Akero Therapeutics Presents New Analyses from Phase 2b SYMMETRY and HARMONY Trials of Efruxifermin at 76th Annual AASLD The Liver Meeting® 2025

November 7, 2025

Post-hoc analyses corroborate previously reported antifibrotic effects of efruxifermin observed in 96-week Phase 2b SYMMETRY trial and indicate potential to reduce risk of disease progression in compensated cirrhosis (F4c) due to MASH

Digital pathology reinforces fibrosis improvements observed through conventional pathology in the 96-week Phase 2b HARMONY trial

SOUTH SAN FRANCISCO, Calif., Nov. 07, 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 new findings from the SYMMETRY and HARMONY Phase 2b trials of efruxifermin in patients with compensated cirrhosis (F4c) due to metabolic dysfunction-associated steatohepatitis (MASH) and pre-cirrhotic (F2-F3) MASH, respectively. The data will be shared during two oral and two poster presentations at the 76th Annual American Association for the Study of Liver Diseases (AASLD) The Liver Meeting® 2025, taking place November 7-11, 2025, in Washington, D.C.

“Patients with cirrhosis due to MASH are at a high risk for hepatic decompensation and development of life-threatening complications. The results we are presenting at AASLD bolster our confidence in the potential of efruxifermin to provide a meaningful and differentiated therapeutic option for F4c and earlier stages of MASH,” said Kitty Yale, chief development officer of Akero Therapeutics. “Efruxifermin has consistently demonstrated clear antifibrotic activity in clinical trials. These new analyses provide further evidence of fibrosis reversal and reduced risk of disease progression with efruxifermin in patients with MASH, which is being validated in our ongoing Phase 3 clinical trial program.”

New post-hoc analyses of 96-week data from the SYMMETRY trial reinforce the antifibrotic activity of efruxifermin in F4c MASH:

- Efruxifermin was associated with statistically significant improvements in clinically significant portal hypertension (CSPH) risk, as assessed by Baveno criteria. CSPH, a serious complication of cirrhosis, increases risk of hepatic complications.
- Significantly more participants treated with efruxifermin vs. placebo met thresholds for clinically meaningful improvements in noninvasive measures of fibrosis that predict reduced risk of liver-related events.
- Evaluation of liver biopsies from SYMMETRY using AI-assisted digital pathology (HistoIndex) corroborated the fibrosis improvements previously demonstrated by conventional pathology and revealed that efruxifermin consistently reduced total fibrosis and septa area, key features of cirrhosis related to disease severity.

Additionally, an AI-powered digital pathology analysis (PathAI) of liver biopsies from the 96-week HARMONY trial in participants with F2/F3 MASH corroborated the previously reported fibrosis improvements shown by conventional pathology, providing further support for the improvements in fibrosis and MASH observed with efruxifermin.

Details for the presentations are as follows:

Oral Presentations

Title: Efruxifermin was associated with improvements in multiple non-invasive tests indicative of fibrosis regression in participants with compensated cirrhosis due to MASH (SYMMETRY)
Presenter: Vlad Ratziu
Session: Clinical Plenary #1
Date/Time: Sunday, November 9, 2025, 12:00 PM ET

Title: Efruxifermin improved markers of portal hypertension as evaluated by Baveno VII criteria in compensated cirrhosis due to MASH: results from a 96-week, placebo-controlled, phase 2b trial
Presenter: Mazen Noureddin
Session: MASH Clinical Trials
Date/Time: Sunday, November 9, 2025, 2:45 PM ET

Poster Presentations

Title: Efruxifermin reduced fibrosis and septa area by quantitative digital pathology in participants with compensated cirrhosis due to MASH: Results from the 96-week, placebo-controlled, phase 2b SYMMETRY trial
Presenter: Mary E. Rinella
Session: Late Breaking Poster Session
Date/Time: Saturday, November 8, 2025

Title: AI-powered histology analysis of HARMONY reveals Efruxifermin-driven changes in the liver microarchitecture in F2/F3 MASH
Presenter: Jörn M. Schattenberg
Session: MASLD/MASH Therapeutics: New Agents and Approved / Available Agents
Date/Time: Monday, November 10, 2025

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 metabolic dysfunction-associated steatohepatitis (MASH). Akero's lead product candidate, efruxifermin, is currently being evaluated in three ongoing Phase 3 clinical trials: SYNCHRONY *Histology* in patients with pre-cirrhotic (F2-F3 fibrosis) MASH, SYNCHRONY *Outcomes* in patients with compensated cirrhosis (F4c) due to MASH, and SYNCHRONY *Real-World* in patients with MASH or MASLD (metabolic dysfunction-associated steatotic liver disease). The Phase 3 SYNCHRONY program builds on the results of two Phase 2b clinical trials, the HARMONY trial in patients with pre-cirrhotic MASH and the SYMMETRY trial in patients with compensated cirrhosis due to MASH. 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; the potential therapeutic effects, reduced risk of disease progression and anti-fibrotic activity 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 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.

Investor Contact:
Christina Tartaglia
Precision AQ
212.362.1200
IR@akerotx.com

Media Contact:
Peg Rusconi
Deerfield Group
617.910.6217
Peg.rusconi@deerfieldgroup.com