Akero Therapeutics to Present Late-Breaking Oral and Poster Presentations on EFX at AASLD's The Liver Meeting® 2023

November 10, 2023

Phase 2b SYMMETRY 36-week data, including new subgroup analysis, showed that EFX is active in patients with advanced cirrhosis and support continued development of EFX for treatment of cirrhosis due to NASH/MASH

22% and 10% of patients with more advanced cirrhosis in the 50mg and 28mg dose groups, respectively, had at least a one-stage improvement in fibrosis without worsening of NASH, over 7 and 3 times, respectively, the placebo rate of 3%

Additional analyses from the HARMONY and SYMMETRY studies indicate that histological improvements associated with EFX do not appear to be attributable to concomitant use of GLP-1

SOUTH SAN FRANCISCO, Calif., Nov. 10, 2023 -- Akero Therapeutics, Inc. (Nasdaq: AKRO), a clinical-stage company developing transformational treatments for patients with serious metabolic disease marked by high unmet medical need, today announced it will present a late-breaking oral presentation and a poster featuring its lead product candidate efruxifermin (EFX) at the American Association for the Study of Liver Diseases' (AASLD) The Liver Meeting® 2023 being held November 10-14 in Boston, MA.

The oral presentation will detail a recently announced 36-week analysis of SYMMETRY, a 96-week Phase 2b study evaluating the efficacy and safety of EFX in patients with compensated cirrhosis (F4) due to metabolic dysfunction-associated steatohepatitis (NASH/MASH). A new analysis of a subgroup comprised of 84 patients diagnosed with cirrhosis due to NASH/MASH at least 6 months before treatment with EFX or those with cryptogenic cirrhosis at baseline provides further evidence of EFX's activity in this advanced cirrhotic population, with a trend to higher rates of fibrosis improvement without NASH worsening in 10% and 22% of those treated with 28mg and 50mg EFX, respectively, compared to 3% for placebo. Another analysis of the 36-week SYMMETRY study data showed that the trend for EFX to reverse cirrhosis did not appear to be attributable to concomitant use of GLP-1.

The poster describes data from SYMMETRY Cohort D, which evaluated treatment of EFX in combination with a GLP-1 receptor agonist in patients with F1-F3 NASH/MASH and Type 2 diabetes. The poster also includes subgroup analyses from HARMONY showing that improvements in liver histology among patients with F2-F3 NASH/MASH associated with EFX treatment with EFX, do not appear to be attributable to concomitant use of GLP-1.

EFX was reported to be generally well-tolerated in the SYMMETRY main study and Cohort D. Overall, the most frequent adverse events were transient, mild-to-moderate gastro-intestinal grade 1 or 2 events.

"Analyses of data from the SYMMETRY and HARMONY Phase 2b studies, which will be presented at The Liver Meeting®, underscore EFX's promising activity profile and support continued development in both the pre-cirrhotic and cirrhotic NASH/MASH patient populations," said Kitty Yale, chief development officer of Akero. "Although the primary endpoint of fibrosis improvement without worsening of NASH was not met in SYMMETRY, we remain encouraged by the totality of data and consistency of EFX's anti-fibrotic effects by either histopathology or non-invasive tests evident across four 4 separate cohorts in patients with pre-cirrhotic (F1-F3) and cirrhotic (F4) NASH/MASH. We therefore believe that longer periods of treatment with EFX may result in higher rates of fibrosis improvement, including cirrhosis reversal. We are also encouraged that EFX appears to provide additional benefit when dosed on top of GLP-1 therapy."

Details of the presentations are as follows:

Oral Presentation Title: Efruxifermin in Compensated Cirrhosis due to NASH/MASH: Results from a Randomized, Double-blind, Placebo-controlled, Phase 2b Trial (SYMMETRY)

- **Presenter:** Stephen A. Harrison, M.D., Medical Director, Pinnacle Clinical Research and principal investigator for the SYMMETRY study
- **Late Breaker Abstract Number:** 5005
- **Session Title:** Late Breaking Abstract #1
- **Presentation Type:** Oral, Late Breaking Parallel Session
- **Session Date and Time:** Monday, November 13, 2023, 2:00 PM - 3:30 PM
- **Presentation Time:** 3:15 PM
- **Location:** General Session Ballroom ABC

Poster Presentation Title: Safety and Efficacy of Efruxifermin in Combination With a GLP-1 Receptor Agonist (GLP-1RA) in Patients with NASH/MASH and T2D: a Randomized, Placebo-controlled Study (Cohort D)

- **Presenter:** Stephen A. Harrison, M.D., Medical Director, Pinnacle Clinical Research and principal investigator for the SYMMETRY Cohort D study

- **Late Breaker Abstract Number:** 48626
- **Presentation Type:** Late Breaking Poster Presentation
- **Presentation Time:** Monday, November 13: 1:00 PM – 2:00 PM
- **Location:** Poster Hall

About NASH/MASH
NASH/MASH is a serious form of non-alcoholic fatty liver disease (NAFLD) that is estimated to affect 17 million Americans. NASH/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. Approximately 20% of patients with NASH/MASH will progress to cirrhosis, which has a higher risk of mortality. There are no approved treatments for the condition and NASH/MASH is the fastest growing cause of liver transplants and liver cancer in the US and Europe.

About SYMMETRY
The Phase 2b SYMMETRY main study is a multicenter, randomized, double-blind, placebo-controlled, clinical trial in biopsy-confirmed NASH/MASH 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 EFX, 50mg EFX, or placebo. The primary endpoint for the trial was the proportion of subjects who achieve ≥ 1 stage improvement in fibrosis with no worsening of NASH at week 36. Patients are continuing as randomized to receive EFX or placebo for up to 96 weeks.

About Efruxifermin
Efruxifermin is Akero's lead product candidate for NASH/MASH, 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/MASH, including improvements in lipoprotein risk factors linked to cardiovascular disease – the leading cause of death in NASH/MASH 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/MASH, 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. EFX is currently being evaluated in two ongoing, 96-week Phase 2b clinical trials: the HARMONY study in patients with pre-cirrhotic NASH/MASH (F2-F3 fibrosis), and the SYMMETRY study in patients with cirrhotic NASH/MASH (F4 fibrosis, compensated). Screening began in the first two of three Phase 3 clinical trials in September 2023, known as the SYNCHRONY Histology and SYNCHRONY Real-World studies. 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 and efficacy of EFX, as well as the dosing, safety and tolerability of EFX; and upcoming milestones, including the results, and expected timing to report the long-term follow-up week 96 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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