# All AKR-001 Dose Groups Met Week 12 Efficacy Endpoints in NASH Phase 2a BALANCED Study

March 31, 2020

**All AKR-001 dose groups met the primary endpoint, with statistically significant absolute reductions in liver fat of 12-14%**
**All AKR-001 dose groups met the secondary endpoint of relative reduction in liver fat, with the 50mg and 70mg dose groups achieving >70% relative reductions**
**Blinded tolerability profile appears consistent with results from previous clinical trials evaluating AKR-001 in patients with Type 2 diabetes**

SAN FRANCISCO, March 31, 2020 /PRNewswire/ -- Akero Therapeutics, Inc. (Nasdaq: AKRO) today announced that all three AKR-001 dose groups in the BALANCED study met the primary endpoint of absolute change from baseline in liver fat as measured by magnetic resonance imaging – proton density fat fraction (MRI-PDFF) – at week 12. Results for the primary endpoint as well as other week 12 efficacy endpoints are summarized in the table below.

**Summary of Week 12 Efficacy Endpoints**

| | | AKR-001 (once weekly dose) | | |
|---|---|---|---|---|
| **Measure (Mean)** | **Placebo (N=21)** | **28 mg (N=19)** | **50 mg (N=20)** | **70 mg (N=20)** |
| Absolute reduction in liver fat (%) | -0.3 | -12.3*** | -13.4*** | -14.1*** |
| Relative reduction in liver fat (%) | 0% | -63*** | -71*** | -72*** |
| ≥30% relative reduction in fat (%) | 10 | 84*** | 85*** | 75*** |
| Reduction in ALT (U/L) | -6 | -24*** | -30*** | -32*** |

***p<0.001, versus placebo

"The magnitude and rate of improvements in liver fat content and ALT observed over 12 weeks in the BALANCED study are among the most robust NASH clinical trial results reported to date," said Stephen Harrison, M.D., medical director of Pinnacle Clinical Research. "AKR-001 is emerging as one of the most promising drug candidates in development for this serious disease."

The BALANCED study is an ongoing randomized, double-blind, placebo-controlled study in NASH patients. While the study remains blinded, the tolerability profile appears consistent with results from previous clinical trials evaluating AKR-001 in patients with Type 2 diabetes. The adverse events observed most frequently in prior trials were mild/moderate gastrointestinal events and injection site reactions.

After 12 weeks of treatment, patients who have achieved at least a 30% relative reduction in liver fat are eligible for an end-of-study biopsy. Across the AKR-001 dose groups, 75-85% of patients are eligible for biopsies. As of March 30, 2020, 25 end-of-study biopsies have been collected from a total of 50 eligible patients.

We expect to report the top-line safety/tolerability, laboratory measures and paired biopsy data from the BALANCED study in the second quarter of this year. The extent to which the COVID-19 pandemic will interfere with collection of the remaining biopsies and data from other scheduled clinical visits, including the safety follow-up visit at week 20, is unclear. We are delaying the planned initiation of the BALANCED study cohort C in NASH patients who have compensated cirrhosis (F4), Child-Pugh Class A.

"We are encouraged by these results, which support continued development of AKR-001 for treatment of NASH," said Andrew Cheng, M.D., Ph.D., president and CEO of Akero. "AKR-001 has the potential to provide NASH patients with an important treatment option when there are still no approved therapies. We look forward to the full data set with anticipation and are preparing for the next steps in AKR-001's development."

**Conference Call / Webcast Details**
The company will host a conference call and webcast with slide presentation today at 8:30 a.m. ET (5:30 a.m. PT). The conference call will be made available on the company's website at www.akerotx.com under the Investors tab in the Events, Presentations & Webcasts section. To access the call via dial-in, please dial 1-866-652-5200 (U.S. toll free) or 1-412-317-6060 (international) five minutes prior to the start time. Following the live audio webcast, a replay will be available on the company's website for 90 days.

**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.

**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. 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; 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, which has been labelled a pandemic by the World Health Organization, 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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