



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

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## 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

15/12/2020

### 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 بروهولوسيزوماب 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  $\geq 160$  mmHg or diastolic value  $\geq 100$  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](http://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	Sami Richa	cue@usj.edu.lb	961421229
Other Hotel Dieu De France ( Eye and Ear Hospital International)	02/10/2018	Sami Richa	cue@usj.edu.lb	961421229
Beirut Eye and ENT Specialist Hospital	21/12/2018	Sami Richa	cue@usj.edu.lb	961421229



## 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**