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Long-term Efficacy, Safety and Tolerability of Iptacopan in C3G or IC-MPGN

Last Update: Jun 30, 2025

An Open-label, Non-randomized Extension Study to Evaluate the Long-term Efficacy, Safety and Tolerability of Iptacopan (LNP023) in C3 Glomerulopathy or Idiopathic Immune-complex-membranoproliferative Glomerulonephritis

ClinicalTrials.gov Identifier:
NCT03955445

Novartis Reference Number:CLNP023B12001B

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

This is an open-label extension study to evaluate the long-term efficacy, safety and tolerability of iptacopan in subjects with C3 glomerulopathy or idiopathic immune-complex-membranoproliferative glomerulonephritis The primary purpose of this extension study is to collect long-term efficacy, safety and tolerability data in eligible participants receiving open-label iptacopan after completing treatment in the C3G Phase 2 proof of concept study CLNP023X2202.

The primary (at 9 months) and longer-term (\>9 months) efficacy and safety data of iptacopan collected from CLNP023X2202 participants will be used to support health authority submissions.

This umbrella protocol will also allow:

* continued access to iptacopan to patients enrolled in the ongoing Phase 3 programs (C3G and IC-MPGN)
* C3G study (CLNP023B12301): adults and adolescents
* IC-MPGN study (CLNP023B12302): adults and adolescents
* provision of additional efficacy and safety information following longer-term treatment in C3G and IC-MPGN populations to support health authority submissions.

Efficacy and safety assessments at the 9 month visit of this extension study in combination with data from CLNP023X2202 (baseline plus 3 months of treatment) allowed evaluation of the effects of iptacopan on potential endpoint(s) at 12 months of iptacopan treatment in C3G participants. The enrollment of C3G and IC-MPGN participants (adults and adolescents) from Phase 3 studies, CLNP023B12301 and CLNP023B12302, permits longer-term evaluation of the persistence of effects observed after iptacopan treatment. These longer term efficacy and safety assessments may be compared to historical/concurrent control data available from relevant real world databases in C3G or IC-MPGN patients and used as supportive information for registration purposes.

This extension study is expected to continue until the drug product becomes commercially available and accessible (anticipated to be up to approximately 168 months from the first patient first visit date), or the

benefit-risk profile is no longer positive, or the program is discontinued for business or strategic reasons.

"Baseline" refers to the Day 1 visit (pre-dose) of CLNP023X2202, CLNP023B12301 or CLNP023B12302, whereas the Day 1 visit for this C3G/IC-MPGN extension study (CLNP023B12001B) is identified as "Extension Day 1".

Condition
C3 Glomerulopathy, Immune-complex-membranoproliferative Glomerulonephritis
Phase
Phase3
Overall Status
Recruiting
Number of Participants
225
Start Date
Oct 03, 2019
Completion Date
May 30, 2036
Gender
All
Age(s)
12 Years - 100 Years (Child, Adult, Older Adult)

Interventions

Drug

LNP023

LNP023 capsules

Eligibility Criteria

Inclusion Criteria:

- Patients must have completed the treatment period of the CLNP023X2202, CLNP023B12301 or CLNP023B12302 study on study drug

Exclusion Criteria:

* Severe concurrent co-morbidities, e.g. advanced cardiac disease (NYHA class IV), severe pulmonary arterial hypertension (WHO class IV), or any illness or medical condition that in the opinion of the investigator and sponsor is likely to prevent the patient from safely tolerating LNP023 or complying with the requirements of the study
* Participants with an active systemic bacterial, viral or fungal infection within 14 days prior to screening, or the presence of fever ≥ 38oC (100.4oF) within 7 days prior to screening.
* History or current diagnosis of ECG abnormalities indicating significant risk of safety for subjects
* History of HIV or any other immunodeficiency disease

Other protocol-defined inclusion/exclusion criteria may apply

Argentina

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Recruiting

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