

**XyloCor Therapeutics Positive EXACT Phase 2 Data for Lead Candidate XC001 Simultaneously Presented at Society for Cardiovascular Angiography & Interventions (SCAI) 2024 Scientific Sessions and Published in *Circulation: Cardiovascular Interventions***

- Positive Phase 2 EXACT Trial results validate transformative potential of novel gene therapy XC001 for treatment of refractory angina and support continued clinical development
- Novel therapeutic approach aims to fill significant unmet medical need for patients with refractory angina who have exhausted available treatment options and have a debilitating quality-of-life

**Wayne, PA, May 2, 2024** —XyloCor Therapeutics, Inc., a clinical-stage biopharmaceutical company developing novel gene therapies for cardiovascular disease, today presented final 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 Society for Cardiovascular Angiography & Interventions (SCAI) 2024 Scientific Sessions, May 2-4, 2024 in Long Beach, CA. These encouraging results supporting XC001's safety and efficacy potential are being simultaneously published in [\*Circulation: Cardiovascular Interventions\*](#).

The EXACT trial assessed the use of one-time gene therapy with XC001 as a new therapeutic approach in refractory angina – a debilitating and chronic condition that impacts over one million people in the United States and is growing in prevalence. XC001 is 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 minimally-invasive transepical delivery (direct administration to the heart).

“The results of the EXACT trial suggest that angiogenic gene therapy with XC001 has the potential to improve cardiovascular outcomes for refractory angina patients without revascularization or other treatment options,” said Thomas Povsic, M.D., Ph.D., Professor of Medicine, Duke University School of Medicine and Kenta Nakamura, M.D., Assistant Professor at the University of Washington, lead authors of the EXACT study results. “There is significant need for novel therapies for this serious and disabling condition and we hope that the clinically meaningful evidence emerging from the EXACT trial is the catalyst for continued development that will further validate the potential of this innovative gene therapy for patients.”

The Phase 2 results validated the transformative disease modifying potential of XC001 to reduce ischemia and improve the quality-of-life for cardiac patients who have no treatment options. The results demonstrated that treatment with XC001 can be safely administered and achieve durable clinical improvements including: increases in exercise duration, decrease in ischemic burden as measured by Positron Emission Tomography (PET) imaging, and a reduction in angina frequency. Notably, 93% of patients in the trial entered the trial with chest pain so severe that it markedly limited daily activities and six months after treatment 43% of patients had no chest pain with ordinary activities. VEGF gene therapy with XC001 was well tolerated in the patient population and there were no serious adverse events related to the drug or unexpected serious adverse events related to XC001 administration.

“The results from the EXACT trial represent a promising moment for people with refractory angina and the cardiovascular community as we drive forward toward our goal to deliver a long overdue new treatment option,” said Al Gianchetti, President and CEO of XyloCor. “We are preparing our next clinical trial to advance the development of XC001 and further unlock its transformative medical potential for patients and their families.”

## **Details regarding the SCAI 2024 scientific session is as follows:**

**Title:** VEGF Gene Therapy Improves Exercise Time, Ischemia, and Symptoms in Patients with Refractory Angina: Results of the Phase II EXACT Trial

**Lead Presenter:** Kenta Nakamura, M.D., Associate Professor at the University of Washington

**Date and Time:** Thursday, May 2, 2024; 9:31-9:38 AM PT

**Location:** Long Beach Convention Center, 104A, First Level

An additional press release from SCAI on the Phase 2 EXACT Trial results and poster session is available [here](#).

The *Circulation: Cardiovascular Interventions* full article titled “Angiogenic Gene Therapy for Refractory Angina: Results of the EXACT Phase 2 Trial” is available [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 ( $1 \times 10^{11}$  vp, the highest tested dose). In the EXACT trial, this investigational gene therapy was 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](http://www.xylocor.com).

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