XyloCor Therapeutics Reports Positive Topline Safety and Efficacy Results from Phase 2 EXACT Clinical Trial of XC001 Novel Gene Therapy for Refractory Angina

-No serious adverse events related to drug product were reported

-Patients demonstrated improvements in exercise capacity and reductions in episodes of chest pain

-Cardiac imaging results provide mechanistic evidence supporting the therapeutic potential of XC001 in cardiovascular disease

Wayne, PA, January 26, 2023 — XyloCor Therapeutics, a clinical-stage biopharmaceutical company developing novel gene therapies for cardiovascular disease, today announced completion of the Phase 2 portion of its Phase 1/2 clinical trial (EXACT) designed to assess the safety and preliminary evidence of efficacy of lead gene therapy candidate XC001 (encoberminogene rezmadenovec) in patients with refractory angina. EXACT met both safety and efficacy objectives. There were no safety issues related to drug product or unexpected serious adverse events related to XC001 administration. Six-month data from 28 patients in the Phase 2 portion of the study showed improvements in several key efficacy measures, including reduction in ischemic burden.

"We are excited to see EXACT completing its 6-month endpoint. The trial met all of its safety and exploratory objectives, showing intriguing benefits in these needy patients across a variety of objective and subjective measures," said Thomas Povsic, M.D., Ph.D., Professor of Medicine, Duke University School of Medicine and National Principal Investigator for the EXACT study. "The strong range of mechanistic evidence demonstrate that administration of XC001 is a scientifically-sound approach for achieving a biological effect that has the potential to improve patients' quality of life."

XC001 is a one-time gene therapy designed to reduce ischemic burden by creating new blood vessels in the heart. In the Phase 2 portion of the EXACT trial, evidence of the drug's mechanism of action was demonstrated by the reduction of ischemic burden measured by cardiac positron emission tomography (PET) imaging. The reduction in ischemic burden was accompanied by an improvement in total exercise duration, an important measure of exercise capacity. Prior to treatment, almost all subjects had marked limitations on ordinary physical activity. Six months after treatment, nearly half of all subjects were able to conduct ordinary physical activity without causing angina. The data from the Phase 2 EXACT study are potentially meaningful for patients with refractory angina, which includes more than one million people in the United States, who have no treatment options.

"We are excited to share this positive topline data from the Phase 2 portion of the EXACT trial, reinforcing our confidence in XC001 as a novel therapeutic approach with the potential to address the significant unmet medical needs of people with refractory angina," said Al Gianchetti, President and CEO of XyloCor. "We now look forward to pursuing key upcoming milestones in XC001's continued development, including finalizing our pivotal trial design through our ongoing discussions with the FDA and other regulatory authorities."

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 recently completed 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 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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