Akebia Therapeutics Reports Fourth Quarter and Full Year 2024 Financial Results and Vafseo® (vadadustat) Commercial Launch Progress Update

March 13, 2025

Strong results to date of Vafseo U.S. launch; expect Vafseo Q1 2025 net product revenues of approximately $10-$11 million

Cash resources and cash from operations expected to fund current operating plan for at least two years

Akebia to Host Conference Call at 8:00 a.m. ET on March 13, 2025

CAMBRIDGE, Mass., March 13, 2025 (GLOBE NEWSWIRE) -- Akebia Therapeutics®, Inc. (Nasdaq: AKBA), a biopharmaceutical company with the purpose to better the lives of people impacted by kidney disease, today reported financial results for the fourth quarter and full year ended December 31, 2024 and recent business highlights. As previously announced, Vafseo® (vadadustat) shipments to customers began January 9, 2025. Akebia expects Vafseo first quarter 2025 net product revenues of approximately $10-$11 million.

Commenting on the Vafseo launch, John P. Butler, Chief Executive Officer of Akebia said: “We believe Vafseo can be a new standard of care for the treatment of anemia due to chronic kidney disease (CKD). The U.S. product launch is underway and our initial execution across multiple initiatives demonstrates we are making significant early progress towards that goal for dialysis patients. We launched Vafseo with commercial supply contracts in place with dialysis organizations caring for nearly 100% of dialysis patients in the U.S., which we believe is the first time a drug with Transitional Drug Add-on Payment Adjustment (TDAPA) reimbursement has done so. We are very pleased with the early results and expect to generate Vafseo net product revenue of approximately $10-$11 million in the first quarter of 2025.”

Mr. Butler continued, “We are also excited about our potential to expand the Vafseo label to the non-dialysis CKD population, and plan to take advantage of the opportunity to meet with the U.S. Food and Drug Administration to discuss the Phase 3 VALOR study protocol. We believe taking the time for this meeting can help drive our efforts to bring a new product to market to treat this underserved patient population. We expect to initiate the VALOR study in the second half of this year.”

Vafseo U.S. Commercial Update:

- Vafseo began shipping to dialysis centers and authorized distributors on January 9, 2025 and the first prescription was written on January 13, 2025.
- As of today, three of the top four dialysis organizations have placed orders.
- Through the end of February, more than 500 prescribers have written a prescription for Vafseo and each prescriber, on average, has written approximately 8 prescriptions.

Additional Key Business Updates:

- In December 2024, Akebia announced that U.S. Renal Care enrolled the first patients in VOICE, a collaborative clinical trial of Vafseo designed to assess mortality and hospitalization in patients treated with Vafseo compared to current standard of care. U.S. Renal Care has now enrolled more than half of the total target of 2,200 patients.
- Vafseo has been recommended for symptomatic anemia in adults undergoing dialysis for CKD by the United Kingdom (U.K.) National Institute for Health and Care Excellence (NICE), a distinction especially relevant for practitioners and commissioners making care choices for patients in the U.K. and of interest globally. Akebia’s partner Medice has now launched Vafseo in the U.K.
- Akebia plans to initiate a Phase 3 clinical trial (VALOR) to study the use of vadadustat in treating anemia in late-stage CKD patients who are not on dialysis. Akebia expects the VALOR clinical trial to begin in the second half of 2025.

Financial Results

- **Revenues:** Total revenues were $46.5 million in the fourth quarter of 2024 compared to $56.2 million in the fourth quarter of 2023, and $160.2 million for the full-year 2024 compared to $194.6 million for the full-year 2023.
    - Auryxia® (ferric citrate) net product revenues were $44.4 million in the fourth quarter of 2024 compared to $53.2 million in the fourth quarter of 2023, and $152.2 million for the full-year 2024 compared to $170.3 million for the full-year 2023. These decreases were primarily driven by a reduction in volume, partially offset by price increases

and execution of our contracting strategy with third party payors.

  - License, collaboration and other revenues were $2.1 million in the fourth quarter of 2024 compared to $3.0 million in the fourth quarter of 2023, and $8.0 million for the full-year 2024 compared to $24.3 million for the full-year 2023. License, collaboration and other revenue in the full-year 2023 included a one-time $10 million license agreement-related upfront payment.

- **COGS:** Cost of goods sold was $20.4 million in the fourth quarter of 2024 compared to $18.7 million in the fourth quarter of 2023, and $63.2 million for the full-year 2024 compared to $74.1 million for the full-year 2023. In the full-year 2024 and during the fourth quarter of 2023, we realized a $12.3 million benefit, and a $4.3 million benefit, respectively, due to our ability to sell inventory previously written down as excess inventory. In addition, the decrease in cost of goods sold in both period-over-period comparisons reflects lower Auryxia sales volumes in 2024 as compared to 2023.

- **R&D Expenses:** Research and development expenses were $11.8 million in the fourth quarter of 2024 compared to $9.9 million in the fourth quarter of 2023, and $37.7 million for the full-year 2024 compared to $63.1 million for the full-year 2023. The quarterly increase was driven by expense related to the amendment of our license agreement with Cyclerion. The yearly decrease was driven by the completion of activities related to certain clinical trials, lower headcount-related costs and decreased professional service and consulting expenses.

- **SG&A Expenses:** Selling, general and administrative expenses were $27.7 million in the fourth quarter of 2024 compared to $25.4 million in the fourth quarter of 2023, and $106.5 million for the full-year 2024 compared to $100.2 million for the full-year 2023. These increases were driven by costs incurred in connection with preparatory activities related to the Vafseo U.S. launch.

- **Net Income / Loss:** Net loss was $22.8 million in the fourth quarter of 2024 compared to net income of $0.6 million in the fourth quarter of 2023. Net loss was $69.4 million for the full-year 2024 compared to $51.9 million for the full-year 2023. The increases in net loss were impacted by lower period-over-period revenues, as well as by non-cash interest expense incurred in 2024 related to the settlement royalty liability in connection with the Vifor Termination and Settlement Agreement we signed in July 2024, which was $4.9 million in the fourth quarter of 2024 and $9.3 million for the full-year 2024.

- **Cash Position:** We expect our existing cash resources and cash from operations will be sufficient to fund our current operating plan for at least two years. Cash and cash equivalents as of December 31, 2024, were approximately $51.9 million as compared to $42.9 million as of December 31, 2023. Post year-end, we further strengthened our financial position, including through share sales under our at-the-market facility, which raised $18.4 million. In addition, on February 3, 2025, we elected to access Tranche C of the BlackRock Credit Agreement, resulting in net proceeds of $9.3 million.

Conference Call

Akebia will host a conference call on Thursday, March 13 at 8:00 a.m. Eastern Time to discuss fourth quarter and full year 2024 earnings. To access the call, please register by clicking on this Registration Link, and you will be provided with dial in details. To avoid delays and ensure timely connection, we encourage dialing into the conference call 15 minutes ahead of the scheduled start time.

A live webcast of the conference call will be available via the “Investors” section of Akebia's website at: https://ir.akebia.com/. An online archive of the webcast can be accessed via the Investors section of Akebia's website at https://ir.akebia.com approximately two hours after the event.

About Akebia Therapeutics

Akebia Therapeutics, Inc. is a fully integrated biopharmaceutical company with the purpose to better the lives of people impacted by kidney disease. Akebia was founded in 2007 and is headquartered in Cambridge, Massachusetts. For more information, please visit our website at www.akebia.com, which does not form a part of this release.

About Vafseo® (vadadustat) tablets

Vafseo® (vadadustat) tablets is a once-daily oral hypoxia-inducible factor prolyl hydroxylase inhibitor that activates the physiologic response to hypoxia to stimulate endogenous production of erythropoietin, increasing hemoglobin and red blood cell production to manage anemia. Vafseo is approved for use in 37 countries.

INDICATION

VAFSEO is indicated for the treatment of anemia due to chronic kidney disease (CKD) in adults who have been receiving dialysis for at least three months.

Limitations of Use

- VAFSEO has not been shown to improve quality of life, fatigue, or patient well-being.
- VAFSEO is not indicated for use:
  - As a substitute for red blood cell transfusions in patients who require immediate correction of anemia.

- In patients with anemia due to CKD not on dialysis.

IMPORTANT SAFETY INFORMATION about VAFSEO (vadadustat) tablets

WARNING: INCREASED RISK OF DEATH, MYOCARDIAL INFARCTION, STROKE, VENOUS THROMBOEMBOLISM, and THROMBOSIS OF VASCULAR ACCESS.

VAFSEO increases the risk of thrombotic vascular events, including major adverse cardiovascular events (MACE).

Targeting a hemoglobin level greater than 11 g/dL is expected to further increase the risk of death and arterial and venous thrombotic events, as occurs with erythropoietin stimulating agents (ESAs), which also increase erythropoietin levels.

No trial has identified a hemoglobin target level, dose of VAFSEO, or dosing strategy that does not increase these risks.

Use the lowest dose of VAFSEO sufficient to reduce the need for red blood cell transfusions.

CONTRAINDICATIONS

- Known hypersensitivity to VAFSEO or any of its components
- Uncontrolled hypertension

WARNINGS AND PRECAUTIONS

- **Increased Risk of Death, Myocardial Infarction (MI), Stroke, Venous Thromboembolism, and Thrombosis of Vascular Access**

  A rise in hemoglobin (Hb) levels greater than 1 g/dL over 2 weeks can increase these risks. Avoid in patients with a history of MI, cerebrovascular event, or acute coronary syndrome within the 3 months prior to starting VAFSEO. Targeting a Hb level of greater than 11 g/dL is expected to further increase the risk of death and arterial and venous thrombotic events. Use the lowest effective dose to reduce the need for red blood cell (RBC) transfusions. Adhere to dosing and Hb monitoring recommendations to avoid excessive erythropoiesis**.**

- **Hepatotoxicity**

  Hepatocellular injury attributed to VAFSEO was reported in less than 1% of patients, including one severe case with jaundice. Elevated serum ALT, AST, and bilirubin levels were observed in 1.8%, 1.8%, and 0.3% of CKD patients treated with VAFSEO, respectively. Measure ALT, AST, and bilirubin before treatment and monthly for the first 6 months, then as clinically indicated. Discontinue VAFSEO if ALT or AST is persistently elevated or accompanied by elevated bilirubin. Not recommended in patients with cirrhosis or active, acute liver disease.

- **Hypertension**

  Worsening of hypertension was reported in 14% of VAFSEO and 17% of darbepoetin alfa patients. Serious worsening of hypertension was reported in 2.7% of VAFSEO and 3% of darbepoetin alfa patients. Cases of hypertensive crisis, including hypertensive encephalopathy and seizures, have also been reported in patients receiving VAFSEO. Monitor blood pressure. Adjust anti-hypertensive therapy as needed.

- **Seizures**

  Seizures occurred in 1.6% of VAFSEO and 1.6% of darbepoetin alfa patients. Monitor for new-onset seizures, premonitory symptoms, or change in seizure frequency.

- **Gastrointestinal (GI) Erosion**

  Gastric or esophageal erosions occurred in 6.4% of VAFSEO and 5.3% of darbepoetin alfa patients. Serious GI erosions, including GI bleeding and the need for RBC transfusions, were reported in 3.4% of VAFSEO and 3.3% of darbepoetin alfa patients. Consider this risk in patients at increased risk of GI erosion. Advise patients about signs of erosions and GI bleeding and urge them to seek prompt medical care if present.

- **Serious Adverse Reactions in Patients with Anemia Due to CKD and Not on Dialysis**

  The safety of VAFSEO has not been established for the treatment of anemia due to CKD in adults not on dialysis and its use is not recommended in this setting. In large clinical trials in adults with anemia of CKD who were not on dialysis, an increased risk of mortality, stroke, MI, serious acute kidney injury, serious hepatic injury, and serious GI erosions was observed in patients treated with VAFSEO compared to darbepoetin alfa.

- **Malignancy**

  VAFSEO has not been studied and is not recommended in patients with active malignancies. Malignancies were observed in 2.2% of VAFSEO and 3.0% of darbepoetin alfa patients. No evidence of increased carcinogenicity was observed in animal studies.

ADVERSE REACTIONS

- The most common adverse reactions (occurring at ≥ 10%) were hypertension and diarrhea.

DRUG INTERACTIONS

- **Iron supplements and iron-containing phosphate binders:** Administer VAFSEO at least 1 hour before products containing iron.
- **Non-iron-containing phosphate binders:** Administer VAFSEO at least 1 hour before or 2 hours after non-iron-containing phosphate binders.
- **BCRP substrates:** Monitor for signs of substrate adverse reactions and consider dose reduction.
- **Statins:** Monitor for statin-related adverse reactions. Limit the daily dose of simvastatin to 20 mg and rosuvastatin to 5 mg.

USE IN SPECIFIC POPULATIONS

- Pregnancy: May cause fetal harm.
- Lactation: Breastfeeding not recommended until two days after the final dose.
- Hepatic Impairment: Not recommended in patients with cirrhosis or active, acute liver disease**.**

Please note that this information is not comprehensive. Please click here for the Full Prescribing Information, including BOXED WARNING and Medication Guide.

Forward-Looking Statements

Statements in this press release regarding Akebia Therapeutics, Inc.'s ("Akebia's") strategy, plans, prospects, expectations, beliefs, intentions and goals are forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995, as amended, and include, but are not limited to, statements regarding: Akebia's commercial supply contract coverage for Vafseo with dialysis organizations and Akebia's ability to make Vafseo available to nearly 100% of patients on dialysis in the U.S.; Akebia's plans and expectations with respect to potential Vafseo label expansion to treat anemia in late-stage CKD patients who are not on dialysis, including Akebia's expectations as to the timing of a Phase 3 trial; Akebia's statements regarding meeting with the FDA to discuss its Phase 3 study protocol; Akebia's expectation with respect to its net product revenue for the first quarter 2025; Akebia's plans to establish Vafseo as the new standard of care for dialysis patients with anemia due to CKD and progress towards that goal; Akebia's expectations regarding the VOICE trial; and Akebia's expectations that its existing cash resources and cash from operations will be sufficient to fund its current operating plan for at least two years.

The terms "intend," "believe," "plan," "goal," "potential," "anticipate, "estimate," "expect," "future," "will," "continue," derivatives of these words, and similar references are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Actual results, performance or experience may differ materially from those expressed or implied by any forward-looking statement as a result of various risks, uncertainties and other factors, including, but not limited to, risks associated with: the commercial availability of Vafseo; the potential demand and market potential and acceptance of, as well as coverage and reimbursement related to, Auryxia® and Vafseo, including estimates regarding the potential market opportunity; the competitive landscape for Auryxia and Vafseo, including potential generic entrants; the ability of Akebia to attract and retain qualified personnel; Akebia's ability to implement cost avoidance measures and reduce operating expenses; decisions made by health authorities, such as the FDA, with respect to regulatory filings and other interactions; the potential therapeutic benefits, safety profile, and effectiveness of Vafseo; the results of preclinical and clinical research; manufacturing, supply chain and quality matters and any recalls, write-downs, impairments or other related consequences or potential consequences; and early termination of any of Akebia's collaborations. Other risks and uncertainties include those identified under the heading "Risk Factors" in Akebia's Quarterly Report on Form 10-Q for the quarter ended September 30, 2024, and other filings that Akebia may make with the U.S. Securities and Exchange Commission in the future. These forward-looking statements (except as otherwise noted) speak only as of the date of this press release, and, except as required by law, Akebia does not undertake, and specifically disclaims, any obligation to update any forward-looking statements contained in this press release.

Akebia Therapeutics Contact

Mercedes Carrasco

mcarrasco@akebia.com

AKEBIA THERAPEUTICS, INC.
Consolidated Statements of Operations

	Quarters Ended December 31,		Years Ended December 31,	

(in thousands, except share and per share data)	2024	2023	2024	2023
Revenues:				
Product revenue, net	$ 44,370	$ 53,233	$ 152,180	$ 170,301
License, collaboration and other revenue	2,127	2,963	8,000	24,322
Total revenues	46,497	56,196	160,180	194,623
Cost of goods sold:				
Cost of product and other revenue	11,355	9,656	27,135	38,107
Amortization of intangibles	9,010	9,010	36,042	36,042
Total cost of goods sold	20,365	18,666	63,177	74,149
Operating expenses:				
Research and development	11,787	9,866	37,652	63,079
Selling, general and administrative	27,674	25,434	106,545	100,233
License expense	978	856	3,220	3,237
Restructuring	—	—	58	181
Total operating expenses	40,439	36,156	147,475	166,730
Operating income (loss)	(14,307)	1,374	(50,472)	(46,256)
Other income (expense), net	(6,822)	(761)	(18,091)	(5,145)
Change in fair value of warrant liability	(1,675)	—	(330)	—
Loss on extinguishment of debt	—	—	(517)	—
Loss on lease termination	—	—	—	(524)
Net income (loss)	$ (22,804)	$ 613	$ (69,410)	$ (51,925)
Net income (loss) per share				
Basic and diluted	$ (0.10)	$ —	$ (0.33)	$ (0.28)
Weighted-average number of common shares outstanding:				
Basic	218,699,008	189,903,365	210,946,658	187,465,448
Diluted	218,699,008	190,496,470	210,946,658	187,465,448

Selected Balance Sheet Data
(unaudited)

	December 31,	
(in thousands)	2024	2023
Cash and cash equivalents	$ 51,870	$ 42,925
Working capital	$ 32,917	$ 18,279
Total assets	$ 220,670	$ 241,703
Total stockholders' (deficit) equity	$ (49,185)	$ (30,584)

Source: Akebia Therapeutics, Inc.