ASX and Media Release
4 October 2021

# Opthea Opens Patient Recruitment in Europe for Pivotal Phase 3 ShORe and COAST Wet AMD Trials of OPT-302

**Melbourne, Australia; 4 October 2021** – Opthea Limited (ASX:OPT; Nasdaq: OPT), a clinical stage biopharmaceutical company developing novel therapies to treat highly prevalent and progressive retinal diseases, today announced that enrollment for its Phase 3 pivotal clinical program of OPT-302 for the treatment of wet (neovascular) age-related macular degeneration (AMD) is now open in Europe. The two concurrent global Phase 3 registrational clinical trials, ShORe (Study of OPT-302 in combination with Ranibizumab) and COAST (Combination OPT-302 with Aflibercept Study) will be conducted in up to 20 countries across Europe.

The ShORe and COAST registrational studies are expected to each enroll approximately 990 treatment naïve patients and are evaluating OPT-302 combination therapy as a potential treatment for wet AMD. Enrollment has been ongoing in the U.S. and Canada and is being expanded into Europe and the rest of the world.

“We are excited to expand the ShORe and COAST trials outside North America to European investigative sites which is an important step in our continued commitment to improve the lives of patients around the world suffering from retinal diseases” said Dr Megan Baldwin, CEO and Managing Director of Opthea. “Europe represents another key market, given the large population of patients that reside there, and establishing a presence will help support the development of OPT-302, as well as future regulatory submissions and commercialization plans.”

Opthea is conducting ShORe and COAST as two concurrent global, multi-center, double-masked, sham-controlled Phase 3 trials to assess the efficacy and safety of intravitreal 2.0 mg OPT-302 in combination with either 0.5 mg ranibizumab (Lucentis®), or 2.0 mg aflibercept (Eylea®) respectively. The primary endpoint of both studies is the mean change in best corrected visual acuity from baseline to week 52 for OPT-302 combination therapy compared to anti-VEGF-A monotherapy. The top-line 52-week data from the ShORe and COAST Phase 3 studies is anticipated in the second half of 2023. Opthea intends to submit Biologics License and Marketing Authorisation Applications with the U.S Food and Drug Administration (FDA) and European Medicines Agency (EMA), respectively, following completion of the 12-month primary efficacy phase of the trials.

The FDA recently awarded OPT-302 Fast Track designation, which helps to speed clinical development, U.S. regulatory review, and market entry upon approval of treatments with a potential to address serious conditions. In addition, regulatory guidance received from the FDA and EMA, including alignment on the pivotal study designs, has provided Opthea with a pathway to advance OPT-302 through Phase 3 registrational trials for the treatment of wet AMD in support of future filings for global marketing approval and commercial launches in the U.S. and Europe.

Additional information on Opthea’s technology and the Phase 3 pivotal clinical trials can be found at www.opthea.com and at www.ClinicalTrials.gov (ShORe trial, ID#: NCT04757610; COAST trial, ID#: NCT04757636).

**About Opthea**

Opthea (ASX:OPT; Nasdaq: OPT) is a biopharmaceutical company developing novel therapies to address the unmet need in the treatment of highly prevalent and progressive retinal diseases, including wet age-related macular degeneration (wet AMD) and diabetic macular edema (DME). Opthea's lead product candidate OPT-302 is in pivotal Phase 3 clinical trials and being developed for use in combination with anti-VEGF-A monotherapies to achieve broader inhibition of the VEGF family, with the goal of improving overall efficacy and demonstrating superior vision gains over that which can be achieved by inhibiting VEGF-A alone.

**Inherent risks of Investment in Biotechnology Companies**

There are a number of inherent risks associated with the development of pharmaceutical products to a marketable stage. The lengthy clinical trial process is designed to assess the safety and efficacy of a drug prior to commercialization and a significant proportion of drugs fail one or both of these criteria. Other risks include uncertainty of patent protection and proprietary rights, whether patent applications and issued patents will offer adequate protection to enable product development, the obtaining of necessary drug regulatory authority approvals and difficulties caused by the rapid advancements in technology. Companies such as Opthea are dependent on the success of their research and development projects and on the ability to attract funding to support these activities. Investment in research and development projects cannot be assessed on the same fundamentals as trading and manufacturing enterprises. Therefore, investment in companies specializing in drug development must be regarded as highly speculative. Opthea strongly recommends that professional investment advice be sought prior to such investments.

**Forward-looking statements**

Certain statements in this announcement may contain forward-looking statements, including within the meaning of the U.S. Private Securities Litigation Reform Act of 1995. Any statement describing Company goals, expectations, intentions or beliefs is a forward-looking statement and should be considered an at-risk statement, including, but not limited to, the continuation of patient recruitment for Opthea's pivotal Phase 3 clinical trials of OPT-302 in wet AMD. Such statements are based on Opthea's current plans, objectives, estimates, expectations, and intentions and are subject to certain risks and uncertainties, including risks and uncertainties associated with clinical trials and product development and the impact of general economic, industry or political conditions in Australia, the United States or internationally. These and other risks and uncertainties are described more fully in the section titled "Risk Factors" in the final prospectus filed with the SEC on October 19, 2020. The Company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events, or otherwise, except as required under applicable law. You should not place undue reliance on these forward-looking statements as predictions of future events, which statements apply only as of the date of this announcement. Actual results could differ materially from those discussed in this ASX announcement.

**Authorized for release to ASX by Megan Baldwin, CEO & Managing Director**


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