Opthea Data for OPT-302 in Patients with Polypoidal Choroidal Vasculopathy (PCV) Presented at Angiogenesis 2022

February 14, 2022

- ***Professor Gemmy Cheung, Singapore Eye Research Institute, presented prespecified subgroup analysis of PCV patients enrolled in Opthea's Phase 2b clinical trial of OPT-302 in combination with ranibizumab (Lucentis ®), compared to ranibizumab alone***
- ***+6.7 letters comparative superiority of 2 mg OPT-302 combination therapy (p = 0.0253) in patients with PCV – a subtype of AMD, prevalent among Asian populations with high unmet medical need***

MELBOURNE, Australia, Feb. 14, 2022 (GLOBE NEWSWIRE) -- **Opthea Limited** (ASX:OPT; Nasdaq:OPT), a clinical stage biopharmaceutical company developing novel therapies to treat highly prevalent and progressive retinal diseases, today announced data was presented at the Bascom Palmer 19th annual Angiogenesis, Exudation, and Degeneration 2022 Conference. The presentation, entitled "OPT-302 Combination Therapy with Ranibizumab for Treatment of Polypoidal Choroidal Vasculopathy," was held virtually on Saturday, February 12, 2022, and appeared in a session highlighting "Emerging and Current Therapies for Exudative AMD." Professor Gemmy Cheung MBBS, FRCOphth, FAMS, MCI, Head and Senior Consultant, Medical Retina Department, Singapore National Eye Center, Singapore Eye Research Institute, Singapore, presented.

"We are proud to share these findings, which build on our previous work to demonstrate the far-reaching potential of OPT-302," said Dr. Megan Baldwin, Opthea's Chief Executive Officer. "Polypoidal Choroidal Vasculopathy (PCV) is a subtype of AMD that is particularly prevalent among Asian populations and demonstrates variable response to anti-VEGF-A therapy. As one of the most common forms of wet AMD globally, we are excited by the results in PCV patients that further demonstrate the potential of OPT-302 to be a truly differentiated treatment option that, when used in combination, may offer patients improved vision outcomes over standard of care anti-VEGF-A monotherapy."

The data presented was a prespecified subgroup analysis of a Phase 2b dose-ranging study of intravitreal OPT-302 in combination with ranibizumab, compared with ranibizumab alone, in participants with neovascular age-related macular degeneration (wet AMD). Sixty-six participants (18%) with PCV out of a total study population of 366 were included in the analysis. Eyes were randomized to receive a total of 6 intravitreal injections, once every 4 weeks, of either ranibizumab (0.5 mg) plus OPT-302 (0.5 mg or 2 mg) or ranibizumab plus sham.

OPT-302 combination therapy had a safety profile consistent with standard of care anti-VEGF-A monotherapy while demonstrating greater improvements in best-corrected visual acuity (BCVA) and less retinal fluid compared to ranibizumab monotherapy. The +6.7 letters comparative superiority of 2 mg OPT-302 combination therapy over ranibizumab (p = 0.0253) was accompanied by a greater improvement in secondary vision and anatomical outcome measures at week 24.

"These promising results demonstrate that patients receiving OPT-302 combination therapy showed meaningful improvements in vision over those receiving monotherapy," commented Dr. Cheung. "This analysis further supports the potential added value of OPT-302 combination therapy for patients with wet AMD. We look forward to continuing to partner with Opthea to investigate the safety and efficacy of OPT-302 combination therapy targeting PCV."

Dr. Megan Baldwin added "Vision gains in patients with PCV are consistent with the statistically superior visual acuity gains following OPT-302 combination therapy observed in the total Phase 2b study population. Additional data on PCV lesions will be obtained from Opthea's ongoing Phase 3 ShORe and COAST trials, which are also expected to enroll a number of treatment naïve patients with PCV."

Additional information on Opthea's technology and the Phase 3 pivotal clinical trials can be found at www.opthea.com and at 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 advancement of Opthea's Phase 3 registrational program and commercialization efforts for OPT-302 and Opthea's goal of building out a substantial presence in the United States. 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 Opthea's Annual Report on Form 20-F filed with the SEC on October 28, 2021. 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.

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