Opthea Data for OPT-302 in Combination with Ranibizumab for Polypoidal Choroidal Vasculopathy (PCV) Presented at ARVO 2022

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MELBOURNE, Australia., May 05, 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 the clinical data was presented at the Association for Research in Vision and Ophthalmology (ARVO) 2022 Annual Meeting. The presentation, titled "Efficacy and Safety of OPT-302 in combination with Ranibizumab for Polypoidal Choroidal Vasculopathy," was held on Sunday, May 1, 2022, and appeared in a session on clinical and translational research and AMD therapies excluding anti-VEGF. Dr. Jason Slakter, MD, Clinical Professor, Department of Ophthalmology at NYU Grossman School of Medicine, presented.

"We are pleased to present and share these clinical findings with the global vision research community at the ARVO 2022 annual meeting," said Dr. Megan Baldwin, Chief Executive Officer of Opthea. "We have received positive feedback on the potential utility of OPT-302 combination therapy for patients with PCV lesions and we look forward to evaluating additional data which is being obtained from the ongoing OPT-302 Phase 3 ShORe and COAST trials which are expected to enroll a significant number of treatment naïve patients with PCV," commented Dr. Baldwin.

The ARVO poster presented results of a pre-specified subgroup analysis of subjects with Polypoidal Choroidal Vasculopathy (PCV type CNV) enrolled in the Phase 2b randomized, sham-controlled study of patients with treatment naive exudative AMD. In this study, subjects received either monotherapy with ranibizumab (Lucentis®) or combination therapy with ranibizumab and one of two doses of OPT-302. Of the 366 participants, 66 (18%) were identified as having PCV lesions at baseline based on multimodal imaging analysis of color fundus photography, fluorescein angiography and SD-OCT.

OPT-302 (2.0 mg), used in combination with ranibizumab (0.5 mg), achieved superior visual acuity gains and anatomic improvements compared to monthly ranibizumab monotherapy in these subjects with PCV type CNV. Specifically, following OPT-302 combination therapy over the 6 months of the study: an additional 6.7 letter gain was achieved over ranibizumab monotherapy, a greater proportion of patients gained ≥ 10 and ≥15 letters from baseline, or achieved 20/40 vision or better, while fewer participants lost 5 letters or more of vision.

A copy of the poster is available on Presentations page of the Opthea website: www.opthea.com

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 expected enrollment of a significant number of patients for the trials, 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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