Akero Therapeutics Announces First Patient Dosed in Phase 3 SYNCHRONY Outcomes Study of Efruxifermin in Patients with Compensated Cirrhosis Due to MASH

September 9, 2024

Outcomes is the third study in the Phase 3 SYNCHRONY clinical trial program

SOUTH SAN FRANCISCO, Calif., Sept. 09, 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 reported the first patient was dosed in the Phase 3 SYNCHRONY *Outcomes* trial. The study will evaluate the efficacy and safety of EFX for the treatment of compensated cirrhosis, fibrosis stage 4 (F4), due to metabolic dysfunction-associated steatohepatitis (MASH).

"Dosing the first patient in the SYNCHRONY *Outcomes* trial is an exciting milestone that rounds out our Phase 3 SYNCHRONY program evaluating EFX in patients with varied levels of MASH severity. There continues to be a substantial unmet need for treatments that delay or prevent liver failure among patients with MASH, and the SYNCHRONY program has the potential to show that treatment with EFX can do so in different stages of disease progression," said Kitty Yale, chief development officer of Akero. "We look forward to advancing clinical development of EFX as a potentially differentiated therapeutic for liver fibrosis and cirrhosis as well as metabolic dysregulation."

Outcomes is part of Akero's broader SYNCHRONY Phase 3 program, which includes two other ongoing, randomized, placebo-controlled trials that began enrolling patients in the fourth quarter of 2023. SYNCHRONY *Histology* is evaluating the efficacy and safety of EFX in patients with biopsy-confirmed pre-cirrhotic MASH (F2-F3), while SYNCHRONY *Real-World*, is assessing the safety and tolerability of EFX in patients with non-invasively diagnosed MASH or metabolic dysfunction-associated steatotic liver disease (MASLD) (F1-F4). The SYNCHRONY program is evaluating extent of improvement in fibrosis and resolution of MASH, as well as liver-related long-term clinical outcomes and all cause mortality, with the potential to support marketing applications for treatment of both pre-cirrhotic liver fibrosis and compensated cirrhosis due to MASH.

In all Phase 3 studies, patients are self-administering EFX using the LyoJect 3S dual chamber syringe, a pre-filled device intended for commercial use in the event EFX is approved for marketing.

Week 96 results from the ongoing Phase 2b SYMMETRY study, evaluating the efficacy and safety of EFX in patients with compensated cirrhosis due to MASH (F4), are anticipated in the first quarter of 2025.

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 lipid metabolism. 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) in which patients have been treated for up to 96 weeks. Akero is headquartered in South San Francisco. Visit us at akerotx.com and follow us on LinkedIn and X 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; expectations regarding the SYNCHRONY Phase 3 clinical trials, including that of the Phase 3 SYNCHRONY *Outcomes* trial; the timing to report results of the ongoing Phase 2b SYMMETRY Study; 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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