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PRESS RELEASE

Novartis IgAN data in New England Journal of Medicine show Fabhalta® slowed kidney function decline by 49.3%

- *Fabhalta lowered likelihood of progression to kidney failure by 43% in APPLAUSE-IgAN study*[1]
- *40.7% of patients on Fabhalta demonstrated sustained reduction of protein in urine over two years*[1]
- *Fabhalta granted priority review by FDA for traditional approval*

Basel, March 29, 2026 – Novartis today announced final two-year results from the Phase III APPLAUSE-IgAN study of Fabhalta® (iptacopan) in IgA nephropathy (IgAN). Fabhalta demonstrated a statistically significant, clinically meaningful improvement in estimated glomerular filtration rate (eGFR) slope, a key marker of kidney function, compared with placebo[1]. Fabhalta consistently outperformed placebo across key kidney outcomes over two years, demonstrating a slowing of disease progression and the potential to preserve kidney function in IgAN[1].

The results were published in the *New England Journal of Medicine* and simultaneously presented as late-breaking data at the 2026 World Congress of Nephrology (WCN).

“Persistent kidney inflammation is a hallmark of IgAN, and a key driver of disease progression, leading to ongoing kidney damage and loss of function over time,” said Vlado Perkovic, MD, Professor of Medicine and Provost, University of New South Wales, and Steering Committee Co-Chair of the APPLAUSE-IgAN study. “These results are important because they show that Fabhalta can reduce the risk of disease progression, help preserve kidney health, and address outcomes associated with long-term disease burden.”

Key efficacy results over two years[1]

Endpoint	Fabhalta	Placebo	Effect vs. placebo
Kidney function (eGFR slope)	–3.10 mL/min/1.73 m²/yr	–6.12 mL/min/1.73 m²/yr	3.02 mL/min/1.73 m^2/yr (49.3% slower decline)
Composite kidney failure events*†	21.4%	33.5%	HR 0.57 (43% lower likelihood)
Proteinuria† (24-hour UPCR <1g/g)	40.7% achieved target	23.7% achieved target	—

**Composite kidney failure endpoint: reaching either sustained ≥30% decline in eGFR relative to baseline, sustained eGFR <15 mL/min/1.73 m², initiation of maintenance dialysis, kidney transplant, or death from kidney failure*
†As measured by percentage of patients

“The two-year results demonstrate that Fabhalta consistently and meaningfully slows kidney function decline in high-risk patients with IgAN,” said Ruchira Glaser, MD, MS, Global Head, Cardiovascular, Renal and Metabolic Development, Novartis. “This progress reflects years of focused research and supports our efforts to advance more targeted treatment options to help preserve kidney health in people living with IgAN.”

The safety profile of Fabhalta over two years was consistent with previous findings. Rates of adverse events and treatment discontinuation were low and similar between Fabhalta and placebo[1,2].

Fabhalta received accelerated approval in the U.S. and China for proteinuria reduction in adults with IgAN based on data from a prespecified interim analysis of the APPLAUSE-IgAN study[2,3]. The two-year data were submitted to the U.S. Food and Drug Administration for traditional approval. Fabhalta was granted priority review based on the novel mode of action and the strength of the data. Alongside Fabhalta, Novartis continues to advance its multi-asset IgAN portfolio, which also includes Vanrafia® (atrasentan) and investigational compound zigakibart.

About IgAN
IgAN is a progressive autoimmune kidney disease, with approximately 25 people per million worldwide newly diagnosed each year[4,5]. IgAN is highly debilitating as it leads to inflammation in the small filters of the kidneys, excess protein in urine, and a gradual decline in eGFR[6]. Up to 50% of patients with persistent proteinuria progress to kidney failure within 10 to 20 years of diagnosis, often requiring dialysis or kidney transplantation as part of long-term disease management[5-10].

Furthermore, people living with IgAN often face mental and social challenges[6-9]. Supportive care has not addressed the underlying causes of the disease and often fails to slow disease progression, reinforcing the need for more targeted therapies for IgAN[7-12].

About APPLAUSE-IgAN
APPLAUSE-IgAN (NCT04578834) is a global, randomized, double-blind, placebo-controlled Phase III study evaluating Fabhalta in adults with biopsy-confirmed IgAN and persistent proteinuria despite optimized supportive care. Patients were randomized 1:1 to receive Fabhalta or placebo and were followed for up to 24 months[11]. The primary endpoint was the annualized total eGFR slope over 24 months. Key secondary endpoints included time to first composite kidney failure event and changes in proteinuria over 9 months[1].

The most common adverse events with Fabhalta were mainly mild-to-moderate infections (such as COVID-19 and upper respiratory tract infection), headache, diarrhea, and hyperlipidemia, with overall adverse event rates comparable to placebo[1].

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 inflammation and kidney damage in IgAN[4,12,13]. 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.

Disclaimer
This press release contains forward-looking statements within the meaning of the United States Private Securities Litigation Reform Act of 1995. Forward-looking statements can generally be identified by words such as "potential," "can," "will," "plan," "may," "could," "would," "expect," "anticipate," "look forward," "believe," "committed," "investigational," "pipeline," "launch," or similar terms, or by express or implied discussions regarding potential

marketing approvals, new indications or labeling for the investigational or approved products described in this press release, or regarding potential future revenues from such products. You should not place undue reliance on these statements. Such forward-looking statements are based on our current beliefs and expectations regarding future events, and are subject to significant known and unknown risks and uncertainties. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those set forth in the forward-looking statements. There can be no guarantee that the investigational or approved products described in this press release will be submitted or approved for sale or for any additional indications or labeling in any market, or at any particular time. Nor can there be any guarantee that such products will be commercially successful in the future. In particular, our expectations regarding such products could be affected by, among other things, the uncertainties inherent in research and development, including clinical trial results and additional analysis of existing clinical data; regulatory actions or delays or government regulation generally; global trends toward health care cost containment, including government, payor and general public pricing and reimbursement pressures and requirements for increased pricing transparency; our ability to obtain or maintain proprietary intellectual property protection; the particular prescribing preferences of physicians and patients; general political, economic and business conditions, including the effects of and efforts to mitigate pandemic diseases; safety, quality, data integrity or manufacturing issues; potential or actual data security and data privacy breaches, or disruptions of our information technology systems, and other risks and factors referred to in Novartis AG's current Form 20-F on file with the US Securities and Exchange Commission. Novartis is providing the information in this press release as of this date and does not undertake any obligation to update any 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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