Akero Therapeutics Presents Analysis at the 2022 International Liver Congress Showing that Efruxifermin Improved Histopathology and Markers of Liver Injury Across PNPLA3 Genotypes in Patients with NASH Fibrosis

June 27, 2022

Post hoc analysis shows potential for EFX to treat patients at highest genetic risk for progressive and advanced NASH

SOUTH SAN FRANCISCO, Calif., June 27, 2022 (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 the presentation of an analysis from its Phase 2a BALANCED study of efruxifermin (EFX) in patients with biopsy-confirmed F1-F3 fibrosis associated with non-alcoholic steatohepatitis (NASH). The data was presented at the 2022 International Liver Congress in a poster titled “Efruxifermin treatment improved histopathology and non-invasive markers of liver injury and fibrogenesis in NASH patients across PNPLA3 genotypes: a post hoc analysis of the Ph2a BALANCED study” (Poster SAT-114). The poster is available on Akero’s website.

Genetic variants in the PNPLA3 gene have been shown to significantly increase risk of NASH-related disease progression and fibrosis severity. Carriers of the I148M variant, which is prevalent among NASH patients, have a greater-than-threefold increased risk of NASH fibrosis and are at increased risk for progressing to end-stage liver disease, including hepatocellular carcinoma. A therapeutic that is proven to be effective in treating patients who carry the I148M variant could therefore help address an important unmedical need. The data presented at the 2022 International Liver Congress show that EFX treatment improved histopathology and noninvasive markers of liver injury across PNPLA3 genotypes, including in patients carrying the I148M variant. The data presented are based on 58 of the 80 study patients with biopsy-confirmed F1-F3 fibrosis in the BALANCED main study who consented to undergo genetic analyses. In addition to NASH histology across PNPLA3 I148M genotypes, the data also included analyses of EFX effects on liver fat content, serum triglycerides, and markers such as ALT, AST, GGT, Pro-C3, HbA1C, C-peptide, adiponectin, and HOMA-IR, across PNPLA3 I148M genotypes.

“We believe that EFX has the potential to treat patients with NASH who are at highest risk of disease progression, including patients who carry certain genetic variants in the PNPLA3 gene,” said Tim Rolph, chief scientific officer of Akero. “This new analysis of the Phase 2a BALANCED data, showing that response rates among patients who carry the PNPLA3 I148M variant were generally comparable to the response rates of those without it, provide further evidence of EFX’s potential to meet an important unmet medical need in NASH.”

EFX is currently being evaluated in two, parallel Phase 2b clinical trials, HARMONY and SYMMETRY, with results from the HARMONY study of patients with F2-F3 fibrosis expected in the third quarter of this year.

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 non-alcoholic steatohepatitis (NASH), a disease without any approved therapies. Akero's lead product candidate, efruxifermin (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 www.akerotx.com 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 the Company's business plans and objectives, including future plans or expectations for EFX, upcoming milestones, and therapeutic effects of EFX, as well as the dosing, safety and tolerability of EFX; the Company’s Phase 2a BALANCED study, including results and post hoc analysis of its data; conduct of the Company’s Phase 2b HARMONY study, including expected timing to report results; and the potential impact of COVID-19 on strategy, future operations, manufacturing, and clinical trial enrollment and data collection. 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: risks related to the impact of COVID-19 on the Company's ongoing and future operations, including potential negative impacts on the Company’s employees, third-parties, manufacturers, supply chain and production as well as on global economies and financial markets; the success, cost, and timing of the Company's product candidate development activities and planned clinical trials; the Company'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; the Company's ability to fund operations; as well as those risks and uncertainties set forth more fully under the caption "Risk Factors" in the Company’s most recent 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 the Company’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. The Company 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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