17-Jul-2024

National Competent Authorities and Ethics Committees of the Member States concerned

Re:	Clinical Trial Application for Part I and II (initial submission)
Sponsor:	Eyebiotech Ltd.
EU trial number:	2024-510944-30
Sponsor Protocol Number:	EYE-RES-102
Title of the trial:	A Randomized, Double-masked, Multi-center, 3-Arm Pivotal Phase 2/3 Study to Evaluate the Efficacy and Safety of Intravitreal EYE103 Compared with Intravitreal ranibizumab (0.5mg) in Participants with Diabetic Macular Edema

Dear Madam/Sir,

On behalf of the Sponsor, Eyebiotech Ltd., we hereby apply for authorisation of the above-mentioned Clinical Trial.

This application is proposed in the member states Austria, Croatia, Czech Republic, France, Germany, Hungary, Italy, Latvia, Poland, Portugal, Slovakia and Spain. It is a phase II/III randomized, double-masked, multi-center study evaluating the efficacy and safety of two doses of Intravitreal EYE103 Compared with Intravitreal ranibizumab. Approximately 960 eligible participants older than 18 years of age will be randomized in a 1:1:1 ratio to 1 of 3 treatment groups.

The primary objective of the study is to demonstrate non-inferiority of EYE103 (0.5 mg or 0.8mg) to ranibizumab 0.5 mg, as measured by mean change in best-corrected visual acuity (BCVA) up to and including Week 52.

Subjects who are not able to give informed consent will be excluded from participation in this clinical trial. Pregnant or breastfeeding women are excluded from participation in this trial, as listed in the inclusion criteria, as part of the application form.

The reference safety information for EYE103 can be found in the Investigator's Brochure, section 7.

In accordance with the trial protocol, the following investigational medicinal product (IMP) will be used in the above-mentioned clinical trial. This is listed on the application form, under the medicinal product details section.

Name of the investigational medicinal product	Regulatory status
EYE103	Not authorised
Ranibizumab	Authorised

EYE103 has not been approved. Ranibizumab is an already authorized product.

The Investigational Medicinal Product (IMP), EYE103, is not a narcotic, psychotropic substance, nor radiopharmaceutical.

The Investigational Medicinal Product (IMP), EYE103, does not consist of/contain genetically-modified organism.

In accordance with the trial protocol, the following auxiliary medicinal product (AxMP) will be used in the above-mentioned clinical trial. This is listed on the application form, under the medicinal product details section.

Role and Name of the auxiliary medicinal product	Regulatory status
Fluorescein	Authorized (except in Czech Republic)

The auxiliary medicinal products (AxMP) are not narcotics, psychotropic substances, nor radiopharmaceuticals. Please find enclosed in the application a representative SmPC for each AxMP treatment above mentioned.

The Sponsor did not obtain an orphan drug designation for EYE103 for Diabetic Macular Edema.

No scientific advice to the trial or to the investigational medicinal product has been given in the EU. Therefore, no information related to this has been provided in the application form.

This trial is not part of and is not intended to be part of a Paediatric Investigation Plan (PIP). Therefore, no information related to this has been provided in the application form.

There are no medical devices to be investigated in this proposed trial. Therefore, no information related to this has been provided in the application form.

The sponsor does not consider the trial to be a low interventional clinical trial, as indicated on the application form.

Country Specific Information:

Austria
N/A

Croatia
N/A

Czech Republic
N/A

France
N/A

Germany
N/A

Hungary
Hungarian translation of the Cover Letter is attached to the application.
Hungarian language list of submitted documents for Part II to be uploaded as well

Italy
The proposed Territorial Ethics Committee to review this submission is: "Comitato Etico Lazio Area 4".
Virtual Duty Stamp will be paid by CRO, TFS Trial Form Support Srl, on behalf of the Sponsor Eyebiotech Ltd. *(Italian Revenue Agency - Agenzia delle Entrate, authorization n. 327791/2021 of 20 September 2021)*.

Latvia
N/A

Poland
N/A

Portugal
N/A

Slovakia
N/A

Spain
This is to confirm that no medical devices are investigated in this Clinical Trial and that IMPs are not manufactured in a Hospital Pharmacy service.

Should you have any questions concerning this application or require further information, the contact email in Spain for CA and EC is: tfsstartupspain@tfscro.com.

Please use the following e-mail address for the invoice: ap.spa@tfscro.com.

Responsible Ethics Committee and contact details:
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