Opthea Announces “Sozinibercept” as the Nonproprietary Drug Name for OPT-302

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MELBOURNE, Australia, July 26, 2023 (GLOBE NEWSWIRE) -- Opthea Limited (NASDAQ:OPT; ASX:OPT), a clinical stage biopharmaceutical company developing novel therapies to treat highly prevalent and progressive retinal diseases, announced today that the American Medical Association’s United States Adopted Names (USAN) Council, in consultation with the World Health Organization’s International Nonproprietary Names (INN) Expert Committee, has approved and adopted the nonproprietary drug name “sozinibercept” (pronounced soe" zi nib' er sept) for the Company’s lead biologic drug candidate, OPT-302.

Sozinibercept (OPT-302) is the company’s novel recombinant “trap” fusion protein targeting inhibition of vascular endothelial growth factors C and D (VEGF-C and VEGF-C), two ligand mediators of angiogenesis and vascular leakage involved in retinal vascular diseases. Sozinibercept administered by intravitreal injection in combination with standard of care anti-VEGF-A therapy is currently being evaluated in two Phase 3 clinical trials for the treatment of neovascular (“wet”) age-related macular degeneration, for which it holds fast track designation from the U.S. Food and Drug Administration (FDA). Sozinibercept is proprietary to Opthea with issued patents running to at least 2034 and currently pending patents that are expected to extend coverage.

The USAN Council (tri-sponsored by the American Medical Association, the United States Pharmacopeia, and the American Pharmacists Association), together with the INN Program of the World Health Organization and in consultation with various national nomenclature groups, aims for global standardization and unification of drug nomenclature classifications based on pharmacological and/or chemical relationships, to ensure clear and accurate communication of drug information.

Going forward, Opthea will use the name sozinibercept in upcoming publications and public statements, at conferences and other forums, and in corporate-related materials as the company continues to advance the clinical development toward commercialization of the product in wet AMD and other indications. The company is also pursuing a formal global proprietary brand name for sozinibercept. Obtaining regulatory approval of these adopted drug names is a necessary step for marketing authorization.

Opthea is currently conducting two global pivotal registrational Phase 3 studies, the ShORe trial of 2 mg sozinibercept + 0.5 mg ranibizumab, and the COAST trial of 2 mg sozinibercept + 2 mg aflibercept. The primary endpoint for both studies is superiority in visual acuity gains at 12 months for the combination therapy compared with standard-of-care monotherapy.

For more information regarding the Phase 3 ShORe (Clinicaltrials.gov identifier: NCT04757610) and COAST (Clinicaltrials.gov identifier: NCT04757636) trials, please visit www.opthea.com and https://clinicaltrials.gov.

About Opthea Limited

Opthea (ASX:OPT; Nasdaq:OPT) is a biopharmaceutical company developing novel therapies to address the unmet need in the treatment of highly prevalent and progressive retinal diseases, including wet age-related macular degeneration (wet AMD) and diabetic macular edema (DME). Opthea’s lead product candidate OPT-302 is in pivotal Phase 3 clinical trials and being developed for use in combination with anti-VEGF-A monotherapies to achieve broader inhibition of the VEGF family, with the goal of improving overall efficacy and demonstrating superior vision gains over that which can be achieved by inhibiting VEGF-A alone.

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 commercialization 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 specializing in drug development must be regarded as highly speculative. Opthea strongly recommends that professional investment advice be sought prior to such investments.

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