Akero Therapeutics Presents at the American Diabetes Association's 81st Scientific Sessions, Demonstrating that Improvements in Adipose Tissue Metabolism Contributed Substantially to Improved Liver Health and Better Glycemic Control in Efruxifermin (EFX)-

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SOUTH SAN FRANCISCO, Calif., June 25, 2021 (GLOBE NEWSWIRE) -- Akero Therapeutics, Inc. (Nasdaq: AKRO), a cardio-metabolic biotechnology company developing transformational treatments for non-alcoholic steatohepatitis (NASH), today announced additional analyses from its Phase 2a BALANCED study of efruxifermin (EFX) in NASH patients with F1-F3 fibrosis, which are being presented by Juan Frias, MD, medical director of the National Research Institute, as two posters at the American Diabetes Association's 81st Scientific Sessions (ADA). The posters are available starting at 11:30am ET on June 25, 2021 and will be posted to the company's website. The company's EFX program in NASH is also being featured in a video presentation at the ADA, which can be accessed from the company's website.

In a poster presentation titled "Efruxifermin is associated with improved glucose metabolism in patients with NASH and type 2 diabetes" (Abstract 116-LB), Dr. Frias reports improvements in markers of glucose metabolism, insulin sensitivity and lipoprotein profile, with a trend to reduce body weight, in patients with NASH and type 2 diabetes mellitus after 16 weeks of treatment with EFX. These improvements, including a clinically meaningful and statistically significant reduction in HbA1c, were seen on top of concomitant anti-diabetic medications.

"Improving insulin sensitivity and glucose metabolism is a critical component in the management of NASH because metabolic dysregulation plays a major role in the pathophysiology of this disorder, and because roughly one third of patients with type 2 diabetes also have NASH—often with suboptimal glycemic control," said Dr. Frias. "These preliminary data demonstrating improvements in glucose metabolism with EFX are very encouraging and indicate that EFX may play an important future role in the management of NASH in patients with glucose intolerance."

In a second poster presentation titled "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" (Abstract 119-LB), Dr. Frias reports the contribution of FGFR1c activation by EFX in adipose tissue, as indicated by increased serum adiponectin, to the beneficial effects observed on liver health and glucose metabolism. These secondary analyses highlight the potential of FGFR1c-mediated reprogramming of adipose metabolism in NASH patients to improve liver health. Insulin-sensitizing therapeutics acting predominantly on adipose tissue, such as pioglitazone, have historically been associated with weight gain. A consistent trend toward weight loss in the BALANCED study suggests that EFX may redirect fat away from the liver to adipose tissue in a weight-neutral manner, contributing to the potentially unique therapeutic profile of EFX.

"The only way to really treat NASH is to treat the whole body and not just the liver," said Tim Rolph, chief scientific officer of Akero Therapeutics. "The breadth, consistency and magnitude of effects observed following treatment with EFX across clinical trials in patients with metabolic disease appear to derive from EFX's balanced agonism of FGF21's receptors in adipose tissue and liver."

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 shown a trend to lower 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 2a BALANCED clinical trial, including additional analysis of its data and potential therapeutic benefits; Akero's Phase 2b HARMONY clinical trial; 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) and quarterly reports on Form 10-Q filed with the 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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