

Novartis's Fabhalta: a first-in-class complement inhibitor and the third therapy in a wave of IgAN therapies

Market Event Summary

Fabhalta, a new approach to treat IgAN

Background and context

- The heterogenous and progressive nature of IgA nephropathy (IgAN) has made its treatment a challenge. The primary strategies focus on supportive care therapies to control proteinuria and blood pressure, thereby preserving kidney function. However, the introduction of Calliditas Therapeutics' Tarpeyo / Kinpeygo and Travele Therapeutics' Filspari is ushering in a new era in IgAN treatment, offering promising alternatives to specifically address this challenging condition.

Event

- Fabhalta (iptacopan), a first-in-class complement inhibitor, specifically targets the alternative complement pathway, one of four key processes believed to contribute to IgAN pathogenesis. In 2023, Fabhalta was approved for paroxysmal nocturnal hemoglobinuria (PNH).
- The FDA's accelerated approval of Fabhalta for the treatment of IgAN is based on the prespecified interim results from the Phase 3 APPLAUSE-IgAN trial, in which it achieved a clinically meaningful 38% reduction in proteinuria versus placebo at nine months.
- Fabhalta is approved to treat IgAN patients at risk of rapid disease progression (UPCR \geq 1.5 g/g).
- Long-term eGFR data from the APPLAUSE-IgAN trial, expected to be completed in 2025, will support Fabhalta's full approval.

Clarivate's takeaways



Fabhalta's market outlook

- With its unique complement inhibitory mechanism, Fabhalta addresses a crucial need in IgAN treatment, especially given that IgAN patients often progress to kidney failure within 10-20 years of diagnosis. Its approval will be a significant addition, particularly for patients at high risk of disease progression.
- As the third approved therapy for high-risk IgAN patients, Fabhalta is expected to experience gradual adoption as physicians await long-term data on its effectiveness in reducing eGFR.
- However, Fabhalta's twice-daily dosing may hinder its uptake to some extent because it is more burdensome than the once-daily dosing of Tarpeyo / Kinpeygo and Filspari.
- Another potential hurdle to its rapid adoption is the need for patients to be vaccinated at least two weeks before the first dose of Fabhalta to reduce the risk of invasive disease caused by encapsulated bacteria. This step is required by the agent's REMS program.



Market access and reimbursement

- Novartis's Fabhalta Bridge Program, initiated for PNH, offers significant financial support and free Fabhalta for up to 12 months if initially denied by private insurance. Including IgAN patients in this program could improve Fabhalta's access to this patient population.

About the author



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V Anuhya has worked on several CMRH indications, including pulmonary hypertension (PH), nonalcoholic steatohepatitis (NASH), IgA nephropathy (IgAN), and heart failure (e.g., HFpEF, HFrEF). She holds a master's degree in general pharmacy from BITS Pilani in Rajasthan, India, and a bachelor's degree in pharmacy from G. Pulla Reddy College of Pharmacy, which is affiliated with Osmania University, in Hyderabad, India.

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 IgAN in the G7 markets
- Current Treatment: Treatment Algorithms: US—a claims data analysis on the current prescribing trends of drugs for IgAN
- Unmet Need: IgAN: 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
- Current Treatment: Treatment Algorithms: US—a claims data analysis on the current prescribing trends of drugs for chronic kidney disease
- Current Treatment: Treatment Algorithms: 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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