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PRESS RELEASE

Novartis Vanrafia® Phase III data support slowing of kidney function decline in patients with IgA nephropathy

- *In ALIGN study, Vanrafia (atrasentan) showed positive difference in eGFR change from baseline vs. placebo at Week 136, 4 weeks after study treatment ended*[1]
- *Results favored Vanrafia across multiple timepoints, measures of kidney function and in patients additionally receiving SGLT2 inhibitors*[1]
- *Vanrafia received accelerated approval in U.S. and China for reduction of proteinuria in adults with IgAN in 2025; Novartis plans to submit for traditional approval in 2026*[2]

Basel, February 13, 2026 – Novartis today announced final results from the Phase III ALIGN study supporting a slowing decline in kidney function in adults with IgA nephropathy (IgAN) who were treated with Vanrafia® (atrasentan). Vanrafia showed a difference of 2.39 ml/min/1.73m^2 in estimated glomerular filtration rate (eGFR) change from baseline vs. placebo (2-sided p = 0.057) at Week 136, 4 weeks after the end of study treatment[1].

Clinically meaningful results were observed with Vanrafia compared to placebo in eGFR change from baseline at the end of study treatment at Week 132, and in the prespecified exploratory group of patients additionally receiving sodium-glucose co-transporter-2 (SGLT2) inhibitors[1]. At the end of treatment at Week 132, the eGFR change from baseline compared to placebo was 2.59 ml/min/1.73 m^2 (nominal 2- sided p = 0.039)[1].

“Progressive and complex diseases such as IgAN present an urgent need for medicines that can target the different drivers of the disease. Vanrafia can be seamlessly integrated into patients’ existing treatment plans, with a consistent safety profile,” said Ruchira Glaser, M.D., Global Head, Cardiovascular, Renal & Metabolic Development Unit, Novartis. “We are pleased with today’s Phase III ALIGN results, which add to the growing evidence of Vanrafia as a potential foundational therapy to slow kidney function decline.”

ALIGN provides the longest follow-up period in pivotal Phase III studies for IgAN[3]. Safety was consistent with previous findings[1].

Alongside Vanrafia, Novartis continues to advance its multi-asset IgAN portfolio, which also includes Fabhalta® (iptacopan) and investigational compound zigakibart.

About IgAN
IgAN is a progressive autoimmune kidney disease with approximately 25 per million people newly diagnosed worldwide each year[4]. IgAN is highly debilitating as it leads to glomerular inflammation (when the small filters in the kidneys are inflamed), proteinuria (excess protein in urine), and a gradual decline in eGFR[5]. 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[5-7].

Furthermore, people living with IgAN often face mental, social, and economic challenges[5-8]. 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[4-9].

About Vanrafia® (atrasentan)
Vanrafia (atrasentan) is a potent and highly selective endothelin A (ETA) receptor antagonist, which is part of the endothelin system, a key system involved in the progression of IgAN[10-13].

Vanrafia is the first and only selective ETA receptor antagonist approved for primary IgAN, a once-daily, oral treatment and can be seamlessly added to, or used alongside, existing supportive care (e.g. renin-angiotensin system (RAS) inhibitor with or without SGLT2 inhibitor) without the need for titration[2]. Vanrafia does not require a Risk Evaluation and Mitigation Strategy (REMS) program. Because some endothelin receptor antagonists have caused elevations of aminotransferases, hepatotoxicity, and liver failure, clinicians should obtain liver enzyme testing before initiating Vanrafia and during treatment when clinically indicated. Vanrafia may cause serious birth defects[2].

About ALIGN
The ALIGN study (NCT04573478) is a global, randomized, multicenter, double-blind, placebo-controlled Phase III clinical trial comparing the efficacy and safety of Vanrafia versus placebo in patients with IgAN at risk of progressive loss of kidney function[1-3]. In total, 340 patients with biopsy-proven IgAN with baseline total proteinuria ≥1 g/day despite optimized RAS inhibitor treatment were randomized to receive once-daily, oral Vanrafia (0.75 mg) or placebo for approximately 132 weeks[1,11]. Patients continue receiving a maximally tolerated and stable dose of a RAS inhibitor as supportive care[1,11]. An additional cohort of 64 patients receiving an SGLT2 inhibitor in addition to RAS inhibitor for at least 12 weeks was also enrolled[1,11]. The primary efficacy endpoint for the interim analysis (in 270 patients) was change in proteinuria, as measured by 24-hour urine protein-to-creatinine ratio (UPCR) from baseline to 36 weeks[1,3,11]. The key secondary endpoint for the final analysis is the change from baseline to 136 weeks in kidney function as measured by eGFR. Other secondary efficacy endpoints as well as safety and tolerability are also assessed[1-3].

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 nearly 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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