Adagio Medical Submits Premarket Approval Application to FDA for vCLAS® Ventricular Ablation System for the Treatment of Ventricular Tachycardia

May 21, 2026

PMA Submission Supported by FULCRUM-VT Pivotal Trial Data — 209 Patients Across 20 Leading Centers; Breakthrough Device Designation Previously Granted

Marks the First-Ever PMA Submission for a Purpose-Built VT Ablation System in a $5.8B Market

LAGUNA HILLS, Calif.--(BUSINESS WIRE)--May 21, 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 submission of its Premarket Approval ("PMA") application to the U.S. Food and Drug Administration ("FDA") for the vCLAS Ventricular Ablation System for the treatment of drug-refractory, recurrent, sustained monomorphic ventricular tachycardia ("VT") in patients with ischemic or non-ischemic structural heart disease.

The PMA submission is supported by the FULCRUM-VT pivotal IDE trial, a single-arm study that enrolled 209 patients across 20 leading electrophysiology centers. The trial achieved 97.4% acute clinical success and demonstrated compelling 6-month outcomes, including 84.3% freedom from ICD shock, only 2.4% major adverse events and a 78% reduction or elimination of anti-arrhythmic drug ("AAD") use. Importantly, vCLAS demonstrated equivalent clinical effectiveness in both ischemic and non-ischemic cardiomyopathy, addressing the largest unmet need in VT ablation today.

"The submission of our PMA application is a defining moment for Adagio Medical and, more importantly, for the hundreds of thousands of patients suffering from ventricular tachycardia who currently have no purpose-built solution," said Todd Usen, Chief Executive Officer of Adagio Medical. "We believe FULCRUM-VT demonstrated that Adagio's proprietary ULTA is not just a different approach to VT ablation – it is a fundamentally better solution, which achieved compelling outcomes across the metrics that matter most to physicians and patients: safety, freedom from ICD shock, reduction in AAD use, and consistent results across the broadest patient population ever studied in a VT ablation trial. Our endocardial-only approach has the potential to democratize VT ablation for electrophysiologists and offers physicians a purpose-built tool capable of treating every eligible VT patient — ischemic and non-ischemic alike — without compromise. We look forward to working closely with the FDA through the review process and are energized by the possibility of bringing this technology to a broad population of patients suffering from VT."

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 therapy beyond previously failed dose.

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: anticipated timing and outcome of the FDA's review of the Company's PMA application for the vCLAS Ventricular Ablation System; the potential for FDA approval to lead to the broadest industry indication for purely endocardial ablation of scar-mediated VT; 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 Quarterly Report on Form 10-Q for the quarter ended March 31, 2026, filed with the SEC on May 12, 2026 and 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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