Adagio Medical, Inc., reports pre-clinical effectiveness combining their existing ultra-low temperature cryoablation catheter with Pulsed Field Ablation (PFA) in a single Pulsed Field Cryoablation (PFCA) catheter

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LAGUNA HILLS, Calif., June 1, 2019 /PRNewswire/ –Adagio Medical, Inc., announces that it has received CE Mark approval for its ultra-low temperature intelligent Continuous Lesion Ablation System (iCLAS) for the endocardial treatment of paroxysmal (PAF) and persistent (PsAF) atrial fibrillation and atrial flutter.

"More than half of all atrial fibrillation (AF) patients are diagnosed with PsAF. There is a strong demand to treat this patient group with endocardial, continuous, transmural lesion sets with results similar to what has been shown with the surgical Maze procedure. Using a single iCLAS catheter, the procedure can be completed in less than one hour," says Olav Bergheim, CEO of Adagio Medical, Inc.

The 8.5Fr iCLAS catheter combines ablation and diagnostic capabilities, thereby requiring only a single transseptal puncture. The iCLAS procedure can be done utilizing an anatomical approach which eliminates the need for electromagnetic mapping. The ability to exchange stylets, without removing the catheter, allows for unlimited shapes and sizes of both the ablation and diagnostic sections of the catheter.

"The multicenter European CryoCure II clinical study has shown that we can perform pulmonary vein isolation (PVI) in combination with other ablations in both atria (e.g. posterior wall box and cavo tricuspid isthmus isolation), even in the most difficult to treat PsAF patients. The uniquely versatile delivery system enables the ablation procedure to be performed with a single catheter. Ablations beyond PVI only add a few minutes to the total procedure time," says Tom De Potter MD, FEHRA, Associate Director, Cardiovascular Center OLV Hospital, Aalst, Belgium. "Similar to what was presented at the 2019 Heart Rhythm Society meeting, the CryoCure II data continues to show PsAF outcomes with 85% freedom from atrial arrythmias at 12 months."

Adagio Medical GmbH was formed in Munich, Germany and is preparing for a limited European commercial launch of the iCLAS in early summer of this year. "With this CE Mark approval, we are excited to offer this novel treatment to the large PsAF patient population," says Michael Heuer, General Manager, Europe.

Adagio Medical is conducting a prospective, single-arm, controlled IDE study in 20 centers in the United States, Western Europe, and Canada. The study is designed to demonstrate the safety and efficacy of iCLAS for the treatment of PsAF. ClinicalTrial.gov Identifier: NCT04061603 U.S. FDA IDE #G180263.

ABOUT ADAGIO

Adagio (www.adagiomedical.com) is a privately held company located in Laguna Hills, California developing innovative cryoablation technologies that create continuous, linear, 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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