Akero Therapeutics Initiates Phase 2a Clinical Trial of Investigational Therapy AKR-001 for the Treatment of NASH

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SAN FRANCISCO, May 29, 2019 /PRNewswire/ -- Akero Therapeutics, Inc., a biotechnology company developing transformational treatments for non-alcoholic steatohepatitis (NASH) and other serious metabolic diseases, today announced that it has screened the first patient for its Phase 2a clinical trial evaluating AKR-001, the company's lead product candidate for the treatment of NASH. The U.S. Food and Drug Administration (FDA) cleared the company's Investigational New Drug application on May 24, 2019.

"The commencement of our Phase 2 clinical program is an important milestone for Akero," said Andrew Cheng, M.D., Ph.D., President and CEO of Akero Therapeutics. "We believe AKR-001 has the potential to become a cornerstone therapy for the treatment of NASH by addressing its underlying metabolic drivers and the liver inflammation and fibrosis these drivers cause, and by improving risk factors for cardiovascular disease, which is the leading cause of mortality for these patients."

The Phase 2a clinical trial is designed to evaluate the safety, tolerability and efficacy of AKR-001. The trial is a multicenter, randomized, double-blind, placebo-controlled, dose-ranging trial in biopsy-confirmed patients with NASH, and is expected to enroll up to 80 patients for randomization to receive subcutaneous dosing of AKR-001 or placebo for 16 weeks. The primary endpoint for the trial is absolute change from baseline in hepatic fat fraction as measured by Magnetic Resonance Imaging – Proton Density Fat Fraction (MRI-PDFF) at Week 12.

About AKR-001
AKR-001 is an Fc-FGF21 fusion protein that has been engineered to mimic the biological activity profile of native FGF21, an endogenous hormone that regulates lipid and energy metabolism, and is secreted throughout the body to alleviate cellular stress. Observations from clinical trials of AKR-001 and other FGF analogs suggest AKR-001's potential to reduce liver fat, cellular stress, inflammation and fibrosis in people with non-alcoholic steatohepatitis (NASH), as well as to improve risk factors of cardiovascular disease, a major cause of death among NASH patients.

About NASH
Non-alcoholic steatohepatitis (NASH) is a serious, life-threatening disease that is rapidly emerging as the leading cause of liver failure in the world. An estimated 17.3 million Americans had NASH in 2016, a number that is expected to increase to 27.0 million by 2030. NASH is a severe form of nonalcoholic fatty liver disease (NAFLD) characterized by hepatocyte injury, liver inflammation, and fibrosis that can progress to scarring (cirrhosis), liver failure, cancer and death. There are currently no approved therapies for the disease.

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 disease with high unmet medical need by restoring metabolic balance. Akero's lead program, AKR-001, an engineered Fc-FGF21 fusion protein, is being evaluated in clinical trials as a potential fibroblast growth factor analog for treatment of NASH, a disease without any approved therapies.