ASX and Media Release

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Opthea's Phase 2b Study of OPT-302 in Wet AMD to be Presented in Late-Breaking Session of EURETINA

Melbourne, Australia; 4 Sept 2019 – Opthea Limited (ASX:OPT), a clinical biopharmaceutical company developing novel biologic therapies for eye diseases, announced today that data from its Phase 2b randomised, controlled study of OPT-302 with Lucentis® (ranibizumab) compared to Lucentis alone, will be presented at the European Society of Retina Specialists EURETINA Congress in Paris, France, on Thursday 5th September 2019 (CET).

The Phase 2b study data will be presented for the first time at an international ophthalmology congress by Professor Tim Jackson, Chief Investigator of the study, and Consultant Ophthalmic Surgeon at King's College London. Professor Jackson's presentation will be made in the "Novelties and Late Breaking Developments in Retina & Technology" session and will include an overview of the study design, safety outcomes and patient demographics and baseline characteristics across treatment groups. Primary and secondary outcomes of the study, including treatment effects on visual acuity outcomes and retinal anatomical changes will also be presented.

The European Society of Retina Specialists includes over 1800 members from over 170 nationalities. The EURETINA Congress is the largest annual gathering of vitreoretinal and macular specialists and attracts professionals from the global investor, pharmaceutical and clinical ophthalmology communities.

Dr Megan Baldwin, CEO & Managing Director, Opthea Limited commented "We thank the EURETINA organizers for including the OPT-302 Phase 2b study as a late breaking presentation at this prestigious meeting. We look forward to sharing additional detail on the outcomes of our Phase 2b clinical trial with the ophthalmic community."

A copy of the late-breaking presentation will be made available on Opthea's website at www.opthea.com and follows the recent announcement of the topline results from the Phase 2b trial demonstrating that the primary endpoint of the study was achieved. OPT-302 (2.0 mg) + Lucentis combination therapy demonstrated statistically significant vision benefit of +3.4 letters compared to Lucentis + sham administered monthly over 24 weeks ($p = 0.0107$).

The Phase 2b, randomised, double-masked, sham-controlled clinical trial recruited 366 wet AMD patients who were allocated to two intravitreal doses of OPT-302 (0.5 mg and 2.0 mg), administered monthly in combination with 0.5 mg Lucentis® over 24 weeks, versus a control group that received standard of care 0.5 mg Lucentis administered monthly.

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

About OPT-302

OPT-302 is a soluble form of vascular endothelial growth factor receptor 3 (VEGFR-3) or 'Trap' molecule that blocks the activity of two proteins (VEGF-C and VEGF-D) that cause blood vessels to grow and leak, processes which contribute to the pathophysiology of retinal diseases. Opthea is developing OPT-302 for use in combination with inhibitors of VEGF-A (e.g. Lucentis®/Eylea®). Combination therapy of OPT-302 and a VEGF-A inhibitor achieves more complete blockade of members of the VEGF family, blocking mechanisms contributing to sub-optimal responses to selective VEGF-A inhibitors and has the potential to improve vision outcomes by more completely inhibiting the pathways involved in disease progression.

Phase 2b Study Design

Opthea's Phase 2b clinical trial was an international, multi-centre, prospective, sham-controlled, double-masked, superiority study that enrolled 366 treatment-naïve patients with wet AMD who were randomized in a 1:1:1 ratio to receive one of the following treatment regimens administered every 4 weeks for 24 weeks: OPT-302 (0.5 mg) in combination with ranibizumab (0.5 mg); OPT-302 (2.0 mg) in combination with ranibizumab (0.5 mg); or sham in combination with ranibizumab (0.5 mg).

Further details on the Company's clinical trials can be found at: www.clinicaltrials.gov, Clinical trial identifiers: NCT02543229, NCT03345082 and NCT03397264.

About Wet AMD

Wet (neovascular) age-related macular degeneration, or wet AMD, is a disease characterized by the loss of vision of the middle of the visual field caused by degeneration of the central portion of the retina (the macula). Abnormal growth of blood vessels below the retina, and the leakage of fluid and protein from the vessels, causes retinal degeneration that leads to severe and rapid loss of vision. Wet AMD is the leading cause of blindness in the developed world in individuals aged over 50 years and its prevalence is increasing. Without treatment, wet AMD patients often experience a rapid decline in visual acuity.

Standard of care treatments for wet AMD and DME include the VEGF-A inhibitors Lucentis® (Roche/Novartis) and Eylea® (Regeneron/Bayer), which do not inhibit VEGF-C or VEGF-D. Sales of Lucentis® and Eylea were over $US3.7BN and $US6.2BN in 2018 respectively. Approximately half of the people receiving Lucentis®/Eylea® do not experience a significant gain in vision and/or have persistent retinal vascular leakage despite regular intravitreal injections. Combined administration of OPT-302 with a VEGF-A inhibitor, has the potential to improve visual acuity by more effective inhibition of the pathways involved in disease progression.

About Opthea Limited

Opthea (ASX:OPT) is a biologics drug developer focusing on ophthalmic disease therapies. It controls exclusive worldwide rights to a significant intellectual property portfolio around VEGF-C, VEGF-D and VEGFR-3. Opthea's intellectual property is held within its wholly-owned subsidiary Vegenics Pty Ltd. Opthea's product development programs are focused on developing OPT-302 for retinal diseases.

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 commercialisation 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 specialising 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 ASX announcement may contain forward-looking statements regarding Company business and the therapeutic and commercial potential of its technologies and products in development. Any statement describing Company goals, expectations, intentions or beliefs is a forward-looking statement and should be considered an at-risk statement. Such statements are subject to certain risks and uncertainties, particularly those risks or uncertainties inherent in the process of developing technology and in the process of discovering, developing and commercialising drugs that can be proven to be safe and effective for use as human therapeutics, and in the endeavour of building a business around such products and services. Opthea undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events, or otherwise. Actual results could differ materially from those discussed in this ASX announcement.

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