Akero Therapeutics Announces Dosing of First Patient in Phase 2a Study of AKR-001 to Treat NASH (BALANCED)

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SAN FRANCISCO, July 2, 2019 /PRNewswire/ -- Akero Therapeutics, Inc. (Nasdaq: AKRO), a clinical-stage biotechnology company developing transformational treatments for patients with non-alcoholic steatohepatitis (NASH) and other serious metabolic disorders, today announced the dosing of the first patient in its Phase 2a clinical study of AKR-001, a novel FGF21 analog, for the treatment of NASH (the BALANCED study).

"Akero's AKR-001 clinical program is progressing as planned and we remain on track to report study results in the first half of 2020," said Kitty Yale, Chief Development Officer, Akero Therapeutics. "We are excited about the potential benefits that AKR-001 may offer to patients with NASH, a serious metabolic disease for which there are no FDA-approved treatment options."

The Phase 2a BALANCED study is a multicenter, randomized, double-blind, placebo-controlled, dose-ranging trial in biopsy-confirmed patients with NASH. Up to 80 patients are expected to be randomized to receive weekly subcutaneous dosing 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) Week 12.

About AKR-001
AKR-001 is an engineered human Fc-FGF21 fusion protein designed to harness the inherent benefits of an endogenous hormone called FGF21, which has the potential to reduce liver fat, mitigate inflammation, and reverse fibrosis in NASH patients. AKR-001 is uniquely designed to deliver sustained signaling through FGF21's receptors with once-weekly subcutaneous dosing.

About NASH
NASH is a leading cause of liver failure around the world, driven by the growing global epidemic of obesity. NASH is a severe form of non-alcoholic fatty liver disease (NAFLD) characterized by liver cell (hepatocyte) damage, liver inflammation, and fibrosis that can progress to cirrhosis, liver failure, cancer and death.

About Akero Therapeutics
Akero Therapeutics is a clinical-stage biotechnology company focused on the development and commercialization of transformative treatments for patients with serious metabolic diseases with high unmet medical need. The company's lead program AKR-001 is being evaluated in a Phase 2a clinical trial for the treatment of NASH.

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 the company's business plans and objectives, including future plans or expectations for AKR-001, therapeutic effects of AKR-001, and expectations regarding the design, implementation, timing, and success of its current and planned clinical trials for AKR-001. 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: 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 through 2020; as well as those risks and uncertainties set forth more fully under the caption "Risk Factors" in the final prospectus dated June 19, 2019 and filed pursuant to Rule 424(b) under the Securities Act of 1933, as amended, with the United States Securities and Exchange Commission (SEC) and elsewhere in Akero Therapeutics' 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 Therapeutics 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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