Opthea Phase 2b Trial Results of OPT-302 in Combination with Lucentis® for wet AMD Published in the Journal Ophthalmology

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MELBOURNE, Australia, Feb. 13, 2023 (GLOBE NEWSWIRE) -- Opthea Limited (NASDAQ:OPT; ASX:OPT), a clinical stage biopharmaceutical company developing novel therapies to treat highly prevalent and progressive retinal diseases, announced today that the Phase 2b study results of OPT-302, the Company's anti-VEGF-C/-D "trap" agent administered in combination with Lucentis® (ranibizumab) for the treatment of wet age-related macular degeneration (AMD), have been published online in *Ophthalmology*, the journal of the American Academy of Ophthalmology

The prospective, randomized, controlled Phase 2b trial of 366 treatment-naive patients with wet AMD, conducted at 109 clinical sites across the United States, Europe and Israel, demonstrated that monthly intravitreal administration of 2.0 mg OPT-302 with ranibizumab standard of care, met the pre-specified primary efficacy endpoint of a statistically superior gain in visual acuity at 24 weeks, compared to ranibizumab alone. In addition, secondary outcomes were positive for the OPT-302 combination therapy including more participants with gains in vision of 10 or more letters, improved anatomy of reduction in swelling and vascular leakage, with a favorable safety profile.

"We are gratified that these important clinical findings from the Phase 2b trial have been published in *Ophthalmology*, an internationally recognized peer-reviewed journal and we also wish to thank the patients, investigators and their staff for participating and their efforts in ensuring the success of this study," said Dr. Megan Baldwin, CEO and Managing Director of Opthea. "The robust results of this large Phase 2b trial have informed and provided the foundation for our ongoing Phase 3 registrational program of OPT-302 in combination with anti-VEGF-A therapy for the treatment of wet AMD."

The published research article in *Ophthalmology*, titled "A randomized controlled trial of OPT-302, a VEGF-C/D inhibitor for neovascular age-related macular degeneration" can be accessed under "Articles in Press" at: https://www.aaojournal.org/article/S0161-6420(23)00066-0/fulltext.

Professor Tim Jackson, lead author and Consultant Ophthalmic Surgeon at King's College London, commented, "Recently, a focus in wet AMD has been on emerging approaches to extend dosing intervals, which is important, but patient surveys indicate that they rank their main goal as achieving better vision over durability. The promising results of this Phase 2b trial show that OPT-302 combination therapy can deliver vision that is significantly superior to anti-VEGF-A monotherapy, and so we look forward to the results of the ongoing Phase 3 studies in wet AMD."

The U.S. Food and Drug Administration (FDA) granted OPT-302 Fast Track Designation for the treatment of wet AMD, which facilitates the development and expedites the review of investigational therapies to treat serious conditions and fill an unmet medical need.

Opthea is currently conducting two global confirmatory Phase 3 studies, ShORe (2 mg OPT-302 + 0.5 mg ranibizumab), and COAST (2 mg OPT-302 + 2 mg aflibercept). The primary endpoint for both studies is superiority in visual acuity gains at 12 months for the combination therapy compared with standard-of-care monotherapy. More information regarding ShORe (NCT04757610) and COAST (NCT04757636) can be found at https://clinicaltrials.gov.

About Opthea Limited

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.

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