Safety, Efficacy and Tolerability of Ianalumab Versus Placebo, Combination With SoC Therapy, in Participants With Active Lupus Nephritis

NCT05126277

Status	RECRUITING
Phase	Phase 3
Sponsor	Novartis Pharmaceuticals
Enrollment	462 participants

Key Eligibility Criteria

Inclusion (6)

- Participants eligible for inclusion in this study must meet all of the following criteria:
- Adult male and female participants aged 18 years or older at the time of screening
- Weigh at least 35 kg at screening
- Have a confirmed clinical diagnosis of SLE according to European League Against Rheumatism/American College of Rheumatology (EULAR/ACR) Systemic Lupus Erythematosus (SLE) classification criteria
- Have a positive anti-nuclear antibody (ANA) test result; ANA titer e 1:80 at screening visit based on central or local laboratory result

... and 1 more (see full listing online)

Exclusion (37)

- UPCR e 1.0 g/g on 24h urine collection at Screening
- eGFR e 25mL/min/1.73 m2. Participants with eGFR \< 30 mL/min/1.73 m2 require renal biopsy during the screening period showing sclerosis in d 50% of glomeruli
- Newly diagnosed participants as well as pre-treated LN participants (including refractory cases) can be included, as long as they are currently on, or willing to initiate SoC induction therapy for LN using MPA
- Induction therapy, as defined by treatment including both high dose corticosteroids and MPA, should be initiated prior to or on day of randomization
- Anti-malarial treatment at stable dosing prior to randomization is strongly recommended, in the absence of contraindications

... and 32 more (see full listing online)

Locations (188 total)

University Of Alabama, Birmingham, Alabama, United States
Advanced Medical Research, La Palma, California, United States
Wallace Rheumatic Study Center, Los Angeles, California, United States
... and 185 more locations