Opthea Secures up to US$170 Million in Non-Dilutive Financing for OPT-302 in wet AMD

August 14, 2022

- *Carlyle and its life sciences franchise Abingworth, working with their recently formed development company Launch Therapeutics (Launch Tx), to provide non-dilutive financing of up to US$170M, consisting of a US$120M commitment and an option to increase funding by a further US$50M*
- *If OPT-302 is approved in a major market, Carlyle and Abingworth will be eligible to receive fixed success payments and variable success payments of 7% on annual net sales, which terminate after reaching four times the funded amount*
- *In addition, Opthea has received commitments for US$90M[1] (A$128.57M) via a private institutional equity placement for new shares and launched an A$5M Share Purchase Plan (SPP)*
- *Opthea is expected to be fully funded through pivotal Phase 3 topline data and pre-commercial activities and retains full worldwide commercial rights to OPT-302*
- *Financing decision driven by the potential of superior visual outcomes demonstrated in Phase 2b unlike competitors who focus on extended dosing*

MELBOURNE, Australia and BOSTON, Aug. 14, 2022 (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 a non-dilutive financing transaction for up to US$170 million from investment funds working with Launch Therapeutics (Launch Tx) to finance and advance the ongoing Phase 3 clinical trials and pre-commercialization activities of OPT-302 for wet age-related macular degeneration (wet AMD). Launch Tx is the recently formed development company backed by funds managed by global investment firm Carlyle (NASDAQ: CG) and its life sciences franchise, Abingworth.

Under the terms of the agreement, the funds managed by Carlyle and Abingworth, in collaboration with Launch Tx, will commit US$120 million in three installments at fixed time points and retain an option to commit another US$50 million, representing total funding of up to US$170 million for Opthea. If OPT-302 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 OPT-302 and has the option to prepay its obligations in full at any time.

Details of the US$90M[1] (A$128.57M) private institutional placement and SPP offering launched today have been separately announced.

"Opthea is thrilled to enter this strategic arrangement with Launch Tx, and to receive funding from world-leading investors in Carlyle and Abingworth. This strategic transaction is expected to fund us through Phase 3 topline data expected in mid-2024 and strengthens our strategic position to maximize the value of OPT-302," said Dr Megan Baldwin, Chief Executive Officer at Opthea. "This transaction with Launch Tx is non-dilutive for shareholders of Opthea, and we are proud to have been selected as Launch Tx's first partner since its formation."

Anshul Thakral, CEO of Launch Tx, commented, "We are excited to partner with Opthea on OPT-302, a novel drug candidate that has demonstrated superior visual acuity in Phase 2 trials over standard of care anti-VEGF-A therapy in patients with wet AMD. With this collaboration, we will advance OPT-302 through its ongoing Phase 3 trials and hope to reach regulatory approval in a timely manner, with the intention of bringing this important medicine to patients in need. At Launch Tx, we are committed to working with pharma and biotech partners to expedite late-stage drug development programs. We do this by designing innovative funding models tailored to our partners' specific needs and leveraging our extensive clinical development, regulatory, and commercialization expertise as needed. This partnership with Opthea is a great example of one such model."

OPT-302 is a first-in-class intravitreally administered biologic "trap" inhibitor of vascular endothelial growth factors C (VEGF-C) and D (VEGF-D) currently being investigated in two concurrent Phase 3 pivotal registrational trials that will each enroll ~990 treatment naïve patients, in combination with two approved anti-VEGF-A treatments, ranibizumab (ShORe trial) and aflibercept (COAST trial). OPT-302 has the potential to be positioned as complementary and agnostic with any combined anti–VEGF-A therapy for the treatment of wet AMD, a strategy intended to maximize the commercial opportunity for the therapy.

Global expert in the treatment of retinal diseases and Chief Investigator for the Phase 3 COAST study, Dr. Charles Wykoff, MD PhD, Director of Research, Retina Consultants of Texas, commented, "In a treatment landscape increasingly crowded with biosimilars and long-acting VEGF-A inhibitors, it is exciting to contribute to the advancement of OPT-302, the only investigational agent in late stage development with the potential to improve vision outcomes over standard of care for patients with wet AMD."

Cooley LLP (US) and Gilbert+Tobin (Australia) served as legal advisors to Opthea. Goodwin Procter LLP, DLA Piper LLP (US) and DLA Piper LLP (Australia) served as legal advisors to Launch Tx.

Additional details regarding the transactions described in this release and related operational updates will be included in a Report on Form 6-K, which Opthea will furnish separately with the U.S. Securities and Exchange Commission and the contents of which will be lodged with ASX in a separate announcement.

About OPT-302

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 pivotal Phase 3 clinical trials for the treatment of wet AMD. The global, multi-centre, 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 ~990 treatment-naive patients and assess the efficacy and safety of intravitreal 2.0 mg OPT-302 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 OPT-302 treatment effect on clinical outcomes with less frequent every eight-weekly dosing will be compared with OPT-302 administered on an every four-weekly dosing regimen, in combination with each VEGF-A inhibitor. If successful, the investigation of OPT-302 in combination with two approved standard of care VEGF-A inhibitors in the Phase 3 program could enable OPT-302 to be administered with either Eylea or Lucentis which had combined sales for retinal diseases of >USD$12 billion in 2021. The primary endpoint for both trials is the mean change in Best Corrected Visual Acuity from baseline to week 52 for OPT-302 combination therapy compared to anti-VEGF-A monotherapy. Each patient 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 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. To learn more, visit www.opthea.com.com and follow us on Twitter and LinkedIn.

About Launch Therapeutics

Launch Therapeutics (Launch Tx) is a clinical development company with a mission to disrupt the late-stage development paradigm, accelerate timelines to regulatory success and bring new medicines to patients faster. To deliver this, Launch Tx offers pharmaceutical and biotech partners a variety of innovative models that combine access to capital with deep drug development, medical, clinical operations, regulatory and commercialization expertise. These models include significant risk financing, clinical co-development and full in-licensing, all of which we believe offer partners an aligned and efficient approach to realizing the potential of late-stage clinical programs across any therapeutic area. Founded in 2022, Launch Tx is backed by leading investors, Carlyle and its life sciences franchise, Abingworth, and is led by a committed, experienced team with an enthusiastic passion to fulfil its mission. For more information, visit launchtx.com and follow us on LinkedIn.

About Carlyle

Carlyle (NASDAQ: CG) is a global investment firm with deep industry expertise that deploys private capital across three business segments: Global Private Equity, Global Credit and Global Investment Solutions. With $376 billion of assets under management as of June 30, 2022, Carlyle's purpose is to invest wisely and create value on behalf of its investors, portfolio companies and the communities in which we live and invest. Carlyle employs more than 1,900 people in 26 offices across five continents. Further information is available at www.carlyle.com. Follow Carlyle on Twitter @OneCarlyle.

About Abingworth

Abingworth is a leading transatlantic life sciences investment firm with approximately $2 billion under management. Abingworth helps transform cutting-edge science into novel medicines by providing capital and expertise to top caliber management teams building world-class companies. Since 1973, Abingworth has invested in 179 life science companies, leading to 74 IPOs and 48 M&As. Abingworth's therapeutic focused investments fall into three categories: seed and early-stage, development stage and clinical co-development. Abingworth supports its portfolio companies with a team of experienced professionals at offices in London, Menlo Park (California) and Boston. Abingworth is now part of Carlyle (NASDAQ: CG). For more information, visit www.abingworth.com

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 Opthea's goals, expectations, intentions or beliefs is a forward-looking statement and should be considered an at-risk statement, including, but not limited to, the expected enrollment of a significant number of patients for the trials, the advancement of Opthea's Phase 3 registrational program and commercialization efforts for OPT-302, the expected timing of Opthea's Phase 3 program and trials, Opthea's anticipated funding needs and cash runway, including following financing activities such as the non-dilutive financing transaction with Launch Tx, Opthea's ability to meet its payment and other obligations under the agreement with Launch Tx, Opthea's ability to draw the entire US$170 million of funding capacity under the agreement with Launch Tx in a timely manner or at all, and Opthea's goal of building out a substantial presence in the United States. 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, including unexpected costs or delays in the clinical trial process, risks from the continuing COVID-19 pandemic, 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 Opthea's Annual Report on Form 20-F filed with the SEC on October 28, 2021. If the risks materialize or assumptions prove incorrect, actual results could differ materially from the results implied by these forward-looking statements. 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

Contacts:

For Opthea	***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

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[1] Assumes AUD/USD exchange rate of A$1.00/US$0.70