



A Study of the Efficacy and Safety of Brolucizumab vs. Aflibercept in Patients With Visual Impairment Due to Diabetic Macular Edema

31/01/2025 06:30:57

Main Information

Primary registry identifying number

LBCTR2019030200

Protocol number

RTH258B2302

MOH registration number

31193/2018

Study registered at the country of origin

Yes

Study registered at the country of origin: Specify

Type of registration

Retrospective

Type of registration: Justify

LCTR was recently initiated, original file was previously submitted by Paper

Date of registration in national regulatory agency

23/07/2018

Primary sponsor

Novartis Pharma Services Inc.

Primary sponsor: Country of origin

Novartis Pharmaceuticals

Date of registration in primary registry

10/11/2020

Date of registration in national regulatory agency

23/07/2018

Public title

A Study of the Efficacy and Safety of Brolucizumab vs. Aflibercept in Patients With Visual Impairment Due to Diabetic Macular Edema

Acronym

KITE

Scientific title

A Two-Year, Two-Arm, Randomized, Double Masked, Multicenter, Phase III Study Assessing the Efficacy and Safety of Brolucizumab Versus Aflibercept in Adult Patients With Visual Impairment Due to Diabetic Macular Edema

Acronym

Brief summary of the study: English

The purpose of this study is to evaluate the efficacy and safety of brolucizumab in treatment of patients with visual impairment due to diabetic macular edema (DME).

Brief summary of the study: Arabic

دراسة مرحلة ثالثة، متعددة المراكز، مزدوجة التعمية، عشوائية التوزيع، من مجموعتين، مدتها سنتان، لتقييم فعالية وسلامة دواء بروتوكيزوماب مقابل دواء أفليبرسبت لدى المرضى البالغين المصابين بضعف بصري ناتج عن الوذمة البقعية السكرية

Health conditions/problem studied: Specify

Patients With Visual Impairment Due to Diabetic Macular Edema

Interventions: Specify

•Drug: Brolucizumab
Intravitreal injection

Other Name: RTH258, ESBA1008

•Drug: Aflibercept





Intravitreal injection

Other Name: Eylea

Key inclusion and exclusion criteria: Inclusion criteria

- Written informed consent before any assessment
- Patients with type 1 or type 2 diabetes mellitus and HbA1c of $\leq 10\%$ at screening
- Medication for the management of diabetes stable within 3 months prior to randomization and is expected to remain stable during the course of the study

Key inclusion and exclusion criteria: Gender

Both

Key inclusion and exclusion criteria: Specify gender

Key inclusion and exclusion criteria: Age minimum

18

Key inclusion and exclusion criteria: Age maximum

90

Key inclusion and exclusion criteria: Exclusion criteria

- Active proliferative diabetic retinopathy in the study eye
- Active intraocular or periocular infection or active intraocular inflammation in the study eye
- Uncontrolled glaucoma in the study eye defined as intraocular pressure (IOP) > 25 millimeters mercury (mmHg)
- Previous treatment with anti-VEGF drugs or investigational drugs in the study eye
- Stroke or myocardial infarction during the 6-month period prior to baseline
- Uncontrolled blood pressure defined as a systolic value ≥ 160 mmHg or diastolic value ≥ 100 mmHg

Other protocol-specified inclusion/exclusion criteria may apply

Type of study

Interventional

Type of intervention

Pharmaceutical

Type of intervention: Specify type

N/A

Trial scope

Other

Trial scope: Specify scope

Study design: Allocation

Randomized controlled trial

Study design: Masking

Blinded (masking used)

Study design: Control

Active

Study phase

3

Study design: Purpose

Treatment

Study design: Specify purpose

N/A

Study design: Assignment

Parallel

Study design: Specify assignment

N/A

IMP has market authorization

No

IMP has market authorization: Specify

Name of IMP

RTH258 (Brolucizumab)

Year of authorization

Month of authorization

Type of IMP

Immunological

Pharmaceutical class

Anti VEGF-A

Therapeutic indication



Diabetic Macular Edema

Therapeutic benefit

Change from baseline in best-corrected visual acuity (BCVA) at Week 52

Study model

N/A

Study model: Explain model

N/A

Study model: Specify model

N/A

Time perspective

N/A

Time perspective: Explain time perspective

N/A

Time perspective: Specify perspective

N/A

Target follow-up duration

Target follow-up duration: Unit

Number of groups/cohorts

Biospecimen retention

Samples with DNA**

Biospecimen description

Samples will be exported to :
Q2 solutions
The Alba campus
Rosebank Livingston EH547EG
United Kingdom
Phone : 44 (0) 2033 184 884 x2401
Biosamples include Urine and Blood
Urine for general analysis
Blood : CBC, Chemistry, HbA1c, Lipids Panel, Anti Drug Ab,
Pharmacogenomics

Target sample size

10

Actual enrollment target size

4

Date of first enrollment: Type

Actual

Date of first enrollment: Date

01/03/2019

Date of study closure: Type

Actual

Date of study closure: Date

22/12/2021

Recruitment status

Complete

Recruitment status: Specify

Date of completion

19/06/2019

IPD sharing statement plan

No

IPD sharing statement description



Novartis is committed to sharing with qualified external researchers, access to patient-level data and supporting clinical documents from eligible studies. These requests are reviewed and approved by an independent review panel on the basis of scientific merit. All data provided is anonymized to respect the privacy of patients who have participated in the trial in line with applicable laws and regulations. This trial data availability is according to the criteria and process described on www.clinicalstudydatarequest.com.

Additional data URL

<https://clinicaltrials.gov/ct2/show/record/NCT03481660?term=CRTH258B2302&rank=1&view=record>

Admin comments**Trial status**

Approved

Secondary Identifying Numbers

| Full name of issuing authority | Secondary identifying number |
|--------------------------------|------------------------------|
| Clinical Trials. gov | NCT03481660 |

Sources of Monetary or Material Support

| Name |
|-------------------------------|
| Novartis Pharma Services Inc. |

Secondary Sponsors

| Name |
|------|
| NA |

Contact for Public/Scientific Queries

| Contact type | Contact full name | Address | Country | Telephone | Email | Affiliation |
|--------------|-------------------|------------|---------|------------------------|-------------------------------|--|
| Public | Naji Waked | Beirut | Lebanon | 009613252552 | wakednaji@yahoo.com | Hotel Dieu De France |
| Scientific | Hind Khairallah | Sin El Fil | Lebanon | +961 1 512002 Ext. 271 | Hind.Khairallah@fattal.com.lb | Khalil Fattal et Fils s.a.l. |
| Public | Joseph Nehme | Dbayeh | Lebanon | 0096103136120 | drjosephnehme@gmail.com | Eye and Ear Hospital International |
| Public | Hala El Rami | Beirut | Lebanon | 76367510 | ramielhala@hotmail.com | Beirut Eye and ENT specialist Hospital |



Centers/Hospitals Involved in the Study

| Center/Hospital name | Name of principles investigator | Principles investigator speciality | Ethical approval |
|--|---------------------------------|------------------------------------|------------------|
| Hotel Dieu De France | Naji Waked | Ophthalmology | Approved |
| Eye and Ear Hospital International | Joseph Nehme | Ophthalmology | Approved |
| Beirut Eye and ENT specialist Hospital | Hala El Rami | Ophthalmology | Approved |

Ethics Review

| Ethics approval obtained | Approval date | Contact name | Contact email | Contact phone |
|--|---------------|--------------|-----------------------|----------------------------|
| Hotel Dieu de France | 30/04/2018 | Nancy Alam | nancy.alam@usj.edu.lb | +961 (0) 1 421000 ext 2335 |
| Other Hotel Dieu De France (Eye and Ear Hospital International) | 02/10/2018 | Nancy Alam | nancy.alam@usj.edu.lb | +961 (0) 1 421000 ext 2335 |
| Beirut Eye and ENT Specialist Hospital | 21/12/2018 | Nancy Alam | nancy.alam@usj.edu.lb | +961 (0) 1 421000 ext 2335 |



Countries of Recruitment

| Name |
|-------------------|
| Lebanon |
| Belgium |
| Bulgaria |
| Czech Republic |
| Denmark |
| Estonia |
| France |
| Germany |
| Hungary |
| India |
| Republic of Korea |
| Latvia |
| Lithuania |
| Malaysia |
| Norway |
| Singapore |
| Slovakia |
| Sweden |
| Switzerland |
| Turkey |

Health Conditions or Problems Studied

| Condition | Code | Keyword |
|------------------------|-----------------------------|---------------|
| Diabetic macular edema | Oedema, unspecified (R60.9) | Macular Edema |



Interventions

| Intervention | Description | Keyword |
|---|---|---|
| Physical Exam, Vital signs, ophtalmic Exam, IOP, Optical Coherence Tomography, Fluorescein Angiography, Color Fundus photography, Urinalysis, Serum/ urine pregnancy test, lab test, completion of QoL questionnaires | ICF, Lab, questionnaires, Medication administration, physical examination | ICF, Lab tests, Questionnaires, Medication administration |

Primary Outcomes

| Name | Time Points | Measure |
|---|-------------------|-------------------|
| Change from baseline in best-corrected visual acuity (BCVA) | Baseline, week 52 | baseline, week 52 |

Key Secondary Outcomes

| Name | Time Points | Measure |
|---|-----------------------|-----------------------|
| Average change from baseline in BCVA | wk 40 till wk 52 | wk 40 till wk 52 |
| Proportion of patients with injections per planned dosing regimen | wk8,12,16 | wk8,12,16 |
| Change from baseline in central subfield thickness | baseline up to wk 100 | baseline up to wk 100 |



Trial Results

Summary results

Study results globally

Date of posting of results summaries

Date of first journal publication of results

Results URL link

Baseline characteristics

Participant flow

Adverse events

Outcome measures

URL to protocol files