ASX and Media Release

26 October 2021

Opthea Granted Chinese Patent Covering OPT-302

Melbourne, Australia; 26 October 2021 – Opthea Limited (ASX:OPT; Nasdaq:OPT), a clinical stage biopharmaceutical company developing novel therapies to treat highly prevalent and progressive retinal diseases, is pleased to announce the grant of Chinese Patent Number (CN) 106414487 B covering OPT-302, its soluble VEGFR-3 "trap" molecule currently being investigated in two global Phase 3 registrational clinical trials, ShORE (Study of OPT-302 in combination with Ranibizumab) and COAST (Combination OPT-302 with Aflibercept Study). The patent granted in the name of Opthea's wholly-owned subsidiary, Vegenics Pty Limited.

The Chinese patent covers OPT-302, pharmaceutical compositions comprising OPT-302, nucleic acid molecules that code for OPT-302, and the use of OPT-302 in the manufacture of preparations for the treatment of disorders associated with aberrant angiogenesis and/or lymphangiogenesis, including eye diseases such as wet age-related macular degeneration (wet AMD) and diabetic macular edema (DME). The patent term in China extends to February 2034.

Other patents in the same patent family and covering OPT-302 have already been granted in the United States, Europe, Japan, South Korea, Canada, Russia, Israel, Australia, Mexico, South Africa, Malaysia, Singapore, Indonesia, New Zealand and Colombia. Patent applications are currently pending in three other countries.

"We are pleased with the issuance of this patent which will support the potential development of OPT-302 as a new treatment for retinal diseases in China," said Megan Baldwin, Ph.D., Chief Executive Officer, Opthea. "This new patent in China expands the reach of our innovative therapy which is focused on improving patient outcomes. China has a burgeoning biologics industry and expanding life sciences sector, and together with the promising evidence of efficacy of OPT-302 in patients with polypoidal choroidal vasculopathy (PCV), a difficult-to-treat wet AMD subtype predominant in Asian populations, we view patent coverage in China as strategically important to our commercialization plans for OPT-302."

PCV is a common form of wet AMD with a high unmet need as PCV typically does not respond well to VEGF-A inhibitor therapy. In Opthea's Phase 2b randomised, controlled wet AMD study of OPT-302 with ranibizumab (Lucentis®) compared to ranibizumab alone, the mean BCVA gain from baseline to week 24 in the OPT-302 combination group was 13.5 letters (n = 22), compared to 6.9 letters in the ranibizumab control group (n = 20), a benefit of +6.7 letters (p = 0.025).

Information on Opthea's technology and clinical trials in wet AMD and DME can be found at www.opthea.com and ClinicalTrials.gov (ID#: NCT03345082 and ID#: NCT03397264, respectively).

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:

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

Join our email database to receive program updates:

Tel: +1 212-600-1902
info@opthea.com
www.opthea.com