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

05/04/2025 01:31:16

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
06/03/2019

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، متعدّدة المراكز، مزدوجة التعمية، عشوائيّة التوزيع، من مجموعتين، مدّتها سنتان، لتقييم فعاليّة وسلامة دواء بروليوسيزوماب مقابل دواء أفليبرسبت لدى المرضى البالغين المصابين بضعف بصريّ ناتج عن الوذمة البقعيّة السكريّة

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 ≤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

1

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

Recruiting

Recruitment status: Specify

Date of completion

24/06/2019

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 ww.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	00961325 2552	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	Georges Azar	Dbayeh	Lebanon	00961355 0891	georgesazar@hotmail.com	Eye and Ear Hospital International

Centers/Hospitals Involved in the Study

Center/Hospital name	Name of principles investigator	Principles investigator speciality	Ethical approval
Hotel Dieu De France	Dr. Naji Waked	Ophthalmology	Approved
Eye and Ear Hospital International	Dr. Georges Azar	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

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