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Vertexâ??s Povetacicept BLA Accepted by US FDA for IgA Nephropathy

June 4, 2026 | News

The FDA has set a November 30, 2026 PDUFA target date for the investigational BAFF and APRIL dual inhibitor, which could become Vertexâ??s first commercial nephrology therapy if approved.



Vertex Pharmaceuticals has received US FDA acceptance of its Biologics License Application for accelerated approval of povetacicept in adults with immunoglobulin A nephropathy.

The regulatory milestone moves Vertex closer to a potential first commercial therapy in its emerging nephrology franchise. IgA nephropathy is a serious, progressive kidney disease driven by uncontrolled autoreactive B cell activity and is estimated to affect approximately 330,000 people in the United States and Europe, and more than 1.5 million people globally.

Povetacicept is an investigational engineered fusion protein designed as a dual inhibitor of BAFF and APRIL cytokines, which play a role in B cell activation, differentiation and survival. Its mechanism is intended to address the underlying immune drivers of IgA nephropathy, rather than only managing downstream disease manifestations.

The FDA has assigned a Prescription Drug User Fee Act target action date of November 30, 2026. Povetacicept has also received FDA Breakthrough Therapy Designation for IgA nephropathy, reflecting its potential relevance in a disease area with significant unmet need.

The BLA is supported by data from a pre-specified Week 36 interim analysis of the ongoing Phase III RAINIER trial. Patients treated with povetacicept achieved a 52.0 percent reduction from baseline in urine protein-to-creatinine ratio, with a statistically significant and clinically meaningful 49.8 percent reduction compared with placebo. The treatment group also showed a 77.4 percent reduction from baseline in serum galactose-deficient IgA1, compared with a 9.1 percent increase in the placebo group.

In patients with baseline hematuria, 85.1 percent of those receiving povetacicept achieved hematuria resolution, compared with 23.4 percent in the placebo group. The therapy was generally safe and well tolerated, with most adverse events reported as mild to moderate and no serious adverse events related to povetacicept.

If approved, Vertex plans to launch povetacicept as a low-volume subcutaneous auto-injector administered once every four weeks at home. This delivery profile may support treatment convenience and long-term adherence, both of which are

important considerations for chronic kidney disease management.

Commercial adoption will depend on FDA review outcomes, durability of clinical benefit, long-term kidney function data, payer assessment and physician confidence in targeting BAFF and APRIL biology in IgA nephropathy. The RAINIER trial's final analysis will evaluate total estimated glomerular filtration rate slope through Week 104, which will be important for assessing longer-term disease modification.

The BLA acceptance underscores growing biopharma interest in immune-mediated kidney diseases. As nephrology drug development moves toward targeted disease-modifying therapies, povetacicept's regulatory pathway may help define how next-generation biologics are positioned in IgA nephropathy and related autoimmune kidney conditions.