



## Adagio Medical Holdings, Inc. Receives FDA Breakthrough Device Designation for the vCLAS(TM) Cryoablation System

April 18, 2025

**LAGUNA HILLS, CA, April 17, 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 that it has received Breakthrough Device designation from the U.S. Food and Drug Administration (“FDA”) for its vCLAS™ Cryoablation System for the treatment of drug-refractory, recurrent, sustained monomorphic ventricular tachycardia (“VT”) in patients with ischemic or non-ischemic structural heart disease. Adagio’s vCLAS™ Cryoablation System, which is currently the subject of an Investigational Device Exemption (“IDE”) study called FULCRUM-VT, is a purpose-built system using the Company’s proprietary Ultra-Low Temperature Cryoablation (“ULTC”) technology and is designed to improve the safety and effectiveness of VT ablations and patient outcomes.

The FDA Breakthrough Device Program, which reflects the FDA’s commitment to device innovation and protecting public health, is intended to help patients and health care providers receive more timely access to select medical devices. To be eligible for Breakthrough Device designation, a device must meet two criteria set by the FDA. First, the device must have the potential to provide more effective treatment or diagnosis for life-threatening or irreversibly debilitating diseases or conditions. Second, the device must also meet at least one of the following: it must represent breakthrough technology, there must be no approved or cleared alternative, the device must offer significant advantages over existing approved or cleared alternatives, and/or device availability must be in the best interest of patients.

Under the program, the FDA will provide Adagio with priority review and interactive communication during the vCLAS™ Cryoablation System premarket review phase.

“Receiving Breakthrough Device Designation is an important milestone for Adagio, validating our proprietary vCLAS™ Cryoablation System with our ULTC technology as a potentially unique solution for the large, underserved population of patients suffering from ventricular tachycardia,” said Todd Usen, Chief Executive Officer of Adagio. “Our team has been working hard to bring this transformational technology to patients, and we are thrilled to be the only technology to be granted Breakthrough Device designation for endocardial treatment of both ischemic and nonischemic structural heart disease patients with sustained monomorphic VT. We are encouraged that, based in part on the strength of the clinical data from our European CRYOCURE-VT study, the FDA has determined that vCLAS™ qualifies as a Breakthrough Device, and we look forward to working collaboratively with the agency to make the vCLAS™ System available to U.S. physicians and patients as expeditiously as possible.”

VT is a rapid, abnormal heart rhythm, or arrhythmia, that originates in the heart’s lower chambers, or ventricles, leading to blood flow issues and significant symptoms. If sustained, VT can become fatal.

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.

### About Adagio

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.

### 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 regarding: the vCLAS™ Cryoablation System FULCRUM-VT IDE clinical trial, as well as the timing and outcome of any results therefrom, potential FDA approval, or potential

launch or commercialization in the United States or elsewhere; the vCLAS™ Cryoablation System's ability to improve the safety and effectiveness of VT ablations and patient outcomes; and the Company's ability to work collaboratively with the FDA to make the vCLAS™ Cryoablation System available to U.S. physicians and 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 the Company's business are described in detail in the Company's Securities and Exchange Commission ("SEC") filings, including in the Company's Annual Report on Form 10-K for the full-year ended December 31, 2024, which is available on the SEC's website at [www.sec.gov](http://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.

**Contact:**

Debbie Kaster  
Adagio Medical  
IR@adagiomedical.com