Akero Therapeutics Reports First Quarter 2021 Financial Results and Provides Business Update

May 13, 2021

SOUTH SAN FRANCISCO, Calif., May 13, 2021 (GLOBE NEWSWIRE) -- Akero Therapeutics, Inc. (Nasdaq: AKRO), a cardio-metabolic biotechnology company developing transformational treatments for non-alcoholic steatohepatitis (NASH), today reported first quarter financial results for the period ending March 31, 2021.

"We continued to build on the strong foundation provided by last year's reports from the Phase 2a BALANCED main study, with new data showing signs of reversing fibrosis in biopsy-confirmed F4 NASH patients with compensated cirrhosis after only 16 weeks of treatment," said Andrew Cheng, M.D., Ph.D., president and chief executive officer of Akero. "Our histology results, as well as non-invasive markers of fibrosis, indicate that efruxifermin (EFX) acts both directly and indirectly to rapidly reverse fibrosis. Consistent data across three placebo-controlled clinical trials increase our confidence that EFX will be efficacious as a treatment for all stages of NASH. This confidence is reflected in our initiation of two parallel, separate Phase 2b clinical trials in F2-F3 and F4 NASH this year, for which we expect to begin reporting data in the third quarter of 2022."

First Quarter Business Highlights & Company Updates

- During the first quarter, Akero reported positive, topline, preliminary results for its 16-week evaluation of EFX in the treatment of adult NASH patients with compensated cirrhosis (F4), Child-Pugh Class A (BALANCED study, Cohort C).
    - Among 12 EFX-treated patients who volunteered to have end-of-treatment biopsies, 7 of 12 (58%) achieved either a one-stage improvement in fibrosis without worsening of NASH or NASH resolution, compared with 0 of 5 (0%) for the placebo group.
    - 4 of 12 (33%) EFX-treated patients achieved a one-stage improvement of fibrosis without worsening of NASH, compared to 0% for placebo, indicating rapid reversal of fibrosis among cirrhotic NASH patients after only 16 weeks of treatment.
    - 3 of 12 (25%) EFX-treated patients achieved NASH resolution compared to 0% for placebo.
    - Improvements in histology were supported by improvements in noninvasive serum-based and imaging markers of fibrosis.
    - EFX-treated patients also experienced improvements in ALT, serum lipids and glycemic control, with a trend toward weight loss, consistent with the results previously observed for patients with F1-F3 fibrosis.
- During the first quarter, Akero initiated its HARMONY study, a Phase 2b, multicenter, randomized, double-blind, placebo-controlled, clinical trial in biopsy-confirmed NASH patients with fibrosis stage 2 or 3, with the first patient randomized in March.

Multiple Milestones Anticipated for 2021 and 2022

- Akero plans to report additional data from the BALANCED main study at the upcoming meeting of the European Association for the Study of the Liver (EASL) on June 23-26, 2021.
    - EASL Abstract No. 1314: “The role of reduction in liver fat content (MRI-PDFF) and ALT in predicting treatment response in NASH: A secondary analysis of the randomized, controlled BALANCED trial,” presented by Rohit Loomba, M.D.
    - EASL Abstract No. 1762: “Correlation between changes in liver fat content and improvements in serum markers of liver injury, fibrosis, metabolism, and in histologic parameters following treatment with efruxifermin,” presented by Stephen Harrison, M.D.
- Akero plans to present new data at the upcoming meeting of the American Diabetes Association on June 25-29, 2021, for which two abstracts have been accepted for presentation.
- Akero expects to initiate its planned SYMMETRY study, a Phase 2b, multicenter, randomized, double-blind, placebo-controlled, clinical trial in biopsy-confirmed NASH patients with compensated cirrhosis (F4), Child-Pugh Class A, in the second half of 2021.
- Akero expects to report topline, preliminary results for the HARMONY study in the third quarter of 2022, based on the primary histology endpoint after 24 weeks of treatment.
- Akero expects to complete manufacturing of its planned Phase 3 combination drug/device product in 2022, with release for clinical trials in the first half of 2023.

First Quarter 2021 Financial Results

- Akero's cash, cash equivalents and short-term marketable securities for the period ended March 31, 2021 were $250.0 million.

- Akero believes that its cash, cash equivalents and marketable securities will be sufficient to fund its current operating plan into the third quarter of 2023.
- Research and development expenses for the three-month period ended March 31, 2021 were $10.6 million, compared to $8.8 million for the comparable period in 2020. These increases are attributable to higher costs related to Akero's EFX program, including third-party contract manufacturing, contract research organization costs associated with the BALANCED and HARMONY studies and internal personnel costs.
- General and administrative expenses for the three-month period ended March 31, 2021 were $4.5 million, compared to $3.6 million for the comparable period in 2020. These increases are attributable to higher expenses for personnel, including non-cash stock-based compensation, and professional services and other costs associated with operating as a public company.
- Total operating expenses were $15.1 million for the three-month period ended March 31, 2021, compared to $12.4 million for the comparable period in 2020.

About NASH
Non-alcoholic steatohepatitis (NASH) is a serious, life-threatening disease that has rapidly emerged as a leading cause of liver failure in the world and is the leading indication for liver transplant among women. 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 Cohort C
Cohort C was an expansion cohort of the Phase 2a BALANCED study, which evaluated EFX in patients with NASH who have compensated cirrhosis (F4), Child-Pugh Class A. Thirty cirrhotic NASH subjects with a biopsy-confirmed fibrosis score of F4 were randomized 2:1 to receive either 50mg of EFX or placebo for 16 weeks. The primary objective of the expansion cohort was to assess safety and tolerability of EFX in NASH patients at the greatest risk of progressing to end-stage liver disease, including liver failure and liver cancer. The trial design included various non-invasive measures of liver health, including markers of liver fibrosis such as Enhanced Liver Fibrosis (ELF) score and Pro-C3, as well as liver ultrasound imaging. The trial design also permitted patients to volunteer for end-of-treatment biopsies.

About the HARMONY Study
The Phase 2b HARMONY study is a multicenter, randomized, double-blind, placebo-controlled, clinical trial in biopsy-confirmed NASH patients with fibrosis stage 2 or 3. Patients are being randomized to receive once-weekly subcutaneous dosing of 28 or 50mg EFX or placebo. The primary endpoint for the trial is regression of fibrosis at 24 weeks. Patients will continue to receive EFX or placebo during long-term follow-up to provide additional safety data.

About Efruxifermin
Efruxifermin (EFX) is an Fc-FGF21 fusion protein that has been engineered to mimic the balanced biological activity profile of native FGF21, an endogenous hormone that alleviates cellular stress and regulates metabolism throughout the body. Previous clinical trials show that EFX has the potential to reverse fibrosis, resolve NASH, reduce liver fat, improve glycemic control, improve lipoprotein profile, and reduce body weight. EFX is designed to offer convenient once-weekly subcutaneous dosing.

About Akero Therapeutics
Akero Therapeutics is a clinical-stage cardio-metabolic company developing transformational treatments for non-alcoholic steatohepatitis (NASH), a disease without any approved therapies. Akero's lead product candidate, EFX, an engineered Fc-FGF21 fusion protein, is currently being evaluated in Phase 2 clinical trials as a potential treatment for NASH. Akero is headquartered in South San Francisco. Visit us at www.akerotx.com for more information.

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, including, but not limited to, statements regarding Akero's business plans and objectives, including future plans or expectations for EFX, upcoming milestones, and therapeutic effects of EFX, as well as the dosing, safety and tolerability of EFX; Akero's Phase 2b HARMONY study and Phase 2b SYMMETRY study including expected timing to complete enrollment and report preliminary results; the availability of a new combination drug product-device to support Phase 3 clinical trials; expectations regarding Akero's use of capital, expenses and other future financial results; and the potential impact of COVID-19 on strategy, future operations, enrollment and clinical trials. Any forward-looking statements in this press release 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 COVID-19 on Akero's ongoing and future operations, including potential negative impacts on Akero's employees, third-parties, manufacturers, supply chain and production as well as on global economies and financial markets; the success, cost, and timing of Akero's product candidate development activities and planned clinical trials; Akero'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; Akero's ability to fund operations; as well as those risks and uncertainties set forth more fully under the caption "Risk Factors" in Akero's most recent Annual Report on Form 10-K, as filed with the Securities and Exchange Commission (SEC) as well as discussions of potential risks, uncertainties and other important factors in Akero's other 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 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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Akero Therapeutics, Inc.
Condensed Consolidated Balance Sheets
(Unaudited)
(In thousands)

	March 31, 2021	December 31, 2020
Assets		
Cash, cash equivalents and short-term marketable securities	$ 249,984	$ 268,387
Other current assets	5,792	2,958
Non-current assets	1,847	1,994
Total assets	$ 257,623	$ 273,339
Liabilities and Stockholders' Equity		
Current liabilities	$ 10,136	$ 13,111
Non-current liabilities	1,467	1,516
Stockholders' equity	246,020	258,712
Total liabilities and stockholders' equity	$ 257,623	$ 273,339

Akero Therapeutics, Inc.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(Unaudited)
(In thousands, except share and per share amounts)

	Three Months Ended March 31,	
	2021	2020
Operating expenses:		
Research and development	$ 10,602	$ 8,791
General and administrative	4,526	3,588
Total operating expenses	15,128	12,379
Loss from operations	(15,128)	(12,379)
Other income	38	493
Net loss	$ (15,090)	$ (11,886)
Comprehensive loss	$ (15,089)	$ (11,835)
Net loss per common share, basic and diluted	$ (0.43)	$ (0.42)
Weighted-average number of shares used in computing net loss per common share, basic and diluted	34,744,275	28,499,475