



Akerio Therapeutics To Present Data From Phase 2a BALANCED Study Of Efruxifermin In NASH Patients In Presidential Plenary Talk At The Liver Meeting® 2020

October 2, 2020

SOUTH SAN FRANCISCO, Calif., Oct. 2, 2020 /PRNewswire/ -- Akerio 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 an abstract detailing additional analyses of the data from its Phase 2a BALANCED study of efruxifermin (EFX) has been accepted for presentation at The Liver Meeting Digital Experience™ 2020 of the American Association for the Study of Liver Diseases (AASLD) to be held November 13 - 16.



The new analyses will be presented in the presidential plenary oral session by Stephen Harrison, M.D., medical director of Pinnacle Clinical Research, in a presentation titled "Efruxifermin (EFX), a long-acting Fc-FGF21 fusion protein, administered for 16 weeks to patients with NASH substantially reduces liver fat and ALT, and improves liver histology: analysis of a randomized, placebo-controlled, Phase 2a study (BALANCED)." The abstract was [published](#) in the October supplement of *Hepatology*, the peer-reviewed journal of AASLD.

Abstract Title: Efruxifermin (EFX), a long-acting Fc-FGF21 fusion protein, administered for 16 weeks to patients with NASH substantially reduces liver fat and ALT, and improves liver histology: analysis of a randomized, placebo-controlled, Phase 2a study (BALANCED).

Abstract Number: 8

Presenting Author: Stephen Harrison, M.D.

Session Date: November 15, 2020

Session Time: 9-10:30 a.m. ET

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 Akerio's lead product candidate for NASH. EFX increases insulin sensitivity, improves lipoproteins, reduces liver fat and inflammation, and reverses fibrosis. The breadth of desirable metabolic effects offers potential to address the complex, multi-organ/tissue pathogenesis of NASH, including 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. Based on guidance from the U.S. Food and Drug Administration (FDA), EFX will be evaluated in an innovative adaptive Phase 2b/3 pivotal study in biopsy confirmed NASH patients to be initiated in the first half of 2021.


About Akerio Therapeutics

Akerio 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. Akerio 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; expectations regarding the design, implementation, timing, and success of its current and planned clinical trials for EFX; and the potential impact of COVID-19 on strategy, future operations, 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 Aker'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 Aker'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 Aker'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. Aker 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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SOURCE Aker Therapeutics, Inc.

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