

ASX and Media Release 28 July 2020

# Opthea to Host Wet AMD and DME Key Opinion Leader (KOL) Symposium on August 6, 2020 (AEST)

**Melbourne, Australia; 28 July 2020** – Opthea Limited (ASX:OPT), a clinical stage biopharmaceutical company developing a novel therapy to treat highly prevalent and progressive retinal diseases, is pleased to announce that it will host a KOL symposium with a live Q&A for shareholders, investors and analysts focused on OPT-302, the Company's first-in-class biologic inhibitor of VEGF-C/D, in development for the treatment of wet age-related macular degeneration (wet AMD) and diabetic macular edema (DME). The event will be held on Thursday, August 6, 2020 at 9:00AM AEST (Wednesday, August 5, 2020 at 7:00PM EDT).

This event will feature the following independent Key Opinion Leaders:

- Dr Jason Slakter, MD (Vitreous Retina Macula Consultants, New York City, NY)
- Dr Arshad Khanani, MD, MA (Sierra Eye Associates, Reno, NV)

To register for this event, please click here: Wet AMD and DME KOL Registration

The forum, entitled "Beyond VEGF-A: Targeting VEGF-C/D for Wet-AMD and DME" is intended to provide a review of the therapeutic landscape and unmet medical needs in these two indications. The program will also spotlight the need and opportunity for novel therapeutic approaches, including an overview of recent clinical data of Opthea's OPT-302, being developed for use in combination with standard of care anti-VEGF-A therapies to achieve broad blockade of the VEGF-axis and improve clinical outcomes for patients. Dr Megan Baldwin, Opthea's Chief Executive Officer will also provide an update on the Company's ongoing and future clinical development path for OPT-302 and its commercial opportunity. This will be followed by an open-forum discussion, including an audience Q&A session.

Additional 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 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 wet age-related macular degeneration (wet AMD) and diabetic macular edema (DME). 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.

The OPT-302 DME trial was a prospective, proof-of-concept, clinical study consisting of a dose escalation (Phase 1b) followed by a randomized dose expansion (Phase 2a) in treatment refractory participants with the aim to evaluate the safety, visual function and anatomic outcomes of switching from anti-VEGF-A monotherapy to combination therapy of

OPT-302 with aflibercept. In the Phase 1b, patients received escalating doses of OPT-302 (either 0.3, 1 or 2 mg) + aflibercept (2 mg) across 3 cohorts. In the Phase 2a, 144 patients were randomized in a 2:1 ratio to either 2 mg aflibercept + 2 mg OPT-302 or aflibercept + sham. Aflibercept ± OPT-302 was given once every 4 weeks for a total of 3 doses, and patients then assessed through week 12 for outcomes including safety, effects on BCVA, and anatomic changes. A total of 115 patients enrolled in the study complied sufficiently with the protocol and were included in the Per Protocol population.

Opthea has also reported outcomes from an international, multi-centre, prospective, sham-controlled, double-masked, superiority study that enrolled 366 treatment-naïve patients with wet AMD. Participants in the study were randomized in a 1:1:1 ratio to receive one of the following treatment regimens administered once every 4 weeks for 24 weeks (six treatments in total): OPT-302 (0.5 mg) in combination with ranibizumab (Lucentis®) (0.5 mg); OPT-302 (2.0 mg) in combination with ranibizumab (0.5 mg). The study met the primary endpoint demonstrating superior vision gains in participants who received OPT-302 (2.0 mg) in combination with ranibizumab at week 24. Opthea is also investigating OPT-302 in a Phase 2a clinical trial in patients with persistent, centre-involved DME. Further details on the Company's clinical trials can be found at: <a href="www.clinicaltrials.gov">www.clinicaltrials.gov</a>, Clinical trial identifiers: NCT02543229, NCT03345082 and NCT03397264.

## 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.

# Authorised for release to ASX by Megan Baldwin, CEO & Managing Director

## Company & Media Enquiries:

Megan Baldwin, PhD CEO & Managing Director Opthea Limited Tel: +61 (0) 447 788 674 megan.baldwin@opthea.com

Australia:

Rudi Michelson Monsoon Communications Tel: +61 (0) 3 9620 3333 Join our email database to receive program updates:

Tel: +61 (0) 3 9826 0399 info@opthea.com www.opthea.com

U.S.A. & International:

Jason Wong Blueprint Life Science Group Tel: +1 415 375 3340, Ext 4 Jwong@bplifescience.com