Opthea's Patent Application Covering OPT-302 to be Granted by European Patent Office

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MELBOURNE, Australia, July 30, 2019 (GLOBE NEWSWIRE) -- Opthea Limited (ASX:OPT) is pleased to announce that the European Patent Office (EPO) has issued a "Notice of Intention to Grant" in relation to Opthea's European patent application covering OPT-302, a soluble form of Vascular Endothelial Growth Factor Receptor (VEGFR-3) that binds and inhibits the activity of VEGF-C and VEGF-D.

The European patent will cover both the OPT-302 product and compositions containing OPT-302 for use in treating disorders associated with aberrant angiogenesis and/or lymphangiogenesis, including eye diseases such as wet age-related macular degeneration (wet AMD) and diabetic macular edema (DME). The patent term will extend to February 13, 2034. Patents covering OPT-302 and extending out to 2034 have now been granted in the U.S.A., Japan, Australia, South Africa and Singapore and applications have been accepted for grant by the EPO, in Malaysia and in Russia. Patent applications remain pending in 11 other jurisdictions.

OPT-302 is being investigated in two ongoing clinical trials: A 366-patient Phase 2b trial in wet AMD and an approximately 108 patient Phase 2a trial in patients with persistent DME despite prior anti-VEGF-A therapy. Reporting of primary data analysis from the Phase 2b wet AMD is expected in the third quarter of calendar year 2019. Primary data from the Phase 2a DME trial is expected to report early in 2020.

"Europe accounts for approximately 30% of the global market for anti-VEGF-A therapies for the treatment of wet AMD and DME. Obtaining patent protection for OPT-302 in Europe is therefore key to our business strategy and this decision by the European Patent Office further reinforces our already strong IP position," commented Dr Megan Baldwin, CEO and Managing Director of Opthea.

European Patent Application No. 14752057.1 covering OPT-302 will grant in the name of Opthea's wholly-owned subsidiary, Vegenics Pty Limited.

Additional information on Opthea's technology and clinical trials in wet AMD and diabetic macular edema (DME) can be 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 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 members of the VEGF family of growth factors. VEGFs, including VEGF-A and VEGF-C, stimulate vascular permeability or vascular 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® (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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