Study of Efficacy and Safety of Iptacopan in Patients With C3 Glomerulopathy.

Last Update: Mar 04, 2025
A Multicenter, Randomized, Double-blind, Parallel Group, Placebo-controlled Study to Evaluate the Efficacy and Safety of Iptacopan (LNP023) in Complement 3 Glomerulopathy.
ClinicalTrials.gov Identifier:
NCT04817618
Novartis Reference Number:CLNP023B12301
See if you Pre-qualify
All compounds are either investigational or being studied for (a) new use(s). Efficacy and safety have not been established. There is no guarantee that they will become commercially available for the use(s) under investigation.

Study Description

The Primary Completion Date and Study Completion Date have been updated to reflect completion of the adolescent cohort, which has been added to the protocol.

The study is designed as a multicenter, randomized, double-blind, parallel group, placebo-controlled study to evaluate the efficacy and safety of iptacopan (LNP023) in complement 3 glomerulopathy. The purpose of this study is to evaluate the efficacy and safety of iptacopan compared to placebo and standard of care in patients with native C3G. CLNP023B12301 is a Phase 3 pivotal trial for registration of iptacopan in C3G. The study aims to determine the reduction in UPCR and improvement in eGFR in participants treated with iptacopan compared to placebo, as well as the proportion of participants who achieve a composite renal endpoint consisting of eGFR and UPCR elements. These effects of iptacopan in conjunction with increases in serum C3 levels will provide support for an iptacopan profile that includes stabilization of eGFR, clinically meaningful reductions in proteinuria and inhibition of the complement AP. Kidney biopsies will be performed in adult participants to evaluate histopathological improvements in immunofluorescence and light microscopy that support these functional benefits of iptacopan.

Condition
C3G
Phase
Phase3
Overall Status
Recruiting
Number of Participants
98
Start Date
Jul 28, 2021
Completion Date
Jul 04, 2026
Gender

All
Age(s)
12 Years - 60 Years (Child, Adult)

Interventions

Drug

iptacopan

iptacopan 200 mg b.i.d. (Adults 200mg b.i.d; Adolescents 2x 100mg b.i.d)
Drug

Placebo

Placebo to iptacopan 200mg b.i.d. (Adults 200mg b.i.d; Adolescents 2x 100mg b.i.d)

Eligibility Criteria

Inclusion Criteria:

* Male and female participants age ≥ 12 and ≤ 60 years at screening.
* Diagnosis of C3G as confirmed by renal biopsy within 12 months prior to enrollment in adults and within 3 years in adolescents.
* Prior to randomization, all participants must have been on a maximally recommended or tolerated dose of an angiotensin converting enzyme inhibitor (ACEI) or angiotensin receptor blocker (ARB) for at least 90 days. The doses of other antiproteinuric medications including mycophenolic acid, corticosteroids and mineralocorticoid receptor antagonists should be stable for at least 90 days prior to randomization.
* Reduced serum C3 (defined as less than 0.85 x lower limit of the central laboratory normal range) at Screening.
* UPCR ≥ 1.0 g/g sampled from the first morning void urine sample at Day -75 and Day -15.
* Estimated GFR (using the CKD-EPI formula for ages ≥ 18 years and modified Schwartz formula for ages 12 to 17 years) or measured GFR ≥ 30 ml/min/1.73m2 at screening and Day -15.
* Mandatory vaccination against Neisseria meningitidis and Streptococcus pneumoniae prior to the start of study treatment.
* If not previously vaccinated or if a booster is required, vaccination against Haemophilus influenzae infections should be given, if available and according to local regulations, at least 2 weeks prior to the first study treatment administration. If study treatment has to start earlier than 2 weeks post vaccination, prophylactic antibiotic treatment should be initiated.

Exclusion Criteria:

* Participants who have received any cell or organ transplantation, including a kidney transplantation.
* Rapidly progressive crescentic glomerulonephritis defined as a 50% decline in the eGFR within 3 months with renal biopsy findings of glomerular crescent formation seen in at least 50% of glomeruli.
* Renal biopsy showing interstitial fibrosis/tubular atrophy (IF/TA) of more than 50%
* Monoclonal gammopathy of undetermined significance (MGUS) confirmed by the measurement of serum free light chains or other investigation as per local standard of care.
* Participants with an active systemic bacterial, viral or fungal infection within 14 days prior to study treatment

administration
* The presence of fever ≥ 38°C (100.4°F) within 7 days prior to study treatment administration.
* A history of recurrent invasive infections caused by encapsulated organisms, e.g., N. meningitidis and S. pneumoniae.
* The use of inhibitors of complement factors (e.g., Factor B, Factor D, C3 inhibitors, anti C5 antibodies, C5a receptor antagonists) within 6 months prior to the Screening visit.
* The use of immunosuppressants (except mycophenolic acids), cyclophosphamide or systemic corticosteroids at a dose \>7.5 mg/day (or equivalent for a similar medication) within 90 days of study drug administration.
* Acute post-infectious glomerulonephritis at screening based upon the opinion of the investigator.

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