Adagio Medical Announces US FDA Investigational Device Exemption Approval With Conditions To Conduct A Clinical Study For Treatment Of Persistent Atrial Fibrillation Using The Ultra-Low Temperature Cryoablation System

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LAGUNA HILLS, Calif., Aug. 19, 2019 /PRNewswire/ — Adagio Medical, Inc. (Adagio), the developer of iCLAS™, the company's ultra-low temperature intelligent continuous lesion ablation system, announced that it has received an Investigational Device Exemption approval with conditions from the US Food and Drug Administration (FDA) to conduct a non-randomized, single-arm clinical study for persistent atrial fibrillation (AF). The study will support a Pre-Market Approval application for the treatment of patients with AF that has persisted more than seven days but less than twelve months, who have not had prior AF ablation therapy. Research centers will include both private practice and academic sites in the US, Canada, and Europe.

"The Adagio procedure aims to improve current outcomes, reduce the procedure time and improve the profitability of the provider. Our recent press release dated July 31, 2019, regarding the use of anatomical markers only in the treatment of AF, including PsAF announced an important step in that direction," said Olav Bergheim, Chief Executive Officer of Adagio. "The Adagio iCLAS procedure is a transformational approach to AF ablation."

"Adagio has been working diligently toward, and is extremely pleased with, this important corporate milestone," said Nabil Jubran, Vice President of Regulatory Affairs and Quality. "We have started the approval process of our clinical sites and may have patients enrolled and treated by the fall. We are pleased with the strong interest expressed by the clinical community in participating in this clinical study."

The study will utilize the Adagio cryoablation console with the One Shot™ and the One Shot+™ cryoablation catheters. Each has been uniquely designed to effectively create continuous, transmural linear and focal lesions in the left and right atria. Patients will receive an ablation with one of the two catheters and will be followed for 12 months for evidence of a recurrence of the arrhythmia. In a similar clinical study conducted in Europe, single treatment of patients with persistent AF has approached 90% efficacy one year after treatment using standard endpoint measurements for AF ablation.

About Adagio Medical
Adagio Medical, Inc. 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. For additional information please send an email to info@adagiomedical.com.

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