For Immediate Release

XyloCor Therapeutics Announces Presentation of Preliminary Clinical Data from Phase 1 Portion of the EXACT Phase 1/2 Study of XC001 Novel Gene Therapy for Refractory Angina at AATS and ASGCT

- *Data from the Phase 1 dose-escalation portion of the Phase 1/2 EXACT study demonstrate XC001 was well-tolerated at all dose levels tested; highest dose level evaluated selected for ongoing Phase 2 portion of the study*
- *Preliminary efficacy data highlight XC001 potential for patients with refractory angina with no other treatment options*
- *Treatment strategy is to use local administration to achieve higher gene expression in the heart while minimizing systemic vector circulation and associated side effects*
- *Completion of Phase 2 enrollment is expected by the end of May 2022*

Wayne, PA, **May 18, 2022** — XyloCor Therapeutics, a clinical-stage biopharmaceutical company developing novel gene therapies for cardiovascular disease, today announced presentation of initial clinical data from the Phase 1 portion of its ongoing Phase 1/2 clinical trial (EXACT) for refractory angina at the American Association for Thoracic Surgery (AATS) Annual Meeting on May 15, 2022, and at the American Society of Gene and Cell Therapy (ASGCT) Annual Meeting on May 18, 2022.

XC001: Locally administered, single-dose gene therapy candidate to address the unmet need in refractory angina

XyloCor's lead investigational drug, XC001 (encoberminogene rezmadenovec), is under development as a novel approach to treating patients with refractory angina who have exhausted other medical and surgical options. This investigational gene therapy is designed to activate naturally occurring biological pathways by creating new vessels to improve blood flow to areas of the heart not receiving adequate blood supply. This restored blood supply could potentially improve patients' quality of life by enabling them to resume physical activities and it could reduce episodes of chest pain associated with refractory angina.

In the Phase 1 portion of the EXACT study, 12 subjects with Canadian Cardiovascular Society (CCS) angina class 2-4 without revascularization options were divided into four escalating dose groups with three subjects each. Each subject received 15 epicardial injections of XC001 at one of the four dosage levels. Safety, efficacy and tolerability evaluations were measured as adverse events (AEs), serious adverse events (SAEs) and change from baseline from three to six months post-treatment in exercise capacity, ischemic burden by positron emission tomography (PET) imaging, and patient-reported symptomatology.

No drug-related SAEs, bleeding complications or ventricular arrhythmias were observed in this Phase 1 dose-escalation study. Over a six-month follow up there were a total of 17 SAEs in seven subjects. Eleven SAEs were related to the underlying disease process or other causes. The other six SAEs which occurred in four subjects were judged to be related to the administration procedure, with none of those being unexpected nor resulting in patient death.

"The administration of XC001 appears to have been well-tolerated at all tested doses," said Nahush Mokadam, M.D., presenting author at AATS, Division Director, Cardiac Surgery, The Ohio State University Wexner Medical Center and Associate Director of the Heart and Vascular Center and site Principal Investigator for this study. "Objective criteria, including results from exercise tolerance tests and PET scans, suggest therapeutic potential."

Although the Phase 1 portion of the study was primarily focused on safety and Phase 2 dose selection, initial clinical efficacy data appeared promising. Notably, the data showed positive trends in total exercise duration and reductions in patient symptoms and ischemic burden. Although patient numbers are small, preliminary data suggest that response may be correlated to administered dose.

“The preliminary efficacy evaluation suggests a dose response which is encouraging for the development of XC001 as a therapeutic strategy,” said Thomas Povsic, M.D., Ph.D., Professor of Medicine, Duke University School of Medicine and National Principal Investigator for the EXACT study. “We anticipate that the Phase 2 expansion portion of this study, which is testing the highest and most efficacious dose from Phase I, will complete enrollment this month. We are incredibly excited by the potential for this investigational therapy to improve the quality of life for these cardiac patients.”

“In many other gene therapy trials, safety concerns arose due to systemic administration of high viral particle loads,” added Dr. Povsic. “In contrast, because we can inject XC001 directly into the heart, we can dramatically reduce overall viral particle loads and systemic exposure while increasing efficacy.”

EXACT Phase 1/2 Study Data Presentations at AATS and ASGCT

Lead author, Dr. Mokadam presented three-month data from the Phase 1 study in the presentation, *Dose Escalation Study of Encoberminogene Rezmadenovec (Adenoviral Vector with Multiple Isoforms of Vascular Endothelial Growth Factor) in Refractory Angina: Phase 1 Results* at the AATS Annual Meeting.

Dr. Povsic will present six-month data from the Phase 1 study in the presentation, *Preliminary Safety, Tolerability and Efficacy of Direct Epicardial Administration of Encoberminogene Rezmadenovec to Ischemic Myocardium in Patients with Refractory Angina: Six Month Phase 1 Data* at the ASGCT 25th Annual Meeting.

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, to be followed by an expansion phase of the trial with 27 additional subjects at the highest tolerated dose. The trial is designed to assess the preliminary safety and efficacy of XC001. The investigational gene therapy is administered directly to the heart muscle through a mini-thoracotomy by an experienced cardiac surgeon. The EXACT trial is being conducted 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. An estimated one million people suffer from refractory angina in the United States.

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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