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Study of Efficacy and Safety of Iptacopan in Participants With IC-MPGN

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A Multicenter, Randomized, Double-blind, Parallel Group, Placebo-controlled Study to Evaluate the Efficacy and Safety of Iptacopan (LNP023) in Idiopathic Immune-complex-mediated Membranoproliferative Glomerulonephritis (IC-MPGN)

ClinicalTrials.gov Identifier:
NCT05755386

Novartis Reference Number:CLNP023B12302

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 study is designed as a multicenter, randomized, double-blind, parallel group, placebo-controlled study to evaluate the efficacy and safety of iptacopan (LNP023) in idiopathic immune complex mediated membranoproliferative glomerulonephritis. The purpose of this Phase III study is to evaluate the efficacy and safety of iptacopan compared to placebo (both administered in combination with standard of care) in participants (adults and adolescents aged 12-17 years) with idiopathic IC-MPGN. The study aims to demonstrate a reduction in proteinuria and improvement in estimated glomerular filtration rate (eGFR) in participants treated with iptacopan compared to placebo. Change in patient-reported fatigue will also be evaluated. Alternative complement pathway (AP) dysregulation is believed to underlie the clinical manifestations and progression of IC-MPGN. Upon completion of study treatment, participants will have the option to discontinue iptacopan treatment and enter a 30 day safety follow-up or continue iptacopan treatment by transitioning to an open label extension study (CLNP023B12001B; NCT03955445) and continue iptacopan treatment.

Condition
IC-MPGN
Phase
Phase3
Overall Status
Recruiting
Number of Participants
106
Start Date
Oct 02, 2023
Completion Date
May 29, 2029
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 patients including adults (aged at least 18 years to ≤ 60 years) and adolescents (12 -17 years in non-EU countries at screening and 16-17 years in EU countries at screening).
* Diagnosis of idiopathic IC-MPGN as confirmed by kidney biopsy within 12 months prior to screening in adults and within 3 years of screening in adolescents (a biopsy report, review and confirmation by the Investigator is required). If such a biopsy is not available in an adult participant, this must be obtained at screening (performed and assessed locally for adults only).
* Prior to randomization, all participants must have been on a maximally recommended or tolerated dose of renin angiotensin system inhibitors (RASi), e.g an ACEi or ARB for at least 90 days (or as according to local guidelines). The doses of other drugs administered to reduce proteinuria and control the disease including mycophenolic acids (MPAs - mycophenolate mofetil or mycophenolate sodium), corticosteroids, SGLT2 inhibitors and mineralocorticoid receptor antagonists should be stable for at least 90 days prior to randomization
* UPCR ≥ 1.0 g/g (≥ 113 mg/mmol) sampled from the first morning void urine sample at Day -75 and Day -15
* Estimated GFR (using the chronic kidney disease \[CKD\]-EPI formula for adult participants and modified Schwartz formula for adolescents aged 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 infection prior to the start of study treatment. If the participant has not been previously vaccinated, or if a booster is required, the vaccine should be given according to local regulations at least 2 weeks prior to the first administration of study treatment. If the study treatment has to start earlier than 2 weeks post vaccination, prophylactic antibiotic treatment should be initiated in accordance with local standard of care.
* 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.

Exclusion Criteria:

* Participants who have undergone cell or solid organ transplantation, including kidney transplantation.
* Participants diagnosed with secondary IC-MPGN including but not limited to any of the following conditions:

* Deposition of antigen-antibody immune complexes as a result of any chronic infections, including

* Hepatitis C virus (HCV) including HCV-associated mixed cryoglobulinemia, hepatitis B virus (HBV);
* Bacterial-endocarditis, infected ventriculo-atrial shunt, visceral abscesses, leprosy, meningococcal meningitis; chronic bacterial infections
* Protozoa/other infections- malaria, schistosomiasis, mycoplasma, leishmaniasis, filariasis, histroplasmosis

Renal deposition of immune complexes as a result of a systemic autoimmune disease:

* Systemic lupus erythematosus (SLE)
* Sjögren syndrome
* Rheumatoid arthritis
* Mixed connective tissue disease Deposition of monoclonal immunoglobulins because of a monoclonal gammopathy due to plasma cell or B cell disorders. Monoclonal gammopathy of undetermined significance (MGUS) confirmed by the measurement of serum free light chains or other investigation as per local standard of care.

Fibrillary glomerulonephritis

* Rapidly progressive crescentic glomerulonephritis defined as a 50% decline in the eGFR within 3 months with kidney biopsy findings of glomerular crescent formation seen in at least 50% of glomeruli on the most recent biopsy.
* Kidney biopsy showing interstitial fibrosis/tubular atrophy (IF/TA) of more than 50%.
* Participants with an active systemic bacterial, viral or fungal infection within 14 days prior to study treatment administration or 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., Neisseria meningitidis and Streptococcus pneumoniae.
* The use of inhibitors of complement factors (e.g., Factor B, Factor D, complement 3 (C3) inhibitors, anti-Complement 5 (C5) antibodies, C5a receptor antagonists) within 3 months or 5 half-lives prior to the Screening visit.
* The use of immunosuppressants (except MPAs), cyclophosphamide or systemic corticosteroids at a dose \>7.5 mg/day (or equivalent for a similar corticosteroid medication) within 90 days of study drug administration.
* The use of MPAs is not permitted within 90 days prior to randomization in India, as per the local health authority requirement.
* Acute post-infectious glomerulonephritis at screening, based upon the opinion of the investigator.
* Body mass index (BMI) \>38 kg/m2 at screening and randomization. Body weight \<35 kg at screening and randomization

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