



## **Adagio Medical Announces First Patient Enrollment in its iCLAS™ U.S. IDE Clinical Trial Evaluating Ultra-Low Temperature Cryoablation for Persistent Atrial Fibrillation**

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**LAGUNA HILLS, Calif., Dec. 16, 2019 /PRNewswire/** — Adagio Medical, Inc. (Adagio) today announced it has enrolled the first patient in its iCLAS™ Investigational Device Exemption (IDE) trial. The FDA approved study aims to evaluate the safety and efficacy of Adagio's ultra-low temperature intelligent Continuous Lesion Ablation System (iCLAS) in the treatment of persistent atrial fibrillation (PsAF). Data will be used to support a pre-market application. The first patient was enrolled by Suneet Mittal, M.D., FHRS at The Valley Hospital in Ridgewood, New Jersey.

"We are pleased to be the first site to enroll a patient in this study," said Suneet Mittal, M.D., National Principal Investigator for the iCLAS Trial at The Valley Hospital. "This novel cryoablation system offers multiple advantages, including a single catheter to address all ablation needs, irrespective of whether right or left atrium is targeted for ablation, no 3D mapping required, and more comprehensive lesion sets may favorably impact long-term results of ablation in this difficult to treat patient population."

The One Shot+ Cryoablation Catheter used in the trial makes true continuous, transmural lesions and combines ablation and diagnostics in the same catheter, thereby requiring only a single transseptal puncture. This catheter enables a simplified procedure that utilizes an anatomical approach to guide navigation, eliminating the need for electromagnetic mapping. Interchangeable stylets allow for unlimited shapes of both the ablation and diagnostic sections of the catheter, enabling any targeted lesion set.

"We are privileged to work with leading electrophysiologists to advance the treatment of atrial fibrillation," says Olav Bergheim, CEO of Adagio. "Current ablation therapies are used to treat less than 5% of eligible patients due to disappointing clinical outcomes, long procedure times and unsatisfactory profitability for the providers. The Adagio procedure aims to transform ablation therapy by addressing each of these challenges, making catheter ablation therapy available to the broader AFib patient population."

### **ABOUT ADAGIO**

Adagio Medical, Inc. ([www.adagiomedical.com](http://www.adagiomedical.com)) is a privately held company located in Laguna Hills, California developing 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.

**SOURCE** Adagio Medical, Inc.

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