

FDA ALIGNs with Vanrafia, grants accelerated approval for IgA nephropathy

Market Event Summary

Vanrafia approved for IgA nephropathy

Event

In April 2025, the FDA granted accelerated approval to Vanrafia (atrasentan), a second-in-class oral endothelin receptor antagonist (ERA), for the treatment of adults with primary IgA nephropathy (IgAN) at risk for rapid disease progression. The accelerated approval was based on interim data from the Phase 3 ALIGN study, which showed that Vanrafia achieved a **36.1% reduction in proteinuria at 36 weeks versus placebo from baseline**. Novartis seeks full FDA approval in 2026, based on long-term estimated glomerular filtration rate (eGFR) data at week 136.

Background

- **The treatment landscape for IgAN has seen a surge in novel therapies in the last five years.** Until recently, no therapies were approved to manage IgAN. Asahi Kasei's Tarpeyo / Kinpeygo (budesonide delayed release) and Novartis's Fabhalta (iptacopan) received FDA approvals in 2022 and 2024, respectively, in adults with primary IgAN at risk for rapid disease progression, while Traver Therapeutics' Filspari (sparsentan) received approval in 2023 in adults with primary IgAN at risk for disease progression.
- **Novartis's acquisition of Chinook Therapeutics** in 2023 brought two Phase 3 assets for IgAN: Vanrafia (atrasentan) and zigakibart. Along with Fabhalta (iptacopan), the acquisition helped create a diverse portfolio in IgAN, with assets that span several drug classes and therapeutic targets.
- **Filspari (sparsentan)**, the first-in-class dual endothelin and angiotensin receptor antagonist, received U.S. accelerated approval in February 2023, and full approval in September 2024.

Clarivate's takeaways



Expected positioning in IgA nephropathy

Vanrafia will be a direct competitor to Filspari (owing to their similar mechanisms of action) and to Fabhalta (positioned as add-on therapies to baseline supportive care of RAAS inhibitors, with or without SGLT-2 inhibitors, in patients at risk for rapid disease progression).

- The once-daily oral regimen of Vanrafia provides a dosing advantage over its competitor Fabhalta, which is administered twice daily orally.
- Unlike its competitor Filspari, Vanrafia can be added to supportive care, without the need to discontinue use of RAAS inhibitors. However, adding Vanrafia to the baseline RAAS inhibitor therapy will increase patients' pill burden.
- Unlike its competitor Filspari, there is no requirement for patient enrollment in a REMS (Risk Evaluation Mitigation Strategy) program for Vanrafia.



Commercial potential

Based on the current market positioning and regulatory status, we expect Vanrafia to garner sales of \$300 million in the United States in 2033 and be used as an add-on therapy to baseline supportive care of RAAS inhibitors, with or without SGLT-2 inhibitors, in adults with primary IgA nephropathy at risk for rapid disease progression.

About the author



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Before joining Clarivate, Ms. Kukreja was a manager at Sanofi Healthcare India Pvt. Ltd. (SHIPL), where she was responsible for supporting the Sanofi Global Dupixent Commercial Analytics team. She holds two master's degrees, one in business administration (M.B.A) and one in science (M.S.) with a specialization in biotechnology from Amity University in Noida and Jamia Millia Islamia University in Delhi, respectively.

Clarivate coverage of IgA nephropathy and other renal disorders:

- Disease Landscape & Forecast: IgA nephropathy - G7
- Epidemiology: Diagnosed incidence and prevalence data on various population segments of IgA nephropathy in the G7 markets
- Treatment Algorithms: Claims Data Analysis US—a claims data analysis on the current prescribing trends of drugs for IgA nephropathy
- Unmet Need: IgA nephropathy: US and EU5
- Disease Landscape & Forecast: Chronic kidney disease - G7
- Current Treatment: Physician Insights: US - Explores the current prescribing trends of nephrologists treating chronic kidney disease
- Treatment Algorithms: Claims Data Analysis : US—a claims data analysis on the current prescribing trends of drugs for chronic kidney disease
- Treatment Algorithms: Claims Data Analysis : US—a claims data analysis on the current prescribing trends of drugs for focal segmental glomerulosclerosis
- Current Treatment: Physician Insights: US—explores the current prescribing trends of nephrologists treating glomerulonephritis



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