



Adagio Medical Announces Publication of Cryocure-2 Data Reporting 85% Freedom from AF at 12 Months After a Single Ablation Procedure in Patients with Persistent Atrial Fibrillation and Discusses Current Status of iCLAS™ Cryoablation System

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LAGUNA HILLS, Calif., July 28, 2022 /PRNewswire/ -- Adagio Medical, Inc., a leading innovator in catheter ablation technologies for atrial fibrillation (AF) and ventricular tachycardia (VT), announced the publication of the results of its Cryocure-2 ultra-low temperature cryoablation (ULTC) study in patients with AF in the *Journal of American College of Cardiology (JACC), Clinical Electrophysiology*.¹ The study prospectively enrolled 79 patients at OLV Hospital, Aalst, Belgium, St. Antonius Hospital in Nieuwegein, Netherlands and University of Bordeaux, Bordeaux, France, of which 45 patients had persistent AF (PsAF). The one-year freedom from AF after a single procedure was 82%, with 1.5% procedural complications rate when using ULTC technology. In PsAF patients, freedom from AF was 85%.

"We reported preliminary results of Cryocure-2 at the 2021 Heart Rhythm Society meeting in Boston," said Dr. Tom De Potter, MD, Associate Director, Cardiovascular Center Department of Cardiology, Electrophysiology Section at OLV Hospital, and the first author of the manuscript. "Today's publication reaffirms the interest of the EP community in ULTC technology for the treatment of AF and other cardiac arrhythmias. The 85% freedom from AF in PsAF patients after a single percutaneous procedure is by far the best result reported in such patients, and needs conformation in the larger study, which is currently ongoing."

"Almost all patients with persistent AF in the Cryocure-2 study underwent ablations which combined pulmonary vein isolation with additional lesions, mostly on the posterior wall of the left atrium," added Lucas Boersma, MD, PhD at St. Antonius Hospital Nieuwegein, Netherlands and Professor at Amsterdam UMC. "There is a preponderance of clinical evidence that additional lesions improve effectiveness of the ablation in persistent AF patients, however, creating such lesions using traditional RF and cryoballoon ablation procedures is often too burdensome as a first-line treatment. The unique feature of Adagio's catheter design is how little incremental work those lesions require, adding only 7 minutes to the procedure time at the experienced Cryocure-2 sites. We are now incorporating this approach into routine clinical practice."

Adagio Medical iCLAS™ cryoablation system received CE-mark and is commercial in Europe. The Cryocure-PMCF (NCT # 05416086) open-label post-market clinical follow-up evaluation of iCLAS system is enrolling both paroxysmal and persistent AF patients at several European centers. The safety and effectiveness of the iCLAS system for the treatment of persistent AF is a subject of FDA IDE trial in the US (NCT # 04061603).

"The publication of Cryocure-2 data is seen as a significant step in the validation of Adagio's ULTC technology," said Olav Bergheim, President and CEO of Adagio Medical. "As additional ULTC outcome data becomes available,² we have high expectations for the results of our ongoing FDA IDE trial. We also believe the iCLAS outcome data will further the recognition of the Adagio technology in both Europe and the US and will contribute to increased penetration of catheter ablation in the large and growing AF patient population, which is an underserved market today."

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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¹ De Potter T, Klaver M, Babkin A, Iliodromitis K, et al. Ultra-Low Temperature Cryoablation For Atrial Fibrillation: Primary Outcomes for Efficacy and Safety: The Cryocure-2 Study. *J Am Coll Cardiol EP* 2022; available online at

² [Tohoku S, Schmidt B, Bordignon S, Chen S, et al. Initial clinical experience of pulmonary vein isolation using the ultra-low](#)

[temperature cryoablation catheter for patients with atrial fibrillation. J Cardiovasc Electrophysiol. 2022;1–9.](#)