Opthea Opens Patient Enrollment in the Asia-Pacific Region for the OPT-302 ShORe and COAST Phase 3 Trials in Wet AMD

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MELBOURNE, Australia, Oct. 19, 2021 (GLOBE NEWSWIRE) -- Opthea Limited (ASX:OPT; Nasdaq:OPT), a clinical stage biopharmaceutical company developing novel therapies to treat highly prevalent and progressive retinal diseases, today announced that the first clinical trial sites in the Asia-Pacific region are now open for patient enrollment into the OPT-302 Phase 3 pivotal clinical program for the treatment of wet (neovascular) age-related macular degeneration (AMD). The clinical trial sites, located in Australia, further build upon the progress of other international regions including the U.S., Canada and Europe that are also actively recruiting patients.

"We are delighted to open enrollment in the Asia-Pacific region. This is a significant milestone for the OPT-302 development program and enables eligible patients to participate in the ShORe and COAST Phase 3 trials which are designed based on strong scientific rationale, prior positive clinical efficacy results and extensive safety data in the wet AMD target population. Over the following weeks we anticipate opening sites in additional countries in the Asia Pacific region including South Korea and the Philippines," said Dr Megan Baldwin, CEO and Managing Director of Opthea.

The ShORe and COAST studies are both double-masked, sham-controlled Phase 3 registrational trials to evaluate efficacy and safety of intravitreal 2.0 mg OPT-302 in combination with either 0.5 mg ranibizumab (Lucentis®), or 2.0 mg aflibercept (Eylea®) respectively. The primary endpoint of the studies is the mean change in best corrected visual acuity from baseline to week 52 for OPT-302 combination therapy compared to standard of care anti-VEGF-A monotherapy. The read-out of the top-line results through 52 weeks is anticipated in the second half of 2023, and following completion of this primary efficacy phase, the Company plans to file Biologics License and Marketing Authorization Applications with the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) respectively.

Recently, the FDA granted Fast Track status for OPT-302, in combination with anti-VEGF-A therapy for the treatment of patients with wet AMD and this regulatory designation offers benefits to help advance development and expedite the review of novel therapies for serious conditions for which there is an unmet medical need, with the aim of getting important new therapies to patients more quickly.

Additional information on Opthea's technology and the Phase 3 pivotal clinical trials can be found at www.opthea.com and at ClinicalTrials.gov (ShORe trial, ID#: NCT04757610; COAST trial, ID#: NCT04757636).

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 OPT-302 is in pivotal Phase 3 clinical trials and being developed for use in combination with anti-VEGF-A monotherapies to achieve broader inhibition of the VEGF family, with the goal of improving overall efficacy and demonstrating superior vision gains over that which can be achieved by inhibiting VEGF-A alone.

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

Certain statements in this announcement may contain forward-looking statements, including within the meaning of the U.S. Private Securities Litigation Reform Act of 1995. Any statement describing Company goals, expectations, intentions or beliefs is a forward-looking statement and should be considered an at risk statement, including, but not limited to, the continuation of patient recruitment for Opthea's pivotal Phase 3 clinical trials of OPT-302 in wet AMD. Such statements are based on Opthea's current plans, objectives, estimates, expectations and intentions and are subject to certain risks and uncertainties, including risks and uncertainties associated with clinical trials and product development and the impact of general economic, industry or political conditions in Australia, the United States or internationally. These and other risks and uncertainties are described more fully in the section titled "Risk Factors" in the final prospectus filed with the SEC on October 19, 2020. The Company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events, or otherwise, except as required under applicable law. You should not place undue reliance on these forward-looking statements as predictions of future events, which statements apply only as of the date of this announcement. Actual results could differ materially from those discussed in this ASX announcement.

Authorized for release to ASX by Megan Baldwin, CEO & Managing Director

Company & Media Enquiries: ***Join our email database to receive program updates:***

U.S.A. & International:
Sam Martin
Argot Partners
Tel: +1 212-600-1902
opthea@argotpartners.com

Australia:
Rudi Michelson
Monsoon Communications
Tel: +61 (0) 3 9620 3333

Tel: +61 (0) 3 9826 0399
info@opthea.com
www.opthea.com