Opthea Clinical Data of OPT-302 in Diabetic Macular Edema to be Presented at American Society of Retina Specialists 2020 Annual Meeting

July 23, 2020

MELBOURNE, Australia, July 23, 2020 (GLOBE NEWSWIRE) -- 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 clinical trial results from the Phase 1b/2a study of OPT-302 in diabetic macular edema (DME) patients refractory to anti-VEGF-A therapy, will be presented at the upcoming American Society of Retina Specialists Annual (ASRS) 2020 Virtual Annual Meeting.

The ASRS is the largest vitreoretinal specialty society in the world, with more than 3,000 members from 63 countries and the annual meeting represents one of the largest U.S. conferences for retinal specialists.

Dr David Boyer, MD, an internationally recognized vitreo-retinal specialist ophthalmologist and prominent principal investigator will present clinical data from the OPT-302 Phase 1b/2a DME study for the first time at the ASRS 2020 Virtual Annual Meeting.

Details of the presentation are as follows:

Oral presentation: Switching to combination OPT-302 with aflibercept from prior anti-VEGF-A monotherapy in eyes with persistent diabetic macula edema (DME)
Presenter: David Boyer, MD, Senior Partner Retina Vitreous Associates Medical Group, Los Angeles, and Clinical Professor at the University of Southern California Roski Eye Institute, Keck School of Medicine
Virtual Meeting Session: Diabetic Retinopathy Symposium
Date: Saturday, July 25, 2020

"The Phase 1b/2a clinical data to be presented at ASRS 2020 includes results of OPT-302 combination therapy from nearly 300 injections in over 150 patients with persistent DME despite prior anti-VEGF-A monotherapy. The acceptance of the oral presentation demonstrates the depth of our science and high level of interest and we look forward to Dr Boyer sharing the data for the first time with the retina specialist community during ASRS," said Megan Baldwin, CEO and Managing Director, Opthea Limited.

The OPT-302 DME trial was a prospective, proof-of-concept, clinical study consisting of a dose escalation (Phase 1b) followed by a randomized double-masked, dose expansion study (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 study, 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 three doses. The primary analysis was conducted at week 12, four weeks after the final dose.

The slide presentation will be available on the Opthea website at https://www.opthea.com/ following completion of the presentation. 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.

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); 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 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: 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.

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