Opthea to Receive US$35M Commitment and Additional US$50M Funding

December 27, 2023

- *Opthea to receive remaining US$35m funding under the Development Funding Agreement (**DFA**) with Carlyle and its life science franchise Abingworth, as well as a further US$50m financing under an Amended DFA to include a new co-investor*
- *This financing is non-dilutive to shareholders, with no equity issued to Carlyle, Abingworth or the new co-investor*
- *Investment driven by the potential of sozinibercept (OPT-302) to provide superior visual outcomes for wet AMD patients and to provide a multi-billion dollar commercial opportunity*

MELBOURNE, Australia, Dec. 27, 2023 (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 it expects to receive the remaining US$35 million committed funds under the Development Funding Agreement (DFA) with Carlyle and Abingworth, and has entered into binding documentation with a new co-investor under an Amended DFA to secure an additional US$50 million in funding.

Under the terms of the DFA, Carlyle and Abingworth committed US$120 million, of which US$85 million has been received to date. The remaining committed funds of US$35 million and the additional US$50m announced today will be received on or around December 31, 2023, bringing the total committed funding under the amended DFA to US$170 million, the maximum amount allowed under the terms of the DFA.

Dr. Fred Guerard, Chief Executive Officer of Opthea Limited, commented, “We are extremely pleased with this funding that demonstrates investors’ confidence in sozinibercept and its potential for future clinical, regulatory and commercial success. Both global pivotal trials in wet AMD (COAST and ShORe) are now over 80% enrolled, and aim at confirming the superior efficacy outcomes observed in Opthea’s Phase 2b trial.”

This total US$85 million funding will be used to advance Opthea’s Phase 3 clinical trials and pre-commercialization activities of sozinibercept for wet AMD.

Under the terms of the DFA, if sozinibercept is approved in a major market, Opthea will make a milestone payment after regulatory approval and then six subsequent annual fixed success payments and variable success payments of 7% of net sales, with cumulative payments capped at four times the amount funded to Opthea. Opthea retains full worldwide commercial rights for sozinibercept and has the option to prepay its obligations in full at any time. The foregoing description of certain terms of the DFA is qualified in its entirety by reference to the full text of the Amended DFA, which will be separately filed with the Securities and Exchange Commission.

About sozinibercept

Sozinibercept (OPT-302) is a soluble form of vascular endothelial growth factor receptor (VEGFR)-3 expressed as an immunoglobulin G1 (IgG1) Fc-fusion protein. It binds and neutralizes the activity of vascular endothelial growth factor (VEGF)-C and VEGF-D on their endogenous receptors, VEGFR-2 and VEGFR-3. Targeted inhibition of VEGF-C and VEGF-D can prevent blood vessel growth and vascular leakage, which contribute to the pathophysiology of retinal diseases including neovascular “wet” AMD.

About ShORe and COAST Phase 3 Clinical Studies

Opthea currently is enrolling patients for its two ongoing concurrent Global pivotal Phase 3 clinical trials for the treatment of wet AMD. The multi-center, double-masked, sham-controlled Phase 3 ShORe (*Study of OPT-302 in combination with Ranibizumab*) and COAST (*Combination OPT-302 with Aflibercept Study;*) clinical trials will each enroll approximately 990 treatment-naïve patients and assess the efficacy and safety of intravitreal 2.0 mg sozinibercept in combination with 0.5 mg ranibizumab (Lucentis®) (ShORe trial) or 2.0 mg aflibercept (Eylea®) (COAST trial), compared to ranibizumab or aflibercept monotherapy, respectively. In addition, extended durability of the sozinibercept treatment effect on clinical outcomes with less frequent every eight-weekly dosing will be compared with sozinibercept administered on an every four-weekly dosing regimen, in combination with each VEGF-A inhibitor. If successful, the investigation of sozinibercept in combination with two approved standard of care VEGF-A inhibitors in the Phase 3 program could enable sozinibercept to be administered with either Eylea or Lucentis which had combined sales for retinal diseases of >USD$12 billion in 2022. The primary endpoint for both trials is the mean change in Best Corrected Visual Acuity from baseline to week 52 for sozinibercept combination therapy compared to anti-VEGF-A monotherapy. Patients will continue to be treated for a further year to evaluate extended safety and tolerability over a two-year period. To learn more, visit www.opthea.com and 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 sozinibercept is in pivotal Phase 3 clinical trials and being developed for use in combination with anti-VEGF-A monotherapies to improve overall efficacy and deliver superior vision gains over that which can be achieved by inhibiting VEGF-A alone. To learn more, visit www.opthea.com and follow us on Twitter 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 the additional funding commitment under the DFA, including satisfaction of conditions to such commitment and timing of Opthea's receipt of funding, expectations regarding the outcomes of Opthea's Phase 3 clinical trials of OPT-302, the potential for OPT-302 to improve vision outcomes for patients with wet AMD, the market opportunity for OPT-302, 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 the availability of funding, the receipt of funding under the DFA, including the co-investor commitment and risks relating to the satisfaction of conditions to funding, 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 OPT-302 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 CRO 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. 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 Fred Guerard, CEO

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Source: Opthea Limited