Akero Therapeutics Initiates Phase 2b HARMONY Study of Efruxifermin (EFX) for the Treatment of NASH

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SOUTH SAN FRANCISCO, Calif., Feb. 24, 2021 /PRNewswire/ -- Akero Therapeutics, Inc., a cardio-metabolic biotechnology company developing transformational treatments for non-alcoholic steatohepatitis (NASH), today announced it has screened the first patients for its Phase 2b HARMONY study evaluating efruxifermin (EFX), the company's lead product candidate for the treatment of NASH.

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 will be randomized to receive once-weekly subcutaneous dosing of 28 or 50mg EFX or placebo. The primary endpoint for the trial is fibrosis regression at 24 weeks. Patients will continue to receive EFX or placebo during a long-term follow-up period to provide additional safety data.

The company expects to dose patients beginning early in the second quarter of this year and to report topline results in the second half of 2022.

About NASH
Non-alcoholic steatohepatitis (NASH) is a serious, life-threatening disease that has rapidly emerged as a leading cause of liver failure in the world and is the leading indication for liver transplant among women. An estimated 17.3 million Americans had NASH in 2016, a number that is expected to increase to 27.0 million by 2030. NASH is a severe form of nonalcoholic fatty liver disease (NAFLD) characterized by hepatocyte injury, liver inflammation, and fibrosis that can progress to scarring (cirrhosis), liver failure, cancer and death. There are currently no approved therapies for the disease.

About Efruxifermin
Efruxifermin (EFX) is an 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. Previous clinical trials show that EFX has the potential to reverse fibrosis, resolve NASH, reduce liver fat, improve glycemic control, improve lipoprotein profile, and reduce body weight. EFX offers convenient once-weekly subcutaneous dosing.

About the Phase 2a BALANCED Study
The Phase 2a BALANCED study was a multicenter, randomized, double-blind, placebo-controlled, clinical trial in biopsy-confirmed patients with NASH. The main study enrolled 80 patients for randomization to receive once-weekly subcutaneous dosing of 28, 50 or 70mg EFX or placebo. All three EFX dose groups met the primary endpoint and multiple secondary endpoints, including absolute reductions in liver fat of 12 to 14% as measured by MRI-PDFF at week 12, compared with 0.3% for placebo and relative reductions in liver fat of 63 to 72%, compared with 0% for placebo. Among treatment responders, defined as patients who achieved at least a 30% relative reduction in liver fat, 48% of all EFX patients achieved at least a one-stage improvement of fibrosis without worsening NASH after 16 weeks of treatment, compared with 0% for placebo. Among patients with baseline F2 or F3 fibrosis and end-of-treatment biopsy, 50% of EFX patients achieved at a 2-stage improvement in fibrosis while an additional 18% achieved a 1-stage improvement in fibrosis.

An expansion cohort (Cohort C) evaluated EFX for treatment of cirrhotic NASH patients (F4 fibrosis) and enrolled 30 patients randomized to receive once-weekly subcutaneous dosing of 50mg or placebo. Topline results of Cohort C, including the results of voluntary end-of-treatment biopsies, will be reported in the first half of this year.

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 program, EFX, an engineered Fc-FGF21 fusion protein, is currently being evaluated in Phase 2 clinical trials as a potential treatment for NASH. 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 the Company'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 study including results and expected timing to complete the Phase 2b trial and Cohort C; 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 the Company'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 the Company's product candidate development activities and planned clinical trials; the Company'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; the Company's ability to fund operations; as well as those risks and uncertainties set forth more fully under the caption "Risk Factors" in Akero's Annual Report on Form 10-K for the year ended December 31, 2019 and most recently filed 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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