Opthea Completes Drug Product PPQ Campaign

Three consecutive commercial-scale drug product batches successfully produced

Supports potential sozinibercept BLA filing in 1H CY2026

Melbourne, Australia, and Princeton, NJ, US, February 26, 2025 -- 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 the completion of its drug product Process Performance Qualification (PPQ) campaign for sozinibercept.

The PPQ campaign consisted of the successful production of three consecutive commercial-scale drug product batches required to further validate Opthea's manufacturing process in preparation for a potential biologics license application (BLA) filing and commercialization of sozinibercept in wet AMD. The batches have been produced subsequent to the successful completion of the drug substance PPQ campaign announced in September 2024.

"The successful completion of the drug product PPQ campaign is a critical step in support of a potential BLA filing of sozinibercept in wet AMD in the first half of CY2026," commented Fred Guerard, PharmD, Chief Executive Officer of Opthea. "As we continue to work towards the Phase 3 topline data readout of COAST in early Q2 CY2025 and ShORe in mid-CY2025, we now have demonstrated our ability to consistently manufacture quality drug product at commercial scale to support a potential approval and launch of sozinibercept in 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 to 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 potential BLA filing and approval and launch of sozinibercept in wet AMD; Opthea’s ability to produce consistent quality batches of drug product at commercial scale going into potential approval and commercialization; expected timing for topline results for the COAST and ShORe clinical trials; 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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