Opthea Completes COAST Final Week 52 Patient Visit

February 18, 2025

COAST Phase 3 trial evaluates superiority and safety of sozinibercept combined with aflibercept in wet AMD

Company confirms topline results for COAST anticipated in early 2Q CY25

MELBOURNE, Australia and PRINCETON, N.J., Feb. 18, 2025 (GLOBE NEWSWIRE) -- Opthea Limited (ASX/NASDAQ:OPT, "Opthea", the "Company"), a clinical-stage biopharmaceutical company developing novel therapies to treat highly prevalent and progressive retinal diseases, including wet age-related macular degeneration (wet AMD), today announced that it has completed the final week 52 patient visit in COAST, the first of two Phase 3 pivotal trials investigating the superiority and safety of sozinibercept in combination with aflibercept (COAST) or ranibizumab (ShORe), compared to standard of care alone for the treatment of wet AMD. The topline results from both trials are anticipated in early Q2 CY25 (COAST) and mid-CY25 (ShORe).

"The completion of the final week 52 patient visit in COAST is an important milestone in the development of sozinibercept, as we deliver on our mission of improving visual outcomes in patients with wet AMD to enable fuller and healthier lives," commented Frederic Guerard, PharmD, Chief Executive Officer of Opthea. "I would like to thank Charles Wykoff, MD, PhD as well as all of the COAST investigators and their clinical staff for their excellent work as we plan to announce the anticipated topline data in early Q2 CY25."

Opthea is conducting two concurrent global pivotal Phase 3 clinical trials for the treatment of wet AMD, aiming to demonstrate superiority of sozinibercept combination therapy versus standard of care alone: COAST (Combination OPT-302 with Aflibercept Study) and ShORe (Study of OPT-302 in combination with Ranibizumab). The primary endpoint for both trials is the mean change in Best Corrected Visual Acuity (BCVA) from baseline to week 52 for sozinibercept combination therapy compared to anti-VEGF-A monotherapy. Beyond week 52, patients will continue to be treated for an additional year to evaluate extended safety and tolerability up to a two-year period. Opthea's Phase 3 program is designed to support a broad label and, if successful, enable sozinibercept to be approved for use in combination with any anti-VEGF-A therapy in wet AMD patients. Sozinibercept has received Fast Track Designation from the US FDA for the treatment of wet AMD.

About Opthea

Opthea (ASX/NASDAQ:OPT) is a biopharmaceutical company developing novel therapies to treat vision-threatening eye diseases, including wet age-related macular degeneration (wet AMD) and diabetic macular edema (DME), which remain leading causes of vision loss worldwide.

Opthea's lead product candidate in Phase 3 development, sozinibercept, is a first-in-class VEGF-C/D 'trap' inhibitor being evaluated in combination with standard-of-care anti-VEGF-A therapies to deliver superior vision to wet AMD patients. Sozinibercept has the potential to become the first therapy in 20 years to enable patients with wet AMD live fuller and healthier lives.

To learn more, visit our website at www.opthea.com and follow us on X and LinkedIn.

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

This announcement contains certain forward-looking statements, including within the meaning of the U.S. Private Securities Litigation Reform Act of 1995. The words "expect", "believe", "should", "could", "may", "will", "plan" and other similar expressions

are intended to identify forward-looking statements. Forward-looking statements in this announcement include statements regarding the expected timing for topline results for the COAST and ShORe clinical trials; Opthea's Phase 3 program being designed to support a broad label, and the commercial and clinical potential of sozinibercept, including its potential use in combination with any anti-VEGF-A therapy in wet AMD patients, if approved, its potential to become the first therapy in 20 years to enable patients with wet AMD to live fuller and healthier lives and its potential to deliver superior vision to wet AMD patients. Forward-looking statements, opinions and estimates provided in this announcement are based on assumptions and contingencies which are subject to change without notice, as are statements about market and industry trends, which are based on interpretations of current conditions. Forward-looking statements are provided as a general guide only and should not be relied upon as an indication or guarantee of future performance. They involve known and unknown risks and uncertainties and other factors, many of which are beyond the control of Opthea and its directors and management and may involve significant elements of subjective judgment and assumptions as to future events that may or may not be correct. These statements may be affected by a range of variables which could cause actual results or trends to differ materially, including but not limited to future capital requirements, the development, testing, production, marketing and sale of drug treatments, regulatory risk and potential loss of regulatory approvals, ongoing clinical studies to demonstrate sozinibercept's safety, tolerability and therapeutic efficacy, clinical research organization and labor costs, intellectual property protections, and other factors that are of a general nature which may affect the future operating and financial performance of Opthea including risk factors set forth in Opthea's Annual Report on Form 20-F filed with the U.S. Securities and Exchange Commission (the "SEC") on August 30, 2024, and other future filings with the SEC. Actual results, performance or achievements may vary materially from any projections and forward-looking statements and the assumptions on which those statements are based. Subject to any continuing obligations under applicable law or any relevant ASX listing rules, Opthea disclaims any obligation or undertaking to provide any updates or revisions to any forward-looking statements in this announcement to reflect any change in expectations in relation to any forward-looking statements or any change in events, conditions or circumstances on which any such statement is based, except as otherwise required by applicable law.

Authorized for release to ASX by Frederic Guerard, PharmD, CEO

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