Opthea Announces Completion of Drug Substance PPQ Campaign Validating Manufacturing Process of Sozinibercept

September 18, 2024

Three consecutive commercial-scale batches successfully produced

Major milestone for potential BLA filing of sozinibercept in wet AMD

Progress update of drug product PPQ campaign expected in early 2025

MELBOURNE, Australia and PRINCETON, N.J., Sept. 18, 2024 (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 the completion of its drug substance Process Performance Qualification (PPQ) campaign for sozinibercept. The PPQ campaign consisted of the production of three successful consecutive commercial-scale drug substance batches required for the validation of Opthea's manufacturing process. The batches have been produced following an extensive manufacturing process development program.

"The successful completion of the drug substance PPQ campaign is an important step towards de-risking the program and a potential biologics license application (BLA) filing of sozinibercept in wet AMD," commented Fred Guerard, PharmD, Chief Executive Officer of Opthea. "While we continue to advance our two fully enrolled, pivotal Phase 3 trials of sozinibercept in wet AMD, we now have demonstrated our ability to consistently manufacture quality drug substance at commercial scale, which will serve as a key component of our BLA Chemistry, Manufacturing and Controls (CMC) module."

"In achieving this commercialization milestone, we believe Opthea is well positioned to supply both our planned drug product PPQ campaign, as well as our initial launch materials," concluded Mark O'Neill, Vice President, Technical Operations, Opthea. "We expect to share a progress update of our drug product PPQ campaign in early 2025."

About Opthea

Opthea (ASX/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, sozinibercept, is being evaluated in two fully enrolled pivotal Phase 3 clinical trials (COAST, NCT04757636, and ShORe, NCT04757610) for use in combination with standard-of-care anti-VEGF-A monotherapies to improve overall efficacy and deliver superior vision gains compared to standard-of-care anti-VEGF-A agents.

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

Forward Looking Statements

This ASX 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 ASX announcement include statements regarding the Company's continued efforts to advance its BLA preparations for FDA approval, the Company's commercialization potential and timing of the progress update of the Company's drug product PPQ campaign. Forward-looking statements, opinions and estimates provided in this ASX 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 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 the Company 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 achievement 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 ASX 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, CEO

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