Opthea Strengthens Team with Key Clinical and Regulatory Hires

February 1, 2024

Dr. Julie Clark, SVP Clinical Development; Dr. Fang Li, SVP Regulatory Affairs, to join February 1st
Experienced executives bring extensive track record in products for retinal and ophthalmology diseases

MELBOURNE, Australia, Feb. 01, 2024 (GLOBE NEWSWIRE) -- Opthea Limited (ASX:OPT; NASDAQ:OPT, "Opthea"), a clinical-stage biopharmaceutical company developing novel therapies to treat highly prevalent and progressive retinal diseases, today announced the appointment of Julie Clark, MD, MS, as Senior Vice President (SVP), Clinical Development, and Fang Li, Ph.D. RAC, as SVP, Regulatory Affairs, effective February 1, 2024. Dr. Clark and Dr. Li will report to Opthea Chief Executive Officer, Frederic Guerard, PharmD, MS, and will join the Opthea Executive Management Team.

"It is my great pleasure to welcome two ophthalmology experts, Dr. Clark and Dr. Li, to the Company as we prepare for the next stage in our growth and work towards advancing the development of sozinibercept (OPT-302)," said Dr. Guerard. "Their past contributions to the development and registration of ophthalmology therapies such as IZERVAY™, BEOVU®, and EYLEA®, will be instrumental to the potential success of our lead program investigating sozinibercept, currently in two Phase 3 pivotal trials."

Dr. Clark shared, "I am thrilled to join Opthea as we prepare to complete patient enrollment in the pivotal Phase 3 clinical program for sozinibercept in the first half of 2024. The majority of my career has been dedicated to the clinical development of novel therapies for retinal diseases. Sozinibercept could be the first new drug for wet age-related macular degeneration (AMD) in more than 15 years, with the potential to deliver superior visual gains when administered in combination with standard of care therapy. I look forward to contributing to bringing this novel product candidate to patients with serious retinal disease."

Dr. Li commented, "As we work towards the potential release of topline results for our Phase 3 program in mid-2025, I am excited to apply my expertise to support the development and execution of our regulatory strategy and potential filings for sozinibercept in the U.S. and other markets. I look forward to the opportunity to bring Opthea's innovative potential medicine through the regulatory process for the benefit of patients with retinal diseases."

Julie Clark, MD, MS

With more than 15 years of experience in ophthalmology medical and clinical development, Dr. Clark brings expertise in both early and late-stage programs, regulatory submissions, and approvals. Her contributions include substantial support for the approval and launches of retinal therapies such as EYLEA®, JETREA® and BEOVU®.

In Dr. Clark's most recent position as Vice President Clinical Development at IVERIC bio, Inc., An Astellas Company, she oversaw the development program leading to the August 2023 U.S. Food and Drug Administration (FDA) approval of IZERVAY ™ , a complement inhibitor approved for the treatment of geographic atrophy secondary to age-related macular degeneration. Dr. Clark previously served as Chief Medical Officer at Adverum Biotechnologies Inc, where she played a crucial role in developing intravitreal delivered gene therapy for retinal diseases.

Dr. Clark is a graduate of Wake Forest University and Wake Forest University School of Medicine in Winston-Salem, NC, U.S.

Fang Li, PhD, RAC

Dr. Li brings over 30 years of expertise in drug development and more than 20 years in regulatory affairs experience. Her experience spans various domains including small molecules, biologics, gene therapy, over-the-counter products, *in-vitro* diagnostic products and medical devices, with a specific focus on ophthalmology. She has held key roles at prominent ophthalmology companies such as Novartis AG, Alcon Inc., and Bausch + Lomb Corporation.

Dr. Li's extensive background includes significant involvement in health authority interactions, U.S. FDA advisory committee meeting preparation and the establishment and leadership of regulatory teams. She has a proven track record of success in obtaining product approvals in the U.S. and other regions. Throughout her career, Dr. Li has played a pivotal role in leading numerous FDA drug approvals, specifically contributing to the approval of ophthalmology products like JETREA®, LOTEMAX® Ointment, SYSTANE® COMPLETE. She has also contributed to the development and registration of other ophthalmology drug products such as BEOVU®, PAZEO®, LOTEMAX® GEL, BESIVANCE®, and VYZULTA®.

Fang holds a PhD in Medicinal Chemistry from China Pharmaceutical University, China.

About Opthea

Opthea Limited (ASX:OPT; NASDAQ:OPT, "Opthea") is a biopharmaceutical company developing novel therapies to address the unmet need in the treatment of highly prevalent and progressive retinal diseases, including neovascular (wet) age-related macular degeneration (wet AMD). Opthea's lead product candidate sozinibercept is being evaluated in two pivotal Phase 3 clinical trials (ShORe, NCT04757610, and COAST, NCT04757636) 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. To learn more, visit 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 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 expectations on the outcomes of Opthea's Phase 3 clinical trials of sozinibercept, the potential for sozinibercept as a combination therapy to be the first therapy to achieve superior visual outcomes over anti-VEGF-A monotherapy and improve vision outcomes for patients with wet AMD, the expected timing for completion of enrollment for the Phase 3 studies and topline data, the market opportunity for sozinibercept, and the future performance of Opthea. 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, additional analysis of data from Opthea's Phase 3 clinical trials, timing of completion of Phase 3 clinical trial patient enrollment and 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 September 28, 2023 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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