CiVi Biopharma Resumes AURORA Phase 3 Clinical Trial of CIVI030 to Treat Systemic Sclerosis

On Track to Complete Enrollment in First Quarter 2021 and for Top Line Data in Mid-2021

CHEVY CHASE, MD, October 1, 2020 – **CiVi Biopharma, Inc.,** ("CiVi" or "the Company"), a privately held company focused on creating novel therapies against diseases where the unmet medical need exists, today announces that the Company, through its wholly-owned subsidiary, Eicos Sciences, Inc., has resumed recruitment in the AURORA Phase 3 clinical trial of the Company's lead product, CIVI030 (intravenous iloprost), for the treatment of Systemic Sclerosis (SSc). The AURORA study was paused due to the COVID-19 pandemic in March 2020.

The AURORA study is a multicenter, double-blind, randomized, placebo-controlled, Phase 3 study evaluating the safety and efficacy of intravenous (IV) iloprost in patients with SSc experiencing symptomatic digital ischemic episodes (symptomatic Raynaud's Phenomenon). Patients will receive study drug for 5 consecutive days as an IV infusion over 6 hours each day. The primary efficacy endpoint is the change in the weekly frequency of symptomatic Raynaud's Phenomenon (RP) attacks from baseline to Day 21. Secondary endpoints will evaluate severity of RP attacks as determined by symptoms, duration of attacks and percentage of patients who reach a pre-defined symptomatic response.

The study is targeted to enroll approximately 180 patients across 30 U.S. sites. The Company expects to complete enrollment in the first quarter of 2021 and to have topline data in mid-2021.

"In people with SSc, digital ischemic episodes (RP) are often excruciatingly painful and associated with varying symptoms of pain, numbness, tingling, and discomfort. This causes significant disability and impacts quality-of-life and day-to-day functioning and may be the initial sign of long-term progressive complications due to inflammation and scarring of the vessels that supply blood to the digits," said Dinesh Khanna, M.D., Professor of Medicine at University of Michigan and Chief Medical Officer of Eicos Sciences.

"We look forward to completing enrollment in this registrational study as there are currently no U.S. Food and Drug Administration (FDA) approved therapies to improve symptoms in patients with SSc," stated Shalom Jacobovitz, Chief Executive Officer of CiVi Biopharma. "Completing this pivotal study will bring us one step closer to achieving our goal to develop the first FDA-approved treatment that can improve outcomes in patients experiencing this painful and debilitating condition."

CIVI030 has been granted Orphan Drug Designation by the U.S. FDA, which provides certain benefits, including tax credits for qualified clinical testing, waiver or partial payment of FDA application fees and seven years of market exclusivity, if approved.[1]

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[1] FDA Industry Guidance: Designating an Orphan Product: Drugs and Biological Products (**https://www.fda.gov/industry/developing-products-rare-diseases-conditions/designating-orphan-product-drugs-and-biological-products**)

For complete study details, please view the study listing on: www.ClinicalTrials.gov Identifier: NCT04040322. For Systemic Sclerosis patients who would like to learn more about the AURORA study, please visit the study website at: https://www.aurorasscstudy.com/

About Systemic Sclerosis

Systemic Sclerosis (SSc), a form of Scleroderma, is a rare autoimmune disease characterized by inflammation, immune system dysfunction, vasculopathy, and fibrosis of the skin and internal organs. Symptomatic digital ischemic episodes (Raynaud's Phenomenon) are characterized by color changes in the fingers (and often the toes) in response to cold exposure or emotion and are associated with symptoms of pain, numbness, discomfort, and/or tingling. Over time, progressive changes in digital vasculature can cause more severe and longer lasting ischemic episodes. If untreated, these can lead to digital ulcers, gangrene, and ultimately result in amputations.

This chronic disease affects approximately 75,000 people in the US, of which 80% are women, with typical onset of disease at 30-50 years of age. Of the US adult SSc population, approximately 40,000 (or 58%) present with moderate to severe digital ischemia.

About CiVi Biopharma

CiVi Biopharma, Inc. is a privately held, clinical stage biotechnology company whose mission is to create novel cardiovascular and metabolic therapies that have meaningful value to patients. Founded in 2016, the company has multiple assets in various stages of development including CIVI030, IV iloprost, in Phase 3 clinical trials for the treatment of Systemic Sclerosis and CIVI007, a long-acting PCSK9 third generation Locked Nucleic Acid antisense molecule, in development for the treatment and prevention of cardiovascular disease. CiVi Biopharma has been supported by venture financing from Boxer Capital of the Tavistock Group and Roche Ventures, among others.

Contact:

Jared Jacobovitz
Director of Business Development and Planning
CiVi Biopharma, Inc.
Email: jjj@civibio.com
Phone: 650-464-7515

Anne Marie Fields
Managing Director
Rx Communications Group
Email: afields@rxir.com

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