com) is a privately held company located in Laguna Hills, California developing innovative cryoablation technologies that create contiguous, transmural lesions to treat cardiac arrhythmias, including paroxysmal and persistent atrial fibrillation, atrial flutter, and ventricular tachycardia. Adagio Medical, Inc. is a Fjord Ventures portfolio company.

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