

# A Study to Evaluate the Efficacy, Safety, and Pharmacokinetics of Obinutuzumab in Adolescents With Active Class III or IV Lupus Nephritis and the Safety and PK of Obinutuzumab in Pediatric Participants

NCT05039619

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Status	RECRUITING
Phase	Phase 2
Sponsor	Hoffmann-La Roche
Enrollment	40 participants

## Key Eligibility Criteria

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### Inclusion (7)

- Participants who are age 12 to <18 years at the time of randomization
  - Participants who are age 5 to <12 years (younger participant cohort) at the time of randomization once recruitment is open. (Investigators will be notified by the Sponsor when recruitment is open to this younger population)
  - International Society of Nephrology and the Renal Pathology Society (ISN/RPS) 2003 Class III or IV active LN demonstrated on renal biopsy performed in the 12 months prior to or during screening
  - Class V disease may be present in addition to Class III or IV LN, but participants with isolated Class V disease are not eligible
  - Diagnosis of SLE according to the Systemic Lupus International Collaborating Clinics (SLICC) 2012 criteria
- ... and 2 more (see full listing online)

### Exclusion (12)

- Severe, active central nervous system (CNS) SLE, including retinitis, poorly controlled seizure disorder, acute confusional state, myelitis, stroke, cerebellar ataxia, or dementia
  - Sclerosis in >50% of glomeruli on renal biopsy
  - Purely chronic Class III(c) or Class IV(c) disease on renal biopsy, defined as the absence of any active lesions
  - Presence of rapidly progressive glomerulonephritis
  - Pure Class V LN
- ... and 7 more (see full listing online)

## Locations (42 total)

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Loma Linda University health, Loma Linda, California, United States  
UCSF Benioff Childrens Hospital, San Francisco, California, United States  
Children's Hospital Colorado, Anschutz Medical Campus, Aurora, Colorado, United States  
... and 39 more locations

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<https://clinicaltrials.gov/study/NCT05039619>

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