Clarivate™

# Akebia Therapeutics finally scores FDA approval for renal anemia drug vadadustat

Market Event Summary

Tej Pal | March 2024

# Vafseo, a second-in-class oral HIF-PH inhibitor for renal anemia patients

## Key details

### FDA approval of vadadustat

On March 27, 2024, the FDA approved Akebia Therapeutics' Vafseo (vadadustat), a second-in-class oral hypoxia-inducible factor-prolyl hydroxylase (HIF-PH) inhibitor, for the treatment of renal anemia in adults on dialysis for at least three months.

### Background

- In 2022, the FDA issued a CRL to Akebia Therapeutics for vadadustat for the treatment of anemia due to chronic kidney disease (CKD), in both dialysis and non-dialysis patients.
  - Safety concerns were raised. It failed to meet non-inferiority (vs. Aranesp) in MACE in non-dialysis patients, increased thromboembolic events associated with vascular access in dialysis patients, and is associated with liver toxicity concerns.
- In September 2023, Akebia Therapeutics resubmitted its NDA to the FDA for the treatment of anemia due to CKD in adult patients on dialysis.
  - The resubmission included post-approval data from Japan, where it has been available since 2020.
- GSK's Jesduvroq (daprodustat), the first HIF-PH inhibitor available in the United States, was approved in February 2023. Vafseo has a similar label to Jesduvroq.

Clarivate™

## Clarivate takeaways

Jesduvroq and Vafseo will be direct competitors. Given the similarity in the labels and usage restrictions of the two HIF-PH inhibitors available in the United States, Jesduvroq's first-mover advantage will be influential in its market performance. Vafseo's indication of adults on dialysis for at least three months has a slight advantage over Jesduvroq's stipulation of four months.

The boxed warning for increased death / CV risk will limit overall market uptake of the HIF-PH inhibitor class.

- Despite this class having an established position in Japan and European markets since 2019 and 2021, respectively, CV safety is playing a critical role in the U.S. regulatory decisions and labeling regarding the HIF-PH inhibitors.

In the United States, need remains for oral therapies to treat the non-dialysis renal anemia population.

- Great opportunity awaits companies that can address this need.

# About the Author


## Tej Pal

**Senior Healthcare Research & Data Analyst**

http://linkedin.com/in/tejpal-arora-76196a104

**tej.pal@clarivate.com**


## Clarivate coverage of renal anemia

- Disease Landscape & Forecast – Renal anemia: G7
- Current Treatment: Physician Insights: US - Explores the current prescribing trends of nephrologists treating renal anemia
- Current Treatment: Treatment Algorithms: US – Explores the current prescribing trends of nephrologists treating renal anemia
- Epidemiology: Diagnosed incidence and prevalence data for various population segments of renal anemia across the G7 markets
- Unmet Need - Renal anemia: US and EU5
- Access & Reimbursement - Renal anemia: US

## Author Bio

Mr. Pal has authored several reports focusing on metabolic and renal indications. Previously, he was an analyst at IQVIA and at Smart Analyst Inc., where he worked closely with top pharmaceutical companies on commercial and technical ad-hoc requests. During his tenure there, he delivered competitive landscape and market insight projects on various oncology indications. He holds a master's degree in pharmacy with a specialization in pharmaceutical chemistry from the Delhi Institute of Pharmaceutical Sciences and Research in New Delhi, India.


## Have a question?

healthcare.support@clarivate.com
clarivate.com
+1 215 386 0100 (U.S.)
+44 (0) 20 7433 4000 (Europe)

**About Clarivate**

Clarivate is the leading global information services provider. We connect people and organizations to intelligence they can trust to transform their perspective, their work and our world. Our subscription and technology-based solutions are coupled with deep domain expertise and cover the areas of Academia & Government, Life Sciences & Healthcare and Intellectual Property. For more information, please visit clarivate.com