

XyloCor Therapeutics Achieves Target Enrollment in Phase 2 EXACT Study of XC001 Novel Gene Therapy for Ischemic Heart Disease

- *Positive Phase 1 results reported at the American Association for Thoracic Surgery (AATS) and the American Society of Gene and Cell Therapy (ASGCT) revealed XC001 is well tolerated at all dose levels*
- *Phase 1 data support XC001 therapeutic effect and potential dose response*
- *Topline Phase 2 data readout expected in February 2023 with interim results in the second half of this year*

Wayne, PA, June 28, 2022 — XyloCor Therapeutics, a clinical-stage biopharmaceutical company developing novel gene therapies for cardiovascular disease, today announced it has achieved enrollment of target number of subjects in the Phase 2 portion of its ongoing Phase 1/2 clinical trial (EXACT) for refractory angina. Topline results from the Phase 2 study are expected in February 2023 with interim results in the second half of this year.

“Achievement of this important milestone in the Phase 2 portion of the study is a testament to the clinical need in this patient population and I am eager to see the Phase 2 results as they emerge,” said Thomas Povsic, M.D., Ph.D., Professor of Medicine, Duke University School of Medicine and National Principal Investigator for the EXACT study. “Patients with refractory angina have no treatment options, and the [results from the Phase 1 portion of the EXACT trial](#) suggest a dose response and therapeutic potential which is encouraging for the development of XC001 as a treatment to improve these patients’ quality of life. We are very excited to see this more definitive evaluation of the safety and efficacy of this approach.”

“We are pleased to announce this important milestone in enrollment for our Phase 2 study especially during this unprecedented and challenging time,” said Al Gianchetti, President and CEO of XyloCor. “An estimated one million people suffer from refractory angina in the United States, and we are encouraged that XC001 may address the high unmet need in this patient group. XyloCor also plans to study XC001 in other patient groups as well, including as adjunctive therapy in patients undergoing bypass surgery.”

Individuals with refractory angina experience pressure or intense pain in the chest due to insufficient blood flow to the heart muscle. These symptoms can severely impact quality of life and may worsen comorbidities.

XyloCor’s lead investigational drug, XC001 (encoberminogene rezmadenovec) is a locally administered, single-dose gene therapy currently in development as a novel approach to treating patients with refractory angina who have no other medical and surgical options. The treatment strategy is to use local administration to achieve higher gene expression in the heart while minimizing systemic vector circulation and associated side effects. XC001 is designed to promote new blood vessels in the heart that will bypass diseased blood vessels and improve blood flow. By restoring blood flow, chest pain associated with refractory angina may decrease, potentially improving patients’ quality of life by enabling them to engage in daily physical activities that would otherwise cause pain.

About the EXACT Study

The Epicardial Delivery of XC001 Gene Therapy for Refractory Angina Coronary Treatment (EXACT) clinical trial is a Phase 1/2 multicenter, open-label, single-arm trial. Twelve subjects (n=3 per dose cohort) who have refractory angina were enrolled into four ascending dose groups, followed by an expansion phase of the trial with target enrollment of 27 additional subjects at the highest tolerated dose (1×10^{11} vps, the highest tested dose). The investigational gene therapy is administered directly to the heart muscle through a mini-thoracotomy by an experienced cardiac surgeon at top cardiovascular research sites across the United States.

About Chronic Refractory Angina

In the United States, coronary artery disease is a leading cause of death and disability. Chronic angina pectoris occurs when the heart muscle does not receive sufficient oxygen resulting in chest pain. This is usually due to atherosclerotic plaques that block the coronary arteries. Refractory angina is a growing problem that occurs in patients with chronic angina who are symptomatic despite optimal medical therapy and are no longer eligible for mechanical interventions like percutaneous coronary intervention (PCI) and coronary artery bypass grafting (CABG). These patients currently have no treatment options and are frequently highly symptomatic, which severely impacts their quality of life, and may exacerbate comorbidities and cause further deterioration of their health status. Refractory angina results in significant consumption of healthcare resources, including visits to the emergency department as a result of patients' chest pain.

About XyloCor

XyloCor Therapeutics is a private, clinical-stage biopharmaceutical company developing potential best-in-class gene therapies to transform outcomes for patients with cardiovascular disease. The Company's lead product candidate, XC001, is in clinical development to investigate use for patients with refractory angina for which there are no treatment options. XyloCor has a second preclinical investigational product, XC002, in discovery stage, being developed for the treatment of patients with cardiac tissue damage from heart attacks. The company, which was co-founded by Ronald Crystal, M.D., and Todd Rosengart, M.D., has an exclusive license from Cornell University. For more information, visit www.xylocor.com.

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