



PRESS RELEASE

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**EMBARGOED FOR RELEASE UNTIL
November 8, 2025 AT 10:30 AM CST**

High-Impact Clinical Trials Generate Promising Results for Improving Kidney Health

Houston, TX (November 8, 2025) — The results of numerous high-impact phase 3 clinical trials that could affect kidney-related medical care will be presented in-person at the American Society of Nephrology Kidney Week 2025 November 5–9.

- Sodium-glucose co-transporter 2 (SGLT2) inhibitors reduce albuminuria (excess albumin in the urine) and the risk of chronic kidney disease (CKD) progression, and certain mineralocorticoid receptor antagonists have similar effects in people with type 2 diabetes and CKD. Investigators recently assessed the albuminuria-lowering efficacy and safety of the novel mineralocorticoid receptor antagonist balcinrenone combined with the SGLT2 dapagliflozin. In the double-blind, active-controlled clinical trial, both doses of this novel balcinrenone/dapagliflozin combination outperformed dapagliflozin alone, cutting levels of albumin in urine by 23% and 33% in people living with CKD at high risk of disease progression. It was also well tolerated, with a low risk of hyperkalemia (high potassium), addressing a key safety concern seen with similar therapies. “We know that such albuminuria reductions could predict better outcomes, underscoring the potential of this novel combination for patients at risk of kidney failure,” said senior author and nephrologist Patrick Mark, MB, ChB, PhD, of the University of Glasgow. The data were simultaneously published in *The Lancet: Efficacy and Safety of Balcinrenone in Combination with Dapagliflozin on Albuminuria in Participants with CKD*.
- Alport syndrome is a rare genetic disease resulting from collagen IV abnormalities and is characterized by fibrosis, proteinuria, and declining kidney function. A phase 2a trial assessed the safety and preliminary efficacy of setanaxib, an enzyme-driven hydrogen peroxide-depleting agent with anti-fibrotic properties, in patients with Alport syndrome. Patients were randomized 2:1 to receive oral setanaxib (2 different doses) or placebo, plus background therapy for 24 weeks. Setanaxib plus background therapy had an acceptable safety profile, with a trend towards urine protein-to-creatinine ratio reduction (suggesting a potential beneficial effect on kidney function). “We are pleased that the primary objective of the study, which was to explore setanaxib’s safety profile in patients with Alport syndrome, was achieved; however, further research is needed to investigate setanaxib’s clinical efficacy and

confirm its benefit/risk profile in a larger Alport syndrome patient population,” said corresponding author Daniel Gale, PhD, of University College London.

Safety and Preliminary Efficacy Findings from a Phase 2A Randomized, Double-Blind, Placebo-Controlled Trial of Setanaxib in Patients with Alport Syndrome

- The development of immunoglobulin (Ig) A nephropathy involves the production of pathogenic galactose-deficient IgA1, mediated by B-lymphocyte stimulator (BLyS) and a proliferation-inducing ligand (APRIL). In a phase 3 randomized study involving 318 participants in IgA nephropathy, telitacept—a novel dual inhibitor of BLyS and APRIL—resulted in a 55.0% placebo-adjusted reduction in proteinuria (excess albumin in the urine) and stabilized kidney function over the 39-week treatment period. “This efficacy ranks among the most potent observed to date in phase 2/3 trials of emerging therapies for IgA nephropathy,” said corresponding author Jicheng Lv, MD, of Peking University First Hospital. “The trial is scheduled to complete its 2-year follow-up in 2026, with subsequent publication of data on its impact on glomerular filtration rate slope.”

Efficacy and Safety of Telitacept in Patients with IgAN: Results from Stage A of a Phase 3 Clinical Study

- The REGENCY trial randomized adults with active lupus nephritis to placebo or obinutuzumab (a biologic that depletes immune B cells), plus standard therapy. Investigators asked participants if they would undergo a repeat kidney biopsy at the end of the trial, at around week 76, to see how well obinutuzumab resolved kidney inflammation compared with placebo. Biopsies were done in 64 patients, 32 who received obinutuzumab plus standard-of-care and 32 who received placebo plus standard-of-care. Significantly more patients in the obinutuzumab group cleared their kidneys of ongoing inflammation. Even more interesting, many more patients receiving obinutuzumab who did not achieve a clinically defined complete remission (full kidney function recovery) did in fact achieve a complete histologic response (no signs of disease in tissue samples) compared with placebo-treated individuals, suggesting the beneficial impact of obinutuzumab is greater than that indicated by the complete response rate. “Our next investigation will be to see how well obinutuzumab gets rid of B and antibody-producing cells in the kidneys,” said corresponding author Brad Rovin, MD, of The Ohio State University College of Medicine.

Beyond Clinical Response in the REGENCY Trial: The Impact of Obinutuzumab on Histologic Remission in Patients with Active Lupus Nephritis

- Primary membranous nephropathy is driven by autoreactive B immune cells that produce antibodies against podocyte antigens. MIL62 (obinutuzumab- β) is a monoclonal antibody therapy that targets CD20 expressed on B cells to help deplete these cells. In a phase 3 clinical trial, MIL62 was superior to cyclosporine in

achieving remission in patients with primary membranous nephropathy. Remission was also achieved faster with MIL62 than with cyclosporine. Furthermore, MIL62 helped preserve kidney function better than cyclosporine, with acceptable safety. “Next, we’ll follow patients longer and explore blood markers to predict who benefits most and when to fine-tune dosing,” said corresponding author Zhao Cui, MD, of Peking University First Hospital.

Efficacy and Safety of MIL62, a Glycoengineered Type II Anti-CD20 Antibody, in Primary Membranous Nephropathy: A Phase 3, Randomized, Controlled Trial

- Sibeprenlimab is an investigational monoclonal antibody designed to treat immunoglobulin (Ig) A nephropathy by blocking what’s known as a proliferation-inducing ligand (APRIL), a factor that promotes the production of pathogenic galactose-deficient IgA1. In a prespecified interim analysis of the phase 3 placebo-controlled VISIONARY trial, sibeprenlimab led to a reduction in the urine protein:creatinine ratio over 24 hours in patients with IgA nephropathy at 9 months. Investigators now have data through 12 months of treatment. They report that sibeprenlimab reduced proteinuria and biomarkers of IgA nephropathy and led to higher rates of hematuric/proteinuric remission up to 12 months, with favorable safety. Also, benefits were consistent across subgroups. VISIONARY is ongoing and will continue to evaluate sibeprenlimab’s safety and efficacy over 24 months. “The current results of the VISIONARY trial found that sibiprenlimab reduces proteinuria by more than half in people with high-risk IgA nephropathy after 12 months of follow up, with similar benefits observed in subgroups including people already receiving treatments like sodium-glucose co-transporter 2 inhibitors,” said corresponding author Vlado Perkovic, MD, of the University of New South Wales, in Australia. “These data suggest sibiprenlimab may have a strong protective effect on kidney function, which will be assessed in the final results due next year.”

Sibeprenlimab for the Treatment of IgAN: VISIONARY Phase 3 Interim and Prespecified Subgroup Analyses

Join ASN and approximately 12,000 other kidney professionals from across the globe at Kidney Week 2025 in Houston, TX. The world's premier nephrology meeting, Kidney Week, provides participants with exciting and challenging opportunities to exchange knowledge, learn the latest scientific and medical advances, and listen to engaging and provocative discussions with leading experts in the field. Early programs begin on November 5, followed by the Annual Meeting from November 6-9. Follow the conversation at #KidneyWk.

About the American Society of Nephrology (ASN)

Since 1966, ASN has been leading the fight to prevent, treat, and cure kidney diseases throughout the world by educating health professionals and scientists, advancing research and innovation, communicating new knowledge and advocating for the highest quality care for patients. ASN has nearly 22,000 members representing 141 countries. For more information, visit www.asn-online.org and follow us on [Facebook](#), [X](#), [LinkedIn](#), and [Instagram](#).

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