Regulatory Post-Marketing Surveillance Study for Brolucizumab

Last Update: Jan 14, 2025
Regulatory Post-Marketing Surveillance (rPMS) Study for Brolucizumab(Beovu ® Injection, Beovu ®Prefilled Syringe)
ClinicalTrials.gov Identifier:
NCT04985487
Novartis Reference Number:CRTH258AKR01
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 an open-label, multicenter, single-arm, observational post-marketing surveillance. The investigators will collect safety information and evaluate effectiveness in patients who are prescribed Beovu ® Injection, Beovu ®Prefilled Syringe (brolucizumab) in the approved indication after receiving informed consent over a period of 12 weeks. In addition, longer-term data (24 weeks, optionally 36 weeks) will be collected.

Condition
Neovascular Age-related Macular Degeneration
Overall Status
Recruiting
Number of Participants
3000
Start Date
Aug 18, 2021
Completion Date
Jun 14, 2026
Gender
All
Age(s)
18 Years - 100 Years (Adult, Older Adult)

Interventions

Other

brolucizumab

Prospective observational study. There is no treatment allocation. Patients administered brolucizumab, that have started before inclusion of the patient into the study will be enrolled.

Eligibility Criteria

Inclusion Criteria:

1. Patients aged ≥18 years with nAMD that are prescribed with Brolucizumab as per approved local product information
2. Patients who consent to participate in the study after the purpose and nature of the study have clearly explained to them (written informed consent)

Exclusion Criteria:

1. Contraindications as per local prescribing information 1) Hypersensitivity to the active substance or to any of the excipients. 2) Active or suspected ocular or periocular infection. 3) Active intraocular inflammation.
2. Patients participating in other investigational drug trial

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