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PRESS RELEASE

Novartis Fabhalta® (iptacopan) receives FDA traditional approval as first and only complement inhibitor to significantly slow kidney function decline in primary IgAN

- *Fabhalta slowed eGFR decline by 48% vs placebo over two years, demonstrating kidney function preservation[1]*
- *Clinically meaningful improvements of protein in urine observed as early as two weeks, with sustained reduction over treatment period[1]*
- *Fabhalta targets the alternative complement pathway; activation is a key driver of inflammation associated with IgAN[2-4]*

Basel, July 17, 2026 – Novartis today announced that the US Food and Drug Administration (FDA) has granted traditional approval for Fabhalta® (iptacopan) to slow kidney function decline in adults with primary immunoglobulin A nephropathy (IgAN) at risk of disease progression[1]. Fabhalta, a first-in-class complement inhibitor, received approval under a priority review designation after an initial FDA accelerated approval in August 2024 for the reduction of proteinuria in primary IgAN[1].

“IgAN is a chronic, immune-mediated disease leading to kidney failure that can have a severe impact on patients’ lives,” said Dana Rizk, M.D., Professor of Medicine in the Division of Nephrology at the University of Alabama at Birmingham and APPLAUSE-IgAN Steering Committee Member. “The ability to significantly slow kidney function decline is a critical treatment goal. This approval of Fabhalta reinforces the importance of targeting underlying disease mechanisms, including complement activation, in treating IgAN to help preserve kidney health.”

Each year, approximately 25 people per million worldwide are newly diagnosed with IgAN, one of the most common autoimmune kidney diseases[5]. Up to 50 percent of IgAN patients with persistent proteinuria progress to kidney failure within 10 to 20 years of diagnosis, often requiring dialysis and/or kidney transplantation, placing a significant burden on patients[6-10].

“This milestone is a moment of great hope for the IgAN community,” said Bonnie Schneider, Director and Co-Founder, IgA Nephropathy Foundation. “For patients and families impacted by this progressive disease, knowing that Fabhalta can help preserve kidney function brings renewed confidence and optimism for the future of the IgAN treatment landscape.”

Data supporting approval
The approval of Fabhalta was based on data from the Phase III APPLAUSE-IgAN study. Results demonstrated statistically significant and clinically meaningful improvement in estimated glomerular filtration rate (eGFR) over two years, with Fabhalta showing an annualized mean change from baseline in eGFR of -3.0 mL/min/1.73 m^2/yr compared with -5.7 mL/min/1.73 m^2/yr for placebo[1]. Fabhalta consistently outperformed placebo across key kidney outcomes[1].

The APPLAUSE-IgAN study showed that Fabhalta has a favorable safety profile, consistent with previously reported data[1]. The most common adverse events with Fabhalta in patients with IgAN were abdominal pain, dizziness and nausea[1]. Fabhalta may increase the risk of serious infections caused by encapsulated bacteria and is available only through a Risk Evaluation and Mitigation Strategy (REMS) program requiring appropriate vaccinations prior to treatment[1].

Transforming care in kidney disease
“Today’s approval reinforces Fabhalta’s role in preserving kidney function by significantly slowing disease progression, an outcome that matters deeply to patients at risk of long-term kidney damage,” said Victor Bultó, President, US, Novartis. “This milestone underscores the importance of continued innovation for people living with IgAN and our commitment to addressing the underlying drivers of disease.”

As each person’s IgAN journey is unique, access to effective, targeted therapies with different mechanisms of action can help physicians select the most appropriate treatment for their patients[10-13]. Alongside Fabhalta, Novartis is supporting this community through its growing IgAN portfolio, which includes Vanrafia® (atrasentan) and investigational compound zigakibart[1,14]. Novartis is committed to helping IgAN patients access Fabhalta through a variety of support programs, with nearly 100 percent of US patients paying $10 or less per month.

About Fabhalta® (iptacopan)
Fabhalta (iptacopan) is an oral Factor B inhibitor designed to selectively target the alternative complement pathway, one of several key drivers of glomerular inflammation and kidney damage in IgAN[2-4]. By inhibiting Factor B, Fabhalta aims to reduce ongoing complement-mediated injury and slow disease progression. Fabhalta has received regulatory approvals in multiple complement-mediated diseases, including IgAN, and is being evaluated across a range of rare kidney conditions.

Novartis’ commitment to kidney diseases
Building on a legacy of more than 40 years that began in transplant, Novartis is on a mission to empower breakthroughs and transform care in kidney health, starting with kidney conditions that have significant unmet need.

Historically, these conditions have had considerably less funding and research, leading to a treatment landscape largely focused on reactive or end-stage disease management, often with significant physical, emotional, and financial burdens. Our portfolio targets the underlying causes of disease, with an aim to protect kidney health and delay or prevent dialysis and/or transplantation. Our goal is to help patients get back to living life on their terms - whether at work, in school, or with loved ones, and by partnering with patients, advocates, clinicians and policymakers, we aim to raise awareness, accelerate diagnosis, and get patients the right care, sooner.

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forward-looking statements contained in this press release as a result of new information, future events or otherwise.

About Novartis
Novartis is an innovative medicines company. Every day, we work to reimagine medicine to improve and extend people's lives so that patients, healthcare professionals and societies are empowered in the face of serious disease. Our medicines reach more than 300 million people worldwide.

Reimagine medicine with us: Visit us at **https://www.novartis.com** and connect with us on **LinkedIn**, **Facebook**, **X/Twitter** and **Instagram**.

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