



Adagio Medical Highlights First Patient Treated in IDE Study Evaluating Next-Generation vCLAS™ Ultra System for Ventricular Tachycardia at Banner – University Medical Center Phoenix

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Enrollment Underway Across Multiple Sites as Study Advances Faster, Improved ULTA Catheter for the Broadest Population of VT Patients

LAGUNA HILLS, Calif.--(BUSINESS WIRE)--Sep. 16, 2026-- Adagio Medical Holdings, Inc. (Nasdaq: ADGM) ("Adagio" or "the Company"), a leading innovator in catheter ablation technologies for the treatment of cardiac arrhythmias, today announced highlights from the first patient enrolled in the Company's study evaluating its next-generation vCLAS™ Ultra Ultra-Low Temperature Ablation ("ULTA") Ventricular Ablation System. The study is designed to support a Premarket Approval ("PMA") supplement to the Company's PMA for its first generation vCLAS system, which is presently under review by the U.S. Food and Drug Administration ("FDA"). The supplemental study is being conducted under the Company's FDA-approved Investigational Device Exemption ("IDE") designed to evaluate the safety and effectiveness of the vCLAS Ultra System for the treatment of Sustained Monomorphic Ventricular Tachycardia ("SMVT").

The patient, who presented with non-ischemic cardiomyopathy and recurrent ventricular tachycardia following a recent prior catheter ablation, was successfully treated by Dr. Roderick Tung, MD, Director of Banner – University Medicine Heart Institute and Division Chief of Cardiology at the University of Arizona College of Medicine – Phoenix. The target site was a thick anatomic area directly under the mitral valve that typically presents significant challenges in catheter reach and lesion depth.

"Adagio's next generation vCLAS Ultra device handled with the familiarity of traditional catheters while efficiently reaching an especially challenging anatomic location in the ventricle. The catheter reached a sub-valvular substrate just under the mitral valve annulus with ease from both transseptal and retrograde approaches. The maneuverability and contact were exactly what the anatomy required, and the patient continues to do well many weeks post-procedure," said Dr. Tung. "We successfully treated the arrhythmogenic substrate with remarkably short ablation times, aided by the catheter's large surface area and deep ablation footprint. These meaningful improvements in usability over the first generation vCLAS catheter, combined with what we have seen in safety and efficacy profiles of ULTA, have the potential to be game-changing as a solution across the large population of patients suffering from VT."

The vCLAS Ultra System is the next-generation evolution of Adagio's proprietary ULTA technology and is intended to reduce ablation time and simplify the procedure while maintaining the established clinical capabilities of the ULTA platform for treatment of ventricular tachycardia ("VT"). The more maneuverable vCLAS Ultra system is designed to deliver single-freeze ablations at approximately -170°C with pre-clinical data demonstrating a potential 50-75% reduction in ablation time, which could reduce overall procedure time by 30 minutes or more compared to the first-generation system.

"This first patient that kicked off our clinical trial several weeks ago represented a significant milestone as we work with our physician partners to bring the next generation of ULTA technology through formal clinical evaluation. We are honored to have had Dr. Tung and his team at the forefront of this important step for Adagio," said Todd Usen, Chief Executive Officer of Adagio Medical. "We have built the vCLAS Ultra on the foundation of the proven clinical profile of the ULTA platform, and we are now focused on demonstrating the potential of the next-generation system to deliver the same broad clinical capabilities with a faster and more efficient procedural workflow. We believe vCLAS Ultra has the potential to further establish ULTA as a foundational technology for VT ablation and to provide physicians with a single, purpose-built all-endocardial catheter capable of addressing the broad spectrum of VT patients encountered in clinical practice."

About Adagio Medical Holdings, Inc.

Adagio is a medical device company focused on developing and commercializing products for the treatment of cardiac arrhythmias utilizing its novel, proprietary, catheter-based Ultra-Low temperature ablation ("ULTA", formerly known as ULTC) technology. ULTA is designed to create large footprint, titratable lesions extending through the depth of both diseased and healthy cardiac tissue, all through an endocardial approach. The Company is currently focused on the treatment of ventricular arrhythmias with its purpose-built vCLAS Ventricular Ablation System, which is CE Marked, and in May 2026 the Company submitted the results of the FULCRUM-VT pivotal study to support its PMA application to the FDA for the vCLAS Ventricular Ablation System. The Company is also developing a next-generation vCLAS Ultra catheter, designed to support faster ablation procedures with a smaller and more flexible form factor than its predecessor vCLAS device.

About FULCRUM VT

FULCRUM-VT (Feasibility of Ultra-Low Temperature Cryoablation in Recurring Monomorphic Ventricular Tachycardia) is a

prospective, multi-center, open-label, single-arm trial, which has fully enrolled 209 patients with structural heart disease of both ischemic and non-ischemic cardiomyopathy, indicated for catheter ablation of drug refractory VT in accordance with current treatment guidelines. FULCRUM-VT 6-month primary chronic effectiveness was defined as freedom from sustained monomorphic VT lasting longer than 30 seconds or VT requiring appropriate ICD device therapy, in the absence of new or increase in antiarrhythmic drug therapy beyond previously failed dose.

The FDA has granted Investigational Device Exemption (IDE) approval to expand the Company's FULCRUM-VT trial to evaluate the safety and effectiveness of the Company's next-generation vCLAS Ventricular Ablation System (ULTA) for the treatment of Sustained Monomorphic Ventricular Tachycardia (SMVT).

Adagio's vCLAS™ Ventricular Tachycardia System is commercially available for the treatment of monomorphic VT in Europe and select other geographies but is limited to investigational use in the United States.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as "anticipates," "believes," "expects," "intends," "projects," "plans," "potential," "future" or similar expressions are intended to identify forward-looking statements. Forward-looking statements include statements concerning: anticipated timing and outcome of the FDA's review of the Company's PMA application for the vCLAS Ventricular Ablation System; the potential for ULTA technology to address unmet needs in the treatment of VT, including across both ischemic and non-ischemic cardiomyopathy substrates; the potential clinical benefits of ULTA; the potential market opportunity for the vCLAS Ventricular Ablation System; and Adagio's research, development, regulatory and commercialization plans, including communications with the FDA. Forward-looking statements are based on management's current expectations and are subject to various risks and uncertainties that could cause actual results to differ materially and adversely from those expressed or implied by such forward-looking statements. Accordingly, these forward-looking statements do not constitute guarantees of future performance, and you are cautioned not to place undue reliance on these forward-looking statements. Risks regarding Adagio's business are described in detail in Adagio's Securities and Exchange Commission ("SEC") filings, including in its Annual Report on Form 10-K for the full-year ended December 31, 2025, which is available on the SEC's website at www.sec.gov. Additional information will be made available in other filings that Adagio makes from time to time with the SEC. These forward-looking statements speak only as of the date hereof, and Adagio disclaims any obligation to update these statements except as may be required by law.

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