Study Published in JHEP Reports Shows Efruxifermin Rapidly Improved Fibrosis in Cirrhotic NASH patients After 16 Weeks of Treatment

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33% improved by one fibrosis stage without worsening of NASH; 25% of patients treated with efruxifermin showed NASH resolution

Consistent with the results for the pre-cirrhotic population (F1-F3), patients with cirrhosis also had improved markers of liver injury, glucose metabolism, and lipid metabolism

SOUTH SAN FRANCISCO, Calif., Aug. 24, 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, today announced that results from Cohort C of its Phase 2a BALANCED trial in non-alcoholic steatohepatitis (NASH) have been published in *JHEP Reports*. Study results showed that efruxifermin (EFX) was well-tolerated in this cohort of patients with compensated cirrhosis, similar to results observed in the BALANCED main study of patients with pre-cirrhotic NASH.

The paper, available online, provides data on the safety, tolerability, and efficacy of once-weekly subcutaneous injections of 50 mg EFX compared to placebo in Cohort C in adult patients with cirrhotic NASH (compensated stage 4 fibrosis, Child-Pugh Class A), who typically have a worse prognosis and higher mortality than those with an earlier stage of fibrosis. Over 16 weeks of treatment, liver stiffness and serum markers of fibrosis significantly decreased compared to baseline. EFX treatment also improved whole-body metabolism, with significant improvement in lipoprotein profile and decrease in HbA1c.

“These encouraging results reaffirm our confidence in EFX as a potential foundational monotherapy for patients with NASH, including those with advanced-stage fibrosis,” said Kitty Yale, chief development officer of Akero. “We are looking forward to sharing data from our larger Phase 2b HARMONY study in September 2022 and are hopeful they will provide further evidence of EFX’s potential to reverse fibrosis, as well as address the underlying metabolic drivers of the disease. We also look forward to reporting the results of our Phase 2b SYMMETRY study in patients with cirrhotic NASH, which remains on track to be reported in the second half of 2023.”

NASH is a progressive liver disease that can lead to liver cancer, liver failure, and increased risk or cardiac events. There are no approved therapies. EFX is a long-acting FGF21 analog that mimics native FGF21’s biological activities *in vitro*.

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 www.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 and SYMMETRY studies. 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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