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Sibeprenlimab Phase 3 Data Presented at American Society of Nephrology Kidney Week 2025 Showed Proteinuria Reduction through 12 Months for the Treatment of Immunoglobulin A Nephropathy (IgAN)

Trial Interim Analysis Outcomes Published in New England Journal of Medicine

Otsuka Pharmaceutical, Co. Ltd. (Otsuka) announces that findings from a 12-month interim analysis of sibeprenlimab for the treatment of immunoglobulin A nephropathy (IgAN) in adults were presented in a late-breaking presentation session at the 2025 American Society of Nephrology (ASN) annual Kidney Week meeting in Houston, Texas. Summary data was simultaneously published in the online version of The New England Journal of Medicine.[1]

- *12-month interim analysis outcomes for the novel APRIL antibody drug candidate sibeprenlimab, targeting IgA nephropathy, as part of the Phase 3 VISIONARY trial*
- *Study outcome on proteinuria measured at 12 months demonstrated that sibeprenlimab achieved a 54.3% (95% confidence interval [CI], 46.4% to 60.9%) placebo-adjusted reduction. The safety profile was favorable and consistent with placebo.*
- *Trial outcomes presented at a late-breaking presentation session of the American Society of Nephrology (ASN) Kidney Week, November 6 to 9, 2025*
- *Proteinuria reduction is a recognized surrogate marker correlating with delaying progression to kidney failure*
- *Otsuka filed a Biologics License Application (BLA) for sibeprenlimab with the U.S. FDA and received a Priority Review designation from the agency, with a target action date (PDUFA date) of November 28, 2025*

Twelve-month data on proteinuria levels, measured as urine-protein-to-creatinine ratio in 24-hour urine collections (uPCR-24), as well as on safety, from the Phase 3 VISIONARY study (NCT05248646) of sibeprenlimab were presented.

At 12 months, sibeprenlimab showed a reduction in uPCR-24h of 56.6% (95% CI, 50.8% to 61.7%) compared with 5.1% (-6.7% to 15.7%) for placebo, corresponding to a placebo-adjusted reduction in uPCR-24h of 54.3% (95% CI, 46.4% to 60.9%). The safety profile was favorable and consistent with placebo. At the time of the interim analysis cutoff, the incidence of treatment-emergent adverse events in the safety set (n=510) was similar in the sibeprenlimab (74.1%) and placebo (82.1%) groups, the majority of which were mild to moderate in severity. The most common events were upper respiratory tract infections (14.7% for sibeprenlimab vs. 13.9% for placebo) and nasopharyngitis (12.4% for sibeprenlimab vs. 10.0% for placebo).

The 9-month interim analysis results for sibeprenlimab were submitted as part of the BLA (Biologics License Application) submission to the U.S. FDA. The VISIONARY study, the largest Phase 3 IgAN trial conducted to date, also showed that patients taking sibeprenlimab experienced substantially reduced serum immunoglobulins (IgA, IgG, IgM), A PRoliferation-Inducing Ligand (APRIL), galactose-deficient IgA1 (Gd-IgA1) and rates of hematuria, and delivered higher proteinuric remission versus placebo, which is consistent with APRIL inhibition.

Consistent treatment effects with Sibeprenlimab at nine-month effects were seen across prespecified subgroups, including those patients prescribed or not prescribed SGLT2 inhibitors, varying baseline proteinuria and estimated glomerular filtration rate (eGFR), demographics, and prior immunosuppression

Sibeprenlimab works by blocking APRIL, which plays a key role in the process of IgAN pathogenesis and is an important initiating and sustaining factor in IgAN progression by promoting the production of pathogenic galactose-deficient IgA1 (Gd-IgA1).
Inhibition of APRIL results in reduced levels of galactose-deficient IgA1 (Gd-IgA1), which is implicated in the pathogenesis of IgAN.[2] Sibeprenlimab is administered in a single-dose prefilled syringe for subcutaneous injection every four weeks intended for self-administration.

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The VISIONARY study continues in a blinded manner to evaluate the change in kidney function over 24 months as measured by eGFR and is expected to be completed in 2026. Further prespecified and exploratory analyses of the data will be conducted to determine the full potential of sibeprenlimab for the treatment of IgAN.

1. Sibeprenlimab in IgA Nephropathy — Interim Analysis of a Phase 3 Trial
https://www.nejm.org/doi/full/10.1056/NEJMoa2512133?query=featured_home
2. Mathur M, Barratt J, Chacko B, et al. A Phase 2 Trial of Sibeprenlimab in Immunoglobulin A Nephropathy Patients. NEJM. 2023
https://www.nejm.org/doi/full/10.1056/NEJMoa2305635