Adagio Medical Announces Completion of Enrollment in Cryocure-VT Trial, Maps the Pathway to CE-Mark of vCLAS™ VT Ablation Catheter

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LAGUNA HILLS, Calif., May 2, 2023 /PRNewswire/ -- Adagio Medical, Inc., a leading innovator in catheter ablation technologies for atrial fibrillation (AF) and ventricular tachycardia (VT), announced the completion of enrollment in its Cryocure-VT trial (NCT # 04893317) of ultra-low temperature cryoablation (ULTC) for the treatment of monomorphic ventricular tachycardias. 60 patients with ischemic and non-ischemic cardiomyopathies underwent an endocardial ULTC procedure using Adagio's vCLAS™ catheter at nine centers in the European Union and Canada. The results of the trial will be used to support Adagio's CE-mark application for its vCLAS catheter in the second half of 2023.

"For years, with much of the energy in interventional electrophysiology directed towards a larger market of atrial fibrillation treatments, the field of VT ablations, and particularly new catheter technologies, has suffered from underinvestment," said Dr. Petr Neuzil, MD, PhD, the Head of Cardiology at Na Homolce Hospital in Prague, Czech Republic, and the highest European enroller in the trial. "To this day we are forced to use the RF catheters originally developed and labeled for ablation of atrial arrhythmias in a much more stringent environment of a human ventricle, and in a much sicker patient population. The innovative vCLAS catheter is an extension of Adagio's ULTC platform, shown to be highly effective in the treatment of AF, but has been designed specifically for the treatment of ventricular tachycardias, with a bidirectionally deflectable shaft and 15 mm-long ablation element capable of creating large, transmural lesions, enabling the termination of arrhythmias deep in the myocardium."

"The initial data from the Cryocure-VT trial published recently in the Journal of American College of Cardiology EP [1] demonstrated successful and efficient use of ULTC across the range of established ablation strategies in conjunction with multiple commercially available electroanatomic mapping systems, making it an easy drop-in technology for any VT ablation program," added Dr. Tom De Potter, Associate Director, Cardiovascular Center Department of Cardiology at OLV Hospital Aalst, Belgium, and the lead author of the manuscript. "While long term results are still being analyzed, acutely, purely endocardial ultra-low temperature cryoablation appears to be quite effective in both ischemic and nonischemic patients, the latter being challenging for current RF catheters due to mid-myocardial nature of their scars. Bringing Adagio's ULTC technology into routine clinical practice will accelerate the growth in VT ablation volumes, initially for patients with structural heart disease and eventually in patients with idiopathic ventricular arrhythmias."

"We are grateful to all Cryocure-VT investigators for their commitment to the trial , including Drs. Verma and Essebag at McGill University, Dr. Dyrda at Montreal Heart Institute, Dr. Balt and Professor Boersma at St. Antonius Hospital in Nieuwegein, Drs. Darma and Dinov at Leipzig Heart Centrum, Dr. Sacher at University of Bordeaux, Dr. Arya at University Hospital Halle and Dr. Vivek Reddy at Mount Sinai Hospital in New York," said Olav Bergheim, President and CEO of Adagio Medical. "Based on the catheter handling and good acute outcomes, the comfort with ULTC technology for VT ablations grew very fast and, towards the end, we literally had to turn enrollments away. This hopefully speaks to a broader market reception once all the data is analyzed and approved by the regulatory bodies. We have initiated our CE-mark submissions and hope to put the vCLAS catheters in the hands of the European clinicians later this year."

[1]De Potter T, Balt J, Boersma L, Sacher F, et al. First-In-Human Experience with Ultra-Low Temperature Cryoablation for Monomorphic Ventricular Tachycardia. J Am Coll Cardiol EP 2023. in press.

About Adagio Medical

Adagio Medical, Inc. (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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