Akero Therapeutics Completes Enrollment of the Double-Blind Portion of the Phase 3 SYNCHRONY Real-World Study Evaluating Efruxifermin (EFX) in Patients with Non-Invasively Diagnosed MASH or MASLD

January 13, 2025

-- 601 patients have been enrolled in the double-blind portion of the SYNCHRONY Real-World *study since initiation in November 2023 --*

-- Data from SYNCHRONY Real-World *study anticipated in the first half of 2026 --*

SOUTH SAN FRANCISCO, Calif., Jan. 13, 2025 (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 it has completed enrollment of patients in the double-blind portion of the Phase 3 SYNCHRONY *Real-World* study of EFX in patients with metabolic dysfunction-associated steatohepatits (MASH) or metabolic dysfunction-associated steatotic liver disease (MASLD) (F1-F4).

This *Real-World* study is evaluating the safety and tolerability of EFX in a double-blind cohort of 601 patients with MASH and MASLD.

"Completion of enrollment in the double-blind portion of the SYNCHRONY *Real-World* study in just over a year is a testament to the significant need for differentiated MASH treatments and growing enthusiasm around EFX's development," said Kitty Yale, chief development officer. "We are encouraged by the strength of data across our Phase 2 studies, in which improvements in liver histology and multiple non-invasive markers of liver health have been observed. We look forward to reporting results from SYNCHRONY *Real-World* – our first Phase 3 results – in the first half of next year."

SYNCHRONY *Real-World* is a Phase 3 randomized, double-blind, placebo controlled study evaluating the safety and tolerability of EFX in patients with suspected or confirmed clinical diagnosis of MASH or MASLD or non-invasively diagnosed MASH or MASLD, fibrosis stages F1-F4. The study includes an open-label cohort of patients previously assigned to placebo in the Phase 2b HARMONY or SYMMETRY studies. Enrolled patients are receiving once-weekly subcutaneous dosing of either 50mg EFX or placebo. Primary endpoints for the blinded portion of the study include assessments of the safety and tolerability of EFX during 52 weeks of treatment. Secondary endpoints for the blinded portion of the study include changes from baseline in non-invasive markers of liver fibrosis and liver injury, as well as lipoproteins, glycemic control, and body weight.

Results from the SYNCHRONY *Real-World* study are anticipated in the first half of 2026.

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 three ongoing Phase 3 clinical trials in patients with pre-cirrhotic MASH (F2-F3) or compensated cirrhosis (F4) 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 completed HARMONY study in patients with pre-cirrhotic MASH (F2-F3) and the ongoing SYMMETRY study in patients with compensated cirrhosis (F4) due to MASH, in which a total of over 300 patients have been treated with EFX or placebo 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; the therapeutic effects of EFX; the dosing, safety and tolerability of EFX; as well as expected timing for reporting results of ongoing clinical trials, including the SYNCHRONY *Real-World* study. 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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