Akero Therapeutics Doses First Patient in Expansion of Phase 2a Trial in NASH

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Cohort C is enrolling subjects who have compensated cirrhosis (F4), Child-Pugh Class A

SOUTH SAN FRANCISCO, Calif., June 17, 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 the first subject has been dosed in Cohort C, the previously-announced expansion of its Phase 2a BALANCED trial, which will enroll 30 subjects who have NASH with compensated cirrhosis (F4), Child-Pugh Class A.

"People who have compensated cirrhosis as a result of NASH are in acute need of therapeutics that may be able to delay or to help prevent liver failure," said Kitty Yale, chief development officer of Akero. "Dosing this patient demonstrates the focus of our clinical development team and partners to continue advancing this candidate during the current pandemic. Given the strong results in terms of reduction in liver fat in the topline readout of the Phase 2a BALANCED trial prior to expansion, we believe in the potential for AKR-001 to help reverse the course of this serious disease."

Thirty adult NASH subjects, demonstrated at baseline by liver biopsy to have cirrhosis with a fibrosis score of 4, will be randomized 2:1 to receive either 50 mg of AKR-001 or placebo for 16 weeks. The primary objective of Cohort C is to assess safety and tolerability of treatment with AKR-001 in NASH patients at greatest risk of progressing to end-stage liver disease.

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 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, which remain on track to be reported by the end of the second quarter of 2020 together with safety and tolerability.

About AKR-001
AKR-001 is Akero's lead product candidate for NASH, currently being evaluated in the ongoing Phase 2a BALANCED study. AKR-001 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, AKR-001 offers convenient once-weekly dosing and has been 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 of NASH patients. The company's lead product candidate, AKR-001, is currently being evaluated in an ongoing Phase 2a clinical trial. Akero Therapeutics is headquartered in 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 AKR-001, including the therapeutic potential and clinical benefits thereof, as well as the safety and tolerability of AKR-001; Akero's Phase 2a BALANCED clinical trial, including its initial primary efficacy results and expected timing to report the top-line safety/tolerability, laboratory measures and paired biopsy data from the BALANCED study in the second quarter of 2020; the dosing of its first subject in Cohort C; and the potential impact of COVID-19 on 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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