Akero Presents Additional Positive Data from Phase 2a BALANCED Study Demonstrating Potential of Efruxifermin as a Foundational NASH Monotherapy

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Data to be presented at the Presidential Plenary Talk at The Liver Meeting®

100% of patients in 50mg group demonstrated more than 50% relative reduction in liver fat

50% of patients with F2/F3 fibrosis at baseline achieved two stage improvement in fibrosis score

Type 2 diabetic patients showed improved glycemic control with HbA1c reduced by up to 0.9%

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Nov. 13, 2020-- Akero Therapeutics, Inc. (Nasdaq: AKRO) today announced the presentation of additional data analysis from the Phase 2a BALANCED study at the Presidential Oral Plenary Session at The Liver Meeting®. The data continue to demonstrate the potential of efruxifermin (EFX) as a foundational monotherapy for patients with non-alcoholic steatohepatitis (NASH).

Overall, the data show large magnitudes of reduction in liver fat across all EFX dose groups with 100% of participants in the 50mg EFX dose group achieving more than 50% relative reduction in liver fat and 53% of patients in the same dose group achieving more than 70% relative reduction in liver fat.

Among all EFX-treated patients who were fibrosis stage F2 or F3 at baseline (n=22), 50% experienced a two-stage improvement in fibrosis (n=11), while 68% experienced at least a one-stage improvement in fibrosis (n=15).

Additional analysis of the BALANCED data showed substantial improvement in glycemic control for patients with both NASH and Type 2 diabetes, a group that comprises about half of all NASH patients. The company previously reported mean absolute reductions in HbA1c among all study participants of 0.1% for the 28mg dose, 0.4% ($p<0.05$) for the 50mg dose and 0.5% ($p<0.01$) for the 70mg dose. In patients with both NASH and Type 2 diabetes, researchers observed decreases of 0.6% in the 50mg dose and 0.9% ($p<0.01$) in the 70mg dose. Among EFX patients with NASH and Type 2 diabetes, the relative decreases in mean C-peptide levels ranged from 27 to 33% across EFX dose groups, compared to 22 to 29% for all EFX patients.

“Additional analyses from the BALANCED study, including the proportion of subjects with at least 50 and 70% reductions in liver fat and the high proportion of subjects with F2/F3 fibrosis at baseline with fibrosis improvement, strengthens the potential of EFX to be truly transformative for people living with NASH, with improvements across multiple parameters for NASH and cardio-metabolic conditions,” said Andrew Cheng, M.D., Ph.D., president and CEO of Akero. “With some of the strongest results reported to date in NASH, we eagerly anticipate the initiation of our adaptive Phase 2b/3 study of efruxifermin with hopes of improving lives of the more than 17 million Americans who are living with this disease.”

EFX has received European Medicines Agency Priority Medicines (PRIME) designation as a treatment for NASH. Akero plans to begin a Phase 2b/3 adaptive clinical trial in biopsy confirmed NASH patients in the first half of 2021. The company will be using 28mg and 50mg doses for that trial.

Akero previously reported data from the BALANCED study demonstrating that each of the 28, 50 and 70mg EFX dose groups met the primary endpoint compared to placebo, with absolute reductions of 12%, 13% and 14% of liver fat, respectively, compared with 0.3% for placebo, and relative reductions of 63%, 71% and 72% percent, compared to 0% for placebo. All of these results were highly statistically significant at $p<0.001$.

Prior Reporting of secondary and exploratory endpoints revealed that of the 40 EFX treatment responders who had end-of-treatment biopsies, 48% achieved at least a one-stage improvement in fibrosis without worsening of NAFLD activity score (NAS) and 28% achieved at least a two-stage improvement in fibrosis. Additionally, 48% of responders achieved NASH resolution with no worsening of fibrosis. Improvements in glycemic control and dyslipidemia, as well as weight loss, were also observed across all dose groups. Treatment with EFX was generally reported to be well tolerated.

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 the BALANCED Study

The Phase 2a BALANCED study is a multicenter, randomized, double-blind, placebo-controlled, dose-ranging trial in biopsy-confirmed adult patients with NASH. The main study enrolled a total of 80 patients. Participants were randomized to receive weekly subcutaneous doses of efruxifermin (EFX), formerly known as AKR-001, or placebo for up to 16 weeks, with safety and tolerability followed through week 20. The primary efficacy endpoint for the study is absolute change from baseline in hepatic fat fraction measured by magnetic resonance imaging – proton density fat fraction (MRI-PDFF) at week 12. Secondary measures include change from baseline in ALT at 12 weeks, the number of patients who had a decrease of ≥2 points in the NAFLD activity score (NAS) at 24 weeks and safety and tolerability measures.

About Efruxifermin

Efruxifermin (EFX), formerly known as AKR-001, is Akero’s lead product candidate for NASH, currently being evaluated in the ongoing Phase 2a

BALANCED study. 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. Engineered to mimic the biological activity profile of native FGF21, 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 (EFX), formerly known as AKR-001, is currently being evaluated in an ongoing Phase 2a clinical trial. 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 safety and tolerability of EFX and future clinical development plans; Akero's Phase 2a BALANCED clinical trial, including its results and Akero's analysis of such results; Akero's design, implementation and expected timing of the Phase 2b/3 trial; the potential benefits conferred by the EMA on Akero's PRIME designation; and the potential impact of COVID-19 on patient retention, 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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