



Adagio Medical Announces Completion of First Procedures in FULCRUM-VT U.S. FDA Pivotal IDE of Ventricular Tachycardia Cryoablation System

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LAGUNA HILLS, Calif., October 24, 2024 /PRNewswire/ -- Adagio Medical Holdings, Inc. (Nasdaq: ADGM; "Adagio Medical", "Adagio" or the "Company"), a leading innovator in catheter ablation technologies, today announced the completion of the first procedures in FULCRUM-VT U.S. Food and Drug Administration (FDA) Pivotal IDE study of Adagio's VT Cryoablation System. Procedures were performed by Professor William G. Stevenson, MD, at Vanderbilt University Medical Center in Nashville, TN and Dr. J. David Burkhardt at Texas Cardiac Arrhythmias Institute (TCAI) at Austin, TX.

FULCRUM-VT (Feasibility of Ultra-Low Temperature Cryoablation in Recurring Monomorphic Ventricular Tachycardia, NCT05675865) is a prospective, multi-center, open-label, single-arm study, enrolling 206 patients with structural heart disease of both ischemic and non-ischemic cardiomyopathy, indicated for catheter ablation of drug refractory ventricular tachycardia (VT) in accordance with current treatment guidelines. The results of the study will be used to obtain FDA premarket approval (PMA) for Adagio's VT Cryoablation System with the vCLAS™ cryoablation catheter with industry broadest indication for purely endocardial ablation of scar-mediated VT.

"Our center enrolled six patients in the Early Feasibility stage of FULCRUM-VT program, with encouraging results," said Dr. Stevenson, a world-renowned expert in the treatment of cardiac arrhythmias. "Today's procedures mark the expansion of the program to 20 centers in the US and Canada, allowing for the robust evaluation of Adagio's technology in a large and challenging population of patients with structural heart disease. The only approved ablation option we can currently offer these patients is based on radiofrequency, or RF energy, which has well-known limitations for ablations in thicker cardiac tissue and when managing patients at risk of cardiac decompensation, the limitations this system may help overcome."

"This was TCAI's first experience with Adagio's system," added Dr. Burkhardt, "and we successfully and safely ablated a non-ischemic scar in tissue with depth exceeding 10 mm in the proximity of the artificial transcatheter aortic valve, which limited the achievable depth of other available technologies. This gives us confidence and motivation as we continue with study enrollment."

The Adagio Medical VT Cryoablation System with the vCLAS™ cryoablation¹ catheter is based on the Company's proprietary ultra-low temperature cryoablation technology (ULTC) and was designed specifically to address both safety and effectiveness challenges of VT ablation by creating large and deep endocardial lesions with minimal attenuation by scar tissue² without the need for catheter irrigation, a known risk for acute heart failure in patients undergoing RF ablations. The system has recently gained CE-Mark approval and is commercially available in select European countries.

"We are pleased to partner with the top academic institutions to bring a long-overdue innovation in VT ablation technology to patients in the US," said Olav Berghem, President and CEO of Adagio. "Just recently, FULCRUM-VT received Medicare coverage approval from the Center for Medicare and Medicaid Services (CMS) and study approval from Health Canada. We are now focused on accelerating patient enrollment at all study sites. The European launch of vCLAS is also accelerating, with a growing number of centers evaluating ULTC technology across the spectrum of VT etiologies and patient presentations."

¹The Adagio Medical, Inc. VT Cryoablation System (Catheter and Console) is indicated for the treatment of monomorphic ventricular tachycardia by ablation of arrhythmogenic tissues that drive and maintain these arrhythmias. The vCLAS™ Cryoablation Catheter, a component of the Adagio Medical, Inc. VT Cryoablation System is intended to create transmural linear and focal lesions to cardiac structures within the endocardium of the ventricles with cryoablation. Adagio Medical, Inc. PM-006 Rev. E

² Dewland TA, Higuchi S, Venkateswaran R, Lee C, Gerstenfeld EP. AB-452672-2 Ultra-low Temperature Cryoablation Versus Ultra-low Temperature Cryoablation Combined With Pulsed Field Ablation In A Swine Ventricular Infarct Model. Heart Rhythm 2023;20:S92-S93. <https://doi.org/10.1016/j.hrthm.2023.03.395>

About Adagio Medical

Adagio Medical, Inc. is an early commercial stage medical device company located in Laguna Hills, California focusing on developing innovative cryoablation technologies that create contiguous, transmural lesions to treat cardiac arrhythmias, including paroxysmal and persistent atrial fibrillation, atrial flutter, and ventricular tachycardia.

Forward-Looking Statements

Certain statements in this press release may be considered "forward-looking statements" within the meaning of the "safe harbor"

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Nothing in this Press Release should be regarded as a representation or warranty by any person that the forward-looking statements set forth herein will be achieved or that any of the contemplated results of such forward-looking statements will be achieved, in any specified time frame, or at all. You should not place undue reliance on forward-looking statements, which speak only as of the date they are made in this Press Release. Subsequent events and developments may cause those views to change. The Company does not undertake any duty to update these forward-looking statements.

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