Opthea's OPT-302 Granted FDA Fast Track Designation for Wet Age-Related Macular Degeneration

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- *FDA's Fast Track Designation for OPT-302 offers benefits to expedite the OPT-302 Phase 3 clinical program and subsequent potential approval process*

MELBOURNE, Australia, July 06, 2021 (GLOBE NEWSWIRE) -- Opthea Limited (ASX:OPT; Nasdaq:OPT), a clinical stage biopharmaceutical company developing novel therapies to treat highly prevalent and progressive retinal diseases, is pleased to announce that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation for the company's VEGF-C/-D 'trap' inhibitor, OPT-302, in combination with anti-VEGF-A therapy for the treatment of patients with neovascular (wet) age-related macular degeneration (AMD).

The FDA's Fast Track program offers a number of benefits to help advance development and expedite the review of novel therapies for serious conditions for which there is an unmet medical need, with the aim of getting important new therapies to patients more quickly. This Fast Track designation acknowledges the significant unmet medical need in the management of neovascular AMD, and the potential role that OPT-302 may have in addressing it.

With the Fast Track designation, Opthea is eligible for more frequent regulatory meetings and communications with the FDA, as well as a Rolling Review of completed sections of its Biologic Drug Application (BLA) which will help expedite the Phase 3 development program and subsequent approval review process. Under the Fast Track designation, OPT-302 may also be eligible for Accelerated Approval and Priority Review if relevant criteria are met.

"Given the need to improve therapeutic options for wet AMD patients, we welcome this Fast Track designation for OPT-302 and the regulatory support it provides in expediting the Phase 3 development program to advance this promising novel treatment to patients sooner," commented Dr. Megan Baldwin, Chief Executive Officer and Managing Director of Opthea. "The recognition from the FDA to grant OPT-302 Fast Track designation reflects the seriousness of wet AMD as a debilitating eye disease and the importance of advancing new therapies such as OPT-302 to address the significant unmet medical need for wet AMD patients, many of whom experience an incomplete response to VEGF-A inhibitors despite regular, ongoing therapy. By targeting a novel mechanism of action, OPT-302 has the potential to be a truly differentiated treatment option that when used in combination offers patients improved vision outcomes over standard of care anti-VEGF-A monotherapy."

Opthea is currently recruiting patients into two concurrent global, multi-center, randomized, double-masked, sham-controlled Phase 3 trials known as ShORe *(Study of OPT-302 in combination with Ranibizumab)* and COAST *(Combination OPT-302 with Aflibercept Study)*. Both clinical studies will enroll ~990 treatment-naive patients each and assess the efficacy and safety of intravitreal 2.0 mg OPT-302 in combination with 0.5 mg ranibizumab (Lucentis®) or 2.0 mg aflibercept (Eylea®), compared to ranibizumab or aflibercept monotherapy, respectively.

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

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

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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.