Efruxifermin Granted FDA Breakthrough Therapy Designation for NASH

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Designation based on Akero's Phase 2b HARMONY study finding that both the 50mg and 28mg EFX doses achieved statistical significance on primary and secondary histology endpoints after 24 weeks

SOUTH SAN FRANCISCO, Calif., Dec. 08, 2022 (GLOBE NEWSWIRE) -- Akero Therapeutics, Inc. (Nasdaq: AKRO), a clinical-stage company developing transformational treatments for patients with serious metabolic disease marked by high unmet medical need, today announced that efruxifermin (EFX) has received a Breakthrough Therapy Designation from the US Food and Drug Administration (FDA) for the treatment of nonalcoholic steatohepatitis (NASH). There are currently no approved therapies for the treatment of NASH, which is a serious form of liver disease estimated to affect 17 million Americans.

"We are proud to have the FDA recognize the potential therapeutic benefit of EFX through this Breakthrough Therapy Designation," said Andrew Cheng, M.D., Ph.D., president and chief executive officer of Akero. "With the global prevalence of NASH continuing to rise, we are committed more than ever to developing therapeutics that can treat NASH holistically and reverse fibrosis rapidly. This designation is an important milestone for Akero and the NASH community as we continue to evaluate EFX as a potential foundational monotherapy."

The FDA's Breakthrough Therapy Designation is meant to expedite development and review of a therapy for a serious or life-threatening disease or condition when preliminary clinical evidence indicates the drug may demonstrate substantial improvement on one or more clinically significant endpoints over available therapies. The designation is based on topline data released in September from HARMONY, a Phase 2b study of EFX in patients with biopsy-confirmed pre-cirrhotic NASH, fibrosis stage 2 or 3 (F2-F3). The study met its primary and secondary histology endpoints, which were selected to match endpoints accepted by the FDA for registrational trials.

EFX is engineered to mimic the biological activity profile of FGF21, a hormone responsible for alleviating cellular stress and improving metabolic regulation. In HARMONY, Akero observed that both 50mg and 28mg doses of EFX produced at least a one stage improvement in liver fibrosis with no worsening of NASH by week 24 (41% and 39%, respectively) compared with 20% for placebo. In addition to meeting this primary endpoint, the study also met two key secondary endpoints with 76% and 47% of patients treated with 50mg and 28mg, respectively, achieving NASH resolution without worsening of fibrosis, compared with 15% for placebo. Additionally, 41% and 29% of patients treated with 50mg and 28mg, respectively, achieved at least a one-stage improvement in fibrosis and NASH resolution, compared with 5% for placebo.

An additional Phase 2b study, SYMMETRY, was initiated in July of 2021 to assess EFX in patients with compensated cirrhosis (F4) due to NASH, Child-Pugh class A. Akero expects to report results from the ongoing SYMMETRY study in the second half of 2023. Results from a 12-week expansion cohort of the SYMMETRY study, evaluating treatment of EFX in combination with GLP-1 therapy in patients with F1-F3 fibrosis, are expected in the first half of 2023.

About NASH
NASH (non-alcoholic steatohepatitis) is a serious form of NAFLD (non-alcoholic fatty liver disease) that is estimated to affect 17 million Americans. 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. There are no approved treatments for the condition and NASH is the fastest growing cause of liver transplants and liver cancer in the US and Europe.

About Efruxifermin
Efruxifermin (EFX), formerly known as AKR-001, is Akero's lead product candidate for NASH, currently being evaluated in the ongoing Phase 2b HARMONY study. EFX is designed to reverse fibrosis, reduce liver fat and inflammation, 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 is designed to offer convenient once-weekly dosing and has been generally well-tolerated in clinical trials to date.

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 bivalent 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). EFX is also being evaluated in an expansion cohort of the SYMMETRY study, comparing the safety and tolerability of EFX to placebo when added to an existing GLP-1 receptor agonist in patients with pre-cirrhotic NASH (F1-F3 fibrosis) and Type 2 diabetes. Akero is headquartered in South San Francisco. Visit 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, including future plans or expectations for efruxifermin (EFX), the therapeutic effects of EFX, as well as the dosing, safety and tolerability of

EFX; and upcoming milestones, including the results, and expected timing to report such results, of Akero's Phase 2b SYMMETRY main study and an expansion cohort of the SYMMETRY study; and the Breakthrough Therapy Designation of EFX, potential benefits resulting from such designation and related implications. 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 Akero'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 Akero's product candidate development activities and planned clinical trials; Akero'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; 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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