Akebia Therapeutics Announces Vadadustat Post-hoc Win Statistics Analysis Demonstrating Statistically Significant Reduction in Mortality and Hospitalization Composite Endpoint Published in the Journal of American Society of Nephrology

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Peer-reviewed publication in prominent nephrology journal reinforces clinical differentiation of Vafseo® (vadadustat) in dialysis-dependent CKD anemia

CAMBRIDGE, Mass., May 04, 2026 (GLOBE NEWSWIRE) -- Akebia Therapeutics®, Inc. (Nasdaq: AKBA), a biopharmaceutical company with the purpose to better the lives of people impacted by kidney disease, today announced the publication of a post-hoc win statistics analysis of all-cause mortality and hospitalization from its global Phase 3 INNO$_2$VATE program in the *Journal of the American Society of Nephrology (JASN)*, a leading, high-impact, peer-reviewed journal in nephrology.

"The win statistics analysis highlighted favorable outcomes and potential clinical differentiation for Vafseo that we believe are central to ensure informed clinical decision-making for nephrologists and other care providers," said Dr. Steven Burke, Chief R&D and Medical Officer at Akebia. "As we work toward our goal to make Vafseo standard of care in patients with anemia due to CKD receiving dialysis, we believe publication in JASN further validates the strength of the vadadustat dataset and supports strong engagement with prescribers, providers and payors."

As reported in the Research Letter titled, "Comparing Vadadustat and Darbepoetin in Maintenance Dialysis with chronic kidney disease (CKD)-Related Anemia," vadadustat demonstrated a statistically significant improvement relative to the erythropoiesis-stimulating agent (ESA), darbepoetin alfa, on a hierarchical composite endpoint of all-cause mortality and hospitalization in patients with anemia due to chronic kidney disease receiving dialysis, which we believe is clinically meaningful. This post hoc analysis was conducted among all randomized patients who received at least one dose of study drug in the INNO$_2$VATE program. A hierarchical composite end point of time to all-cause mortality and hospitalization with consideration of exposure time was analyzed using win statistics. Among patients with dialysis-dependent CKD and CKD-related anemia, those randomized to vadadustat experienced lower rates of the composite end point of all-cause mortality or hospitalization compared with patients randomized to darbepoetin alfa.

Vafseo® (vadadustat) is approved for the treatment of anemia due to chronic kidney disease (CKD) in adults who have been receiving dialysis for at least three months. Vafseo has been available in the U.S. since January 2025.

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.

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. A pregnancy exposure registry is available to monitor outcomes in women exposed to VAFSEO during pregnancy. Report pregnancies to 1-844-445-3799.
- 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 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 and beliefs about the post-hoc win statistics analysis of all-cause mortality and hospitalization from the Phase 3 INNO2VATE trials of vadadustat, including that such analysis demonstrates a statistically significant improvement relative to the ESA darbepoetin alfa on a hierarchical composite endpoint of all-cause mortality and hospitalization; Akebia's beliefs that such analysis is clinically meaningful and demonstrates favorable outcomes and potential clinical differentiation for Vafseo; Akebia's beliefs that nephrologists and other care providers consider these findings to be central to ensure informed clinical decision making; Akebia's plans to work toward its goal of making Vafseo standard of care in patients with anemia due to CKD receiving dialysis; and Akebia's beliefs regarding the impact of the publication of this analysis in JASN, including Akebia's beliefs that such publication further validates the strength of the vadadustat dataset and will support strong engagement with prescribers, providers and payors. The terms "intend," "believe," "plan," "goal," "potential," "anticipate," "estimate," "expect," "future," "will," "continue," "could," 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 potential therapeutic benefits, safety profile, and effectiveness of Vafseo and Akebia's development candidates; the results of preclinical and clinical research; Akebia's ability to initiate and enroll patients in its clinical trials; decisions made by health authorities, such as the FDA, with respect to regulatory filings and other interactions; 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 generic entrants and the timing thereof; the ability of Akebia to attract and retain qualified personnel; Akebia's ability to achieve and maintain profitability and to maintain operating expenses consistent with its operating plan; manufacturing, supply chain and quality matters and any recalls, write-downs, impairments or other related consequences or potential consequences; early termination of any of Akebia's collaborations; and changes in the geopolitical environment and uncertainty surrounding U.S. trade policy on tariffs. Other risks and uncertainties include those identified under the heading "Risk Factors" in Akebia's Annual Report on Form 10-K for the year ended December 31, 2025, 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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