Expanded Access Policy

Opthea is committed to improving vision in patients suffering with retinal eye diseases.

Consistent with our mission, we are focused on conducting the clinical trials needed to gain regulatory approvals in order make our medicines as broadly available as possible. Clinical trials are the best way for patients to participate in the drug development process, receive access to unapproved investigational drugs, and contribute to the collection of safety and efficacy data needed for review and regulatory approval worldwide.

For further information on Opthea's clinical trials please refer to:

- Opthea's website, www.opthea.com
- ClinicalTrials.gov
    - ShORe Trial ID#: NCT04757610
    - COAST Trial ID#: NCT04757636

To find a clinical study site near you, please refer to:

- https://www.wetamdstudies.com

For patients with a serious or life-threatening disease who are ineligible or unable to participate in a clinical trial, use of an unapproved investigational drug via an Expanded Access Program may be an option. Expanded access, including treatment use in individual patients, is the use of an unapproved investigational drug outside of a clinical trial to treat a patient with a serious or immediately life-threatening disease or condition, when there are no other comparable or satisfactory alternative treatment options. In these circumstances, Opthea may consider providing a product through expanded access.

Opthea's criteria for considering requests for Expanded Access include, but are not limited to:

- The patient is suffering from a serious or life-threatening disease or condition, and there is no comparable or satisfactory alternative therapy.
- The patient is not eligible or able to participate in a clinical trial sponsored by Opthea.
- The investigational product must be part of an active clinical development program.
- Granting access must not interfere with the completion of clinical trials that could support approval of the product or otherwise compromise the potential development or regulatory submissions of the investigational product.
- Providing expanded access must not interfere with clinical trial supply availability.
- Sufficiency of data supporting that the potential benefits of administration of the investigational product to the patient could outweigh the potential risks.
- The patient's treating physician has determined that there is a legitimate medical need and that treating the patient is in the patient's best interests.
- Any request to Opthea for access to Opthea's investigational medicinal products must come from the patient's treating physician.
- The investigational product may only be administered in accordance with applicable laws and regulatory requirements of the country where the patient is treated.

[Note: OPT-302 is currently not available for Expanded Access for the following reasons:]

- *Providing expanded access may interfere with Opthea's ability to supply OPT-302 for its Phase 3 clinical trials ShORe and COAST.*
- *It is not currently possible to determine whether addition of OPT-302 to anti-VEGF-A therapy has an improved benefit over standard of care treatment until completion of Phase 3 clinical trials.*

The decision to provide a drug for Expanded Access will be made by Opthea based upon an impartial evaluation of the requests that meet the conditions above. This decision will be made in a timely manner but will involve consultation with the requesting physician and Opthea's medical and clinical teams, regulatory authorities and advisors. Opthea cannot guarantee that it will grant any request, even if the criteria are met, but will review each request carefully.

All Expanded Access requests will be implemented in compliance with local regulations. Patients should speak to their physicians about requesting Expanded Access. All individual patient access requests must be submitted by a treating physician, should not include confidential patient information and must include:

- Date of Request
- Requesting physician's name, contact information and professional designations and qualifications to administer investigational product/s
- Name of the investigational product and intended treatment plan and duration of treatment

For further information on Opthea's Expanded Access Policy, physicians can contact Opthea via email:

- info@opthea.com

Opthea regularly monitors this inbox and will use best efforts to respond to the requesting physician within 14 days.