XyloCor Therapeutics Reports Sustained Results in 12-Month Extension of Phase 2 EXACT Clinical Trial of XC001 Novel Gene Therapy for Refractory Angina

-XC001 demonstrated durable improvements across multiple efficacy measures 12 months after treatment, underscoring its scientifically-sound approach to achieve biological effect and improve angina symptoms

-Patients showed continued improvements in exercise capacity and reductions in episodes of chest pain that were sustained to 12 months

-Robust body of mechanistic evidence from EXACT trial highlights significant potential of XC001 in cardiovascular disease

Wayne, PA, July 18, 2023 — XyloCor Therapeutics, a clinical-stage biopharmaceutical company developing novel gene therapies for cardiovascular disease, today reported positive 12-month data from the Phase 2 portion of its Phase 1/2 clinical trial (EXACT) designed to assess the safety and provide preliminary evidence of efficacy of lead gene therapy candidate XC001 (encoberminogene rezmadenovec) in patients with refractory angina. At the 12-month mark in the extension period of the trial, XC001 demonstrated durable improvements across multiple efficacy measures, including continued improvement in total exercise duration and reductions in ischemic burden and ischemic symptoms. Earlier this year, XyloCor reported positive results from the primary study period for the Phase 2 portion EXACT trial at six months. New results at 12 months highlight significant, clinically-meaningful impacts that are now sustained out to 12 months, pointing to the potential of XC001 as a novel therapeutic approach for the significant unmet medical need in refractory angina.

“The durability and, in the case of exercise time, continued improvements observed at 12 months signals a sustainable activity which is an exciting step forward in the advancement of gene therapy for cardiovascular disease,” said Thomas Povsic, M.D., Ph.D., Professor of Medicine, Duke University School of Medicine and National Principal Investigator for the EXACT study. “These 12-month data build upon the positive results achieved at the 3- and 6-month marks of the trial. In total, the outcomes of the EXACT study form a robust body of mechanistic evidence to propel the next stage of XC001’s development, suggesting that a single treatment may have long-term benefit.”

XC001 is a one-time gene therapy candidate designed to reduce ischemic burden by creating new blood vessels in the heart. The six-month primary study period in the Phase 2 portion of the EXACT trial was followed by a month 12 follow up period. At 12 months, patients demonstrated sustained and continued increases in total exercise duration (TED) over baseline, representing a significant and clinically meaningful change. In addition, there was a sustained and robust decrease in episodes of chest pain (angina) and nitroglycerin use. Cardiac imaging at 12 months provided additional evidence of the potential mechanism of action to achieve a biological effect, confirmed by a sustained reduction in ischemic burden observed over time.

“With the 12-month results from our EXACT trial, XyloCor continues to take a lead role in fulfilling the promise of gene therapy for people with cardiovascular disease,” said Al Gianchetti, President and CEO of XyloCor. "These results further enhance our confidence that we are on the right path for transforming outcomes in cardiovascular disease.”

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 x 1011 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 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.

Corporate and Investor Relations:

A. Brian Davis, XyloCor Therapeutics

brian.davis@xylocor.com

610-541-2056

Media Contact:

Mike Beyer, Sam Brown Inc. Healthcare Communications

mikebeyer@sambrown.com

312-961-2502