Akebia Therapeutics Announces Corporate Updates and 2026 Pipeline Outlook

January 12, 2026

Positioned to increase depth of Vafseo prescribing entering 2026 with access to approximately 275,000 patients

First patient dosed in Praliciguat Phase 2 clinical trial studying focal segmental glomerulosclerosis (FSGS)

AKB-097 Phase 2 rare kidney disease basket trial scheduled to begin in 2H 2026 with initial data expected in 2027

CAMBRIDGE, Mass., Jan. 12, 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 key corporate updates associated with its Vafseo® (vadadustat) commercial business and provided an outlook on upcoming milestones, including for its next anticipated growth driver, Akebia's mid-stage rare kidney disease pipeline.

"We enter 2026 in a solid financial position and expect increased demand for Vafseo as we believe existing customers will accelerate adoption of the product and new customers will operationalize Vafseo protocols within their organizations," said John P. Butler, Chief Executive Officer of Akebia. "We continue to generate post-marketing Vafseo clinical data that will support our goal to make Vafseo standard of care to treat anemia due to chronic kidney disease (CKD) in dialysis. In parallel, we are aggressively progressing our pipeline, including our recently announced rare kidney disease programs, where we will leverage our scientific leadership in nephrology with an aim to help patients in need of new therapies. Our revenue-generating products are the engine driving advancement of our mid-stage pipeline, which, along with continued adoption of Vafseo, we believe can drive significant shareholder value this year and beyond."

Driving to Standard of Care – 2025 Vafseo Achievements

- Secured broad prescribing access for Vafseo encompassing approximately 275,000 patients on dialysis, which is expected to facilitate additional demand in 2026.
- Supported dialysis organizations' implementation of modified dosing protocols or pilots now underway at the top 5 dialysis organizations with prescribing access.
- Completed enrollment in VOICE, a large Phase IV trial of over 2,100 patients evaluating Vafseo TIW against standard-of-care erythropoietin stimulating agents (ESAs) using a hierarchical composite endpoint of all-cause mortality and all-cause hospitalization. VOICE topline results are expected in early 2027 with the potential to help establish Vafseo as a standard of care to treat anemia due to CKD in dialysis.
- Presented a post-hoc analysis of all-cause mortality and hospitalization from the Phase 3 INNO$_2$VATE trials of vadadustat at the American Society of Nephrology Kidney Week 2025 (ASN Kidney Week). The presentation entitled, *"Win-Odds Analysis of Deaths and Hospitalization in Patients taking Vadadustat or Darbepoetin Alfa for CKD-Related Anemia Undergoing Dialysis,"* demonstrated favorable and statistically significant effects of Vafseo relative to the ESA darbepoetin alfa on the hierarchical composite endpoint of death or hospitalization.
- Enrolled approximately 350 patients in VOCAL, a Phase IV trial evaluating TIW dosing of Vafseo versus ESAs, which is expected to report data in Q4 2026. The VOCAL trial also contains a sub-study of Vafseo's impact on red blood cell characteristics.

Vafseo Q4 2025 Performance Expectations

- Total number of prescribers in Q4 was approximately 785, an increase of 8% over Q3.
- At least 25% of new patients in Q4 came from dialysis organizations other than U.S. Renal Care (USRC), an increase from less than 10% in Q3.
- We believe underlying patient dosing demand for Vafseo in Q4 2025 was between approximately $10.5 and $11.5 million.
- In Q4, we saw fewer patient starts at USRC centers anticipating the initiation of a new in-center observed dosing protocol and a decrease in average dose levels at centers that shifted to the observed dosing protocol. Within centers that adopted this protocol in Q4, first refill adherence rates improved from 75% in the first 9 months of 2025 to 91% in Q4. This new protocol at USRC contributed to an overall decrease in channel inventory of $4.5-$5 million. We expect Q4 2025 Vafseo net product revenue, driven in part by this inventory adjustment, will be in the range of $5-$6 million.
- We expect revenue growth to resume in Q1 2026 from increased patient access as well as anticipated improvement in adherence and compliance.

Rare Kidney Disease Pipeline Activities:

- **Praliciguat** is a soluble guanylate cyclase (sGC) stimulator being evaluated in a Phase 2 clinical trial for the treatment of biopsy-confirmed FSGS, a rare kidney disease, with plans to assess its use in other rare podocytopathies in the future. Akebia dosed the first patient in the FSGS study in December 2025. For more information about this study, please visit NCT07268638.
- **AKB-097** (formerly known as ADX-097) is a tissue-targeted anti-C3d-Factor H fusion protein complement inhibitor that has potential applicability across a wide range of complement-mediated rare kidney diseases and is not expected to result in systemic complement inhibition seen with other inhibitors.
    - Akebia plans to initiate an open label Phase 2 rare kidney disease basket study in the second half of 2026, with initial data generation expected in 2027.
    - Akebia plans to evaluate IgA Nephropathy (IgAN), Lupus Nephritis (LN) and C3 Glomerulopathy (C3G) as part of the study.

Other Kidney Disease Pipeline Activities:

- **AKB-9090** is a HIF-PH inhibitor that is entering Phase 1 for acute kidney injury associated with cardiac surgery in the first half of 2026. The drug candidate was shown to prevent kidney damage in an ischemia-reperfusion injury animal model.

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
In the Unites States, 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 expectations and beliefs about demand for Vafseo in 2026, including the number of patients with access to Vafseo and that demand and depth of prescribing for Vafseo will increase in 2026; Akebia's beliefs and expectations with respect to its financial position; Akebia's beliefs that existing customers will accelerate adoption of Vafseo and new customers will operationalize Vafseo protocols within their organizations; Akebia's plans to generate post-marketing Vafseo clinical data that will support its goal to make Vafseo standard of care to treat anemia due to CKD in dialysis; Akebia's plans and expectations with respect to aggressively progressing its pipeline and leveraging its scientific leadership in nephrology with an aim to help patients in need of new therapies; Akebia's beliefs that revenue-generating products are the engine driving advancement of its mid-stage pipeline, which, along with continued adoption of Vafseo, can drive significant shareholder value this year and beyond; Akebia's beliefs with respect to patient dosing demand for Vafseo in Q4 2025, including impacts from a new observed dosing protocol at USRC; Akebia's expectations with respect to Q4 2025 Vafseo net product revenue and that revenue growth will resume in Q1 2026 from increased patient access and anticipated improvement in adherence and compliance; Akebia's plans and expectations with respect to the VOICE trial, including the timing of topline results and potential to help establish Vafseo as a standard of care to treat anemia due to CKD in dialysis; Akebia's plans and expectations with respect to the VOCAL trial, including timing of data; Akebia's plans to assess the use of praliciguat in other rare podocytopathies; Akebia's plans and expectations with respect AKB-097, including the timing of initiation of, and initial data from, an open label Phase 2 basket study and the indications to be evaluated; and Akebia's plans and expectations with respect to AKB-9090, including the timing of a Phase 1 trial.

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 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, 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 Quarterly Report on Form 10-Q for the quarter ended September 30, 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.

Akebia Therapeutics®, Auryxia® and Vafseo® are registered trademarks of Akebia Therapeutics, Inc. and its affiliates.

Akebia Therapeutics Contact
Mercedes Carrasco
mcarrasco@akebia.com

Source: Akebia Therapeutics, Inc.