Opthea Completes Final Patient Visit in Phase 2b Wet AMD Clinical Trial

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MELBOURNE, Australia, May 15, 2019 (GLOBE NEWSWIRE) -- Opthea Limited (ASX:OPT), a clinical stage biopharmaceutical company developing novel biologic therapies to treat eye diseases, announced today that the final patient in the Company's Phase 2b trial of OPT-302 for wet age-related macular degeneration (AMD) has completed their last clinical visit.

"The final patient's last visit is an important milestone in the clinical development pathway for OPT-302, as it paves the way for the company to finalise data cleaning activities, with top-line results expected to be reported within the coming months," commented Dr Megan Baldwin, CEO & Managing Director, Opthea Limited.

Patients enrolled in Opthea's double-masked Phase 2b trial received intravitreal injections of OPT-302, a selective VEGF-C/D 'trap' therapy, administered in combination with the VEGF-A inhibitor ranibizumab (Lucentis®) or ranibizumab alone, on a monthly basis for 6 months. The final clinical visit was scheduled at week 24, one month after the final dose administration.

Of the 366 patients randomised in the trial, 348 (95.1%) patients completed the week 24 visit, therefore meeting the prospectively defined statistical assumptions for the study.

Opthea's Phase 2b trial enrolled patients who have not received prior therapy (i.e. treatment-naïve) and is designed to investigate whether addition of OPT-302 to ranibizumab therapy over a 6 month dosing period improves visual acuity and anatomical parameters including reductions in retinal thickness, as assessed by a central independent imaging reading centre.

"This milestone brings us closer to assessing the potential of OPT-302 combination treatment to improve vision and ocular anatomical outcomes in wet AMD patients receiving standard of care anti-VEGF-A monotherapy," continued Dr Baldwin. "We are very pleased with the trial's progress, which completed patient recruitment several months ahead of schedule, and has continued to demonstrate a favourable safety profile for OPT-302. We now look forward to reporting outcomes from the Phase 2b trial given encouraging previously reported Phase 1/2a study data as well as the scientific rationale for targeted inhibition of VEGF-C/D, two important regulators of aberrant retinal vessel growth and vascular leakage, which are implicated in mediating resistance to selective VEGF-A inhibitors."

Additional information on Opthea's technology and clinical trials in wet AMD and diabetic macular edema (DME) can found at www.opthea.com and ClinicalTrials.gov (ID#: NCT03345082 and ID#: NCT03397264, respectively).

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®/EYLEA®). 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 completed a Phase 1/2a clinical trial in the US investigating OPT-302 wet AMD patients as a monotherapy and in combination with Lucentis®, and a 9 patient dose-escalation study of OPT-302 in combination with EYLEA® in patients with persistent central-involved diabetic macular edema (DME) despite prior anti-VEGF-A therapy. Further details on the Phase 1/2a trial can be found at: www.clinicaltrials.gov, Clinical trial identifier: NCT02543229. Details on the outcomes of the studies can be found on the Opthea website: www.opthea.com

About Wet AMD

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. Standard of care treatments for wet AMD include the VEGF-A inhibitors Lucentis® (Roche/Novartis) and EYLEA® (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. Simultaneous inhibition of VEGF-A and VEGF-C/-D, by combined administration of OPT-302 with a VEGF-A inhibitor has the potential to improve patient responses, including visual acuity, by more effective inhibition of the pathways involved in disease progression.

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. Opthea's product development programs are focused on developing OPT-302 for retinal diseases.

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.

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