



## Opthea to Present at the 9th Annual SVB Leerink Global Healthcare Conference

February 18, 2020

MELBOURNE, Australia, Feb. 18, 2020 (GLOBE NEWSWIRE) -- Opthea Limited (ASX:OPT), a clinical stage biopharmaceutical company developing novel biologic therapies to treat eye diseases, today announced that Dr Megan Baldwin, CEO of Opthea, will present and provide a corporate update at the 9<sup>th</sup> Annual SVB Leerink Global Healthcare Conference on February 25, 2020 at 11am EST in New York City.

A live webcast of the presentation will be available on the Investors page of the Opthea website at <https://www.opthea.com/presentations/>.

Additional information on Opthea's technology and clinical trials in wet AMD and DME can be found at [www.opthea.com](http://www.opthea.com) and [ClinicalTrials.gov](https://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 Vascular Endothelial Growth Factor (VEGF)-C, VEGF-D and VEGFR-3. Opthea's intellectual property is held within its wholly-owned subsidiary Vegenics Pty Ltd. The applications for the VEGF technology, which functions in regulating blood and lymphatic vessel growth, are substantial and broad. Opthea's product development programs are focused on developing OPT-302 (soluble VEGFR-3) for wet age-related macular degeneration (wet AMD) and diabetic macular edema (DME).

### 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 (eg. Lucentis<sup>®</sup>/Eylea<sup>®</sup>). Combination therapy of OPT-302 and a VEGF-A inhibitor achieves more complete blockade of members of the VEGF family, blocks mechanisms contributing to sub-optimal response to selective VEGF-A inhibitors and has the potential to improve vision outcomes by more completely inhibiting the pathways involved in disease progression.

Opthea has 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<sup>®</sup>) (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 has also completed a Phase 1/2a clinical trial in the US investigating OPT-302 administered as monthly intravitreal injections for 3 months with and without ranibizumab in patients with wet age related macular degeneration (AMD). Of the 51 patients enrolled, 25 were treatment naïve and 26 had received prior intravitreal anti-VEGF-A therapy. Further details on the Phase 1/2a trial can be found at: [www.clinicaltrials.gov](https://www.clinicaltrials.gov), Clinical trial identifier: NCT02543229. Details on the outcomes of the study can be found at: [www.opthea.com](http://www.opthea.com).

### About Wet AMD and DME

Wet (neovascular) age-related macular degeneration, or wet AMD, is a disease characterised 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 and 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 chronic, rapid decline in visual acuity and increase in retinal fluid.

DME is the leading cause of blindness in diabetics and is estimated to affect approximately 2 million people globally. Chronically elevated blood glucose levels in Type 1 and Type 2 diabetics can lead to inflammation, vascular dysfunction and hypoxia, causing upregulation of the VEGF family of growth factors. VEGFs, including VEGF-A and VEGF-C, stimulate vascular permeability or leakage, leading to fluid accumulation in the macula at the back of the eye and retinal thickening which affects vision.

Standard of care treatments for wet AMD and DME include the VEGF-A inhibitors Lucentis<sup>®</sup> (ranibizumab, Roche/Novartis) and EYLEA<sup>®</sup> (aflibercept, 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 IVT injections.

### 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. Thus 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.

*Company & Media Inquiries: Join our email database to receive program updates:*

Megan Baldwin, PhD  
CEO & Managing Director  
Opthea Limited  
Tel: +61 (0) 447 788 674  
[megan.baldwin@opthea.com](mailto:megan.baldwin@opthea.com)  
Tel: +61 (0) 3 9826 0399  
[info@opthea.com](mailto:info@opthea.com)  
[www.opthea.com](http://www.opthea.com)

*Australia:*

Rudi Michelson  
Monsoon Communications  
Tel: +61 (0) 3 9620 3333

*U.S.A. & International:*

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