Akero Therapeutics Completes Enrollment of Phase 2b HARMONY Study in Pre-Cirrhotic NASH Patients

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SOUTH SAN FRANCISCO, Calif., Feb. 08, 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, today announced that it has completed enrollment of the Phase 2b HARMONY study of efruxifermin (EFX), a novel FGF21 analog, for the treatment of non-alcoholic steatohepatitis (NASH).

"We believe EFX has the potential, if approved, to become a leading treatment option for patients with NASH, including those with advanced-stage fibrosis," said Kitty Yale, chief development officer for Akero. "Our confidence in EFX's potential is based on Phase 2a data that showed substantial rates of fibrosis regression after only 16 weeks of treatment. We believe the larger Phase 2b HARMONY study, with a longer 24-week treatment period, will provide further evidence of EFX's potential to reverse fibrosis as well as address the underlying metabolic disease drivers."

Published in Nature Medicine in 2021, results from Akero's Phase 2a BALANCED trial in biopsy-confirmed pre-cirrhotic NASH patients (F1-F3) showed that 48% of patients treated with EFX who had end-of-treatment biopsies achieved at least a one-stage improvement in fibrosis without worsening of NASH and 48% achieved NASH resolution with no worsening of fibrosis. Among patients who had F2/F3 fibrosis at baseline, 68% had at least a 1-stage improvement in fibrosis, while 50% had a 2-stage fibrosis improvement. EFX was also observed to improve glycemic control and lipoprotein profile as well as to reduce liver fat, biomarkers of liver injury and fibrosis, and body weight. EFX was reported to be generally well tolerated.

The Phase 2b HARMONY study is a multicenter, randomized, double-blind, placebo-controlled, clinical trial in biopsy-confirmed NASH patients with fibrosis stage 2 or 3. Patients have been randomized to receive once-weekly subcutaneous dosing of 28mg or 50mg EFX, or placebo. The primary endpoint is fibrosis regression without worsening of NASH at 24 weeks. To provide long-term safety data, patients will continue on treatment with EFX or placebo for a long-term follow-up period of up to 96 weeks.

As is customary for Phase 2 clinical trials, the HARMONY data safety monitoring board was convened to undertake a pre-specified review of all available safety data after a pre-determined number of subjects had received a pre-defined number of doses. There were no changes recommended to the study protocol.

Consistent with prior guidance, results from the HARMONY study remain on track to be reported in the third quarter of this year.

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 pre-cirrhotic patients with F2/F3 fibrosis, and the SYMMETRY study in compensated cirrhotic (F4) patients. Akero is headquartered in South San Francisco. Visit us at 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 and Phase 2b SYMMETRY clinical trials; and the potential impact of COVID-19 on strategy, future operations, as well as enrollment and conduct of 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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