Adagio Medical, Inc. Announces Completion of Enrollment for FULCRUM-VT Pivotal Clinical Trial Evaluating Ultra-Low Temperature Cryoablation for Ventricular Tachycardia

October 1, 2025

Study Results are Intended to Support PMA Approval of Adagio's vCLAS ™ Cryoablation System Designed to Address the Large Population of Patients with Ventricular Arrhythmias

LAGUNA HILLS, Calif.--(BUSINESS WIRE)--Oct. 1, 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 the completion of enrollment of the FULCRUM-VT Pivotal U.S. Food and Drug Administration ("FDA") Investigational Device Exemption ("IDE") study evaluating the Company's vCLAS ™ Cryoablation System ("vCLAS" or "vCLAS System") for ablation of monomorphic ventricular tachycardia (MMVT). The vCLAS System, which has been granted Breakthrough Device Designation by the FDA, is built on the Company's proprietary ultra-low temperature cryoablation ("ULTC") technology platform.

"Adagio's vCLAS System is the first VT-specific ablation technology to complete enrollment in a pivotal IDE study in the United States," said Dr. Atul Verma, Director of Cardiology at McGill University Health Centre and FULCRUM-VT co-principal investigator. "Our center has had the unique opportunity to participate in both the earlier CRYOCURE-VT study, which supported CE Mark in Europe, and the FDA IDE study in the U.S., and we are firm believers in the many advantages of Adagio's ULTC as a potential game-changing technology to treat patients with drug-refractory ventricular tachycardia."

"To date, our options for VT ablation have been limited to catheters and energy sources originally developed to treat atrial arrhythmias, and VT ablation studies were notoriously difficult and slow to enroll," added Dr. Rod Tung, Chief of the Division of Cardiology at Banner University Medical Center and study co-principal investigator. "The fact that the FULCRUM-VT pivotal study completed enrollment in only 11 months speaks volumes to both the market need for a purpose-built VT ablation technology and the positive early experiences with Adagio's ULTC at the top VT ablation programs that participated in the study."

FULCRUM-VT (Feasibility of Ultra-Low Temperature Cryoablation for Recurring Monomorphic Ventricular Tachycardia) is a prospective, single-arm, multi-center, open label, IDE study designed to evaluate the safety and effectiveness of the Adagio vCLAS System in the ablation treatment of scar-mediated sustained MMVT in patients with ischemic and non-ischemic structural heart disease. The primary efficacy endpoint of the FULCRUM-VT is six month freedom from recurrent MMVT in the absence of new or increased dose of pre-ablation antiarrhythmic drugs ("AAD") for VT management. The results of FULCRUM-VT, which has enrolled 208 patients across 20 centers in the United States and Canada, will be used to support a pre-market approval ("PMA") application for the vCLAS System.

"I would like to thank the FULCRUM-VT investigators and research staff who have done an outstanding job working with our team over the last several months to achieve this critical milestone," said Todd Usen, Chief Executive Officer of Adagio Medical. "We are also grateful to the FDA for our collaborative relationship. We are excited for the potential to bring our ULTC technology to the underserved population of VT patients and we anticipate completion of the PMA process for the vCLAS System by year-end 2026, consistent with previous guidance."

Adagio's vCLAS System is commercially available for the treatment of MMVT in Europe and select other geographies, but is limited to investigational use in the United States.

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. Investigational Device Exemption ("IDE") Pivotal Study.

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: Adagio's research, development and regulatory plans for its product candidates and Adagio's ability to bring its proprietary ULTC solutions to patients. 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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