



ASX and Media Release
9 June 2020

Opthea to Host Investor Teleconference

Opthea Limited will host a conference call to discuss the results of the Company's Phase 2a clinical trial evaluating the safety and efficacy of OPT-302 administered in combination with Eylea® (afibercept) for treatment of persistent diabetic macular edema (DME). We welcome participation from interested parties.

To access the call pre-register (preferred option) or dial-in direct (delays possible):

Investor Teleconference
Wednesday 10 June 2020, 9:00am (AEST)
Tuesday 9 June 2020, 7:00pm (EST, USA)
Led by CEO & Managing Director Megan Baldwin
Conference ID <u>10007552</u>

1. Pre-registration

Participants can pre-register by navigating to:

<https://s1.c-conf.com/DiamondPass/10007552-invite.html>

Registered participants will receive their dial in number upon registration to enter the call automatically on the day.

2. Dial-in directly (toll free)

Australia:	1800 455 963	Japan:	0066 3386 8000
Sydney:	02 9007 8048	Malaysia:	1800 816 441
New Zealand:	0800 452 795	Singapore:	800 101 2702
China:	10800 140 1776	South Africa:	0800 984 013
France:	0800 913 734	Spain:	900 823 322
Germany:	0800 183 0918	Switzerland:	0800 802 498
Hong Kong:	800 968 273	Taiwan:	0080 112 7377
India:	0008 0010 08070	UAE:	8000 3570 2706
Indonesia:	007 803 321 8057	UK:	0800 051 1453
Ireland:	1800 948 607	USA/Canada	1 855 624 0077
Other International (metered): +61 7 3145 4005			

Authorised for release to ASX by:

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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 Company's Phase 2a DME trial is a randomized, dose expansion study designed to enrol at least 108 evaluable patients diagnosed with persistent centre-involved DME despite regular administration of prior anti-VEGF-A monotherapy. Participants were allocated in a 2:1 ratio to either aflibercept (2 mg) + OPT-302 (2 mg) or aflibercept monotherapy. Treatments were administered by intravitreal (ocular) injection once every 4 weeks (total of 3 doses). The primary efficacy analysis endpoint is the clinical response rate, defined as the proportion of patients receiving combination OPT-302 and aflibercept achieving a ≥ 5 letter gain in visual acuity at week 12 compared to baseline. Secondary efficacy measures include mean visual acuity, macular thickness, improvement in diabetic retinopathy severity score and durability of response.

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 every 4 weeks for 24 weeks: 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); or sham 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 on a monthly basis over 6 months. 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: www.clinicaltrials.gov, 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.