Akero Therapeutics Reports Fourth Quarter and Full Year 2024 Financial Results and Provides Business Update

February 28, 2025

-- Reported unprecedented, statistically significant reversal of compensated cirrhosis (F4) due to MASH after 96 weeks of treatment with efruxifermin (EFX) in Phase 2b SYMMETRY study --

-- Completed enrollment of the double-blinded portion of the Phase 3 SYNCHRONY Real-World *Study evaluating EFX in patients with either MASLD or MASH --*

-- Presented New Analyses of Week 96 Phase 2b HARMONY in Patients with Pre-Cirrhotic (F2-F3) MASH at the 75th Annual AASLD The Liver Meeting® 2024 --

SOUTH SAN FRANCISCO, Calif., Feb. 28, 2025 (GLOBE NEWSWIRE) -- Akero Therapeutics, Inc. (Nasdaq: AKRO), a clinical-stage company developing transformational treatments for patients with serious metabolic disease marked by high unmet medical need, today reported fourth quarter and full year financial results for the period ending December 31, 2024.

"We made significant strides in 2024 and the first quarter of 2025 to complete our Phase 2b studies of EFX and advance our Phase 3 SYNCHRONY program. The preliminary topline results from our Phase 2b SYMMETRY study, which we reported last month, showed an unprecedented, statistically significant reversal of compensated cirrhosis due to MASH in patients treated with 50mg EFX for 96 weeks," said Andrew Cheng, M.D., Ph.D., president and chief executive officer of Akero. "These exciting results, which build on last year's week 96 results for the Phase 2b HARMONY study in patients with pre-cirrhotic MASH, show EFX's potential to improve outcomes not only for patients with pre-cirrhotic fibrosis, but also for those with compensated cirrhosis—a population in urgent need of effective therapeutic options. We remain committed to advancing EFX as a potential therapeutic breakthrough for individuals living with advanced MASH and look forward to building upon this momentum as we progress our Phase 3 SYNCHRONY program."

Phase 2b SYMMETRY Study Update

- In January 2025, Akero reported preliminary topline results demonstrating statistically significant reversal of compensated cirrhosis (F4) at week 96 in the Phase 2b SYMMETRY study evaluating EFX in patients with biopsy-confirmed compensated cirrhosis (F4), Child-Pugh Class A, due to MASH, including:
  - Among patients with baseline and week 96 biopsies, 39% of the 50mg EFX group (p=0.009) demonstrated ≥1 stage improvement in fibrosis with no worsening of MASH, representing a 24% effect size over placebo at 15%.
  - By ITT analysis, with all missing week 96 biopsies treated as failures, 29% of the 50mg EFX group (p=0.031) demonstrated ≥1 stage improvement in fibrosis with no worsening of MASH, compared to 12% for placebo, representing a 17% effect size.
  - In a subgroup of patients with baseline and week 96 biopsies who were not taking GLP-1 at baseline (n=97), 45% of the 50mg EFX group experienced reversal of cirrhosis with no worsening of MASH (n=29) (p=0.009) compared to 17% for placebo (n=36), suggesting that reversal of cirrhosis was not attributable to GLP-1 therapy.
- The January 2025 preliminary topline results included report of the relative reduction in liver stiffness by VCTE (FibroScan), with 24% observed for the 50mg EFX group (p<0.05), compared to 8% for placebo. Additional analyses of changes in liver stiffness include:
  - A mean reduction of 7.3 kPa (p<0.001, versus baseline) was observed for the 50mg EFX group, compared to 5.0 for placebo (p<0.001, versus baseline); the numerical reduction observed for 50mg EFX represents the largest absolute reduction in liver stiffness reported to date in clinical trials in patients with compensated cirrhosis (F4) due to MASH;
  - 70% of patients treated with 50mg EFX (p=0.017, versus placebo) experienced at least a 25% relative reduction in liver stiffness, compared to 47% for placebo.

Phase 3 SYNCHRONY Program Update

- Akero's Phase 3 SYNCHRONY program is comprised of three ongoing, randomized, placebo-controlled trials evaluating the safety and tolerability of EFX to support marketing applications for both compensated cirrhosis (F4) due to MASH and pre-cirrhotic (F2-F3) MASH. The SYNCHRONY program builds on two biopsy-based Phase 2b studies in corresponding patient populations, with a combined total of 300 patients treated for up to 96 weeks.
- An increased level of screening for the SYNCHRONY *Outcomes* study, which is evaluating the safety and efficacy of EFX in patients with compensated cirrhosis (F4) due to MASH, has been seen following the report of unprecedented reversal of cirrhosis in late January 2025 for the Phase 2b SYMMETRY study. Patients in *Outcomes* receive weekly injections of 50mg EFX or placebo. The primary histology endpoint, for Cohort 1 only, is the proportion of patients experiencing ≥

1-stage improvement in fibrosis and no worsening of steatohepatitis after 96 weeks of treatment. The primary clinical outcomes endpoint for all patients enrolled across Cohort 1 and Cohort 2 is the time from randomization to first occurrence of any protocol-specified clinical event.

- The SYNCHRONY *Histology* study, which is evaluating the safety and efficacy of EFX in patients with biopsy confirmed pre-cirrhotic (F2-F3) MASH, remains on track to report 52-week results for primary histology endpoints during the first half of 2027. Patients in *Histology* receive weekly injections of EFX 28mg, EFX 50mg, or placebo. The primary histology endpoint, for Cohort 1 only, 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. All patients in Cohort 1 and Cohort 2 will be evaluated for long-term clinical outcomes for up to 240 weeks of treatment.
- SYNCHRONY *Real-World* completed enrollment of the double-blind portion of the study in January 2025. The *Real-World* study is evaluating the safety and tolerability of EFX in a double-blind cohort of 601 patients with non-invasively diagnosed metabolic dysfunction-associated steatohepatitis (MASH) and metabolic dysfunction-associated steatotic liver disease (MASLD), fibrosis stages F1-F4. Preliminary topline results from SYNCHRONY *Real-World* remain on track to be reported during the first half of 2026.

New Week 96 Analyses of the Phase 2b HARMONY Study

- In the fourth quarter of 2024, Akero presented new analyses of the Phase 2b HARMONY results at the 75th Annual AASLD The Liver Meeting® 2024. Presentation highlights included:
  - More than 40% of participants treated with EFX 50mg for 96 weeks, compared with 0% for placebo, showed regression of liver fibrosis based on three orthogonal measures:
    - ≥1-stage fibrosis improvement by NASH-CRN stage (conventional histopathology),
    - 30% reduction of liver stiffness by FibroScan® (imaging fibrosis biomarker), and
    - 0.5 point decrease in ELF™ score (serum fibrosis biomarker).
  - Analysis of biopsies by AI-based Digital Pathology (qFibrosis®, Histoindex) corroborated the extent of improvement in fibrosis observed with conventional histopathology after 24 and 96 weeks of EFX treatment.
  - 30% of participants receiving EFX 50mg for 96 weeks, compared to 0% for placebo, had near complete reversal of MASH-related disease.

Full Year and Fourth Quarter 2024 Financial Results

- Akero's cash, cash equivalents and short- and long-term marketable securities for the year ended December 31, 2024 were $797.8 million.
- On January 30, 2025, Akero closed a follow-on offering of common stock that raised gross proceeds of $402.5 million.
- Akero believes that its cash, cash equivalents and short and long-term marketable securities will be sufficient to fund its current operating plan into 2028.
- Research and development expenses for the three-month and twelve-month periods ended December 31, 2024 were $69.3 million and $247.5 million, respectively, compared to $53.4 million and $141.8 million for the comparable periods in 2023. These increases in the three-month and twelve-month periods ended December 31, 2024 compared to the comparable period in 2023 is attributable to higher expenses associated with the Phase 2b SYMMETRY study and the global Phase 3 SYNCHRONY *Outcomes, Histology, and Real-World* studies and to higher expenses for personnel, including non-cash stock-based compensation.
- General and administrative expenses for the three-month and twelve-month periods ended December 31, 2024 were $8.7 million and $37.9 million, respectively, compared to $8.5 million and $31.1 million for the comparable periods in 2023. 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 $78.0 million and $285.4 million for the three-month and twelve-month periods ended December 31, 2024, respectively, compared to $61.9 million and $172.9 million for the comparable periods in 2023.

About EFX

Efruxifermin (EFX), Akero's lead product candidate for MASH, is currently being evaluated in three ongoing Phase 3 studies. In multiple Phase 2 studies, EFX has been observed to reverse fibrosis (including compensated cirrhosis), resolve MASH, reduce non-invasive markers of fibrosis and liver injury, and improve insulin sensitivity and lipoprotein profile. This holistic profile offers the potential to address the complex, multi-system disease state of all stages of MASH, including improvements in lipoprotein risk factors linked to cardiovascular disease – the leading cause of death among MASH patients. Engineered to mimic the biological activity profile of native FGF21, 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 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. 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 metabolic dysfunction-associated steatohepatitis (MASH). Akero's lead product candidate, efruxifermin (EFX), is currently being evaluated in three ongoing Phase 3 clinical studies: SYNCHRONY *Outcomes* in patients with compensated cirrhosis (F4) due to MASH, SYNCHRONY *Histology* in patients with pre-cirrhotic (F2-F3 fibrosis) MASH, and SYNCHRONY *Real-World* in patients with MASH (F1-F4). 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 compensated cirrhosis due to MASH.

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; the potential therapeutic effects of EFX, as well as the dosing, safety and tolerability of EFX, the future potential of EFX following the preliminary topline week 96 results of Akero's Phase 2b SYMMETRY study, which are subject to audit and verification procedures and additional data that could result in material changes in the final data; the SYNCHRONY Phase 3 program, including the SYNCHRONY *Histology*, SYNCHRONY *Outcomes*, and SYNCHRONY *Real-World* studies and design of trials; the ongoing enrollment of Akero's Phase 3 SYNCHRONY program; and upcoming milestones, including the results, and expected timing to report results from the SYNCHRONY Phase 3 program; 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 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; 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)

	December 31, 2024	December 31, 2023
Assets		
Cash, cash equivalents and short-term marketable securities	$ 743,078	$ 550,010
Other current assets	27,302	9,952
Non-current assets	55,506	20,309
Total assets	$ 825,886	$ 580,271
Liabilities and Stockholders' Equity		
Current liabilities	$ 39,754	$ 19,128
Non-current liabilities	36,020	25,837
Stockholders' equity	750,112	535,306
Total liabilities and stockholders' equity	$ 825,886	$ 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 December 31,		Year Ended December 31,	
	2024	2023	2024	2023
Operating expenses:				
Research and development	$ 69,293	$ 53,392	$ 247,497	$ 141,798
General and administrative	8,732	8,481	37,926	31,072
Total operating expenses	78,025	61,873	285,423	172,870

Loss from operations	(78,025)	(61,873)	(285,423)	(172,870)
Interest expense	(1,200)	(897)	(4,668)	(3,099)
Interest and other income, net	9,201	7,584	38,031	24,210
Net loss	$ (70,024)	$ (55,186)	$ (252,060)	$ (151,759)
Comprehensive loss	$ (71,179)	$ (54,410)	$ (251,382)	$ (151,526)
Net loss per common share, basic and diluted	$ (0.99)	$ (0.99)	$ (3.75)	$ (2.89)
Weighted-average number of shares used in computing net loss per common share, basic and diluted	70,573,609	55,717,726	67,136,772	52,568,159