



## **Adagio Medical Announces Initiation and First Procedure in FULCRUM-VT Trial, Starting The Process For Bringing Ultra-Low Temperature Cryoablation for Ventricular Arrhythmias to US Market**

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LAGUNA HILLS, Calif., September 13, 2023 /PRNewswire/ -- Adagio Medical, Inc., a leading innovator in catheter ablation technologies for atrial fibrillation (AF) and ventricular tachycardia (VT), announced the first ultra-low temperature cryoablation (ULTC) procedure performed using the Adagio vCLAS™ catheter system in the United States as part of the FULCRUM-VT (Feasibility of Ultra-Low Temperature Cryoablation for Recurring Monomorphic Ventricular Tachycardia) clinical trial, NCT # NCT05675865. The procedure was performed at Banner - University Medical Center in Phoenix, AZ by Dr. Roderick Tung, MD. Dr. Tung serves as Division Chief of Cardiology and Director of Cardiovascular Clinical Research for the Department of Internal Medicine at the University of Arizona College of Medicine – Phoenix and Banner – University Medical Center Phoenix.

“The ablations of ventricular tachycardias have been historically performed using RF catheters and suffer from insufficient lesion depth to deliver a full thickness treatment to a three-dimensional problem,” said Dr. Tung. “The ability of ULTC to create lesions deeper than the average thickness of ventricular myocardium exclusively from endocardial surface in pre-clinical models is a major potential advantage. Performing early feasibility studies in humans is critical to testing safety and clinical efficacy and we are proud that University of Arizona College of Medicine has emerged as an early feasibility study site in collaboration with Adagio.”

FULCRUM-VT is set to enroll 20 patients across four investigational sites, including Banner - University Medical Center in Phoenix and three other world-renowned VT ablation programs: Vanderbilt University Hospital in Nashville, TN with Dr. William Stevenson, Mount Sinai Hospital, NY, with Dr. Vivek Reddy and University of California in San Francisco with Dr. Edward Gerstenfeld. The enrollment criteria of the trial include both ischemic and non-ischemic heart disease, implanted cardioverter defibrillator, and an indication for ventricular ablation due to recurrent symptomatic monomorphic VTs. Furthermore, the trial will accept the patients for both de-novo and a first repeat ablation, thus encompassing the clinical pathway for vast majority of patients undergoing ventricular ablations. The 64-patient CRYOCURE-VT trial conducted in Europe and Canada to evaluate safety and performance of vCLAS catheter has completed enrollment, and data will be used to support the CE-Mark approval of the device.

“The initiation of the FULCRUM-VT study is the first step towards bringing Adagio’s ULTC platform technology to VT ablations market in the US,” said Olav Bergheim, President and CEO of Adagio Medical. “The initial published data on procedural characteristics, acute effectiveness, and safety of ULTC ablations have been encouraging and, we believe, the combination of CRYOCURE-VT and FULCRUM-VT will result in the robust, multi-center, global dataset, essential for the assessment of this groundbreaking technology. The VT market is largely underserved by industry. Adagio’s dedicated VT catheter is a testimony to our commitment to the advancement of clinical EP and our belief in the future growth of the market based on improved procedure effectiveness and long-term outcomes. The bi-directionally deflectable catheter is compatible with the same ULTC energy source which is currently under evaluation as a part of pivotal FDA IDE trial for the treatment of persistent AF (NCT # 04061603). We believe that if and once approved by regulatory authorities, vCLAS will be a must-have technology at every advanced EP ablation program.”

### **About Banner – University Medical Center Phoenix**

Banner – University Medical Center Phoenix is a large teaching hospital that has provided medical care to Arizona and the Southwest since 1911. It is part of Banner – University Medicine, a premier academic medical network. The institution, which has trained thousands of doctors over decades as a teaching hospital, is the academic medical center for The University of Arizona College of Medicine – Phoenix. The hospital, recognized by U.S. News and World Report as one of the nation’s best hospitals, specializes in heart care, cancer care, high-risk obstetrics, neurosciences, organ transplants, medical toxicology and emergency care, including a Level I trauma center. Banner – University Medical Center Phoenix is part of Banner Health, a nonprofit health care system with 33 hospitals in six states. For more information, visit [bannerhealth.com/universityphoenix](http://bannerhealth.com/universityphoenix).

### **About Adagio Medical**

Adagio Medical, Inc. ([www.adagiomedical.com](http://www.adagiomedical.com)) is a privately held company located in Laguna Hills, California developing innovative cryoablation technologies that create contiguous, transmural lesions to treat cardiac arrhythmias, including paroxysmal and persistent atrial fibrillation, atrial flutter, and ventricular tachycardia. Adagio Medical, Inc. is a Fjord Ventures portfolio company.

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