Adagio Medical Announces Positive Pivotal Results for vCLAS® Ventricular Ablation System

April 26, 2026

84% Freedom From Shock and 59% Freedom From VT Recurrence in FULCRUM-VT Pivotal IDE Trial Meet Safety and Effectiveness Endpoints and Replicate CryoCure-VT Results

First and Only Ablation Technology to Show Equivalent Effectiveness Across Ischemic and Non-Ischemic Cardiomyopathy All From Endocardial Approach

LAGUNA HILLS, Calif.--(BUSINESS WIRE)--Apr. 26, 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 reported six month results from its FULCRUM-VT Investigational Device Exemption ("IDE") clinical trial, which will be used to support the Company's application for Food and Drug Administration ("FDA") Premarket Approval of the vCLAS Ventricular Ablation System. The results were presented today in a late-breaking clinical trial session at the Heart Rhythm Society 2026 conference.

Key findings included:

- 98% non-inducibility of targeted ventricular tachycardias ("VT") at end of procedure
- Promising safety profile with 2.4% protocol-defined Major Adverse Events
- 84% freedom from implantable cardioverter defibrillator ("ICD") shock at 6 months
- 59% freedom from any VT recurrence at 6 months (VT recurrence includes monitoring zone VT > 30 seconds, ICD shock, ATP, and anti-arrhythmic drug ("AAD") escalation [1])
- Equivalent results for ischemic ("ICM") and non-ischemic cardiomyopathy ("NICM") patients
- Over 80% reduction in number of patients experiencing ICD shock over 6-months post ablation compared to equivalent time period pre-ablation
- 72% of patients discontinued or reduced dose of amiodarone at 6 months
- Low 1.9% rate of 30-day VT-related hospital readmission

"FULCRUM-VT represents a seminal step forward in advancing ventricular tachycardia management by delivering positive, clinically meaningful results from the first large-scale, rigorously executed pivotal trial in patients with both ischemic and non-ischemic structural heart disease. Importantly, the study further highlights the potential of an endocardial-only approach using Adagio's purpose-built ventricular ablation technology," said Dr. Atul Verma, Director, Division of Cardiology, McGill University Health Centre in Montreal. "The results of the trial, which were consistent with earlier ULTA studies, combined an excellent safety profile with impressive clinical effectiveness, including reductions in both ICD shocks and the use of toxic antiarrhythmic medication – outcomes that matter most to patients and physicians managing this complex disease. Additionally, the ability to ablate these already compromised patients without ever needing to irrigate or use nitroglycerin, both of which carry added risk, is a real benefit of ULTA. The FULCRUM-VT results are quite encouraging for the broad use of this technology as a long-term solution for patients suffering from VT."

FULCRUM-VT (Feasibility of Ultra-Low Temperature Cryoablation in Recurring Monomorphic Ventricular Tachycardia) is a prospective, multi-center, open-label, single-arm IDE study investigating the vCLAS Cryoablation System at 20 centers in the United States and Canada. The study enrolled 209 patients with structural heart disease, whether ischemic or non-ischemic cardiomyopathy, indicated for catheter ablation of drug refractory VT in accordance with current treatment guidelines.

FULCRUM-VT is the first and only fully enrolled IDE clinical trial for VT to include patients with both ICM and NICM disease and includes one of the most challenging patient cohorts ever treated in a VT ablation trial. Ablation targets for VT associated with NICM disease tend to be in deeper myocardial substrate and therefore are more difficult to treat using an endocardial approach with currently approved technology. These two patient cohorts had equivalent outcomes, as measured by both freedom from VT recurrence and freedom from ICD shock, representing what the Company believes to be the first and only catheter ablation technology to show equivalent effectiveness in these distinct and historically challenging VT substrates.

"These pivotal results represent a noteworthy milestone for Adagio and validate the potential for our ULTA technology to address a significant unmet need for treating one of the most complex and challenging arrhythmias," said Todd Usen, Chief Executive Officer of Adagio Medical. "In the United States alone, ventricular arrhythmias account for approximately 300,000 sudden cardiac deaths each year; VT is difficult to treat, and procedures performed with current devices can be overly complex, with sub-optimal outcomes in both effectiveness and safety. However, our FULCRUM-VT study demonstrated strong clinical effectiveness with a highly favorable safety profile with our vCLAS ablation catheter. Importantly, we achieved these results without compromising catheter stability and without the added risks of irrigation or nitroglycerin, thereby supporting the potential for a more streamlined workflow and reproducible approach to VT ablation. We believe ULTA has the potential to become a foundational ablation

technology for treating the ventricle and we look forward to serving the large, underserved population of patients suffering from VT."

FULCRUM-VT included patients with both ICM and NICM disease (LVEF=35+/-10%, 34% NICM, 79% with congestive heart failure). Freedom from device intervention (ATP or shock) at 6 months was 61% for ICM and 63% for NICM; freedom from ICD shock at 6 months was 84% for ICM and 85% for NICM. Mean ablation time per patient was 54 minutes. Mean lesions per patient: 11.5 ± 6. Key safety findings included a 2.4% rate of major adverse events including four (1.9%) peri-procedural deaths, of which only two (1.0%) were adjudicated by an independent Clinical Events Committee as possibly related to the investigational device. All safety and VT recurrence data were adjudicated by independent Event Committees.

The study also demonstrated clinically meaningful de-escalation of the use of amiodarone, an important clinical goal, with a substantial proportion of patients reducing or discontinuing amiodarone therapy post-procedure. The results also showed a significant reduction in hospital readmission rates compared to those historically reported in the VT ablation literature, underscoring the potential clinical and economic impact of the therapy.

"The FULCRUM-VT results are a significant clinical achievement and compare favorably against published RF (radiofrequency) benchmarks and the emerging PFA (pulsed field ablation) data for VT," said Dr. Matthew Hakimi, Medical Director at Adagio Medical. "It is the only pivotal IDE trial to show consistent endocardial-only outcomes across both ischemic and non-ischemic cardiomyopathy — and the combination of catheter stability, titratable lesion depth, and safe navigation near vulnerable structures such as the coronary arteries positions ULTA to address arguably the broadest spectrum of VT encountered in practice. FULCRUM-VT sets a new benchmark for VT ablation, and I want to commend the many physicians and their clinical coordinators for their diligent work in evaluating this novel technology."

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[1] ATP = anti-tachycardia pacing, or a painless, non-shock pacing therapy delivered by ICDs or pacemakers to terminate rapid heart rhythms. Monitor Zone is a programmed rate range where the device detects and records arrhythmias, but does not deliver active therapies like electric shocks or anti-tachycardia pacing

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, durable 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™ Cryoablation System, which is CE Marked and is currently under evaluation in the Company's FULCRUM-VT U.S. Pivotal IDE Trial.

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 dose beyond previously failed ablation. The results of the study, which have not yet been reviewed or approved by the FDA, will be used to apply for U.S. Food and Drug Administration (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 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: the potential for data from the FULCRUM-VT study to support an application for FDA premarket approval of the vCLAS Cryoablation System and the anticipated timing and outcome thereof; 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 for ULTA to become a foundational ablation technology for treating the ventricle; the potential for a more streamlined workflow and reproducible approach to VT ablation; the potential clinical and economic impact of ULTA, including reductions in hospital readmission rates; the possibility that FDA approval could lead to the broadest industry indication for purely endocardial ablation of scar-mediated VT; and Adagio's research, development and regulatory plans, including communications with, and submissions to, 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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