Adagio Medical Unveils Preliminary Acute Results from FULCRUM-VT U.S. Pivotal Study in Late Breaking Session at VT Symposium

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97% Acute Effectiveness and Favorable Safety Results from Proprietary ULTC for Ventricular Tachycardia

LAGUNA HILLS, Calif.--(BUSINESS WIRE)--Oct. 10, 2025-- 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 preliminary acute (within 7 days) safety and efficacy results from the Adagio's FULCRUM-VT Study evaluating Ultralow Temperature Cryoablation ("ULTC") for the treatment of Sustained Monomorphic Ventricular Tachycardia ("SMVT") in patients with both ischemic and nonischemic cardiomyopathy. The data are being presented by Travis Richardson, MD, Assistant Professor of Medicine, Clinical Cardiac Electrophysiology, Vanderbilt University Medical Center, in a Late Breaking Clinical Trials Session at the 20th Annual International Symposium on Ventricular Arrhythmias being held in Philadelphia on October 10, 2025.

A total of 207 patients underwent ventricular tachycardia ("VT") ablation using Adagio's ULTC system at 19 sites in the United States and Canada. The study included patients with both ischemic ("ICM") and non-ischemic ("NICM") cardiomyopathies (LVEF=35+/-10%, 33% NICM, 75% with congestive heart failure). Mean procedure duration was 206+/- 68 minutes and acute clinical success, defined as non-inducibility of target ventricular arrhythmias, was 97.4%, with all clinically-relevant ventricular tachycardias eliminated in 96.7% of patients tested by post-ablation programmed electrical stimulation. Key safety findings included a 2.5% rate of major adverse events including four (1.9%) peri-procedural deaths, of which one (0.5%) was adjudicated by an independent clinical events committee as definitely related to the investigational device.

A presentation with additional details and accompanying figures are available on a Current Report on Form 8-K, which is being filed concurrently with this press release and available on the SEC's website at www.sec.gov.

"The patient profile in FULCRUM-VT is representative of what we see in real-world practice. The ability of Adagio's ULTC system to produce deep, titratable endocardial lesions without irrigation and without concerns for catheter stability make it a promising tool for a broad patient population. These factors, along with the broad inclusion criteria for the study, fueled swift enrollment," said Dr. Richardson. "FULCRUM-VT not only included patients with ischemic myopathy, but also a large number with nonischemic disease, whose VT is often more difficult to treat due to deep substrate. Despite this, the acute effectiveness across the study population was excellent. This, along with the favorable safety profile of the ULTC System, is encouraging. VT is a largely undertreated condition, partially because the available treatment tools make ablation procedures challenging, and I have hope that ULTC will help to change that. We look forward to the six-month primary efficacy endpoint results of the FULCRUM-VT trial, which the company currently plans to share at the Heart Rhythm 2026 conference."

The FULCRUM-VT Study is a prospective, multi-center investigation of ULTC evaluating acute safety and effectiveness in patients with scar-related VT refractory to antiarrhythmic drug therapy and a left ventricular ejection fraction greater than 20%. Long-term outcomes as well as analysis of the effectiveness in different myocardial substrates will be reported in the future.

"We are pleased with the preliminary FULCRUM-VT acute data, which highlight the potential of Adagio's proprietary ULTC technology to transform treatment for patients with ventricular tachycardia," said Todd Usen, Chief Executive Officer of Adagio Medical. "On behalf of the entire Adagio Medical team, I want to thank all of the investigators, research coordinators and patients who have supported this study and whose commitment to serving this underserved population of patients will bring us one step closer to a purpose-built solution for VT. We thank the VT Symposium for this opportunity to share our results as part of a Late Breaking Session in Philadelphia."

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 Cryoablation (ULTC) technology. ULTC is designed to create large, durable lesions extending through the depth of both diseased and healthy cardiac tissue. The Company is currently focused on the treatment of ventricular tachycardia (VT) with its purpose-built vCLAS™ Cryoablation System, which is CE Marked and is currently under evaluation in the Company's FULCRUM-VT U.S. IDE Pivotal Study.

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 study, enrolling 206 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. The results of the study will be used to apply for FDA premarket approval (PMA) for Adagio's vCLAS™ Cryoablation System, potentially leading to the broadest industry indication for purely endocardial ablation of scar-mediated VT.

Adagio's vCLAS™ Cryoablation System is commercially available for the treatment of monomorphic ventricular tachycardia 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," and "future" or similar expressions are intended to identify forward-looking statements. Forward-looking statements include statements concerning: the reproducibility of any favorable results initially seen in Adagio's preliminary FULCRUM-VT acute data; the ability of Adagio's proprietary ULTC system to become a tool for a broad patient population; Adagio's research, development and regulatory plans for its product candidates; and the ability of Adagio's proprietary ULTC technology to transform treatment for patients with VT. 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, 2024 and Quarterly Report on Form 10-Q for the quarter ended June 30, 2025, which are 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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Debbie Kaster
Chief Financial Officer and Chief Business Officer
dkaster@adagiomedical.com

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