



U.S. Renal Care Enrolled First Patients in the VOICE Collaborative Clinical Trial of Vafseo® (vadadustat) for CKD Patients on Dialysis

December 3, 2024

Outcomes study will assess mortality and hospitalization in patients treated with Vafseo compared to current standard of care

CAMBRIDGE, Mass., Dec. 3, 2024 /PRNewswire/ -- [Akebia Therapeutics®, Inc.](#) (Nasdaq: AKBA), a biopharmaceutical company with the purpose to better the lives of people impacted by kidney disease, announced that in late November U.S. Renal Care (USRC) enrolled the first patient in its Vafseo® (vadadustat) Outcomes In-Center Experience (VOICE) collaborative trial. Akebia [announced the collaborative trial initiation](#) in September 2024.

"We look forward to begin treating CKD anemia patients on dialysis with Vafseo ahead of its anticipated market launch in January 2025," said Steven K. Burke, M.D., Chief Medical Officer of Akebia. "The study has been designed to evaluate Vafseo safety and efficacy when dosed three times a week to align with patients' current dialysis schedule as well as to explore additional potential patient benefits. We congratulate Dr. Geoff Block and his team at USRC on quickly consenting patients for the study and thank him for his commitment to patients impacted by kidney disease."

Vafseo was approved by the U.S. Food and Drug Administration in March 2024 for the treatment of anemia due to chronic kidney disease (CKD) in adults who have been receiving dialysis for at least three months. Vafseo is approved for once-daily oral administration and is expected to be available in the U.S. in January 2025.

The VOICE trial intends to enroll approximately 2,200 patients who will be randomized to oral Vafseo 300 mg tablets administered three times per week or standard-of-care erythropoiesis-stimulating agents. The trial will end approximately 18 months after the last patient is randomized. The primary endpoint is non-inferiority for all-cause mortality and the secondary endpoint will test superiority of Vafseo to reduce all-cause hospitalization. More information about the VOICE trial can be found [here](#).

About U.S. Renal Care

U.S. Renal Care partners with nephrologists across 32 states in the U.S. to care for more than 36,000 people living with kidney disease. Since 2000, U.S. Renal Care has been a leader in clinical quality, innovation, and operational excellence – delivering the best experience and outcomes for our patients. For more information, visit [USRenalCare.com](#).

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 $\geq 10\%$) 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 expectations regarding the VOICE trial, including expectations as to the potential benefits and risks of Vafseo when dosed three times a week in dialysis patients, and Akebia's expectations as to the timing of the market availability of Vafseo in the U.S. 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; manufacturing, supply chain and quality matters and any recalls, write-downs, impairments or other related consequences or potential consequences; the results of preclinical and clinical research; the potential therapeutic benefits, safety profile, and effectiveness of Vafseo; the potential demand and market potential and acceptance of, as well as coverage and reimbursement related to Vafseo; the competitive landscape for Vafseo; the ability of Akebia to attract and retain qualified personnel; decisions made by health authorities, such as the FDA, with respect to regulatory filings; 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; 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.

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