ASX and Media Release
1 October 2019

Opthea Receives A$14.6m R&D Tax Incentive

Melbourne, Australia; October 1 2019 – Opthea Limited (ASX:OPT), a clinical-stage biopharmaceutical company developing novel biologic therapies to treat back-of-the-eye diseases, announced today it received a A$14.6 million research and development (R&D) tax credit from the Australian Taxation Office. The refund is for research and development costs incurred in the 2018/2019 financial year, and represents the same amount disclosed in the company's audited financial statements at 30 June 2019.

Dr Megan Baldwin, CEO & Managing Director of Opthea commented "This R&D tax incentive credit of A$14.6 million increases the company's cash balances to over A$30 million and will contribute to the execution and delivery of outcomes from our clinical trials of OPT-302 in both wet AMD and DME".

The R&D tax incentive credit relates to both Australian and eligible overseas expenditure on the development of Opthea's lead candidate OPT-302. The R&D Tax Incentive is as an Australian Federal Government program under which companies can receive cash refunds for 43.5% of eligible research and development expenditure.

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 eye diseases including 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 and 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®) (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.

Company & Media Enquiries:

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

Join our email database to receive program updates:

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