Akero Therapeutics Reports First Quarter 2023 Financial Results and Provides Business Update

May 15, 2023

-- Results from Cohort D, an expansion cohort of type 2 diabetic, pre-cirrhotic NASH patients treated with EFX or placebo in combination with a GLP-1 agonist, to be reported during the second quarter of 2023 --

-- SYNCHRONY Phase 3 studies on track to begin enrolling in the second half of this year --

-- Results from the Phase 2b SYMMETRY study, evaluating treatment of patients with compensated cirrhosis due to NASH, on track to be reported in the fourth quarter of this year –

-- After close of the first quarter, $124.2 million in net proceeds raised through Akero's ATM Facility

SOUTH SAN FRANCISCO, Calif., May 15, 2023 (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, 2023. In addition, after close of the first quarter, the company raised $124.2 million in net proceeds through an At-the-Market (ATM) facility, which strengthens the company's cash position as it prepares to initiate the Phase 3 SYNCHRONY Histology and SYNCHRONY Real-World studies of Efruxifermin (EFX) in NASH.

"We're pleased to continue the strong momentum from 2022 into the first quarter of this year, with a positive end-of-Phase 2 meeting with the FDA and additional capital from our ATM facility that bolsters our financial position as we prepare to initiate Phase 3 SYNCHRONY studies later this year," said Andrew Cheng, M.D., Ph.D., president and chief executive officer of Akero. "The remainder of 2023 looks promising for both Akero and the NASH community, and we look forward to reporting results from Cohort D and the main SYMMETRY study and beginning enrollment in SYNCHRONY Histology and SYNCHRONY Real-World."

Phase 3 SYNCHRONY Program

- SYNCHRONY Histology and SYNCHRONY Real-World studies remain on track to begin enrollment in the second half of this year.
    - SYNCHRONY Histology will evaluate the efficacy of 28mg and 50mg doses of EFX in patients with biopsy confirmed pre-cirrhotic NASH, fibrosis stage 2 or 3 (F2-F3). The primary endpoint will be ≥ 1-stage fibrosis improvement AND resolution of NASH.
    - SYNCHRONY Real-World will assess safety and tolerability of EFX in patients with non-invasively diagnosed NASH or NAFLD. Key secondary endpoints are to include change in biomarkers of fibrosis and other established non-invasive endpoints.

Phase 2b SYMMETRY Study Update

- Akero remains on track to report Week 36 results of the Phase 2b SYMMETRY main study in adult patients with cirrhotic NASH (F4, compensated) in the fourth quarter of 2023.
- Akero remains on track to report results of Cohort D in the second quarter of 2023. This is an expansion cohort of the Phase 2b SYMMETRY evaluating safety and tolerability of EFX compared to placebo, when dosed for 12 weeks on top of an existing GLP-1 receptor agonist in patients with pre-cirrhotic NASH (F1-F3 fibrosis) and Type 2 diabetes.

First Quarter 2023 Financial Results

- Akero's cash, cash equivalents and short-term marketable securities for the period ended March 31, 2023 were $343.2 million.
- Research and development expenses for the three-month period ended March 31, 2023 were $21.8 million, compared to $20.5 million for the comparable period in 2022. The increase is attributable to a $1.6 million increase in personnel and other R&D expenses, offset by a $0.3 million decrease in direct EFX program costs largely related to CRO expenses for our ongoing HARMONY and SYMMETRY studies.
- General and administrative expenses for the three-month period ended March 31, 2023 were $7.0 million, compared to $5.5 million for the comparable period in 2022. The increase is 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 $28.8 million for the three-month period ended March 31, 2023, compared to $26.1 million

for the comparable period in 2022.

Additional Post-First Quarter Financial Update

- From April 4 through May 11, 2023, Akero raised $124.2 million in net proceeds through the sale of 3,006,052 shares of common stock under its ATM facility at an average price of $42.38 per share.
- Akero believes that its current cash, cash equivalents and short-term marketable securities will be sufficient to fund its current operating plan into 2025.

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 (fibrosis stages 1-4) in 2016, a number that is predicted 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 company developing transformational treatments for patients with serious metabolic diseases marked by high unmet medical need, including non-alcoholic steatohepatitis (NASH), a disease without any approved therapies. Akero's lead product candidate, efruxifermin (EFX), is a differentiated bivalent 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 is designed to offer convenient once-weekly subcutaneous dosing. The consistency and magnitude of observed effects position EFX to be a potentially best-in-class medicine, if approved, for treatment of NASH. EFX is currently being evaluated in two Phase 2b clinical trials: the HARMONY study in patients with pre-cirrhotic NASH (F2-F3 fibrosis), and the SYMMETRY study in patients with cirrhotic NASH (F4 fibrosis, compensated). EFX is also being evaluated in an expansion cohort of the SYMMETRY study, comparing the safety and tolerability of EFX to placebo when added to an existing GLP-1 receptor agonist in patients with pre-cirrhotic NASH (F1-F3 fibrosis) and Type 2 diabetes. Akero is headquartered in South San Francisco.
Visit akerotx.com and follow us on LinkedIn and Twitter 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; the therapeutic effects and potential benefits of EFX, as well as the dosing, safety and tolerability of EFX; the SYNCHRONY Phase 3 program, including the SYNCHRONY Histology and SYNCHRONY Real-World studies and design of trials and expected timing thereof; upcoming milestones, including the results, and expected timing to report such results of Cohort D and the Phase 2b SYMMETRY study; and Akero's growth as a company and expectations regarding its uses of capital, expenses, usage of its ATM program 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: 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 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, 2023	December 31, 2022
Assets		

Cash, cash equivalents and short-term marketable securities	$ 343,222	$ 351,449
Other current assets	4,267	3,724
Non-current assets	1,329	1,397
Total assets	$ 348,818	$ 356,570
Liabilities and Stockholders' Equity		
Current liabilities	$ 16,678	$ 19,083
Non-current liabilities	25,795	10,925
Stockholders' equity	306,345	326,562
Total liabilities and stockholders' equity	$ 348,818	$ 356,570

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,	
	2023	2022
Operating expenses:		
Research and development	$ 21,787	$ 20,514
General and administrative	6,966	5,537
Total operating expenses	28,753	26,051
Loss from operations	(28,753)	(26,051)
Interest expense	(457)	-
Other income, net	3,379	22
Net loss	$ (25,831)	$ (26,029)
Comprehensive loss	$ (25,847)	$ (26,032)
Net loss per common share, basic and diluted	$ (0.55)	$ (0.74)
Weighted-average number of shares used in computing net loss per common share, basic and diluted	46,944,059	35,005,501