A Masked, Placebo-controlled Study to Assess Iptacopan in Age-related Macular Degeneration

Last Update: Jun 25, 2024
A Randomized, Participant and Investigator Masked, Placebo-controlled, Multicenter, Proof-of-concept Study to Assess the Safety and Efficacy of LNP023 (Iptacopan) in Patients With Early and Intermediate Age-related Macular Degeneration
ClinicalTrials.gov Identifier:
NCT05230537
Novartis Reference Number:CLNP023E12201
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 assess the effect of Iptacopan to prevent conversion of early or intermediate age-related macular degeneration (AMD) eyes to new incomplete retinal pigment epithelium and outer retinal atrophy (iRORA) or late AMD. This is a multicenter, randomized, participant and investigator masked, placebo controlled, proof-of-concept study to assess the safety and efficacy of Iptacopan (LNP023) in participants with early to intermediate age-related macular degeneration in one eye and neovascular age-related macular degeneration in the other eye. All enrolled participants must have early/intermediate AMD in one eye, with at least one high risk optical coherence tomography (OCT) feature (study eye) and neovascular AMD in the other eye (fellow eye).

Participants who meet all of the eligibility criteria will be randomized at the Baseline/Day 1 visit in a 1:1 ratio into one of two treatment arms:

* Iptacopan (LNP023) oral capsules
* Placebo oral capsules Approximately 146 participants (73 per arm) will be treated worldwide.

Condition
Age-Related Macular Degeneration
Phase
Phase2
Overall Status
Recruiting
Number of Participants
146
Start Date
Feb 17, 2022
Completion Date
Oct 12, 2026

Gender
All
Age(s)
50 Years - (Adult, Older Adult)

Interventions

Drug

Iptacopan (LNP023)

oral capsules
Drug

Placebo

oral capsules

Eligibility Criteria

Inclusion Criteria:

* Male or female participants ≥ 50 years of age
* Diagnosis of early or intermediate age-related macular degeneration (AMD) in the study eye as determined by the investigator on fundus examination
* Study eye (early/intermediate AMD eye) must have at least one high risk optical coherence tomography (OCT) feature (as defined by a central reading center).
* Diagnosis of neovascular AMD (nAMD) in the fellow eye as determined by the investigator.
* Vaccination against Neisseria meningitidis and Streptococcus pneumoniae infection are required prior to the start of the treatment with LNP023.
* If not received previously, vaccination against Haemophilius influenzae infection should be given, if available and according to local regulations.

Exclusion Criteria:

* History or current diagnosis of ECG abnormalities indicating significant safety risk, such as clinically significant cardiac arrhythmias, e.g., sustained ventricular tachycardia and clinically significant second or third degree atrioventricular block (AV block) without a pacemaker.
* History of familial long QT syndrome or known family history of Torsades de Pointes
* History of stroke or myocardial infarction during the 6-month period prior to Baseline/Day 1, any current clinically significant arrhythmias, or any advanced cardiac or severe pulmonary hypertension
* History of end stage kidney disease requiring dialysis or renal transplant
* History of malignancy of any organ system
* History of solid organ or bone marrow transplantation
* History of recurrent meningitis or history of meningococcal infections despite vaccination
* History of immunodeficiency diseases, including a positive Human Immunodeficiency Virus test result at Screening
* Active Hepatitis B (HBV) or Hepatitis C (HCV) infection
* History of hypersensitivity to any of the study treatments or excipients or to drugs of similar chemical classes

or clinically relevant sensitivity to fluorescein dye as assessed by the Investigator.
* Evidence of cRORA or exMNV in the study eye based on multimodal imaging as determined by the central reading center.
* Participants who have current active TB as evidenced by clinical, radiographic and laboratory tests.

United Kingdom

Novartis Investigative Site

Recruiting

Gloucester,Gl1 3nn,United Kingdom

Worldwide Contacts

If the location of your choosing does not feature any contact detail, please reach out using the information below.

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