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PROMINENT: An Open-Label, Randomized Phase 3 Trial of Felzartamab in Primary Membranous Nephropathy

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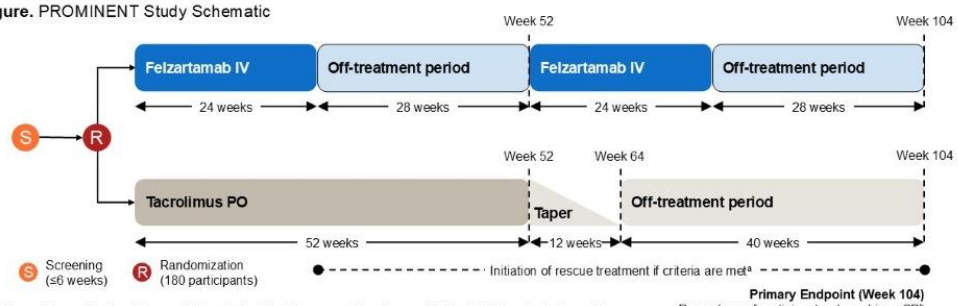
Objectives : Primary membranous nephropathy (PMN) is a rare autoimmune kidney disease in which pathogenic autoantibodies bind to podocyte antigens, resulting in the in-situ formation of subepithelial immune complexes and complement-mediated podocyte injury with damage to the glomerular filtration barrier leading to severe proteinuria and progressive decline in estimated glomerular filtration rate (eGFR) in a subset of patients. Felzartamab, a monoclonal antibody directed against CD38, selectively targets $CD38^+$ plasma cells and plasmablasts that produce pathogenic autoantibodies (eg, anti-phospholipase A2 receptor [PLA2R] autoantibodies). In Phase 2 studies, felzartamab reduced anti-PLA2R titers, improved proteinuria and serum albumin levels, and stabilized eGFR.
Methods : PROMINENT (NCT06962800) is an open-label, multicenter, randomized Phase 3 study in which 180 adults with newly diagnosed or relapsed biopsy-confirmed PMN in need of immunosuppressive therapy will be randomized to IV felzartamab or oral tacrolimus in protocol-specified dosing regimens. Both anti-PLA2R positive and negative participants are eligible; anti-PLA2R positive participants may be eligible without a biopsy. Participants must be on a stable, optimized dose of angiotensin-converting enzyme inhibitor or angiotensin receptor blocker, have an eGFR ≥30 mL/min/1.73 m^2, and a 24-hr urine protein-creatinine ratio of ≥3.0 g/g or total proteinuria ≥3.5 g/day after optimized supportive care for ≥3 months. The primary endpoint is the percentage of participants achieving complete clinical remission at 104 wks. Participants who experience worsening kidney function or proteinuria, relapse, or do not improve on assigned treatment can receive rescue treatment.
Results : Results will be provided at a later date.
Conclusions : PROMINENT is the first Phase 3 trial evaluating the targeting of $CD38^+$ plasma cells and plasmablasts in PMN to reduce proteinuria and preserve kidney function, which may address an unmet need in a disease with no approved therapies.

KSN 2026_PROMINENT (PMN) encore_Figure_04March2026.jpg

Figure. PROMINENT Study Schematic



ADA = anti-drug antibodies; CR = complete remission; IV = intravenous; PK = pharmacokinetics; PLA2R = phospholipase A2 receptor; PMN = primary membranous nephropathy; PRO = patient-reported outcome.
[a] Participants who show signs of worsening kidney function, worsening proteinuria, no improvement, or relapse of PMN based on protocol-specified rescue criteria will have the opportunity to receive rescue therapy and may stay in the study for up to 156 weeks. Participants initially randomized to receive felzartamab or tacrolimus who meet rescue criteria may receive rescue with regional standard of care immunosuppressive therapy per investigator discretion or felzartamab, respectively. [b] CR is defined as a decrease in urine protein levels to a low level, kidney function that remains stable, and improved serum albumin.

Primary Endpoint (Week 104)
Percentage of participants who achieve CR[b]

Secondary Endpoints (multiple time points)
Efficacy, safety, serum anti-PLA2R antibodies, PK/ADA, and PROs