Akebia Therapeutics Announces Multiple Positive Business Updates

January 13, 2025

New Commercial Supply Contracts for Vafseo® (vadadustat) secured, bringing availability and dialysis organization coverage to nearly 100% of patients on dialysis in U.S.

Vafseo tablets now shipping in the U.S.

Plan to start Phase 3 trial in mid-2025 to potentially expand Vafseo label to include treatment of late-stage non-dialysis CKD patients

Company to discuss business updates at 43rd Annual J.P. Morgan Healthcare Conference

CAMBRIDGE, Mass., Jan. 13, 2025 /PRNewswire/ -- Akebia Therapeutics®, Inc. (Nasdaq: AKBA), a biopharmaceutical company with the purpose to better the lives of people impacted by kidney disease, today announced multiple positive business updates. As of January, Vafseo® (vadadustat) tablets are available in the U.S. for adult patients with anemia due to chronic kidney disease (CKD) on dialysis for at least three months, and shipment of product to dialysis centers has commenced. In addition, Akebia recently signed a Vafseo commercial supply agreement with a leading dialysis organization. Akebia now has contracts in place with dialysis organizations caring for nearly 100% of dialysis patients in the U.S. As previously announced, Vafseo qualifies for the Transitional Drug Add-On Payment Adjustment (TDAPA) reimbursement as directed by the Centers for Medicare & Medicaid Services (CMS), and CMS has published billing guidance and reimbursement rates.

Akebia also announced its plans to begin a Phase 3 trial for the use of vadadustat in treating anemia in late-stage CKD patients who are not on dialysis. Akebia received feedback from the U.S. Food and Drug Administration (FDA) on its protocol submission for a label expansion study and is incorporating feedback as appropriate. Akebia expects to begin the trial in mid-2025.

"We believe Akebia is entering a transformational year with the U.S. market availability of Vafseo, which we believe could become a new standard of care for patients with CKD," said John P. Butler, Chief Executive Officer of Akebia. "During 2025 our commercial organization will remain focused on executing the U.S. launch of Vafseo, while our development team pursues label expansion of Vafseo into the non-dialysis population, which represents a potential multiple billion-dollar market opportunity in the U.S. We believe our commercial products and pipeline have the potential to generate significant shareholder value as Akebia strengthens its leadership position in the treatment of kidney disease and the hypoxia-inducible factor (HIF) space."

Vafseo Commercial Update:

- Vafseo began shipping to dialysis centers and authorized distributors on January 9, 2025.
- Akebia has secured broad access for Vafseo as the company has now entered into commercial supply agreements with dialysis organizations treating nearly 100% of patients on dialysis in the U.S., including recently signing agreements with a leading dialysis organization and a mid-size dialysis provider.
- Akebia market research suggests 99% of nephrologists would consider prescribing Vafseo to certain eligible patients, with 75% intending to do so by 6 months after product availability.
- In December 2024, Akebia announced that U.S. Renal Care enrolled the first patients in the VOICE collaborative clinical trial of Vafseo. U.S. Renal Care has now enrolled more than 650 patients in the trial.

Planned Phase 3 Trial of Vadadustat in U.S. Non-Dialysis CKD Patients:

- In March 2024, the FDA approved Vafseo for the treatment of anemia due to chronic kidney disease in adults who have been receiving dialysis for at least three months.
- The FDA acknowledged an unmet need for safer and orally available therapies to treat anemia due to CKD in certain non-dialysis patients.
- Akebia has since engaged with the FDA on potentially expanding vadadustat treatment to this patient population and has received feedback on a protocol submitted for a Phase 3 cardiovascular outcome study of approximately 1,500 U.S. subjects with late-stage CKD anemia not on dialysis, which is expected to begin in mid-2025.
- Akebia plans to request a Type C meeting with the FDA to continue to discuss the statistical analysis plan and regulatory path.
- Akebia expects its existing cash resources and cash from operations will be sufficient to fund its current operating plan, including the U.S. Vafseo launch and planned pipeline advancement, for at least two years.

Presentation at 43rd J.P. Morgan Healthcare Conference

John Butler, Chief Executive Officer, will present on Thursday, January 16th, 2025 at 7:30 a.m. PST. A webcast of the presentation can be accessed through the "Investors" section of Akebia's website for 30 days following the conference.

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 plans with respect to its U.S. commercial launch of Vafseo, including Akebia's statements regarding 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 feedback from the FDA on its protocol submission for a label expansion study and Akebia's plans to request a Type C meeting with the FDA to discuss the statistical plan and regulatory path; Akebia's belief that it is entering a transformational year with U.S. market availability of Vafseo, and Akebia's belief that Vafseo could become a new standard of care for patients with CKD; Akebia's expectations regarding label expansion of Vafseo into the non-dialysis population, including a potential multiple billion-dollar market opportunity in the U.S.; Akebia's belief that its commercial products and pipeline have the potential to generate significant shareholder value as Akebia strengthens its leadership position in the treatment of kidney disease and the HIF space; Akebia's expectations regarding the demand for Vafseo from prescribers; and Akebia's expectations that its existing cash resources and cash from operations will be sufficient to fund its current operating plan, including the U.S. Vafseo launch and planned pipeline advancement, 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.

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