Retrospective analysis of imaging and clinical features from patients treated with brolucizumab in post-marketing setting with reports of intraocular inflammation and/or retinal vascular occlusion

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Last updated: 23/04/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/48564

EU PAS number

EUPAS41014

Study ID

48564

DARWIN EU® study

No

Study countries

Switzerland

Study description

Post-marketing eye cases of RV and/or RO reported to Novartis Patient Safety from which ocular images were requested and provided to Novartis until 31-Jan-2021, from all countries where brolucizumab was approved and used per routine clinical practice, were considered for this study. Of note, the few IOI cases, for which images were provided, were also included in the analysis.

Study status

Finalised

Research institutions and networks

Institutions

Novartis Pharmaceuticals

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Institution

Contact details

Study institution contact

Novartis Clinical Disclosure Office

Study contact

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Primary lead investigator

Novartis Clinical Disclosure Office

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 04/08/2020

Actual: 04/08/2020

Study start date

Planned: 17/05/2021

Actual: 24/08/2021

Data analysis start date

Planned: 17/05/2021

Actual: 04/01/2022

Date of final study report

Planned: 31/01/2022

Actual: 22/02/2022

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Novartis AG

Study protocol

CRTH258A2404_Global NIS Protocol Amendment_Redacted.pdf(308.53 KB)

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Other study registration identification numbers and links

CRTH258A2404

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Data collection methods:

Secondary use of data

Main study objective:

This study provides real-world overview of the images collected at time of event of adverse events (AEs) of interest. The primary objective is to characterize the AEs of interest in terms of independent case classification based on imaging data. 1. Breakdown of imaging classification of the cases 2. Breakdown on location and findings by imaging modality

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Descriptive study

Study drug and medical condition

Study drug International non-proprietary name (INN) or common name

BROLUCIZUMAB

Anatomical Therapeutic Chemical (ATC) code

(S01LA06) brolucizumab

brolucizumab

Medical condition to be studied

Eye inflammation

Retinal vasculitis

Retinal vascular occlusion

Population studied

Short description of the study population

The study considered the post-marketing cases of intraocular inflammation, retinal vasculitis, and retinal vascular/vein occlusion reported to Novartis Patient Safety worldwide, involving brolucizumab use as per routine clinical practice. Images requested and provided to Novartis until 31-Jan-2021, from all countries where brolucizumab was approved. Intraocular inflammation cases also included in the analysis.

Age groups

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Special population of interest

Other

Special population of interest, other

Patients with intraocular inflammation, retinal vasculitis, and retinal vascular/vein occlusion

Estimated number of subjects

198

Study design details

Outcomes

Primary endpoints: 1. Case classification based on imaging data (RV vs. RO vs. RV/RO vs. IOI) 2. Location and findings description by imaging modality

Data analysis plan

Number (%) assessable vs. non assessable cases based on imaging data were summarized among all cases with imaging data sent to the central reviewer. Data on patient characteristics (e.g. age, sex, race, county of origin), treatment, event outcome and visual loss/outcome distribution was retrieved from the ARGUS Safety database. Analyses related to the primary objective • An overall independent eye case classification based on all provided imaging data (“RV only” vs. “RO only” vs. “RV + RO only” vs. “IOI only (involving the posterior segment)” vs. “Not assessable” vs. “None”) acquired at the time the event was provided. • For each imaging finding (by location and finding), number (%) of cases with finding present by event type (RV/RO) as per independent review

Documents

Study results

CRTH258A2404 --legacy-clinical-study-report_2_Redacted.pdf(1.66 MB)

Data management

Data sources

Data sources (types)

Spontaneous reports of suspected adverse drug reactions

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No