New Adagio Medical Publication Highlights Consistent Safety and Effectiveness with Ultralow Temperature Ablation in Broad Range of Patients with Ventricular Tachycardia

February 4, 2026

Early Feasibility Outcomes in a Real-World Patient Cohort of Both Ischemic and Challenging Non-Ischemic Patients Published in Circulation: Arrhythmia and Electrophysiology

LAGUNA HILLS, Calif.--(BUSINESS WIRE)--Feb. 4, 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 the publication of results from the U.S. Early Feasibility Study ("EFS") evaluating ultralow temperature cardiac ablation ("ULTC") for the treatment of scar-related ventricular tachycardia ("VT"). The study was published in *Circulation: Arrythmia and Electrophysiology.*

The prospective, multi-center study was conducted under the U.S. Food and Drug Administration's ("FDA's") EFS program and enrolled 20 patients with both ischemic and non-ischemic cardiomyopathy across four U.S. tertiary referral centers. Investigators evaluated the acute safety and performance of ULTC ablation in patients with drug-refractory scar-related VT.

Results demonstrated a favorable safety profile, with no device- or procedure-related major adverse events measured at both seven and 30 days, and strong acute and chronic performance. Among 14 patients with inducible VT tested both before and after ablation, 92.9% achieved non-inducibility of targeted clinical VT. At a mean follow-up of 24 weeks, antiarrhythmic drugs were either completely discontinued or reduced in 72% of the patients, and 83.3% of the patients were free from implantable cardioverter-defibrillator (ICD) shock, with a notable reduction in the overall VT burden.

"The advantage of Adagio's ULTC technology in ablation of ventricular tachycardia compared to the conventional technologies is its ability to produce deep, titratable lesions required to treat the significant patient population with deep intramural substrate that cause their VT," said J. Peter Weiss, MD, MSc, Associate Professor of Medicine at the University of Arizona College of Medicine–Phoenix and corresponding author of the study. "The results of this EFS were similar to the already highly encouraging results of the CRYOCURE-VT European study, albeit in a more challenging, heavily non-ischemic patient population and with very aggressive de-escalation of antiarrhythmic medication. I believe this bodes well for the results of the FULCRUM-VT pivotal study, which we hope will demonstrate more comprehensive evidence to support the use of ULTC for a broad range of VT patients."

Adagio's proprietary ULTC technology utilizes near-critical nitrogen to achieve temperatures approaching –196°C, enabling the creation of deeper and potentially transmural lesions compared with other existing ablation modalities. This study represents the first published U.S. clinical experience for ULTC under the FDA's EFS framework.

"The publication of this study marks an important milestone for Adagio Medical and for patients with complex ventricular arrhythmias," said Todd Usen, Chief Executive Officer of Adagio Medical. "These results highlight the potential of ultralow temperature ablation to address a significant unmet need in VT treatment and underscores the value of the FDA's Early Feasibility Study program in accelerating patient access to innovative technologies. We look forward to sharing the results of our FULCRUM-VT pivotal trial at the Heart Rhythm Society scientific meeting in April.

Patients enrolled in the EFS will be included in the safety analyses of Adagio Medical's FULCRUM-VT pivotal Investigational Device Exemption (IDE) study. FULCRUM-VT, which completed enrollment in October 2025, is designed to support U.S. regulatory approval of Adagio's vCLAS ™ Cryoablation System, which is expected by year end 2026,

The full publication is available online at: https://www.ahajournals.org/doi/10.1161/CIRCEP.125.014095

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 Ultralow Temperature Cardiac (ULTC) ablation 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 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 Ultralow 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. 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 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," and "future" or similar expressions are intended to identify forward-looking statements. Forward-looking statements include statements concerning: the potential of Adagio's ULTC technology, including the reproducibility and durability of any favorable results initially seen in the U.S. Early Feasibility Study; Adagio's strategy, future operations, the expected timing and results of clinical trials, prospects, plans and objectives of management; and the potential for FDA approval and commercialization of Adagio's product candidates and whether, if approved, these product candidates will be successfully distributed and marketed and the potential market opportunity for Adagio's product candidates. 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 September 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.

View source version on businesswire.com: https://www.businesswire.com/news/home/20260204631610/en/

Debbie Kaster
Chief Financial Officer and Chief Business Officer
dkaster@adagiomedical.com

Source: Adagio Medical Holdings, Inc