Akero Therapeutics Expands Phase 2a Trial in NASH to Include Cohort of Cirrhotic Patients

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SAN FRANCISCO, Jan. 13, 2020 /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 that the ongoing Phase 2a BALANCED study of AKR-001 is being expanded to include an additional cohort of subjects with NASH who have compensated cirrhosis (F4), Child-Pugh Class A.

Thirty 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 the expansion cohort is to assess safety and tolerability of treatment with AKR-001 in NASH patients at greatest risk of progressing to end-stage liver disease. The selection of the 50 mg dose for this cohort is based on modeling of data from the Phase 1b trial in Type 2 diabetes as well as availability of drug product.

"Cirrhotic patients with stage 4 fibrosis present a significant unmet medical need in NASH because of the risk of decompensation and liver failure, where liver transplant becomes the only treatment option," said Kitty Yale, chief development officer of Akero. "AKR-001 may be able to help this vulnerable population."

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. The progressive damage to the liver associated with NASH closely resembles damage caused by excessive alcohol consumption or viral infections, and the disorder is a leading cause of liver transplants in the US and Europe.

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 point to 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, the principal cause of death among NASH patients.

About Akero Therapeutics
Akero Therapeutics is a clinical-stage biotechnology company focused on the development and commercialization of transformative treatments for patients with NASH and other 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. 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 potential patient population that may be addressed by AKR-001; and Akero's Phase 2a BALANCED clinical trial, including its expansion to include an additional cohort of subjects with NASH who have compensated cirrhosis, as well as its design, implementation, and timing of the anticipated results.

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 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 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 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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