Akero Therapeutics Announces Initiation of Phase 3 SYNCHRONY Outcomes Trial of Efruxifermin in Patients with Compensated Cirrhosis (F4) Due to MASH

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SOUTH SAN FRANCISCO, Calif., June 11, 2024 (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 initiation of the SYNCHRONY *Outcomes* study, a Phase 3 trial evaluating the efficacy and safety of efruxifermin (EFX) in patients with compensated cirrhosis, fibrosis stage 4 (F4) due to metabolic dysfunction-associated steatohepatitis (MASH).

“Patients with compensated cirrhosis represent the greatest unmet need among MASH patients due to increased risk of progression to liver failure, hepatocellular carcinoma or death,” said Kitty Yale, chief development officer of Akero. “Based on the encouraging week 36 results of our Phase 2b SYMMETRY study in patients with compensated cirrhosis due to MASH, we believe EFX has the potential to be among the first investigational drugs to be approved for treatment of both pre-cirrhotic and cirrhotic patients.”

SYNCHRONY *Outcomes*, a global, randomized, placebo-controlled, 2-cohort, Phase 3 trial, is actively recruiting patients with compensated cirrhosis (F4) due to MASH to receive weekly injections of EFX 50mg or placebo. The primary histology endpoint (Cohort 1 only) is fibrosis regression without worsening of MASH after 96 weeks of treatment based on histology, after which patients will continue treatment as randomized to be evaluated for the primary outcomes endpoint. The primary outcomes endpoint is all-cause mortality and liver-related clinical outcomes as measured by time to first occurrence of any of the pre-defined, adjudicated events across both study cohorts (Cohorts 1 and 2). Key secondary endpoints for the *Outcomes* study include changes from baseline in non-invasive markers of liver injury and fibrosis, glycemic control and lipids.

Phase 3 SYNCHRONY Program
Akero’s Phase 3 SYNCHRONY program is comprised of three ongoing global, randomized, placebo-controlled clinical trials: SYNCHRONY *Histology*, *Real-World*, and *Outcomes*. SYNCHRONY *Histology* and *Real-World* are respectively investigating EFX in patients with pre-cirrhotic MASH (F2-F3 fibrosis), and patients with MASH (F1-F3 fibrosis) or metabolic dysfunction-associated steatotic liver disease (MASLD). SYNCHRONY *Outcome*s is evaluating EFX in patients with compensated cirrhosis due to MASH (F4 fibrosis). In all EFX Phase 3 studies, patients are using the LyoJect 3S dual chamber syringe, a pre-filled device designed for self-administration and intended for commercial use in the event EFX is approved for marketing. This optimized formulation delivers blood levels of EFX comparable to those of the liquid formulation used in prior clinical studies.

About Efruxifermin
Efruxifermin (EFX), Akero’s lead product candidate for MASH, 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 appears to reduce liver fat and inflammation, reverse fibrosis, increase insulin sensitivity and improve lipids. This holistic approach offers the potential to address the complex, multi-system disease state of MASH, including improvements in lipoprotein risk factors linked to cardiovascular disease – the leading cause of death in MASH patients. EFX is designed to offer convenient once-weekly dosing and has been generally well tolerated in clinical trials to date.

About MASH
MASH is a serious form of MASLD that is estimated to affect more than 17 million Americans. MASH 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. MASH is the fastest growing cause of liver transplants and liver cancer in the US and Europe.

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 MASH. Akero's lead product candidate, EFX, is currently being evaluated in the ongoing SYMMETRY study, a 96-week Phase 2b clinical trial in patients with compensated cirrhosis due to MASH (F4 fibrosis), as well as three ongoing Phase 3 clinical trials in patients with pre-cirrhotic MASH or compensated cirrhosis due to MASH: SYNCHRONY *Histology,* SYNCHRONY *Real-World,* and SYNCHRONY *Outcomes.* The SYNCHRONY program builds on the results of two Phase 2b clinical trials, the HARMONY study in patients with pre-cirrhotic MASH (F2-F3) and the SYMMETRY study in patients with compensated cirrhosis due to MASH (F4). 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 EFX; the SYNCHRONY Phase 3 program clinical trial design; and the therapeutic effects of EFX as well as the dosing, safety and tolerability of EFX. 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: 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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