Evaluate Long-term Safety, Tolerability and Efficacy of Iptacopan in Study Participants With aHUS

Last Update: Apr 06, 2025
A Multi-center, Single Arm, Open-label Extension Study to Evaluate the Long-term Safety, Tolerability and Efficacy of Iptacopan in Participants With Atypical Hemolytic Uremic Syndrome (aHUS) Who Have Completed a Preceding Iptacopan Phase 3 Study in aHUS
ClinicalTrials.gov Identifier:
NCT05795140
Novartis Reference Number:CLNP023F12001B
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 a multicenter, single arm, open-label, extension study to evaluate the long-term safety, tolerability, and efficacy of iptacopan in participants with aHUS. The extension study Baseline/Day 1 visit is equivalent to the End of Treatment visit of the parent study. The study will begin on Day 1 followed by on-site visits every 4 months during the study treatment period. A Safety Follow Up tele-visit must be conducted 7 days after last study treatment to collect information on Adverse Events.

Condition
Atypical Hemolytic Uremic Syndrome
Phase
Phase3
Overall Status
Recruiting
Number of Participants
125
Start Date
May 08, 2024
Completion Date
Jan 03, 2033
Gender
All
Age(s)
18 Years - 100 Years (Adult, Older Adult)

Interventions

Drug

Iptcaopan 200 mg

Open label, participant specific kits, hard gelatin capsules to be taken twice a day

Eligibility Criteria

Inclusion Criteria:

1. Signed informed consent must be obtained prior to participation in the open label extension study
2. Willing and able to comply with the study Schedule of Activities
3. Participants who have completed the full study treatment period of any prior "Novartis sponsored" iptacopan Phase 3 clinical trial in aHUS, are still on iptacopan study treatment and derive benefit from it as per Investigator's judgement
4. Prior vaccinations against Neisseria meningitidis, Streptococcus pneumoniae and Haemophilus influenzae infections should be up to date (i.e., any boosters required should be administered according to local guidelines)

Exclusion Criteria:

1. Concomitant treatment with any complement inhibitor as well as concomitant treatment with any of the prohibited drugs
2. Any comorbidity or medical condition (including but not limited to any active systemic bacterial, viral or fungal infection or malignancy) that, in the opinion of the Investigator could put the participant at risk
3. Active infection or history of recurrent invasive infections caused by encapsulated bacteria such as Neisseria meningitidis, Streptococcus pneumoniae or Haemophilus influenzae
4. History of hypersensitivity to iptacopan or its excipients or to drugs of similar chemical classes
5. Pregnant or nursing (lactating) women
6. Women of child-bearing potential, defined as all women physiologically capable of becoming pregnant, unless they are using effective methods of contraception during dosing of investigational drug and for 1 week after stopping of investigational drug.

Other protocol-defined inclusion/exclusion criteria may apply.

Brazil

Novartis Investigative Site

Recruiting

Sao Paulo,SP,05403 000,Brazil

China

Novartis Investigative Site

Recruiting

Beijing,100034,China

Czechia

Novartis Investigative Site

Recruiting

Ostrava,Poruba,708 52,Czechia

India

Novartis Investigative Site

Recruiting

Nagpur,Maharashtra,440015,India

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Recruiting

Pune,Maharashtra,411011,India

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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Source URL: *https://prod1.novartis.com/clinicaltrials/study/nct05795140*

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