Akero Therapeutics Reports Fourth Quarter and Full Year 2023 Financial Results and Provides Business Update

February 29, 2024

SOUTH SAN FRANCISCO, Calif., Feb. 29, 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 fourth quarter and full year financial results for the period ending December 31, 2023.

“We concluded 2023 by dosing the first patients in our two Phase 3 SYNCHRONY studies evaluating EFX in the treatment of patients with pre-cirrhotic MASH,” said Andrew Cheng, M.D., Ph.D., president and chief executive officer of Akero. “In the first half of 2024, we look forward to reporting results from the second on-treatment biopsy in our 96-week Phase 2b HARMONY study in patients with pre-cirrhotic MASH and initiating our third Phase 3 SYNCHRONY study in patients with cirrhosis due to MASH.”

Phase 3 SYNCHRONY Program Update

- In December 2023 the first patients were enrolled in two of three planned clinical trials comprising the Phase 3 SYNCHRONY program.
- SYNCHRONY *Histology* is evaluating the safety and efficacy of 28 and 50mg doses of efruxifermin (EFX) in patients with biopsy confirmed pre-cirrhotic MASH (F2-F3). The primary endpoint, ≥1-stage fibrosis improvement and resolution of MASH after 52 weeks, is designed to support an application for accelerated approval for pre-cirrhotic MASH. Additional patients will be enrolled and followed for long-term clinical outcomes to support an application for full marketing approval.
- SYNCHRONY *Real-World* is assessing the safety and tolerability of EFX in patients with non-invasively diagnosed MASH or metabolic dysfunction-associated steatotic liver disease (MASLD). Results will support evaluation of safety for inclusion in an application for accelerated approval.
- SYNCHRONY *Outcomes*, which is expected to be initiated in the first half of 2024, will evaluate the safety and efficacy of EFX in patients with compensated cirrhosis (F4) due to MASH. Consistent with feedback from the FDA in a recent Type B meeting, the trial is likely to include two primary endpoints: (1) evaluation of histology from a cohort of patients who will be biopsied after 96 weeks of treatment to assess the extent of regression of hepatic fibrosis and (2) assessment of clinical outcomes to support an application for full marketing approval.
- In all EFX Phase 3 studies, patients will self-administer EFX using the LyoJect 3S dual chamber syringe, a pre-filled device intended for commercial use in the event EFX is approved for marketing. This optimized formulation delivers blood levels of EFX comparable to those of the liquid formulation used in prior clinical studies.

Phase 2b SYMMETRY Week 36 Results and Study Update

- In the fourth quarter of 2023, Akero reported results for the week 36 analysis of the Phase 2b SYMMETRY study in patients with cirrhosis due to MASH.
    - A trend, which was not statistically significant, was observed for the primary endpoint, with 22% and 24% of the 28mg and 50mg EFX-treated groups, respectively, experiencing at least a one-stage improvement in liver fibrosis and no worsening of MASH, compared with 14% for placebo.
    - Statistically significant rates of MASH resolution in 67% and 60% of patients at week 36 were observed for the 28mg and 50mg EFX-treated groups, respectively, compared with 26% for placebo.
    - Statistically significant improvements were also observed for both EFX groups in non-invasive markers of liver injury and fibrosis, insulin sensitization and lipoproteins.
    - EFX was reported to be generally well-tolerated. Overall, the most frequent adverse events were transient, gastrointestinal grade 1 or 2 events.
- Preliminary, topline results for histopathology and noninvasive measurements after 96 weeks of treatment in the SYMMETRY study are expected to be reported in the first quarter of 2025.

Full Year and Fourth Quarter 2023 Financial Results

- Akero's cash, cash equivalents, short-term and long-term marketable securities for the year ended December 31, 2023 were $569.3 million.

- Akero believes that its cash, cash equivalents, short-term and long-term marketable securities will be sufficient to fund its current operating plan into 2026.
- Research and development expenses for the three-month and twelve-month periods ended December 31, 2023 were $53.4 million and $141.8 million, respectively, compared to $18.3 million and $85.3 million for the comparable periods in 2022. These increases are attributable to higher expenses associated with the ongoing Phase 2b HARMONY and SYMMETRY studies, 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 and twelve-month periods ended December 31, 2023 were $8.5 million and $31.1 million, respectively, compared to $7.1 million and $29.9 million for the comparable periods in 2022. 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 $61.9 million and $172.9 million for the three-month and twelve-month periods ended December 31, 2023, respectively, compared to $25.4 million and $115.2 million for the comparable periods in 2022.

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 is designed 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 projected to affect over 25 million Americans by 2030. 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. Approximately 20% of patients with MASH will progress to cirrhosis, which has a higher risk of mortality. There are no approved treatments for the condition and 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, a disease without any approved therapies. Akero's lead product candidate, EFX, is currently being evaluated in 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 or MASLD. A third clinical trial, the SYNCHRONY *Outcomes* study in patients with cirrhosis due to MASH, is expected to be initiated in the first half 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 and the SYMMETRY study in patients with cirrhosis due to MASH. Akero is headquartered in South San Francisco. Visit us at 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 upcoming milestones, including the expected timing to report the week 96 results of Akero's Phase 2b HARMONY and SYMMETRY studies; Akero's business plans and objectives; the potential therapeutic effects of EFX, as well as the dosing, safety and tolerability of EFX; the SYNCHRONY Phase 3 program, including the design and enrollment of the SYNCHRONY *Histology,* SYNCHRONY *Real-World,* and SYNCHRONY *Outcomes* studies; and plans related to use of a new formulation designed for self-administration in Phase 3 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: 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 any of its clinical studies 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; Akero's ability to fully enroll patients in its SYNCHRONY Phase 3 studies including the SYNCHRONY *Histology*, SYNCHRONY *Real-World*, and SYNCHRONY *Outcomes* studies; 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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Condensed Consolidated Balance Sheets
(Unaudited)
(In thousands)

	December 31, 2023	December 31, 2022
Assets		
Cash, cash equivalents and short-term marketable securities	$ 550,010	$ 351,449
Other current assets	9,952	3,724
Non-current assets	20,309	1,397
Total assets	$ 580,271	$ 356,570
Liabilities and Stockholders' Equity		
Current liabilities	$ 19,128	$ 19,083
Non-current liabilities	25,837	10,925
Stockholders' equity	535,306	326,562
Total liabilities and stockholders' equity	$ 580,271	$ 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 December 31,		Year Ended December 31,	
	2023	2022	2023	2022
Operating expenses:				
Research and development	$ 53,392	$ 18,320	$ 141,798	$ 85,284
General and administrative	8,481	7,100	31,072	29,872
Total operating expenses	61,873	25,420	172,870	115,156
Loss from operations	(61,873)	(25,420)	(172,870)	(115,156)
Interest expense	(897)	(362)	(3,099)	(739)
Other income, net	7,584	2,723	24,210	3,862
Net loss	$ (55,186)	$ (23,059)	$ (151,759)	$ (112,033)
Comprehensive loss	$ (54,410)	$ (23,022)	$ (151,526)	$ (111,969)
Net loss per common share, basic and diluted	$ (0.99)	$ (0.49)	$ (2.89)	$ (2.87)
Weighted-average number of shares used in computing net loss per common share, basic and diluted	55,717,726	46,760,783	52,568,159	38,984,772