Opthea Receives FDA Waiver for Pediatric Study Plan for OPT-302 in Wet AMD

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MELBOURNE, Australia, March 31, 2021 (GLOBE NEWSWIRE) -- Opthea Limited (ASX:OPT; Nasdaq:OPT), a clinical stage biopharmaceutical company developing a novel therapy to treat highly prevalent and progressive retinal diseases, today announces that it has received an initial Pediatric Study Plan (iPSP) waiver from the US Food and Drug Administration (FDA) for OPT-302, the Company's lead product candidate currently in Phase 3 clinical development for the treatment of neovascular (wet) age-related macular degeneration.

As part of the regulatory review process, a bio-pharmaceutical company that is planning to submit a marketing application of a new medicine with the FDA is required to provide an iPSP detailing the Company's proposed strategy for investigation of the new medicinal product in the pediatric population. In some instances, a waiver from developing an iPSP for certain conditions may be agreed to by the Agency.

Opthea received from the FDA an official, agreed iPSP waiver for OPT-302 across all subsets of the pediatric population (full pediatric age group from birth to < 17 years) for the treatment of wet AMD in combination with intravitreal anti-VEGF-A therapy. The receipt of the agreed iPSP waiver means the Company will not have to conduct an additional study in the pediatric population.

Dr Megan Baldwin, CEO of Opthea commented: "The agreed iPSP waiver is an important regulatory milestone in the US that is required to be completed before Opthea is able to submit a marketing application for OPT-302 to the FDA. Opthea will continue the process to further fulfilling regulatory requirements by focusing on our pivotal Phase 3 clinical trials in adult patients that are designed to support potential marketing approval of OPT-302 for the treatment of wet AMD."

Additional information on Opthea's technology and clinical trials can be found at www.opthea.com.

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About Opthea

Opthea (ASX:OPT; Nasdaq:OPT) is a biopharmaceutical company developing a novel therapy 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 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.