Novartis' Vanrafia receives FDA accelerated approval for rare kidney disease

Vanrafia is a selective endothelin A (ETA) receptor antagonist. Its long-term impact on slowing kidney function decline in patients with IgAN is still under investigation and will determine its continued market approval.

Basel: Swiss pharmaceutical major Novartis announced that the US Food and Drug Administration (FDA) has granted accelerated approval to its kidney disease drug Vanrafia (atrasentan) for the treatment of adults with immunoglobulin A nephropathy (IgAN) who are at risk of rapid disease progression.

Vanrafia is a once-daily, non-steroidal, oral selective endothelin A (ETA) receptor antagonist, approved as supportive care with or without a sodium-glucose co-transporter-2 (SGLT2) inhibitor.

According to the company, it has not yet been established whether Vanrafia slows the decline of kidney function in patients with IgAN. Continued FDA approval may be contingent upon verification of clinical benefit from the ongoing Phase III ALIGN study, which is evaluating its efficacy in slowing disease progression based on estimated glomerular filtration rate (eGFR).

Novartis expects key data readouts from the ALIGN trial in 2026, which could support a traditional FDA approval pathway.

"Vanrafia effectively reduces proteinuria, a major risk factor in IgAN. Taking early, decisive action is critical to help improve outcomes for these patients who too often progress toward kidney failure," said Dr Richard Lafayette, Director, Glomerular Disease Center, Stanford University Medical Center, and an investigator and Steering Committee member for the Vanrafia ALIGN study.

In its release, Novartis noted that the FDA approval was based on a prespecified interim analysis of the Phase III ALIGN trial, which measured reduction in proteinuria at 36 weeks compared to placebo.

Vanrafia has demonstrated a favorable safety profile in ongoing trials, consistent with previously reported data. However, it may cause serious birth defects during treatment when clinically indicated, and appropriate precautions are necessary.

IgA nephropathy (IgAN) is a progressive and rare kidney disease, with approximately 50% of patients progressing to kidney failure within 10 to 20 years of diagnosis — often requiring maintenance dialysis and/or kidney transplantation.

News Source:

https://pharma.economictimes.indiatimes.com/news/drug-approvals-and-launches/novartis-vanrafia-receives-fda-accelerated-approval-for-rare-kidney-disease/120092348