Opthea Completes Patient Dosing in Phase 2a DME Trial

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Company also provides business update in response to COVID-19

MELBOURNE, Australia, March 30, 2020 (GLOBE NEWSWIRE) -- Opthea Limited (ASX:OPT), a clinical stage biopharmaceutical company developing novel biologic therapies to treat eye diseases, has completed patient dosing and all follow-up week 12 patient visits in the Company's Phase 2a trial evaluating the safety and efficacy of OPT-302 administered in combination with aflibercept (Eylea®) for treatment of diabetic macular edema (DME).

"We are extremely grateful to have reached this clinical milestone, particularly given the current challenges presented by the COVID-19 pandemic and restricted movements of patients globally. With all patients now having completed the treatment phase of the study, Opthea is now focused on data cleaning and preparation for data readout. A large proportion of the data cleaning activities have already been completed for the majority of patients enrolled in the study, and if necessary, the remaining activities may be performed remotely. Therefore, we expect the study to report out in accordance with our timelines, pending any potential impact of government mandated isolation procedures," commented Dr Megan Baldwin, CEO & Managing Director of Opthea.

In addition to advancing the Phase 2a DME trial, Opthea continues to undertake planning for its Phase 3 program in wet AMD, including preparation of documentation for regulatory engagement in the US and Europe, and to progress its manufacturing of OPT-302 for Phase 3 clinical trials. These activities are on-going and not currently impacted by the COVID-19 situation.

Having completed a financing in December 2019, Opthea's current cash position of approximately AUD70m provides sufficient runway to focus on corporate strategic objectives and clinical development activities as the COVID-19 situation continues to evolve.

Dr Megan Baldwin commented, "The fundamentals of our technology remain unchanged despite the global challenges we are facing with the COVID-19 pandemic. Now, more than ever, we are reminded of the vulnerability of our communities and the need for effective treatments to improve the health and quality of life for all individuals – a sentiment that underpins Opthea's programs to improve vision in patients with macular degeneration and diabetic eye disease. Our thoughts are with those affected by this virus globally and we will continue to assess the impact of government policies and the recommendations of health authorities both domestically and internationally on our programs and will update shareholders as appropriate."

Additional information on Opthea's technology and clinical trials in wet AMD and DME can 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 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 are 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.

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