Akero Therapeutics to Present Topline Week 96 Results from Phase 2b HARMONY Study Investigating Efruxifermin in Patients with Pre-Cirrhotic MASH

February 29, 2024

Investor webcast on Monday, March 4 at 8:00 a.m. ET to present clinical data

SOUTH SAN FRANCISCO, Calif., Feb. 29, 2024 (GLOBE NEWSWIRE) -- Akero Therapeutics, Inc. (Nasdaq: AKRO), a clinical-stage company developing transformational treatments for patients with serious metabolic disease, will hold an investor conference on Monday, March 4 at 8:00 a.m. ET to share results after 96 weeks of treatment for its HARMONY study, a double-blind, placebo-controlled Phase 2b study evaluating the efficacy of efruxifermin (EFX) in patients with pre-cirrhotic metabolic dysfunction-associated steatohepatitis (MASH), fibrosis stage 2 or 3 (F2-F3).

Conference Call / Webcast Details
The company will host a conference call and webcast with slide presentation at 8:00 a.m. ET on Monday, March 4. **Please click here to register for the event.** The live webcast will be available on the Events & Presentations page of the Akero website, with the recording and presentation available immediately following the event.

About HARMONY
The Phase 2b HARMONY study was a multicenter, randomized, double-blind, placebo-controlled, dose-ranging trial in biopsy-confirmed adult patients with pre-cirrhotic MASH (F2-F3). The study enrolled a total of 128 patients, randomized to receive once-weekly subcutaneous dosing of 28mg or 50mg EFX, or placebo. The primary efficacy endpoint for the study was the proportion of subjects who achieved at least a one-stage improvement in fibrosis without worsening of MASH at week 24. Week 96 histology endpoints included the proportion of subjects who achieved at least a one-stage improvement in fibrosis without worsening of MASH, a two-stage improvement in fibrosis without worsening of MASH, MASH resolution without fibrosis worsening, and a combination of fibrosis improvement and MASH resolution. Additional secondary measures included change from baseline for noninvasive markers of liver fibrosis, liver enzymes, markers of glycemic control, lipoproteins and body weight as well as safety and tolerability measures.

In September 2022, Akero reported positive results from the study after 24 weeks of EFX treatment, demonstrating both the 50mg and 28mg EFX doses achieved statistical significance on the primary endpoint as well as secondary histology endpoints. 41% and 39% of patients treated with 50mg and 28mg EFX, respectively, experienced at least a one-stage improvement in liver fibrosis with no worsening of MASH by week 24, approximately double the placebo rate of 20%. 76% and 47% of patients treated with 50mg and 28mg EFX, respectively, experienced MASH resolution without worsening of fibrosis, three to five times the placebo rate of 15%. 41% and 29% of patients treated with 50mg and 28mg EFX, respectively, experienced both MASH resolution and fibrosis improvement ≥1 stage, approximately six to eight times the placebo rate of 5%. EFX-treated patients also experienced statistically significant improvements in liver fat, liver enzymes, noninvasive markers of fibrosis, glycemic control, lipoproteins, and body weight. EFX was reported to be generally well-tolerated. Across both dose groups, the most frequent adverse events were grade 1 or 2 gastrointestinal events (diarrhea, nausea, increased appetite, and frequent bowel movements), which were transient in nature.

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 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 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 projected to affect over 25 million Americans by 2030. 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 MASH will progress to cirrhosis, which has a higher risk of mortality. There are no approved treatments for the condition and MASH is the fastest growing cause of liver transplants and liver cancer in the United States 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, a disease without any approved therapies. Akero's lead product candidate, EFX, is currently being evaluated in two ongoing Phase 3 clinical trials, the SYNCHRONY *Histology* study in patients with pre-cirrhotic MASH (F2-F3) and the SYNCHRONY *Real-World* study in patients with MASH or MASLD. A third clinical trial, the SYNCHRONY *Outcomes* study in patients with cirrhosis due to MASH (F4), is expected to be initiated in the first half of 2024. The Phase 3 SYNCHRONY program builds on the results of two Phase 2b clinical trials, the HARMONY study in patients with pre-cirrhotic MASH and the SYMMETRY study in patients with cirrhosis due to MASH. 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; the potential therapeutic effects of EFX, as well as the dosing, safety and tolerability of EFX; the SYNCHRONY Phase 3 program, including the timing of the SYNCHRONY *Outcomes* studies; and upcoming milestones, including the results, and expected timing to report the week 96 results

of Akero’s Phase 2b HARMONY 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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