Oxular Doses First Patients in OXEYE Phase 2 Clinical Trial of Suprachoroidal OXU-001 as a Long-Acting Treatment for Diabetic Macular Edema

Initial safety, efficacy and durability data expected in 2H'24

OXFORD, UK and CAMBRIDGE, Mass. – October 24, 2023 – Oxular Limited, a clinical-stage ophthalmic company developing long-lasting treatments for retinal disorders, today announces that it has begun dosing in its OXEYE Phase 2 clinical trial evaluating the company's lead product candidate, suprachoroidal OXU-001, for the treatment of diabetic macular edema (DME). OXEYE is designed to evaluate the safety, efficacy, and durability of OXU-001 as an innovative treatment option, combining potent broad-acting anti-edema and anti-inflammatory effects with up to one-year durability for high-prevalence retinal disorders, beginning with DME.

"We are thrilled to have started dosing patients with suprachoroidal OXU-001 in our OXEYE clinical trial, which will evaluate the potential for once-a-year treatment by leveraging our Oxusphere™ sustained-release technology. OXEYE builds on the positive clinical experience to date with our Oxulumis® illuminated microcatheter for in-clinic posterior suprachoroidal delivery," said Dr. Friedrich Asmus, MD, Chief Medical Officer of Oxular. "This marks Oxular's most significant milestone to date and brings us closer to our goal of developing safe and highly effective treatments to reduce the treatment burden for patients and retinal specialists. We look forward to clinical data from the OXEYE trial next year."

OXU-001 is dexamethasone formulated in a novel biodegradable drug preparation known as Oxuspheres™. OXU-001 is optimized for delivery to the posterior suprachoroidal space of the eye via Oxulumis®, Oxular's proprietary illuminated microcatheter. This in-office treatment enables routine access closer to the ocular tissues with high disease activity, which could lead to enhanced efficacy, favorable tolerability, and extended durability of up to one-year.

The OXEYE trial is a two-part, randomized Phase 2 trial in patients with DME that is designed to evaluate a single administration of suprachoroidal OXU-001 over 52 weeks. Part A of the trial is expected to randomize 18 patients in the U.S. who have been previously treated with anti-VEGF therapy to one of two dose levels of OXU-001. Gated by interim read-outs from Part A, Part B will be a masked evaluation of 110 DME patients who have either been previously treated with anti-VEGF therapy or are treatment-naïve, randomized to one of the two dose levels of OXU-001 or Ozurdex® (dexamethasone intravitreal implant). Primary endpoints at Week 24 are safety and efficacy, and patients will continue to be monitored monthly for 52 weeks.

"Today's standard-of-care treatments for DME require frequent injections, which create adherence challenges resulting in suboptimal vision outcomes for many patients," stated Dr. Anat Loewenstein, MD, Director of the Department of Ophthalmology at the Tel Aviv Medical Center. "It is very exciting that we will soon see patient data of suprachoroidal OXU-001, a potential treatment option with the goal of one treatment a year."

Oxular expects to report 24-week data from Part A, including safety and durability, in the second half of 2024.

About Oxular
Oxular is a biotechnology company developing safe, long-lasting suprachoroidal retinal treatments to improve patients' vision so they can live better lives. The company has engineered its sustained-release drug formulations to last up to one year following single dosing and delivery technology to access tissues in the posterior suprachoroidal space via a routine, in-office administration. This unique combination aims to improve patients' vision by increasing therapeutic effectiveness, while reducing side-effects and minimizing the frequency of treatments.

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