Akero Therapeutics to Present Results from Phase 2b HARMONY Trial Investigating Efruxifermin in Patients with Pre-Cirrhotic NASH

September 8, 2022

Investor webcast on Tuesday, September 13 at 8:00 a.m. ET to present clinical data

SOUTH SAN FRANCISCO, Calif., Sept. 08, 2022 (GLOBE NEWSWIRE) -- Akero Therapeutics, Inc. (Nasdaq: AKRO), a clinical-stage company developing transformational treatments for patients with serious metabolic disease marked by high unmet medical need, will hold an investor conference on Tuesday, September 13 at 8:00 a.m. ET to share results from its HARMONY study, a double-blind, placebo-controlled Phase 2b study evaluating the efficacy of efruxifermin (EFX) in patients with pre-cirrhotic non-alcoholic steatohepatitis (NASH), fibrosis stage 2 or 3 (F2-F3).

Conference Call / Webcast Details
The company will host a conference call and webcast with slide presentation at 8:00 a.m. ET on Tuesday, September 13. **Please click here to register for the event.** The live webcast will be available on the Events & Presentations page of the Akero website, with the recording and presentation available immediately following the event.

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 a leading cause of liver transplants 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 patients with pre-cirrhotic NASH, fibrosis stage 2 or 3. The study enrolled a total of 128 patients, randomized to receive once-weekly subcutaneous dosing of 28mg or 50mg EFX, or placebo. The primary efficacy endpoint for the study is the proportion of subjects who achieve at least a one-stage improvement in fibrosis without worsening of NASH at week 24. Additional week 24 secondary measures include other liver histology endpoints; noninvasive markers of liver fibrosis; change from baseline in liver fat, liver enzymes, glycemic control, lipoproteins, and body weight as well as safety and tolerability measures. To provide long-term safety data, patients will continue on treatment with EFX or placebo for a follow-up period of up to 96 weeks.

About Efruxifermin
Efruxifermin (EFX) is Akero's lead product candidate for NASH, currently being evaluated in the ongoing Phase 2b HARMONY study. EFX is designed to reverse fibrosis, reduce liver fat and inflammation, 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 offers 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), 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 of EFX, as well as the dosing, safety and tolerability of EFX; and upcoming milestones, including the results, and expected timing to report such results of Akero's Phase 2b HARMONY study. 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.

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