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PREVAIL: A Phase 3 Trial of Felzartamab in Adults With IgA Nephropathy

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Objectives : IgA nephropathy (IgAN), the most common form of primary glomerulonephritis, involves accumulation of immune complexes in the glomerular mesangium, causing kidney injury and dysfunction. Felzartamab, a fully human IgG1 monoclonal antibody, selectively targets $CD38^+$ plasma cells and plasmablasts, the source of pathogenic antibodies that form immune complexes. In the Phase 2 IGNAZ study, felzartamab was generally well tolerated and led to a rapid and durable reduction in proteinuria and a slowing of estimated glomerular filtration rate (eGFR) decline, suggesting potential disease modification.
Methods : PREVAIL (NCT06935357) is a randomized, double-blind, placebo-controlled Phase 3 study. Approximately 454 adults with biopsy-confirmed IgAN will receive IV felzartamab or placebo over 24 weeks and be followed for an additional 80 weeks without treatment. Participants will be assigned to the main study (screening eGFR ≥30 mL/min/1.73 m^2) or exploratory cohort (screening eGFR ≥20 and <30 mL/min/1.73 m^2). Inclusion criteria include proteinuria of ≥1.0 g/day or 24-hr urine protein-creatinine ratio (UPCR) ≥0.8 g/g. Participants must be clinically stable on maximally tolerated angiotensin-converting enzyme inhibitor (ACEI) or angiotensin receptor blocker (ARB) for ≥12 weeks prior to screening. Concomitant stable doses over 12 weeks of sodium-glucose cotransporter-2 inhibitors, endothelin receptor antagonists, and/or mineralocorticoid receptor antagonists, or those intolerant of ACEi/ARBs are allowed. The primary endpoint is percent change from baseline in 24-hr UPCR at 36 weeks. The key secondary endpoint is change from baseline in eGFR at 104 weeks.
Results : Results will be provided at a later date.
Conclusions : PREVAIL is the first Phase 3 trial investigating $CD38^+$ targeting in IgAN. The results

will further inform on the safety and efficacy of this novel therapy with the potential to specifically target the pathogenic cellular drivers of IgAN and disease relevant antibody production.

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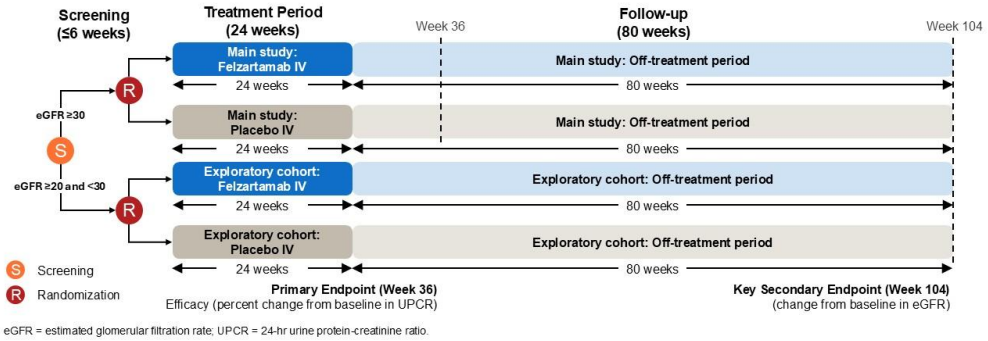
Figure. PREVAIL Study Schematic



eGFR = estimated glomerular filtration rate; UPCR = 24-hr urine protein-creatinine ratio.