Research Published in Cell Reports Medicine Highlights Potential of Akero Therapeutics' NASH Therapeutic Candidate

July 21, 2020

Patients treated with efruxifermin (AKR-001) showed improvements in markers of insulin sensitivity and lipoprotein metabolism; sustained exposure over time

SOUTH SAN FRANCISCO, Calif., July 21, 2020 /PRNewswire/ -- Akero Therapeutics, Inc. (Nasdaq: AKRO), a cardio-metabolic, non-alcoholic steatohepatitis (NASH) company developing pioneering medicines designed to restore metabolic balance, today announced the publication of data in the journal *Cell Reports Medicine* from the Phase 1 clinical trial of efruxifermin (EFX, formerly AKR-001), a fibroblast growth factor 21 (FGF21) analog, demonstrating its potential to modulate biomarkers associated with metabolic diseases, including NASH.

In the article entitled, "AKR-001, an Fc-FGF21 analog, showed sustained pharmacodynamic effects on insulin sensitivity and lipid metabolism in type 2 diabetes patients," researchers found that EFX demonstrated a sufficiently prolonged half-life of 3-3.5 days to support weekly dosing. In addition, with a variation in systemic concentration of only 2-fold when dosed weekly, treatment with EFX delivered larger and more consistent improvements in markers of insulin sensitivity and lipid metabolism than previously reported for FGF21 analogs, and it was reported to be generally well tolerated. Weekly administration of 70mg demonstrated larger metabolic effects than dosing every other week with 140mg, even though exposure to EFX was comparable.

"Efruxifermin is the first FGF21 analog to demonstrate a pharmacokinetic profile that would enable sustained, balanced agonism across all of FGF21's receptors with once weekly dosing," said Tim Rolph, D.Phil., chief scientific officer and co-founder of Akero, and senior author of the manuscript.

Andrew Cheng, M.D., Ph.D., president and CEO of Akero, added, "The data reported in this study provided the rationale for evaluating the efficacy and safety of EFX in NASH patients in our Phase 2a BALANCED study, which met all endpoints. Our recent readouts of liver fat reductions and improvements in histological measures showed the largest reductions in liver fat and improvements in liver histology reported to date and confirm the promising clinical profile of EFX."

In patients dosed weekly with 70mg EFX in the Phase 1 study, treatment was associated with an increase in insulin sensitivity as demonstrated by reductions in HOMA-IR. This enhancement of insulin sensivity by EFX was replicated in NASH subjects and associated with better glycemic control, as recently disclosed for the BALANCED study. Treatment with EFX in the Phase 1 study was associated with amelioration of dyslipidemia, prevalent among type 2 diabetes and NASH patients, who are susceptible to cardiovascular disease. An improved lipoprotein profile was also evident with EFX treatment in the BALANCED study.

About NASH
NASH (non-alcoholic steatohepatitis) is a serious form of NAFLD (non-alcoholic fatty liver disease) and is estimated to affect 17 million Americans. NASH is closely linked to the obesity and diabetes epidemics seen around the world. 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. NASH is a leading cause of liver transplants in the US and Europe.

About Efruxifermin
Efruxifermin (EFX), formerly known as AKR-001, is Akero's lead product candidate for NASH, engineered to mimic the biological activity of native FGF21. EFX is designed to reduce liver fat and inflammation, reverse fibrosis, increase insulin sensitivity and improve lipoproteins. 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. EFX offers convenient once-weekly dosing and has been generally well-tolerated in clinical trials to date.

About Akero Therapeutics
Akero is a cardio-metabolic NASH company dedicated to reversing the escalating NASH epidemic by developing pioneering medicines designed to restore metabolic balance to improve overall health. The company's lead product candidate, efruxifermin (formerly AKR-001), has been evaluated in 80 patients with F1-F3 fibrosis in the main portion of the BALANCED study, and Akero is currently conducting cohort C of the study in non-decompensated F4 NASH patients. Akero Therapeutics is headquartered in South San Francisco, CA. For more information, please visit www.akerotx.com.

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. Such statements include, but are not limited to, statements regarding: Akero's guidance regarding its business plans and objectives for EFX, including the therapeutic potential and clinical benefits thereof, as well as the dosing, safety and tolerability of EFX; Akero's Phase 2a BALANCED clinical trial, including its initial primary efficacy results and the top-line safety/tolerability, laboratory measures and paired biopsy results; and the potential impact of COVID-19 on strategy, future operations and clinical trials.

Any forward-looking statements in this statement 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 public health epidemics affecting countries or regions in which we have operations or do business, such as COVID-19, including potential negative impacts on Akero's employees, manufacturers, supply chain and production as well as on global economies and financial markets; 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 risks related to the competitive landscape. For a discussion of these and other risks and uncertainties, and other important factors, any of which could cause Akero's actual results to differ from those contained in the forward-looking statements, see the section entitled "Risk Factors" in the company's 2019 Annual Report on Form 10-K filed with the United States Securities and Exchange Commission (SEC) and quarterly reports on Form 10-Q filed with the SEC, as well as discussions of potential risks, uncertainties, and other important factors in Akero's other filings 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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