Akero Therapeutics To Continue Efruxifermin Development With Innovative Adaptive Phase 2b/3 Clinical Trial Design Based On FDA Written Guidance

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SOUTH SAN FRANCISCO, Calif., Sept. 24, 2020 /PRNewswire/ -- Akero Therapeutics, Inc. (Nasdaq: AKRO), a cardio-metabolic non-alcoholic steatohepatitis (NASH) company developing pioneering medicines designed to restore metabolic balance and improve the overall health of NASH patients, today announced that written guidance from the U.S. Food and Drug Administration (FDA) enables the company to implement an innovative combined Phase 2b/3 study design for pivotal efruxifermin (EFX) trials in NASH patients.

Under the planned adaptive trial design, Akero will evaluate two EFX doses in a 24-week Phase 2b portion of the trial to inform selection of a single dose for evaluation in the Phase 3 portion of the study. The company remains on track to initiate a Phase 2b/3 trial of EFX in biopsy-confirmed NASH patients in the first half of 2021.

"We are pleased that the FDA found our overall proposed adaptive Phase 2b/3 development program to be acceptable, and we are grateful for the additional clarity the agency provided as we finalize our study protocol," said Andrew Cheng, M.D., Ph.D., president and chief executive officer of Akero. "We believe that the positive histological data in biopsy-confirmed NASH patients obtained from the BALANCED study provided the foundation necessary to align on an adaptive Phase 2b/3 trial design. Further analysis of data from the BALANCED study has strengthened our confidence in EFX's potential to be a foundational monotherapy in NASH."

The company will present the results of additional analyses from the BALANCED study at an upcoming scientific meeting.

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. As a result, NASH has become a leading cause of liver transplants in the US and Europe.

About Efruxifermin

Efruxifermin (EFX), formerly AKR-001, is Akero's lead product candidate for NASH. EFX is designed to increase insulin sensitivity, improve lipoproteins, reduce liver fat and inflammation, and reverse fibrosis. This holistic approach offers the potential to address the complex, multi-organ/tissue pathogenesis of NASH, including improvements in lipoprotein risk factors linked to cardiovascular disease – the leading cause of death in NASH patients. Engineered to mimic the biological activity profile of native human FGF21, EFX offers convenient once-weekly dosing.

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 and improve overall health of NASH patients. The Company's lead product candidate, efruxifermin, has been evaluated in a 16-week Phase 2a clinical trial, the BALANCED study. 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, 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; Akero's Phase 2a BALANCED study, including its results and expected timing to report the analysis of additional data; expectations regarding the design, implementation, timing, and success of its current and planned clinical trials for EFX; expectations regarding successful scale-up of drug substance manufacturing and release of new drug product for use in clinical trials; and the potential impact of COVID-19 on strategy, future operations, enrollment and clinical trials. 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 Akero'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 Akero's Annual Report on Form 10-K for the year ended December 31, 2019 and most recently filed Quarterly Report on 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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