Akero Therapeutics Reports First Quarter 2024 Financial Results and Provides Business Update

May 10, 2024

-- Statistically significant week 96 results from the Phase 2b HARMONY study of EFX in patients with pre-cirrhotic MASH reported during the first quarter of 2024 --

-- Phase 3 SYNCHRONY Histology and SYNCHRONY Real-World studies in patients with pre-cirrhotic MASH (F2-F3) continue to enroll; SYNCHRONY Outcomes study in patients with compensated cirrhosis due to MASH (F4) on track to be initiated in second quarter of 2024 --

SOUTH SAN FRANCISCO, Calif., May 10, 2024 (GLOBE NEWSWIRE) -- Akero Therapeutics, Inc. (Nasdaq: AKRO), a clinical-stage company developing transformational treatments for patients with serious metabolic diseases marked by high unmet medical need, today reported first quarter financial results for the period ending March 31, 2024 and provided business updates.

"We continued to make significant advancements in the clinical development of EFX during the first quarter of this year," said Andrew Cheng, M.D., Ph.D., president and chief executive officer of Akero. "The increased improvements in fibrosis stage observed from weeks 24 to 96 in the Phase 2b HARMONY study in patients with pre-cirrhotic MASH (F2-F3) showed EFX's potential to result in higher rates of fibrosis improvement after longer treatment. With over $900 million in cash, cash equivalents, and short term marketable securities following a March 2024 equity offering, we are well-positioned to progress our Phase 3 SYNCHRONY program through primary endpoint readout for our two studies in patients with pre-cirrhotic MASH and fund Akero's current operating plan into the second half of 2027."

Phase 2b HARMONY Study Week 96 Analysis

- In March 2024, Akero reported Week 96 results from HARMONY, a Phase 2b study evaluating the efficacy and safety of efruxifermin (EFX) in patients with pre-cirrhotic metabolic dysfunction-associated steatohepatitis (MASH), fibrosis stage 2 or 3 (F2-F3).
  - The study previously met its primary endpoint of ≥1 stage improvement in fibrosis with no worsening of MASH after 24 weeks of treatment for both the 50mg EFX (41%) and 28mg EFX (39%) dose groups, compared to 20% for the placebo arm.
  - At week 96, the response rates on this endpoint increased to 75% ($p<0.001$) for 50mg EFX and 46% ($p=0.07$) for 28mg EFX, compared to 24% for placebo.
- The study also demonstrated additional improvements on histology endpoints at week 96, including:
  - 36% ($p<0.01$) and 31% ($p<0.01$) of patients treated with 50mg EFX and 28mg EFX experienced a 2-stage improvement in fibrosis without worsening of MASH—more than 10-fold the placebo rate of 3%.
  - 68% ($p<0.001$) and 27% ($p=0.053$) of patients with F3 fibrosis at baseline in the 50mg EFX and 28mg EFX groups experienced ≥1 stage improvement in fibrosis without worsening of MASH, compared with 14% for placebo.
- Statistically significant effects were also observed for multiple secondary endpoints in both dose groups, including improvements in liver enzymes, non-invasive fibrosis markers, glycemic control, and lipoproteins.
- Treatment with EFX was generally well-tolerated, with a tolerability profile comparable to that observed at week 24 in the HARMONY study. A total of three patients treated with EFX were discontinued due to adverse events between week 24 and week 96 (two in the 28mg group and one in the 50mg group), compared with none for placebo.

Phase 2b SYMMETRY Study

- The ongoing Phase 2b SYMMETRY study, which is evaluating the efficacy and safety of EFX in patients with compensated cirrhosis due to MASH (F4), remains on track to report week 96 results in the first quarter of 2025.

Phase 3 SYNCHRONY Program

- Akero's Phase 3 SYNCHRONY clinical trial program consists of three trials, two of which started enrolling patients in December 2023 and the third of which remains on track to be initiated in the second quarter of 2024.
  - SYNCHRONY *Histology* is evaluating the efficacy and safety of EFX in patients with biopsy-confirmed pre-cirrhotic MASH (F2-F3) and is currently expected to enroll approximately 1,000 patients to receive weekly injections of EFX 28mg, EFX 50mg, or placebo. The primary endpoint, designed to support an application for accelerated approval, is the proportion of patients experiencing ≥ 1-stage fibrosis improvement AND resolution of MASH after 52 weeks of treatment. After 52 weeks, patients will continue treatment as randomized in SYNCHRONY *Histology* to be followed for long-term clinical outcomes, such as progression to cirrhosis.
  - SYNCHRONY *Real-World* is currently expected to enroll approximately 700 patients with MASH or metabolic dysfunction-associated steatotic liver disease (MASLD) diagnosed by either histology or non-invasive tests to receive weekly injections of EFX 50mg or placebo, including up to 100 patients rolled over from Phase 2b studies

of EFX. The primary endpoint of safety and tolerability will be assessed after 52 weeks of treatment.
    - SYNCHRONY *Outcomes*, which remains on track to be initiated in the second quarter of 2024, will evaluate the safety and efficacy of EFX in patients with compensated cirrhosis due to MASH (F4).
- In all EFX Phase 3 studies, patients will use the LyoJect 3S dual chamber syringe, a pre-filled device designed for patient self-administration. This optimized formulation delivers blood levels of EFX comparable to those of the liquid formulation used in prior clinical studies.

Public Offering of Common Stock

- In March 2024, Akero announced the closing of its upsized, underwritten public offering of 12,650,000 shares of its common stock at a public offering price of $29.00 per share, which included the exercise in full by the underwriters of their option to purchase up to an additional 1,650,000 shares of common stock in this offering.
- Gross proceeds from the offering, before deducting underwriting discounts and commissions and estimated offering expenses, were approximately $366.9 million.

First Quarter 2024 Financial Results

- Akero's cash, cash equivalents and short-term marketable securities as of March 31, 2024, were $903.7 million.
    - Akero believes that its current cash, cash equivalents, and short-term marketable securities will be sufficient to fund its Phase 3 SYNCHRONY *Histology* and *Real-World* studies through their respective primary endpoints and Akero's current operating plan into the second half of 2027.
    - Research and development expenses for the three-month period ended March 31, 2024 were $50.7 million, compared to $21.8 million for the comparable period in 2023. These increases are attributable to higher expenses associated with the completion of the Phase 2b HARMONY study, the ongoing SYMMETRY study, initiation of the Phase 3 SYNCHRONY *Histology* and SYNCHRONY *Real-World* studies, manufacturing required to support Phase 3 and potential marketing applications, as well as higher expenses for personnel.
    - General and administrative expenses for the three-month period ended March 31, 2024 were $9.3 million, compared to $7.0 million for the comparable period in 2023. These increases are attributable to higher expenses for personnel, and professional services and other costs associated with operating as a public company.
    - Total operating expenses were $60.0 million for the three-month period ended March 31, 2024, compared to $28.8 million for the comparable period in 2023.

About Efruxifermin
Efruxifermin (EFX), Akero's lead product candidate for MASH, is a differentiated 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. EFX appears to reduce liver fat and inflammation, reverse fibrosis, increase insulin sensitivity and improve lipids. This holistic approach offers the potential to address the complex, multi-system disease state of MASH, including improvements in lipoprotein risk factors linked to cardiovascular disease – the leading cause of death in MASH patients. EFX is designed to offer convenient once-weekly dosing and has been generally well tolerated in clinical trials to date.

About MASH
MASH is a serious form of MASLD that is estimated to affect more than 17 million Americans. MASH 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. MASH is the fastest growing cause of liver transplants and liver cancer in the US and Europe.

About Akero Therapeutics
Akero Therapeutics is a clinical-stage company developing transformational treatments for patients with serious metabolic diseases marked by high unmet medical need, including MASH. Akero's lead product candidate, EFX, is currently being evaluated in the ongoing SYMMETRY study, a 96-week Phase 2b clinical trial in patients with compensated cirrhosis due to MASH (F4 fibrosis), as well as two ongoing Phase 3 clinical trials: the SYNCHRONY *Histology* study in patients with pre-cirrhotic MASH (F2-F3 fibrosis) and the SYNCHRONY *Real-World* study in patients with MASH (F1-F3 fibrosis) or MASLD. A third clinical trial, the SYNCHRONY *Outcomes* study in patients with compensated cirrhosis due to MASH (F4 fibrosis), is expected to be initiated in the second quarter of 2024. The Phase 3 SYNCHRONY program builds on the results of two Phase 2b clinical trials, the HARMONY study in patients with pre-cirrhotic MASH (F2-F3) and the SYMMETRY study in patients with compensated cirrhosis due to MASH (F4). Akero is headquartered in South San Francisco. Visit us at akerotx.com and follow us on LinkedIn and X 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 and clinical trial design; the therapeutic effects of EFX; the timing and initiation of Akero's Phase 3 SYNCHRONY program; upcoming milestones, including week 96 results of the Phase 2b SYMMETRY study; the anticipated benefits and optimization of the LyoJect 3S dual chamber syringe; and Akero's growth as a company and expectations regarding its uses of capital, expenses, and financial results, including the expected cash runway. 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: 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 and Quarterly Report on Form 10-Q, 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, 2024	December 31, 2023
Assets		
Cash, cash equivalents and short-term marketable securities	$ 903,665	$ 550,010
Other current assets	7,615	9,952
Non-current assets	963	20,309
Total assets	$ 912,243	$ 580,271
Liabilities and Stockholders' Equity		
Current liabilities	$ 30,259	$ 19,128
Non-current liabilities	35,731	25,837
Stockholders' equity	846,253	535,306
Total liabilities and stockholders' equity	$ 912,243	$ 580,271

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

	Three Months Ended March31,	
	2024	2023
Operating expenses:		
Research and development	$ 50,650	$ 21,787
General and administrative	9,304	6,966
Total operating expenses	59,954	28,753
Loss from operations	(59,954)	(28,753)
Interest expense	(991)	(457)
Interest and other income, net	7,601	3,379
Net loss	$ (53,344)	$ (25,831)
Comprehensive loss	$ (53,693)	$ (25,847)
Net loss per common share, basic and diluted	$ (0.90)	$ (0.55)
Weighted-average number of shares used in computing net loss per common share, basic and diluted	59,307,759	46,944,059