Opthea Appoints Arshad M. Khanani, MD, MA, FASRS, as Chief Medical Advisor

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Global retina expert joins to support sozinibercept development and launch preparation

MELBOURNE, Australia, Feb. 19, 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 Arshad M. Khanani, MD, MA, FASRS, as Chief Medical Advisor. An internationally recognized retina specialist and clinical scientist, Dr. Khanani is a Managing Partner, Director of Clinical Research, and Director of Fellowship at Sierra Eye Associates, and Clinical Associate Professor at the University of Nevada, Reno School of Medicine.

"We are delighted to have Dr. Khanani join Opthea as Chief Medical Advisor," said Frederic Guerard, PharmD, Chief Executive Officer for Opthea. "Dr. Khanani's extensive experience and informed perspective, from his work as the principal investigator for numerous clinical trials for retinal diseases, will be invaluable to Opthea. Sozinibercept has the potential to be the first new drug for wet age-related macular degeneration (AMD) in more than 15 years to deliver superior visual gains when administered in combination with standard of care therapy. Dr Khanani's expert advice will help us progress this important medicine towards registration and launch."

"I am honored to assume the role of Opthea's Chief Medical Advisor, dedicated to advancing the development of sozinibercept, the pioneering treatment undergoing late-stage clinical trials aimed at enhancing vision outcomes for patients afflicted by wet AMD," remarked Dr. Khanani, Opthea's Chief Medical Advisor. "This juncture marks a pivotal moment for Opthea and the sozinibercept program, with the recent completion of enrollment for the COAST study, expectations to complete enrollment in the ShORe study in calendar Q2 2024 and anticipated topline data disclosure from both pivotal trials by mid-year calendar 2025. With my extensive involvement in guiding numerous recently approved treatment modalities, I am steadfast in my commitment to supporting Opthea in promptly concluding the pivotal trials and ushering sozinibercept towards enhancing vision outcomes for patients worldwide."

Arshad M. Khanani, MD, MA, FASRS

Dr. Khanani is dedicated to advancing innovative treatment options for patients suffering from retinal diseases. Over a decade ago, he established the clinical research department at Sierra Eye Associates, which has since evolved into one of the foremost clinical research sites nationwide. With a wealth of experience, he has assumed the role of principal investigator for more than 120 clinical trials, consistently ranking as a top enroller in the nation across multiple Phase 1-3 trials. Notably, Dr. Khanani recently chaired the Phase 3 GATHER2 steering committee for IZERVAY™, playing a pivotal role in IZERVAY's approval for geographic atrophy. His contributions extend to over 100 authored or contributed scientific publications in prominent ophthalmology journals.

Dr. Khanani actively participates as a member of national and international clinical trial steering committees, in addition to serving on scientific advisory boards. Dr. Khanani also serves as the lead principal investigator for multiple national and global clinical trials. He is often sought after as a guest speaker and lecturer at prestigious national and international gatherings. In pursuit of advancements in vitreoretinal care, Dr. Khanani initiated the Clinical Trials at the Summit (CTS) meeting, aiming to foster dialogue on clinical trial execution, design, and data analysis.

Dr. Khanani holds elected membership in esteemed organizations such as the Macula Society and Retina Society, in addition to being the recipient of numerous distinguished awards. In 2019, he was honored with the Nevada Business Magazine Healthcare Heroes Physician of the Year award in recognition of his unwavering commitment to the field of ophthalmology. Dr. Khanani has been bestowed with the Senior Honor Award from the American Society of Retina Specialists (ASRS) and was also awarded the prestigious ASRS Presidents' Young Investigator Award in 2021. Furthermore, in 2023, he was invited to deliver the esteemed Ernst Bodenheimer Memorial Lecture at the Wilmer Eye Institute at Johns Hopkins University.

About Opthea

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 sozinibercept, is being evaluated in two 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 the standard-of-care anti-VEGF-A agents. To learn more, visit www.opthea.com and follow us on X and LinkedIn.

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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 ShORe 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 ShORe 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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