



Akebia Therapeutics Announces Late-Breaking VOICE Trial Presentation and Posters on Akebia's Rare Kidney Pipeline at ASN Kidney Week 2026

October 6, 2026

Additional poster presentations highlight Vafseo® (vadadustat) clinical and economic data

WALTHAM, Mass., Oct. 06, 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 upcoming presentations at the American Society of Nephrology Kidney Week 2026 (ASN Kidney Week), which will take place in Denver, CO from October 21-25, 2026. U.S. Renal Care will present the results of the VOICE trial evaluating the safety of three-times-weekly vadadustat compared with an erythropoiesis-stimulating agent (ESA) in patients receiving in-center hemodialysis as a late-breaking presentation. Additionally, Akebia will have multiple poster presentations featuring its rare kidney disease pipeline, including a poster highlighting preclinical research of praliguat in focal segmental glomerulosclerosis (FSGS), the Phase 2 trial evaluating praliguat in FSGS, and the Phase 2 basket trial of ebrifafusp alfa in complement-mediated kidney diseases. Akebia will also present posters evaluating clinical and economic outcomes associated with Vafseo® (vadadustat).

ASN Kidney Week attendees can visit Akebia at Booth #682 in the Exhibit Hall.

Late-breaking presentation by U.S. Renal Care details:

Vadadustat Three Times Weekly for the Treatment of Anemia in Patients Receiving Hemodialysis

Presenter: Geoffrey A. Block, M.D., FASN, Associate Chief Medical Officer and Senior Vice President, Clinical Research & Medical Affairs for U.S. Renal Care

Date and Time: October 23, 2026; 12:00 to 12:15 PM MT

Akebia-supported posters to be presented in the Exhibit Hall

Posters related to rare kidney disease pipeline:

Renal-Protective Effects of Praliguat in Preclinical Models of Focal Segmental Glomerulosclerosis

Poster #: TH-PO0380

Date and Time: October 22, 2026; 10:00 AM to 12:00 PM MT

A Phase 2 Trial of Praliguat Therapy in Patients with FSGS

Poster #: INFO18-SA

Date and Time: October 24, 2026; 10:00 AM to 12:00 PM MT

Tissue-Targeted Complement Inhibition in Rare Kidney Disease: A Phase 2 Open-Label Basket Trial of Ebrifafusp Alfa

Poster #: INFO12-SA

Date and Time: October 24, 2026; 10:00 AM to 12:00 PM MT

Posters related to Vafseo® (vadadustat):

Cost Analysis of Hospitalizations for Vadadustat vs. Darbepoetin Alfa Based on the Phase 3 INNO₂VATE Trials

Poster #: FR-PO0609

Date and Time: October 23, 2026; 10:00 AM to 12:00 PM MT

Comparison of Major Adverse Cardiovascular Events with Once-Daily vs. Three-Times-Weekly Vadadustat Dosing in Patients with Dialysis-Dependent CKD

Poster #: SA-PO1096

Date and Time: October 24, 2026; 10:00 AM to 12:00 PM

Comparison Between Vadadustat Exposure (C_{max}) and Major Adverse Cardiovascular Events in Patients with Dialysis-Dependent CKD

Poster #: SA-PO1097

Date and Time: October 24, 2026; 10:00 AM to 12:00 PM MT

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 Waltham, 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. 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 the Full Prescribing Information, including **BOXED WARNING** and Medication Guide.

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