Akero Therapeutics Announces First Patient Randomized for Dosing in Phase 2b Study of Efruxifermin (EFX) in F2/F3 NASH Patients (HARMONY)

March 23, 2021

SOUTH SAN FRANCISCO, Calif., March 23, 2021 (GLOBE NEWSWIRE) -- Akero Therapeutics, Inc. (Nasdaq: AKRO), a cardio-metabolic biotechnology company developing transformational treatments for non-alcoholic steatohepatitis (NASH), today announced the first patient has been randomized for dosing in its Phase 2b clinical study of Efruxifermin (EFX) in the treatment of patients with F2/F3 NASH (the HARMONY study).

"Randomization of the first patient in our Phase 2b HARMONY study in F2/F3 patients is yet another key milestone for Akero, which builds on our recent data in cirrhotic patients (F4) and last year's data in patients with F1-F3 fibrosis," said Kitty Yale, chief development officer of Akero. "Screening and enrollment in HARMONY are ahead of schedule and we remain on track to report topline preliminary results in the second half of 2022. We are excited about the potential benefits that EFX may offer to patients with NASH, a serious metabolic disease for which there is no FDA-approved treatment option."

The Phase 2b HARMONY study is a multicenter, randomized, double-blind, placebo-controlled, clinical trial in biopsy-confirmed NASH patients with fibrosis stage 2 or 3. Patients will be randomized to receive once-weekly subcutaneous dosing of 28 or 50mg EFX, or placebo. The primary endpoint for the trial is fibrosis regression at 24 weeks. Patients will continue to receive EFX or placebo after 24 weeks during a long-term follow-up period to provide additional safety data.

About NASH
Non-alcoholic steatohepatitis (NASH) is a serious, life-threatening disease that has rapidly emerged as a leading cause of liver failure in the world and is the leading indication for liver transplant among women. An estimated 17.3 million Americans had NASH in 2016, a number that is expected to increase to 27.0 million by 2030. NASH is a severe form of nonalcoholic fatty liver disease (NAFLD) characterized by hepatocyte injury, liver inflammation, and fibrosis that can progress to scarring (cirrhosis), liver failure, cancer and death. There are currently no approved therapies for the disease.

About Efruxifermin
Efruxifermin (EFX) is an Fc-FGF21 fusion protein that has been engineered to mimic the balanced biological activity profile of native FGF21, an endogenous hormone that alleviates cellular stress and regulates metabolism throughout the body. Previous clinical trials show that EFX has the potential to reverse fibrosis, resolve NASH, reduce liver fat, improve glycemic control and lipoprotein profile, and reduce body weight. EFX is designed to offer convenient once-weekly subcutaneous dosing.

About Akero Therapeutics
Akero Therapeutics is a clinical-stage cardio-metabolic company developing transformational treatments for non-alcoholic steatohepatitis (NASH), a disease without any approved therapies. Akero's lead product candidate, EFX, an engineered Fc-FGF21 fusion protein, is currently being evaluated in a Phase 2b clinical trial as a potential treatment for NASH. Akero is headquartered in South San Francisco. Visit us at www.akerotx.com for more information.

Forward-Looking Statements
Statements contained in this press release regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements, including, but not limited to, statements regarding the Company's business plans and objectives, including future plans or expectations for EFX, upcoming milestones, and therapeutic effects of EFX, as well as the dosing, safety and tolerability of EFX; the Company's Phase 2b HARMONY study including expected timing to complete enrollment and report preliminary results; the Company's Phase 2b SYMMETRY study, including expected timing for initiation and enrollment of the study; the availability of a new drug product presentation to support Phase 3 clinical trials; expectations regarding the Company's use of capital, expenses and other future financial results; statements regarding a potential meeting with the FDA and timing thereof and the potential impact of COVID-19 on strategy, future operations, enrollment and clinical trials. Any forward-looking statements in this press release are based on management's current expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. Risks that contribute to the uncertain nature of the forward-looking statements include: risks related to the impact of COVID-19 on the Company's ongoing and future operations, including potential negative impacts on the Company's employees, third-parties, manufacturers, supply chain and production as well as on global economies and financial markets; the success, cost, and timing of the Company's product candidate development activities and planned clinical trials; the Company's ability to execute on its strategy; positive results from a clinical study may not necessarily be predictive of the results of future or ongoing clinical studies; regulatory developments in the United States and foreign countries; the Company's ability to fund operations; as well as those risks and uncertainties set forth more fully under the caption "Risk Factors" in the Company's most recent Annual Report on Form 10-K, as filed with the Securities and Exchange Commission (SEC) as well as discussions of potential risks, uncertainties and other important factors in the Company's other filings and reports with the SEC. All forward-looking statements contained in this press release speak only as of the date on which they were made. The Company undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

Investor Contact:
Christina Tartaglia
212.362.1200
IR@akerotx.com

Media Contact:
Jennifer Weismann
612.716.0556
media@akerotx.com