Akero Therapeutics to Present Late-Breaking Oral and Poster presentations on EFX Today at AASLD's The Liver Meeting® 2022

November 7, 2022

Phase 2b HARMONY study presentation selected for inclusion in the Best of the Liver meeting in the NASH/NAFLD category

SOUTH SAN FRANCISCO, Calif., Nov. 07, 2022 (GLOBE NEWSWIRE) -- Akero Therapeutics, Inc. (Nasdaq: AKRO), a clinical-stage company developing transformational treatments for patients with serious metabolic diseases marked by high unmet medical need, announced it will present late-breaking oral and poster presentations on its lead product candidate efruxifermin (EFX) today at the American Association for the Study of Liver Diseases' (AASLD) The Liver Meeting 2022 being held in Washington, D.C.

"We're looking forward to sharing our recently reported Week 24 results from the Phase 2b HARMONY study in patients with pre-cirrhotic NASH (F2-F3) with the scientific community at The Liver Meeting®," said Andrew Cheng, M.D., Ph.D., president and chief executive officer of Akero. "We believe these results are an important milestone for the NASH community and contribute to the growing body of evidence that EFX has the potential to treat the core facets of NASH and become a foundational monotherapy. We also look forward to sharing new data about how EFX's bivalent molecular structure has the potential to deliver differentiated pharmacology through sustained receptor engagement, which may be an important contributing factor to the robustness of our Phase 2b HARMONY results."

Details of the presentations are as follows:

Oral Presentation Title: Efruxifermin (EFX) in nonalcoholic steatohepatitis with fibrosis: results from a randomized, double-blind, placebo-controlled, phase 2b trial (HARMONY)

- **Presenter:** Stephen A. Harrison, M.D., Medical Director, Pinnacle Clinical Research and HARMONY study principal investigator
- **Late-Breaker Abstract Number:** 5006
- **Presentation Date and Time**: 2:00 pm ET on Monday, November 7
- **Location:** General Session Ballroom ABC

Poster Presentation Title: Efruxifermin (EFX), a bivalent Fc-FGF21 analog, demonstrates improved biophysical and pharmacological engagement with live cells compared to monovalent FGF21 analogs

- **Presenter:** Erik Tillman, Ph.D., Associate Director, Translational Biology and Pharmacology, Akero Therapeutics
- **Late-Breaker Abstract Number:** 5051
- **Presentation Date and Time**: 1:00 pm ET on Monday, November 7
- **Location:** Poster Hall

About NASH
NASH (non-alcoholic steatohepatitis) is a serious form of NAFLD (non-alcoholic fatty liver disease) that is estimated to affect 17 million Americans. NASH is characterized by an excessive accumulation of fat in the liver that causes stress and injury to liver cells, leading to inflammation and fibrosis, which can progress to cirrhosis, liver failure, cancer and eventually death. There are no approved treatments for the condition and NASH is the fastest growing cause of liver transplants and liver cancer in the US and Europe.

About the HARMONY Study
The Phase 2b HARMONY study is a multicenter, randomized, double-blind, placebo-controlled, dose-ranging trial in biopsy-confirmed adult NASH patients with fibrosis stage 2 or 3. The study enrolled a total of 128 patients, randomized to receive once-weekly subcutaneous doses of 28mg or 50mg EFX, or placebo for 24-weeks. The primary efficacy endpoint for the study was the proportion of subjects who achieved at least a one-stage improvement in fibrosis without worsening of NASH at week 24. Secondary Week 24 measures included NASH resolution and change from baseline in liver fat, liver enzymes, noninvasive markers of liver fibrosis, glycemic control, lipoproteins and body weight, as well as safety and tolerability measures. Patients are being followed for safety evaluation for up to a total of 96 weeks of dosing.

About Efruxifermin
Efruxifermin (EFX) is Akero's lead product candidate for NASH, currently being evaluated in the ongoing Phase 2b HARMONY and SYMMETRY studies. EFX is designed to reduce liver fat and inflammation, reverse fibrosis, increase insulin sensitivity and improve lipoproteins. This holistic approach offers the potential to address the complex, multi-system disease state of NASH, including improvements in lipoprotein risk factors linked to cardiovascular disease – the leading cause of death in NASH patients. Engineered to mimic the biological activity profile of native FGF21, EFX is designed to offer convenient once-weekly dosing and has been generally well-tolerated in clinical trials to date.

About Akero Therapeutics
Akero Therapeutics is a clinical-stage company developing transformational treatments for patients with serious metabolic diseases marked by high unmet medical need, including 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. EFX is designed to offer convenient

once-weekly subcutaneous dosing. 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 two Phase 2b clinical trials: the HARMONY study in patients with pre-cirrhotic NASH (F2-F3 fibrosis), which is currently in a long-term safety follow-up phase after reporting Week 24 results, and the SYMMETRY study in patients with cirrhotic NASH (F4 fibrosis, compensated). EFX is also being evaluated in an expansion cohort of the SYMMETRY study, comparing the safety and tolerability of EFX to placebo when added to an existing GLP-1 receptor agonist in patients with pre-cirrhotic NASH (F1-F3 fibrosis) and Type 2 diabetes. Akero is headquartered in South San Francisco. Visit us at akerotx.com and follow us on LinkedIn and Twitter 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 efruxifermin (EFX), the therapeutic effects and potential of EFX, as well as the dosing, safety and tolerability of EFX; upcoming milestones, including the results, and expected timing to report such results of Akero's Phase 2b SYMMETRY study; Akero's preparations for commercialization of EFX, if approved; and Akero's growth as a company and expectations regarding its uses of capital, expenses and financial results, including the expected cash runway. 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 and Quarterly Report on Form 10-Q, 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:
Sarah O'Connell
732.456.0092
soconnell@vergescientific.com