Akero Therapeutics Receives FDA Fast Track Designation for Efruxifermin (EFX) for the Treatment of NASH

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SOUTH SAN FRANCISCO, Oct. 19, 2021 (GLOBE NEWSWIRE) -- Akero Therapeutics, Inc. (Nasdaq: AKRO), a cardio-metabolic biotechnology company developing transformational treatments for non-alcoholic steatohepatitis (NASH), today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to its lead program investigating efruxifermin (EFX) for the treatment of non-alcoholic steatohepatitis (NASH).

The Fast Track designation facilitates the development of new drugs to treat serious conditions where there is an unmet medical need. This designation enables more frequent interactions with the FDA and potential eligibility for priority review if clinical data support it. EFX is currently being evaluated in two parallel Phase 2b clinical trials in NASH patients, one (the HARMONY study) in adult patients with F2/F3 fibrosis and a second (the SYMMETRY study) in adult patients with late-stage cirrhotic NASH (F4), who are at elevated risk of liver failure and have the highest unmet medical need.

“The FDA Fast Track designation for EFX is an important step forward in potentially bringing EFX to the growing number of patients impacted by NASH,” said Andrew Cheng, M.D., Ph.D., president and chief executive officer of Akero. “Backed by positive clinical data, including a two-stage improvement in fibrosis for 50% of all treated patients with F2 or F3 fibrosis at baseline, we believe EFX has the potential to be among the first investigational therapies approved for treatment of both advanced fibrotic (F2/F3) and cirrhotic (F4) NASH. We look forward to working closely with the FDA to bring this promising investigational therapy to NASH patients as expediently as possible.”

NASH is a serious, potentially life-threatening condition that is a leading cause of liver failure and liver transplantation globally. An estimated 17 million Americans had NASH in 2016, a number that is expected to increase to 27 million by 2030. There are currently no approved therapies for NASH.

The FDA’s decision to grant EFX Fast Track designation follows recent clinical milestones highlighting EFX’s potential to address multiple drivers of NASH and reverse fibrosis. In July, *Nature Medicine* published full results of the main portion of Akero’s Phase 2a BALANCED trial in biopsy-confirmed NASH patients with F1-F3 fibrosis—the first published clinical evidence of fibrosis regression with an FGF21 analog. Additionally, earlier this year, Akero announced positive topline results from a 30-patient expansion cohort of the Phase 2a BALANCED study of EFX in late-stage (F4) cirrhotic NASH, which showed clinically meaningful improvements in fibrosis after 16 weeks of treatment.

About Akero Therapeutics

Akero Therapeutics is a clinical-stage cardio-metabolic company developing transformational treatments for 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 F2/F3 advanced fibrosis and the SYMMETRY study in cirrhotic (F4) patients. Akero is headquartered in South San Francisco. Visit us at 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 Akero'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 2b HARMONY and Phase 2b SYMMETRY clinical trials; the Fast Track designation of EFX, potential benefits resulting from such designation and related implications; 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 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, as filed with the 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 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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