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A Rollover Extension Program (REP) to Evaluate the Long-term Safety and Tolerability of Open Label Iptacopan/LNP023 in Participants With Primary IgA Nephropathy

Last Update: Apr 23, 2025
A Multicenter Rollover Extension Program (REP) to Evaluate the Long-term Safety and Tolerability of Open Label Iptacopan in Adult Participants With Primary IgA Nephropathy Who Have Completed Study CLNP023X2203 or CLNP023A2301
ClinicalTrials.gov Identifier:
NCT04557462
Novartis Reference Number:CLNP023A2002B
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 purpose of this study is to evaluate the long-term safety and tolerability, of open label iptacopan in primary IgA nephropathy participants who have completed either the CLNP023X2203 or CLNP023A2301 clinical trials. The open-label design of the current study is appropriate to provide study participants the opportunity to receive treatment with iptacopan until marketing authorizations are received and the drug product becomes commercially available while enabling collection of long-term safety and tolerability data for the investigational drug. Furthermore efficacy assessments conducted every 6 months will afford the opportunity to evaluate the clinical effects of iptacopan on long-term disease progression. This is an open-label, non-randomized, multicenter roll-over extension program (REP) to:

* CLNP023X2203, a Phase II trial investigating the dose ranging effects of LNP023 on efficacy, pharmacokinetics (PK), pharmacodynamics (PD), safety and tolerability in primary IgAN patients, and
* CLNP023A2301, a Phase III trial, investigating the efficacy, pharmacokinetics (PK), pharmacodynamics (PD), safety and tolerability of LNP023 in patients with primary IgAN.

Subjects completing the CLNP023X2203 and CLNP023A2301 trials on study drug, who want to continue treatment and who meet the inclusion/exclusion requirements of the roll over extension program, will have the opportunity to receive iptacopan until:

* 3 years from LPFV of this study CLNP023A2002B, or
* the participant no longer derives benefit from iptacopan according to the Investigator, or
* the benefit-risk profile of the product in IgAN is no longer positive, or
* initiation of maintenance hemodialysis, kidney transplantation or eGFR \< 15 mL/min/1.73m2 , or
* the product becomes commercially available in a specific country following product launch and subsequent reimbursement for IgAN, where applicable, or

* if a marketing application or reimbursement of an investigational product is rejected/not pursued in a region/country for the indication under study or which ever is sooner

Condition
Primary IgA Nephropathy
Phase
Phase3
Overall Status
Recruiting
Number of Participants
540
Start Date
Sep 20, 2021
Completion Date
Nov 11, 2032
Gender
All
Age(s)
18 Years - 100 Years (Adult, Older Adult)

Interventions

Drug

LNP023

Capsule 200 mg (b.i.d.) taken orally twice a day

Eligibility Criteria

Inclusion Criteria:

* For LNP023X2203, participants must have completed part 1 or part 2 of the trial. For LNP023A2301, participants must have completed the entire core trial defined as the full 24 month treatment period.
* eGFR* ≥ 20 ml/min/1.73m2

*eGFR calculated using the CKD-EPI formula (or modified MDRD formula according to specific ethnic groups and local practice guidelines)
* Per investigator's clinical judgement, the participant may benefit from receiving the open-label treatment of iptacopan 200 mg b.i.d.
* Prior Vaccination against Neisseria meningitidis, Streptococcus pneumoniae and Haemophilus influenzae infections should be up to date (i.e. any boosters required administered according to local regulations.
* All participants must be on supportive care regimen of ACEi or ARB* as per KDIGO guidelines.

* participants who are not taking KDIGO guideline doses because they have documented allergies or intolerance to ACEi and ARB are eligible for the study

Exclusion Criteria:

* participants who screen or baseline failed in the CLNP023X2203 Part 1 or Part 2, or CLNP023A2301 studies

or who prematurely withdrew from either study for any reason.
* Evidence of severe urinary obstruction or difficulty in voiding; any urinary tract disorder other than IgAN at screening and before dosing with LNP023.
* Current (within 4 weeks of study drug administration in the REP) acute kidney injury (AKI)
* Presence of Rapidly Progressive Glomerulonephritis (RPGN) as defined by 50% decline in eGFR within the last 3 months.
* Participants treated with immunosuppressive or other immunmodulatory agents such as but not limited to cyclophosphamide, rituximab, infliximab, eculizumab, canakinumab, mycophenolate mofetil (MMF) or mycophenolate sodium (MPS), cyclosporine, tacrolimus, sirolimus, everolimus and/or systemic corticosteroids exposure (\>7.5 mg/d prednisone/prednisolone equivalent) within 5 half-lives of respective medication or 90 days prior to first study drug administration, whichever is shorter. Rituximab requires 180 days wash out.
* Use of other investigational drugs at the time of enrolment, or within 5 half-lives of enrolment or within 30 days whichever is longer.
* History of recurrent invasive infections caused by encapsulated organisms, such as meningococcus and pneumococcus.

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