XyloCor Therapeutics Presents Phase 2 Data Highlighting Safety and Efficacy of XC001 at the European Society of Cardiology (ESC) Congress 2023

– Positive Phase 2 EXACT Trial results at 6-months underscore significant potential of investigational therapy in refractory angina

– Six-month data have since been sustained out to 12-months supporting durability of XC001 safety and efficacy profile

– XC001 targets unmet medical need among patients with refractory angina who have a debilitating quality-of-life burden and no available treatment options

Wayne, PA, August 25, 2023 —XyloCor Therapeutics, Inc., a clinical-stage biopharmaceutical company developing novel gene therapies for cardiovascular disease, today presented results from the Phase 2 portion of its Phase 1/2 clinical trial (EXACT) of its lead gene therapy candidate XC001 (encoberminogene rezmadenovec) for refractory angina at the European Society of Cardiology (ESC) Congress 2023. During the ESC Congress poster session, Dr. Thomas Povsic, Principal Investigator of the EXACT trial, presented the primary six-month outcome data from the recently completed EXACT trial, which demonstrated that treatment with XC001 resulted in improvements across all key efficacy endpoints. The findings underscore its strong potential as a novel therapeutic approach for the treatment of this disabling condition.

XC001 is a one-time gene therapy designed to reduce ischemic burden by creating new blood vessels in the heart through the local expression of multiple vascular endothelial growth factor (VEGF) isoforms. In the Phase 2 portion of the EXACT trial, 32 patients with class II-IV angina were dosed with the maximal dose of XC001 through transepicardial delivery (direct administration to the heart). XC001 met all of its safety and exploratory objectives and showed potential transformative benefits for the patient population. Among the notable topline results presented at the ESC Congress 2023 included:

- VEGF gene therapy with XC001 administered via minimally invasive transepicardial delivery was generally well tolerated.
- There were no serious adverse events related to the drug or unexpected serious adverse events related to XC001 administration.
- Patients demonstrated improvements in key efficacy measures most notably total exercise time, time to the development of ST-depression (an objective measure of ischemia), angina frequency, and reduction in ischemic burden as measured by Positron Emission Tomography (PET) imaging.
- The six-month results showed that XC001 achieved a clinically meaningful biologic effect, warranting further study in larger randomized clinical trials.

“Refractory angina is a debilitating and chronic condition that is growing in prevalence and these patients have exhausted all treatment options,” said Thomas Povsic, M.D., Ph.D., Professor of Medicine, Duke University School of Medicine and National Principal Investigator for the EXACT study. “The six-month results from the EXACT trial – which have now been sustained out to 12 months – demonstrate that gene therapy with XC001 has the potential to be safely administered while improving quality of life for these cardiac patients.”

“The clinical research results presented at ESC Congress 2023 highlight XyloCor's continuing efforts to transform the treatment paradigm in refractory angina through the promise of one-time gene therapy,” said Al Gianchetti, President and CEO of XyloCor. “We are excited to share data that provides evidence for angiogenesis and a promising efficacy and tolerability profile for XC001. These results strongly support our continued development of this novel therapeutic approach.”

Further background and results presented in the ESC Congress 2023 poster session titled "***Angiogenic gene therapy for refractory angina: Results of the Epicardial delivery of XC001 Gene Therapy for Refractory Angina Coronary Treatment (EXACT) Phase 2 Trial*** can be found **here).**

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 10^{11} vp, the highest tested dose). In the EXACT trial, this 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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