

About RAINIER



RAINIER (pronounced “RAYN-eer”) (NCT06564142) is an ongoing global Phase 3 randomized, double-blind, placebo-controlled pivotal trial of povetacept 80 mg administered subcutaneously every 4 weeks vs placebo on top of standard of care in adults with immunoglobulin A nephropathy (IgAN).

A total of 605 patients were randomized in the trial, of which N=557 were randomized in the main cohort and N=48 in an exploratory cohort. The inclusion criteria were the same for both cohorts, except that the estimated glomerular filtration rate (eGFR) for the main cohort was ≥ 30 mL/min/1.73m², and for the exploratory cohort it was 20 to < 30 mL/min/1.73m².

The trial was designed to have a pre-planned interim analysis when a pre-specified number of patients complete 36 weeks of treatment. The interim analysis population included 199 patients, with 131 patients randomized to povetacept and 68 randomized to placebo. The main cohort, N=557, serves as the primary population for the assessment of safety.



Primary Endpoints

- Change from baseline in 24-hour urine protein-to-creatinine ratio (UPCR) at Week 36
- Total estimated eGFR slope through Week 104



Secondary Endpoints

- Change from baseline in serum galactose deficient IgA1 (Gd-IgA1) at Week 36
- Proportion of participants achieving hematuria resolution at Week 36 (among participants with hematuria at baseline)
- Change from baseline in eGFR at Week 104
- Time to kidney disease progression through Week 104, defined as greater than or equal to ($\geq$) 30% decline in eGFR, end stage kidney disease, or non-accidental death

About Povetacept

Povetacept is a dual antagonist of the BAFF (B cell activating factor) and APRIL (a proliferation-inducing ligand) cytokines, which play key roles in pathogenesis of multiple autoimmune diseases via their roles in the activation, differentiation and/or survival of B cells, T cells and innate immune cells.

Povetacept was previously studied in IgAN in RUBY-3, an ongoing, multiple-ascending dose, multi-cohort, open label, Phase 1/2 basket study.

Povetacept is an investigational product that has not been approved by any health authority. The safety and effectiveness of povetacept have not been established.