

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

05/11/2025 13:52:34

Main Information

Primary registry identifying number

LBCTR2019030200

MOH registration number

31193/2018

Study registered at the country of origin

Type of registration

Retrospective

Date of registration in national regulatory

agency 23/07/2018

Primary sponsor

Novartis Pharma Services Inc.

Date of registration in primary registry

03/11/2020

Public title

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

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

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 برولوسيزوماب 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

Protocol number

RTH258B2302

Study registered at the country of origin: Specify

Type of registration: Justify

LCTR was recently initiated, original file was previously submitted

by Paper

Primary sponsor: Country of origin

Novartis Pharmaceuticals

Date of registration in national regulatory agency

23/07/2018

Acronym

KITE

Acronym



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

Key inclusion and exclusion criteria: Specify gender

Both

Key inclusion and exclusion criteria: Age minimum

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 Type of intervention: Specify type

Pharmaceutical N/A

Trial scope Trial scope: Specify scope

Other

Study design: AllocationStudy design: MaskingRandomized controlled trialBlinded (masking used)

Study design: Control Study phase

Active

Study design: Purpose Study design: Specify purpose

Treatment

Study design: Assignment Study design: Specify assignment

Parallel

IMP has market authorization IMP has market authorization: Specify

No

Name of IMP Year of authorization Month of authorization

RTH258 (Brolucizumab)

Type of IMP

Immunological

Pharmaceutical class

Anti VEGF-A

Therapeutic indication



Study model: Explain model

N/A

N/A

Diabetic Macular Edema

Therapeutic benefit

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

Study model

N/A

Study model: Specify model

N/A

Time perspective Time perspective: Explain time perspective

Time perspective: Specify perspective

N/A

Target follow-up duration Target follow-up duration: Unit

Number of groups/cohorts

Biospecimen retention

Samples with DNA**

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,

Biospecimen description

Q2 solutions The Alba campus

United Kingdom

Samples will be exported to:

Rosebank Livingston EH547EG

Pharmacogenomics

Target sample size Actual enrollment target size

Date of first enrollment: Type

Actual

Date of study closure: Type

Actual

10

Recruitment status

Complete

Date of completion

19/06/2019

IPD sharing statement plan

No

4

Date of first enrollment: Date

01/03/2019

Date of study closure: Date

22/12/2021

Recruitment status: Specify

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

Contac	Contact for Public/Scientific Queries					
Contact type	Contact full name	Address	Country	Telephone	Email	Affiliation
Public	Naji Waked	Beirut	Lebanon	009613252 552	wakednaji@yaho o.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	009613550 891	georgesazar@ho tmail.com	Eye and Ear Hospital Internation al
Public	Hala El Rami	Beirut	Lebanon	76367510	ramielhala@hot mail.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	Georges Azar	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	