Study of Efficacy and Safety of LNP023 in Participants With Active Lupus Nephritis Class III-IV, +/- V

Status: RECRUITING

Eligibility Criteria

Age: 18 years to 100 years old

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

Unequivocally positive ANA test result and/or a positive anti dsDNA at screening Active biopsy-proven lupus nephritis within 3 months of screening demonstrating Class III or IV lupus nephritis with or without co-existing features of Class V lupus nephritis. Documentation of active renal disease at the time of screening necessitating the commencement of therapy with corticosteroids in combination with MMF/MPS. eGFR ≥ 30 ml/min/1.73 m2 Vaccination against Neisseria meningitidis and Streptococcus pneumoniae infections Vaccination against Haemophilus influenzae infection Supportive care including stable dose regimen of anti-malarials (e.g. hydroxychloroquine) unless contraindicated, ACEi or ARB at either locally approved maximal daily dose or the maximally tolerated dose (per investigators' judgement) at screening, as per the local clinical practice. Doses should remain stable throughout the study. First presentation or flare of lupus nephritis.

Exclusion Criteria:

Induction treatment with cyclophosphamide within 3 months of planned treatment for this study; treatment with calcineurin inhibitors within the previous 3 months prior to randomization. Presence of rapidly progressive glomerulonephritis (RPGN) as defined by 50% decline in eGFR within 3 months prior to screening. Renal biopsy presenting with interstitial fibrosis/tubular atrophy (IF/TA) or glomerulosclerosis of more than 50%, or which in the opinion of the investigator is such that it precludes likely response to immunosuppressive therapy. Participants being treated with systemic corticosteroids (\>5 mg/day prednisone or equivalent) for indications other than SLE or LN e.g. acute asthma, inflammatory bowel disease. Participants being treated with systemic corticosteroids for SLE or LN will be excluded if they have taken more than an average of 15 mg/day prednisone (or equivalent) in the previous 4 weeks and more than an average of 30 mg/day in the previous 1 week Receipt of more than a total dose of 1000 mg equivalent i.v. pulse methylprednisolone (cumulative dose) within 2 weeks prior to enrollment (and at enrollment) Other protocol-defined inclusion/exclusion criteria may apply

Conditions & Interventions

Interventions:
DRUG: Iptacopan (part 1), DRUG: Iptacopan (part 2), DRUG: Placebo + standard of care, DRUG: Iptacopan + placebo
Conditions:
Lupus Nephritis
Keywords:
LNP023, Iptacopan, Lupus Nephritis, proteinuria, Urine Protein-to-Creatinine Ratio, complete renal response, estimated glomerular filtration rate, renal flares, Systemic Lupus Erythematosus

More Information

Contact(s): Novartis Pharmaceuticals - novartis.email@novartis.com
Principal Investigator:
Phase: PHASE2
IRB
Number:
System ID: NCT05268289
