

South Korea approves Everest Medicines' NEFECON for treatment of Primary IgA Nephropathy

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China-based Everest Medicines has announced that NEFECON has received full approval from the Ministry of Food and Drug Safety (MFDS) in South Korea, indicated for the treatment of adults with primary immunoglobulin A nephropathy (IgAN) with a urine protein excretion ≥ 1.0 g/day (or urine protein-to-creatinine ratio ≥ 0.8 g/g). This approval further expands NEFECON's footprint in Asia and provides Asian patients with a groundbreaking etiological treatment option for IgAN.

NEFECON is the first and only fully approved etiological treatment for IgAN, with its clinical value widely recognized by the global medical community. The approval of NEFECON in South Korea is based on the global Phase 3 NeflgArd clinical trial, which showed that compared to placebo, NEFECON not only brought about a sustained reduction in proteinuria and reduced the frequency of microscopic hematuria but also demonstrated clinically relevant and statistically significant treatment benefits in estimated glomerular filtration rate (eGFR).

The study further revealed that NEFECON reduces the decline in kidney function by 50%, over a period of 2 years, comprising 9 months of treatment and 15 months of observation, and potentially delay the progression to dialysis or kidney transplantation by 12.8 years.

Studies have shown that IgAN is highly prevalent among Asian populations, with a 56% higher risk of progression to end-stage renal disease compared to other groups, and often progresses more rapidly. The approval of NEFECON in South Korea provides a breakthrough treatment option for IgAN patients in Asia and highlights its significant commercial potential in the region.

Notably, NEFECON participated in China's National Reimbursement Drug List (NRDL) negotiations this year for the first time. Inclusion in the NRDL would significantly enhance its market penetration and affordability, accelerating its sales growth in China. Industry experts widely view NEFECON as a potential blockbuster drug in the Chinese market, with the ability to drive

Everest Medicines' commercialisation strategy while strengthening its competitive edge in both domestic and international markets.