Results from XyloCor Therapeutics' Phase 1 Portion of EXACT Trial of XC001 for Cardiovascular Disease Published in *Circulation: Cardiovascular Interventions*

- Findings from the Phase 1 dose escalation portion of the EXACT trial of XC001 in refractory angina provided the dose selection and safety justification for the recently completed Phase 1/2 study

-XC001 is a one-time gene therapy candidate designed to reduce ischemic burden by creating new blood vessels in the heart through the local expression of multiple VEGF isoforms

- XyloCor is moving forward with urgency to address potential of XC001 as transformative therapy for patients with ischemic heart disease with significant unmet need

Wayne, PA, August 3, 2023 — XyloCor Therapeutics, Inc., a clinical-stage biopharmaceutical company developing novel gene therapies for cardiovascular disease, announced today that ***Circulation: Cardiovascular Interventions*** has published results from the Phase 1 portion of its Phase 1/2 clinical trial (EXACT) of lead gene therapy candidate XC001 (encoberminogene rezmadenovec) in patients with refractory angina. The findings from the Phase 1 dose escalation study, previously reported at the American Association for Thoracic Surgery (AATS) and the American Society of Gene and Cell Therapy (ASGCT) in May 2022, revealed that XC001 is well tolerated at all dose levels and provided justification to proceed to Phase 2 with the highest dose tested.

"The results from the Phase 1 study provided the mechanistic underpinning that was the catalyst for the successful completion of the Phase 2 EXACT trial," said Thomas Povsic, M.D., Ph.D., lead author of the journal article, Professor of Medicine, Duke University School of Medicine and National Principal Investigator for the EXACT study. "Patients with refractory angina are highly symptomatic and have an exceedingly poor quality of life. With a robust body of positive and sustained safety and efficacy out to 12 months from the EXACT trial, we believe that XC001 has the potential to fill the significant unmet need for this patient population who currently lack treatment options."

"We are thrilled with the publication of these EXACT trial results in ***Circulation: Cardiovascular Interventions***, a highly-regarded and influential international journal for cardiovascular research," said Howard Dittrich, Chief Medical Officer of XyloCor. "We would like to acknowledge all of the authors for their contributions in highlighting the promise of XC001 and thank patients and their families for their participation in the EXACT trial. Our team is singularly focused on continuing to unlock the transformative potential of XC001 for improving outcomes in cardiovascular disease."

The Phase 1 portion of the Phase 1/2 EXACT study was a first-in-human, multicenter, open-label, single-arm, dose-escalation study to evaluate the safety, tolerability, and preliminary efficacy of increasing doses of XC001, and to establish the best dose to carry forward for additional study in Phase 2. Twelve patients were enrolled into four dosing cohorts. Notably, the study demonstrated that adenoviral vector doses higher than those used in previous studies were well tolerated and more robust efficacy was demonstrated at the higher doses. This established a dose of 1×10^{11} viral particles for future clinical research of XC001.

The Circulation: Cardiovascular Interventions full article is available at https://www.ahajournals.org/doi/abs/10.1161/CIRCINTERVENTIONS.123.012997

About XC001

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. XC001 is designed to avoid toxicity issues observed with other gene therapies through a strategy of one-time, local administration. This approach allows XC001 to achieve higher gene expression in the heart while minimizing systemic vector circulation and associated side effects.

About the EXACT Study

The Epicardial Delivery of XC001 Gene Therapy for Refractory Angina Coronary Treatment (EXACT) clinical trial was 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 in which additional subjects were enrolled at the highest tolerated dose (1×10^{11} vp, the highest tested dose). The investigational gene therapy is administered directly to the heart muscle through a mini-thoracotomy by a cardiac surgeon.

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, Inc. 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 whom 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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