Akero Therapeutics to Report Results of Phase 2b SYMMETRY Study in October 2023

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SOUTH SAN FRANCISCO, Calif., Aug. 28, 2023 (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 all samples and data required for a readout of topline results from the Phase 2b SYMMETRY study have been collected, which supports the expected timing of readout in October of this year. The topline week 36 results from the study, evaluating treatment of patients with compensated cirrhosis due to non-alcoholic steatohepatitis (NASH), will include histology and changes from baseline in non-invasive measures of fibrosis, glycemic control, and lipoproteins as well as safety and tolerability.

Akero plans to hold an investor webcast detailing the findings.

About SYMMETRY
The Phase 2b SYMMETRY main study is a multicenter, randomized, double-blind, placebo-controlled, clinical trial in biopsy-confirmed NASH patients with compensated cirrhosis (F4, Child-Pugh class A). One hundred eighty-two patients have been randomized to receive once-weekly subcutaneous dosing of 28mg efruxifermin (EFX), 50mg EFX, or placebo. The primary endpoint for the trial is the proportion of subjects who achieve ≥ 1 stage improvement in fibrosis with no worsening of NASH at week 36. Secondary endpoints include the proportion of patients who achieve NASH resolution with no worsening of fibrosis, the proportion of patients who achieve ≥ 1 stage improvement in fibrosis and NASH resolution, change from baseline to week 36 in non-invasive measures of fibrosis, glycemic control, lipoproteins, and body weight, as well as evaluation of safety and tolerability. To provide longer-term safety data, patients will continue to receive EFX or placebo for up to 96 weeks.

In June 2023, Akero reported topline data from an expansion cohort (N=31) of the Phase 2b SYMMETRY study known as Cohort D. The primary aim of the 12-week study was to assess safety and tolerability of EFX compared to placebo when added to an existing GLP-1 receptor agonist (GLP-1) in patients with Type 2 diabetes and F1-F3 liver fibrosis due to NASH. Results of the Cohort D study showed safety and tolerability endpoints were met. The study also showed that adding EFX to GLP-1 therapy significantly improved non-invasive markers of NASH-related disease, including a 65% relative reduction in liver fat for the EFX-treated group compared with a 10% reduction for the placebo group treated only with GLP-1. Consequently, 88% of EFX-treated patients normalized their liver fat to 5% or less, compared with 10% for the placebo group.

About NASH
NASH is a serious form of NAFLD (non-alcoholic fatty liver disease) that is estimated to affect 17 million Americans. NASH 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. There are no approved treatments for the condition and NASH is the fastest growing cause of liver transplants and liver cancer in the US and Europe.

About Efruxifermin
Efruxifermin (EFX) is Akero’s lead product candidate for NASH, currently being evaluated in the ongoing Phase 2b HARMONY and SYMMETRY studies. EFX is designed 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 NASH, including improvements in lipoprotein risk factors linked to cardiovascular disease – the leading cause of death in NASH patients. Engineered to mimic the biological activity profile of native FGF21, EFX is designed to offer convenient once-weekly dosing and has been generally well-tolerated in clinical trials to date.

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 NASH, a disease without any approved therapies. Akero's lead product candidate, 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 patients with pre-cirrhotic NASH (F2-F3 fibrosis), and the SYMMETRY study in patients with cirrhotic NASH (F4 fibrosis, compensated). 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 therapeutic effects of EFX, as well as the dosing, safety and tolerability of EFX, including in combination with GLP-1 therapies; and upcoming milestones, including the results, and expected timing to report such results of Akero’s Phase 2b SYMMETRY 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 any of its clinical studies 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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