# Akero Therapeutics to Present Efruxifermin (EFX) Results Showing Histologic Improvement in EFX-Treated F4 Cirrhotic Patients as a Late-Breaker Oral Presentation at the 2021 International Liver Congress

June 1, 2021

**This Month, Akero Will Present Three Abstracts at EASL and Two Abstracts at the 81st Meeting of the American Diabetes Association (ADA)**

SOUTH SAN FRANCISCO, Calif., June 01, 2021 (GLOBE NEWSWIRE) -- Akero Therapeutics, Inc. (Nasdaq: AKRO), a cardio-metabolic biotechnology company developing transformational treatments for non-alcoholic steatohepatitis (NASH), today announced that it will present results from the Cohort C extension of its Phase 2a BALANCED study, which found positive histological improvements in F4 NASH patients with compensated cirrhosis after 16 weeks of treatment with efruxifermin (EFX), at the 2021 International Liver Congress hosted by the European Association for the Study of the Liver (EASL) on June 26 at 1:00 p.m., Central European Time. Akero will also report data from the BALANCED main study in F2/F3 NASH patients in two other presentations at EASL and in two presentations at the 81st Meeting of the American Diabetes Association (ADA) taking place June 25-29.

“We believe the consistency, magnitude and reproducibility of treatment effect sets efruxifermin apart in the NASH arena,” said Kitty Yale, chief development officer of Akero. “The data we will present in June at EASL and ADA show consistently strong results for EFX in improving histology, liver health, glycemic control, and lipoprotein profile in patients with F2/F3 NASH, and unprecedented and promising results in patients with F4 compensated cirrhosis. We believe we will continue to see meaningful histologic improvements in our ongoing Phase 2b HARMONY study in NASH patients with F2/F3 fibrosis and the Phase 2b SYMMETRY study in NASH patients with F4 compensated cirrhosis, which we plan to initiate in the second half of this year.”

Presentations at the EASL International Liver Congress, June 23-26:

- EASL Abstract No. 2800 (Late breaker oral presentation), “Efruxifermin (EFX) improved markers of fibrosis, liver injury and metabolism in F4 NASH patients with compensated cirrhosis,” presented by Stephen Harrison, M.D.
- EASL Abstract No. 1314: "The role of reduction in liver fat content (MRI-PDFF) and ALT in predicting treatment response in NASH: A secondary analysis of the randomized, controlled BALANCED trial," presented by Rohit Loomba, M.D.
- EASL Abstract No. 1762: "Correlation between changes in liver fat content and improvements in serum markers of liver injury, fibrosis, metabolism, and in histologic parameters following treatment with efruxifermin," presented by Stephen Harrison, M.D.

Presentations at the 81st ADA Scientific Sessions meeting, June 25-29:

- ADA Abstract 116-LB: “Efruxifermin is associated with improved glucose metabolism in patients with NASH and type 2 diabetes,” presented by Juan P. Frias, M.D.
- ADA Abstract 119-LB: “Increased adiponectin following efruxifermin treatment is associated with improvements in dyslipidemia, glucose metabolism, and liver health in a 16-week, randomized, placebo-controlled NASH trial,” presented by Juan P. Frias, M.D.

“Patients with type 2 diabetes, many of whom also have NASH with fibrosis, have a significant need for novel therapies that can treat NASH while improving diabetes control and reducing the high risk of cardiovascular disease,” said Dr. Juan Frias, Medical Director and Principal Investigator of the National Research Institute. “EFX appears to have the potential to meet this high unmet medical need by reversing liver injury and fibrosis, restoring a healthy lipoprotein profile while enhancing insulin sensitivity, and improving glycemic control even in patients on existing antidiabetic medications.”

**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, efruxifermin (EFX) is a differentiated 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. In prior clinical trials, EFX has reversed fibrosis, resolved NASH, reduced liver fat, improved glycemic control, improved lipoprotein profile, and reduced body weight. The consistency and magnitude of observed effects position EFX to be a potentially best-in-class medicine, if approved, for treatment of NASH. EFX is currently being evaluated in a Phase 2b clinical trial in NASH patients with F2/F3 fibrosis, the HARMONY study. Akero is headquartered in South San Francisco. Visit 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 Akero'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; Akero’s Phase 2b HARMONY study and Phase 2b SYMMETRY study including expected timing to complete enrollment and report preliminary results; the availability of a new combination drug product-device to support Phase 3 clinical trials; 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 Akero's ongoing and future operations, including potential negative impacts on Akero's employees, third-parties, manufacturers, supply chain and production as well as on global economies and financial markets; the success, cost, and timing of Akero's product candidate development activities and planned clinical trials; Akero'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; Akero's ability to fund operations; as well as those risks and uncertainties set forth more fully under the caption "Risk Factors" in Akero'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 Akero'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. Akero 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:**
650.487.6488
media@akerotx.com