Study Assessing the Efficacy and Safety of a Personalized Monotherapy Regimen of Brolucizumab in Patients With Symptomatic Macular Polypoidal Choroidal Vasculopathy

Last Update: Apr 17, 2024
A 60-week, Phase IIIb, Randomized, Multi-center Study Assessing the Efficacy and Safety of a Personalized Monotherapy Regimen of Brolucizumab in Patients With Symptomatic Macular Polypoidal Choroidal Vasculopathy (PROUD Study)
ClinicalTrials.gov Identifier:
NCT05666804
Novartis Reference Number:CRTH258AKR03
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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 a 60-week, two-arm, randomized, open-label, active-controlled, multi-center study in patients with Polypoidal choroidal vasculopathy (PCV) who have not previously received anti-Vascular endothelial growth factor (VEGF) treatment. The purpose of this study is to measure the change in Best-corrected visual acuity (BCVA) with brolucizumab 6 mg Personalized regimen compared with Brolucizumab 6 mg Standard q12w/q8w regimen in participants with Polypoidal choroidal vasculopathy (PCV).

* The study duration will be up to 60 weeks.
* The treatment duration will be up to 56 weeks.
* The visit frequency is not fixed and may be reduced or extended depending on whether disease activity is controlled.

In the Personalized regimen arm, the first loading injection will be performed for all participants. After 4 weeks, treatment response will be judged. If there is no disease activity, injection interval will be extended to 8 weeks. The participants with presence of disease activity will continue 4-week loading injections up to 3 monthly loading dose and commence the Treat-and-extend (T\&E) phase thereafter. In the T\&E phase, the treatment interval can be extended by 4 weeks at a time based on Investigator's judgment of visual and/or anatomic outcomes. The maximal treatment interval is 16 weeks. At the Investigator's discretion, a participant with no disease activity or improvement of disease activity (e.g., reduction of fluid) may also be maintained on the same interval. If disease activity recurs, the interval should be shortened by 4 weeks at a time or to a minimal interval of 8 weeks.

In the Standard q12w/q8w regimen arm, all participants will receive three loading injections every 4 weeks. After loading injection, participants with no disease activity at Week 16 will receive study treatment q12w at Week 20, Week 32, and Week 44. If there is disease activity at any scheduled treatment visit, the study

intervals will be adjusted to 8 weeks thereafter. Treatment intervals can be increased to 12 weeks after a treatment visit with no disease activity.

Condition
Macular Polypoidal Choroidal Vasculopathy (PCV)
Phase
Phase3
Overall Status
Recruiting
Number of Participants
160
Start Date
Feb 06, 2023
Completion Date
Sep 30, 2025
Gender
All
Age(s)
50 Years - 100 Years (Adult, Older Adult)

Interventions

Drug

Brolucizumab 6mg

Brolucizumab 6mg(intravitreal) Standard q12w/q8w regimen arm: 3 x 4-week loading injections and disease activity assessment at week 16 followed by q12w/q8w up to Week 56

Eligibility Criteria

Inclusion Criteria:

1. Signed informed consent must be obtained prior to participation in the study.
2. Participants ≥ 50 years of age at Screening.

Study eye:
3. Presence of active polypoidal lesions in the macula as shown by Indocyanine green angiography (ICGA) AND presence of serosanguinous maculopathy, i.e., exudative or hemorrhagic features involving the macula on color fundus photography (CFP), Fluorescein angiography (FA) and spectral domain optical coherence tomography (SD-OCT) AND presence of Intraretinal fluid (IRF) or Subretinal fluid (SRF) that affects the central subfield as seen by SD-OCT.
4. Best-corrected visual acuity (BCVA) score must be ≤ 78 and ≥ 24 letters at 4 meters starting distance using early treatment diabetic retinopathy study (ETDRS) visual acuity charts at both Screening and Baseline.
5. Greatest liner dimension (GLD) of the total lesion area (branching vascular network \[BVN\] + polypoidal lesion) \< 5400 µm (equivalent to 9 macular photocoagulation study \[MPS\] Disc Area) as delineated by Indocyanin green angiography (ICGA).

Exclusion Criteria:

Ocular conditions:

1. Concomitant conditions or ocular disorders in the study eye at Screening or Baseline which could, in the opinion of the Investigator, prevent response to study treatment or may confound interpretation of study results, compromise visual acuity or require planned medical or surgical intervention during the first 12-month study period.
2. Any active intraocular or periocular infection or active intraocular inflammation (IOI) (e.g., infectious conjunctivitis, keratitis, scleritis, endophthalmitis, infectious blepharitis, uveitis) in study eye or fellow eye at Screening or Baseline.
3. Uncontrolled glaucoma in the study eye defined as intraocular pressure (IOP) \> 25 mmHg on medication, or according to Investigator's judgment, at Screening or Baseline.
4. Any Polypoidal choroidal vasculopathy (PCV) masquerades like macular aneurysms, macular telangiectasia, etc. in study eye.
5. Total area of subretinal hemorrhage larger than 9 DA (Disc Area) or comprising ≥ 50% of the lesion area or presence of vitreous hemorrhage in study eye.

Ocular treatments in the study eye:
6. Previous treatment with any anti-Vascular endothelial growth factor (VEGF) drugs or investigational drugs at any time prior to Baseline.
7. Previous use of intraocular or periocular steroids within the 6-month period prior to Baseline.
8. Macular laser photocoagulation (focal/grid) or Photodynamic therapy (PDT) at any time prior to Baseline and peripheral laser photocoagulation within 3 months prior to Baseline.

Systemic conditions or treatments:
9. Stroke or myocardial infarction during the 6-month period prior to Baseline.
10. Systemic anti-VEGF therapy any time prior to Baseline.

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