

STUDY

Obinutuzumab in patients with lupus nephritis: Post-hoc analyses of the phase II NOBILITY trial

Population: N = 125

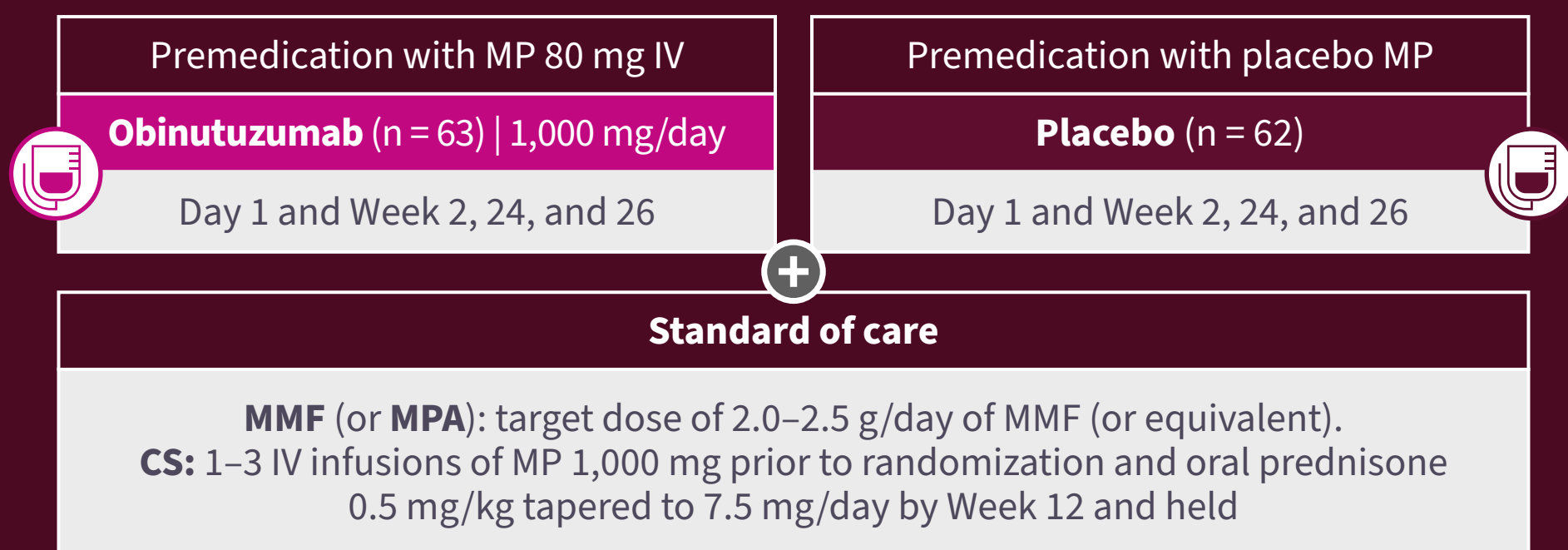
Endpoints: **Long-term kidney function**^{1,2}: Time to unfavorable kidney outcome, LN flare, and 30% and 40% eGFR decline; chronic eGFR slope; sustained eGFR decline; CRR with ≤ 7.5 mg/day prednisone
B-cell recovery³: Time to peripheral B-cell recovery after last dose of obinutuzumab; relationship between time to B-cell recovery and efficacy/safety

Obinutuzumab: (n = 63); mean age, 33.1 years; 87% women
Placebo: (n = 62); mean age, 31.9 years; 82% women

Eligibility: ISN/RPS Class III or IV (\pm V) LN by Bx within 6 months; UPCR >1 on 24-hour collection

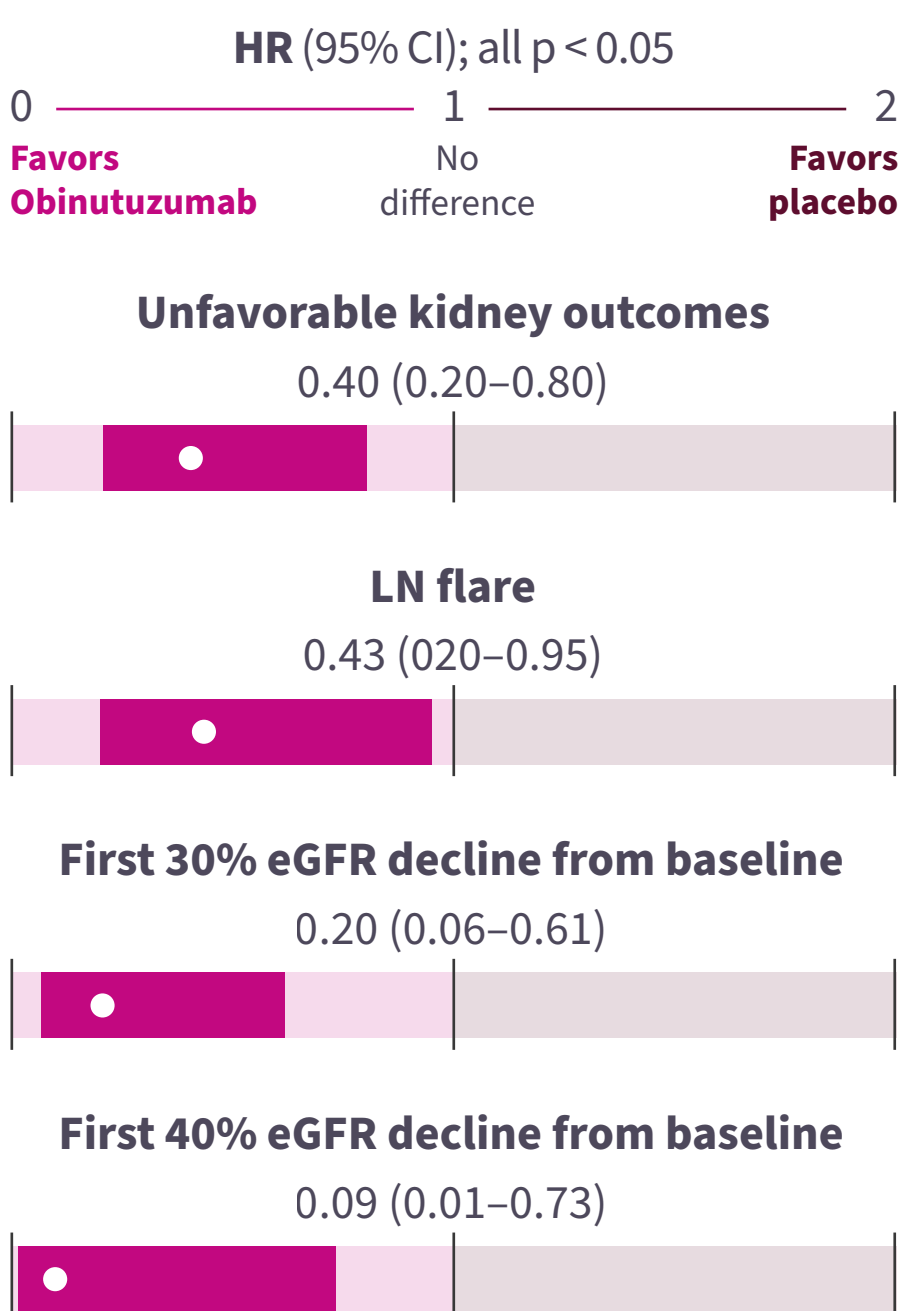
TRIAL DESIGN

Phase II multicenter, 1:1 randomized, 104-week double-blind placebo-controlled trial

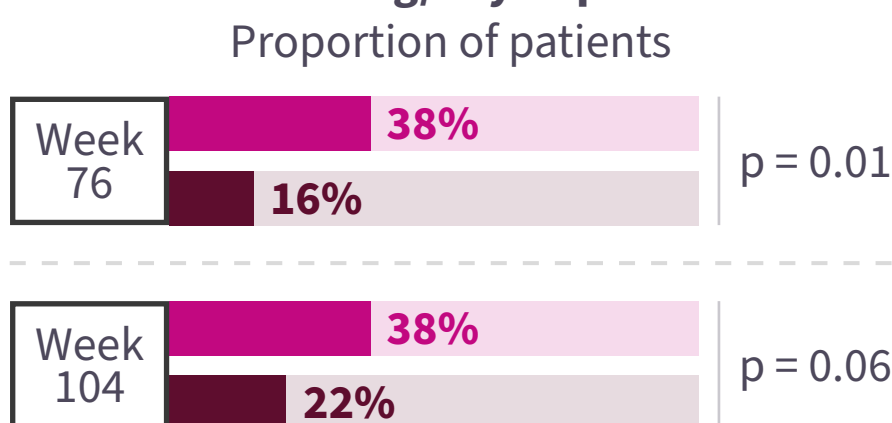


Obinutuzumab Placebo

KIDNEY OUTCOMES^{1,2}



CRR and ≤ 7.5 mg/day of prednisone*



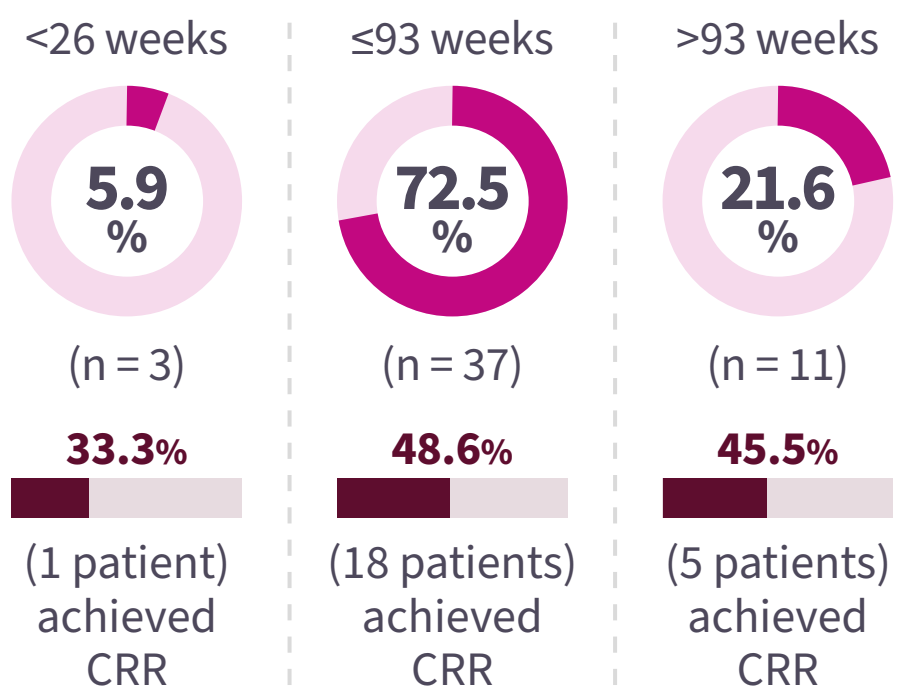
*At Week 76 and 104, ≤ 7.5 mg/day of prednisone was maintained from Week 64 to 76 and Week 92 to 104, respectively.

Sustained eGFR declines of 30% vs 40% were numerically lower in patients receiving obinutuzumab vs placebo. Obinutuzumab was associated with a significant difference in attenuation of eGFR slope decline compared with placebo (difference: 4.10 mL/min/1.73 m²/year; p = 0.043).

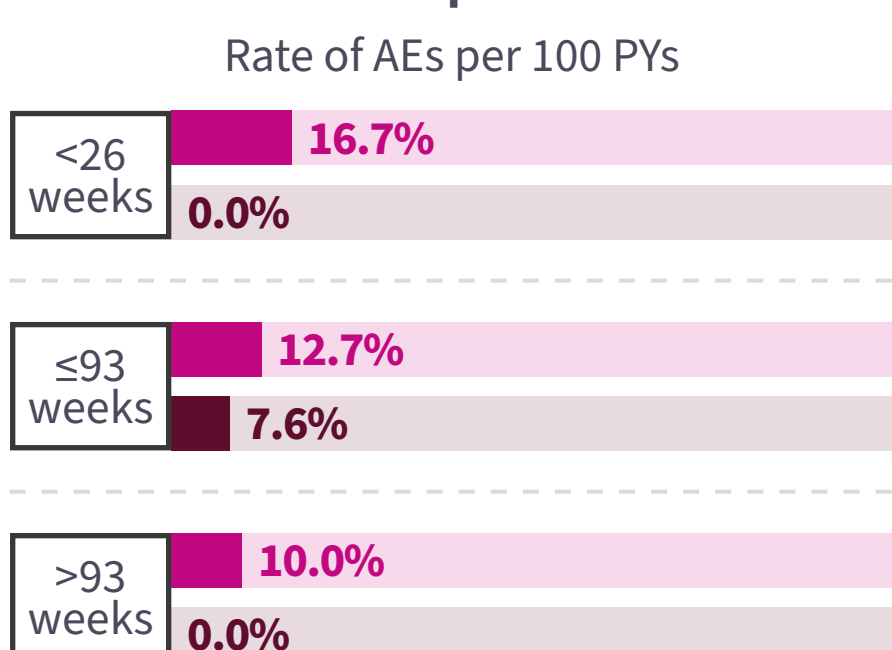
(N = 51)

B-CELL RECOVERY³

Time to B-cell recovery from the last obinutuzumab dose



SAEs SI Safety of obinutuzumab treated patients



Rate of SAEs and SIs appeared similar, irrespective of the duration of B-cell depletion.

Obinutuzumab was associated with improved long-term preservation of kidney function with steroid-sparing effects, with the majority of patients recovering B cells within 93 weeks of the last dose. The phase III REGENCY trial (NCT04221477) is currently ongoing.

Abbreviations: AE, adverse event; Bx, biopsy; CI, confidence interval; CRR, complete renal response; CS, corticosteroid; eGFR, estimated glomerular filtration rate; HR, hazard ratio; IV, intravenous; ISN, International Society of Nephrology; LN, lupus nephritis; MMF, mycophenolate mofetil; MP, methylprednisolone; MPA, mycophenolic acid; PY, patient-year; RPS, Renal Pathology Society; SAE, serious AE; SI, serious infection; UPCR, urine protein-to-creatinine ratio.

1. Rovin B, et al. *Arthritis Rheumatol.* 2023. Online ahead of print. DOI: 10.1002/art.42734
 2. Rovin B. Oral abstract #784. ACR Convergence 2023. Nov 12, 2023; San Diego, US.
 3. Vital E. Poster #1511. ACR Convergence 2023. Nov 10-15, 2023; San Diego US.