Akebia Therapeutics Reports First Quarter 2024 Financial Results and Recent Business Highlights

May 9, 2024

Akebia to host conference call at 8:00 a.m. ET on May 9

- *Vafseo® (vadadustat) tablets FDA approved on March 27, 2024*
- *Vafseo launch activities underway with availability expected in January 2025*
- *Auryxia® (ferric citrate) net product revenues were $31.0 million for the first quarter 2024, Akebia expects 2024 Auryxia net product revenue growth versus 2023*

CAMBRIDGE, Mass., May 9, 2024 /PRNewswire/ -- 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 first quarter ended March 31, 2024. Akebia is launching Vafseo® (vadadustat) tablets, recently approved by the U.S. Food and Drug Administration (FDA) for the treatment of anemia due to chronic kidney disease (CKD) in adults who have been receiving dialysis for at least three months, which will be available in January 2025.

"The recent FDA approval of Vafseo represents a transformational milestone for Akebia as we initiate launch activities that we believe will enable widespread access and rapid adoption when Vafseo is available in January 2025," said John P. Butler, Chief Executive Officer of Akebia. "Upon FDA approval of Vafseo, we initiated work to drive demand from potential prescribers and to contract with dialysis providers. We are progressing plans for generating clinical data to identify additional areas of potential benefit to patients as we remain committed to the kidney community. We also expect to engage with the FDA on label expansion opportunities for Vafseo by the end of this year."

Recent Business Highlights

- Akebia plans to submit its application for Transitional Drug Add-on Payment Adjustment (TDAPA) for Vafseo in June. Akebia expects the application to be accepted in July 2024 and expects TDAPA designation in January 2025.
- In March, Akebia presented posters at the 2024 Annual Dialysis Conference on the cardiovascular safety of vadadustat in patients new to dialysis with CKD-related anemia and the safety and efficacy of vadadustat in the treatment of anemia in U.S. patients with CKD.
- In April, Akebia's licensee Averoa, a biopharmaceutical company, submitted a marketing authorization application to the European Medicines Agency for Ferric Citrate Coordination Complex, and, if approved, Averoa will make the product available to patients in Europe.
- In April, Akebia drew down the second tranche of its $55.0 million BlackRock debt facility and received net proceeds of $7.5 million. Ten million dollars of borrowing capacity remains available under the debt facility until December 31, 2024, subject to the conditions in the loan agreement.
- In May, Akebia signed an amendment to its License Agreement with Vifor International Ltd. (Vifor) to modify the method of repayment of its working capital fund through tiered royalties based upon Akebia's sales of Vafseo, significantly simplifying the repayment terms.

Akebia reported first quarter 2024 Auryxia® (ferric citrate) net product revenues of $31.0 million. Akebia reaffirms that it expects Auryxia net product revenue growth in 2024 versus 2023. The Centers for Medicare and Medicaid Services released guidance on incorporating phosphate binders, including Auryxia, into the dialysis bundle in January 2025. Akebia is accelerating contracting discussions with dialysis organizations with a goal to ensure broad access to Auryxia.

"With continued revenue contributions from Auryxia, revenue from Vafseo beginning in 2025, and our current cash balance, we believe we have sufficient cash to support operations for at least the next two years while investing in the Vafseo launch," Mr. Butler added.

Financial Results

- **Revenues:** Total revenues were $32.6 million for the first quarter of 2024 compared to $40.0 million for the first quarter of 2023.
    - Net product revenues were $31.0 million for the first quarter of 2024 compared to $34.7 million for the first quarter of 2023.
    - License, collaboration and other revenues were $1.6 million for the first quarter of 2024 compared to $5.3 million for the first quarter of 2023.
- **COGS:** Cost of goods sold was $11.6 million for the first quarter of 2024 compared to $20.2 million for the first quarter of 2023. Akebia continues to carry a non-cash intangible amortization charge of $9.0 million per quarter through the fourth quarter of 2024.
- **R&D Expenses:** Research and development expenses were $9.7 million for the first quarter of 2024 compared to $19.7 million for the first quarter of 2023.
- **SG&A Expenses:** Selling, general and administrative expenses were $25.4 million for the first quarter of 2024 compared to $25.1 million for the first quarter of 2023.
- **Net Income / Loss:** Net loss was $18.0 million for the first quarter of 2024 compared to a net loss of $26.9 million for the first quarter of 2023.
- **Cash Position:** Cash and cash equivalents as of March 31, 2024, were approximately $42.0 million. Akebia expects its existing cash resources and cash from operations will be sufficient to fund its current operating plan, including a U.S. Vafseo launch, for at least the next two years.

Conference Call

Akebia will host a conference call on Thursday, May 9 at 8:00 a.m. Eastern Time to discuss first quarter 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.

See full prescribing information for complete boxed warning.

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, 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 use in patients with a history of myocardial infarction, cerebrovascular event, or acute coronary syndrome within the 3 months prior to starting VAFSEO. Targeting a Hb level of greater than 11g/dL is expected to further increase the risk of death and arterial and venous thrombotic events, as occurs with ESAs, which also increase erythropoietin levels. No specific Hb target level, dose of VAFSEO, or dosing strategy has been identified to avoid these risks. Use the lowest effective dose and adhere to dosing and Hb monitoring recommendations to avoid excessive erythropoiesis.

  Advise patients to seek immediate medical attention if they develop signs or symptoms of myocardial infarction, stroke, venous thromboembolism, or thrombosis of vascular access. Evaluate and manage promptly if these occur.

- **Hepatotoxicity**
  Hepatocellular injury attributed to VAFSEO was reported in less than 1% of patients, including one severe case with jaundice. All events were asymptomatic and resolved after discontinuation of VAFSEO. The time to onset was generally within the first 3 months of treatment. 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% (9.4 per 100 person-years [PY]) of patients receiving VAFSEO and 17% (11.8 per 100 PY) of patients receiving darbepoetin alfa. Serious worsening of hypertension was reported in 2.7% (1.7 per 100 PY) of patients receiving VAFSEO and 3% (1.8 per 100 PY) of patients receiving darbepoetin alfa. 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% (1.0 per 100 PY) of patients who received VAFSEO and 1.6% (1.0 per 100 PY) of patients who received darbepoetin alfa. Following initiation of VAFSEO, monitor patients closely for premonitory neurologic symptoms. Monitor for new-onset seizures, premonitory symptoms, or change in seizure frequency.

- **Gastrointestinal Erosion**
  Gastric or esophageal erosions occurred in 6.4% (4.0 per 100 PY) of patients receiving VAFSEO and 5.3% (3.3 per 100 PY) of darbepoetin alfa-treated patients. Serious gastrointestinal (GI) erosions, including GI bleeding and the need for red blood cell transfusions were reported in 3.4% (2.1 per 100 PY) and 3.3% (2.0 per 100 PY) of those receiving VAFSEO and darbepoetin alfa, respectively. Consider the risk of GI erosion in high-risk patients, including those with a history of GI erosion, peptic ulcer disease, and tobacco or alcohol use.

  Advise patients of the signs and symptoms of erosions and GI bleeding and urge them to seek prompt medical care if present.

- **Serious Adverse Reactions in Patients with Anemia Due to Chronic Kidney Disease 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, myocardial infarction, 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% (1.3 per 100 PY) of patients treated with VAFSEO and 3.0% (1.8 per 100 PY) of patients treated with darbepoetin alfa. 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 (20 mg) and rosuvastatin (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 for use 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.

IMPORTANT U.S. SAFETY INFORMATION FOR AURYXIA (ferric citrate)

CONTRAINDICATION
AURYXIA (ferric citrate) is contraindicated in patients with iron overload syndromes, e.g., hemochromatosis.

WARNINGS AND PRECAUTIONS

- **Iron Overload:** Increases in serum ferritin and transferrin saturation (TSAT) were observed in clinical trials with AURYXIA in patients with chronic kidney disease (CKD) on dialysis treated for hyperphosphatemia, which may lead to excessive elevations in iron stores. Assess iron parameters prior to initiating AURYXIA and monitor while on therapy. Patients receiving concomitant intravenous (IV) iron may require a reduction in dose or discontinuation of IV iron therapy.
- **Risk of Overdosage in Children Due to Accidental Ingestion:** Accidental ingestion and resulting overdose of iron-containing products is a leading cause of fatal poisoning in children under 6 years of age. Advise patients of the risks to children and to keep AURYXIA out of the reach of children.

ADVERSE REACTIONS

Most common adverse reactions with AURYXIA were:

- **Hyperphosphatemia in CKD on Dialysis:** Diarrhea (21%), discolored feces (19%), nausea (11%), constipation (8%), vomiting (7%) and cough (6%).
- **Iron Deficiency Anemia in CKD Not on Dialysis:** Discolored feces (22%), diarrhea (21%), constipation (18%), nausea (10%), abdominal pain (5%) and hyperkalemia (5%).

SPECIFIC POPULATIONS

- **Pregnancy and Lactation:** There are no available data on AURYXIA use in pregnant women to inform a drug-associated risk of major birth defects and miscarriage. However, an overdose of iron in pregnant women may carry a risk for spontaneous abortion, gestational diabetes and fetal malformation. Data from rat studies have shown the transfer of iron into milk, hence, there is a possibility of infant exposure when AURYXIA is administered to a nursing woman.

To report suspected adverse reactions, contact Akebia Therapeutics at 1-844-445-3799.

Please click to see the full Prescribing Information for AURYXIA.

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 plans with respect to the commercial launch of Vafseo; timing of the commercial availability of Vafseo, including the belief that launch activities will enable widespread access and rapid adoption when Vafseo is available in January 2025; expectations with respect to Akebia's application for Transitional Drug Add-on Payment Adjustment (TDAPA) for Vafseo and TDAPA designation, including the timing thereof; plans regarding potential label expansion; plans to generate clinical data to identify additional areas of potential benefits to patients; Akebia's expectations with respect to engagement with the FDA on label expansion and the timing thereof; Akebia's expectations for Auryxia net product revenue growth in 2024 and assumptions related thereto; Akebia's goal of ensuring broad access to Auryxia; and Akebia's goals, objectives and expectations with respect to its operating plan, expenses, cash resources and sources of funding for its cash runway, including its belief that its existing cash resources and the cash it expects to generate from product revenue are sufficient to fund its current operating plan, including a U.S. Vafseo launch, for at least the next 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: whether Vafseo will be commercially available when expected; 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; the potential therapeutic benefits, safety profile, and effectiveness of Vafseo; the results of preclinical and clinical research; the direct or indirect impact of the COVID-19 pandemic on the markets and communities in which Akebia and its partners, collaborators, vendors and customers operate; 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 March 31, 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.
Unaudited Condensed Consolidated Statements of Operations

	Three Months Ended March 31,	
(in thousands, except per share data)	**2024**	**2023**
Revenues		
Product revenue, net	$ 31,009	$ 34,706
License, collaboration and other revenue	1,598	5,299
Total revenues	32,607	40,005
Cost of goods sold		
Cost of product and other revenue	2,594	11,178
Amortization of intangible asset	9,011	9,011
Total cost of goods sold	11,605	20,189
Operating expenses		
Research and development	9,731	19,686
Selling, general and administrative	25,438	25,053
License expense	711	568
Restructuring	58	106
Total operating expenses	35,938	45,413
Loss from operations	**(14,936)**	**(25,597)**
Other expense, net	(2,403)	(1,279)
Change in fair value of warrant liability	(129)	—
Loss on extinguishment of debt	(517)	—
Net loss	**$ (17,985)**	**$ (26,876)**
Net loss per share - basic and diluted	$(0.09)	$(0.15)
Weighted-average number of common shares - basic and diluted	204,955,151	184,768,983

Unaudited Selected Balance Sheet Data

(in thousands)	**March 31, 2024**	**December 31, 2023**
Cash and cash equivalents	$ 41,961	$ 42,925
Working capital	$ 46,457	$ 18,279

Total assets	$	225,477	$	241,703
Total stockholders' (deficit) equity	$	(27,258)	$	(30,584)

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