



## **OKYO Pharma Plans to Initiate Phase 2 Trial of OK-101 in Neuropathic Corneal Pain ("NCP") Following Announcement of Clinical Trial Agreement with Tufts Medical Center**

- ***OKYO plans a 40-patient OK-101 open-label clinical trial with Dr Pedram Hamrah, Tufts Medical Center, as Principal Investigator, a leading expert in treating patients with NCP***
- ***Second clinical indication for OK-101 which is currently in 240 patient phase 2 clinical trial to treat dry eye disease, with top-line data anticipated by end of 2023***
- ***NCP trial anticipated to start in Q4 2023***

London and New York, NY, July 28, 2023 – OKYO Pharma Limited (Nasdaq: OKYO), an ophthalmology-focused bio-pharmaceutical company which is developing OK-101 to treat dry eye disease ("DED") to address the significant unmet need in this multi-billion-dollar market, is pleased to announce a new agreement with Tufts Medical Center to conduct a 40-patient open-label clinical trial evaluating the efficacy and safety of OK-101 in patients with neuropathic corneal pain ("NCP"). The Investigational New Drug ("IND") application for NCP is planned to be filed in Q4 of 2023, with study enrollment planned to commence shortly after IND allowance by the FDA.

NCP is a debilitating condition characterized by chronic and severe eye discomfort, leading to decreased quality of life for affected individuals. OK-101, a novel and investigational therapeutic developed by OKYO Pharma, offers a promising solution to alleviate the symptoms associated with NCP. The open-label trial will provide an opportunity to evaluate the safety and efficacy of OK-101 in a real-world clinical setting, fostering a better understanding of its potential benefits for patients.

The trial is anticipated to take 6-9 months to conduct, and is anticipated to have a minor budgetary impact, with a total cost for the trial, including cost of drug manufacture and formulation for investigational use, amounting to under \$1 million. NCP remains a major unmet medical need for the ocular community, as there is no FDA-approved drug to treat NCP and this trial provides the opportunity to establish OK-101's potential to treat this condition.

This NCP trial will be led by Pedram Hamrah, MD, Professor and Vice Chair of Research and Academic Programs, Co-Director of the Cornea Service and Director of the Center for Translational Ocular Immunology at Tufts Medical Center. An ophthalmologist and a clinician-scientist, Dr. Hamrah is a leading expert in NCP and co-inventor on the OK-101 patent. He is a member of OKYO's Scientific Advisory Board and plans to serve as Principal Investigator of the study, which will be conducted at Tufts Medical Center. This collaborative effort is focused on evaluating OK-101 as a potential non-opioid analgesic to reduce neuropathic corneal pain, a major unmet medical need.

"NCP, which can exhibit as a severe, chronic or debilitating condition in patients suffering from a host of ophthalmic conditions, is presently treated by various topical and systemic treatments in an off-label fashion," said Dr. Hamrah. "However, there are no approved commercial treatments currently available for this condition, and consequently we are looking forward to initiating the clinical trial to investigate the potential efficacy of OK-101 to treat symptoms of NCP."

Using a mouse model of NCP, pioneered by Dr. Hamrah's laboratory and which is based on the ligation of the ocular ciliary nerve, OK-101, administered topically to mice, demonstrated a reduced

corneal pain response similar to that of gabapentin administered by intraperitoneal injection (a commonly used oral drug for NCP). These observations demonstrated preclinical 'proof-of-concept' for the topical administration of OK-101 as a potential non-opioid analgesic for NCP. Current treatments for NCP are limited to short term NSAIDs, steroids, oral gabapentin and, in severe cases, opioids. Side effects and the risk of addiction to opioids are currently serious ongoing causes of concern.

"We are excited about OK-101's dual combination of anti-inflammatory ocular activity and NCP reducing activity and are eagerly awaiting the top-line data from the DED trial," said Dr. Gary S. Jacob, CEO of OKYO. "But we are also eager to move forward with our plan to evaluate this drug to treat NCP, which has gained considerable significance this past year as a major unmet medical need for patients specifically diagnosed with this debilitating ocular condition."

OK-101 is currently in a Phase 2, multi-center, double-masked, placebo-controlled trial of topical ocular OK-101 to treat dry eye disease. This Phase 2, multi-center, randomized, double-blinded, placebo-controlled study is planned to enroll approximately 240 subjects with DED who will be randomly divided into three cohorts of 80 patients each. The three cohorts are comprised of one cohort treated with placebo, a second cohort treated with 0.05% OK-101, and the third cohort receiving 0.1% OK-101. The protocol for the study includes two primary endpoints; and key exploratory and secondary endpoints will be used to inform future studies. Further details regarding the specifics of the trial are posted on the clinicaltrials.gov public website (clinicaltrials.gov Identifier: NCT05759208 or <https://clinicaltrials.gov/ct2/results?term=Okyo&cond=Dry+Eye+Syndromes>).

#### **About OK-101**

OK-101 is a lipid conjugated chemerin peptide agonist of the ChemR23 G-protein coupled receptor which is typically found on immune cells of the eye responsible for the inflammatory response. OK-101 was developed using a membrane-anchored-peptide (MAP) technology to produce a novel long-acting drug candidate for treating dry eye disease. OK-101 has been shown to produce anti-inflammatory and pain-reducing activities in mouse models of dry eye disease and NCP; and is designed to combat washout through the inclusion of the lipid 'anchor' contained in the candidate drug molecule to enhance the residence time of OK-101 within the ocular environment.

#### **About OKYO Pharma**

OKYO Pharma Limited (Nasdaq: OKYO) is a life sciences company focusing on the discovery and development of novel molecules to treat inflammatory dry eye diseases and chronic pain. For further information, please visit [www.okyopharma.com](http://www.okyopharma.com)

#### **Forward-Looking Statements**

Certain statements made in this announcement are forward-looking statements. These forward-looking statements are not historical facts but rather are based on the Company's current expectations, estimates, and projections about its industry; its beliefs; and assumptions. Words such as 'anticipates,' 'expects,' 'intends,' 'plans,' 'believes,' 'seeks,' 'estimates,' and similar expressions are intended to identify forward-looking statements. These statements are not guarantees of future performance and are subject to known and unknown risks, uncertainties, and other factors, some of which are beyond the Company's control, are difficult to predict, and could cause actual results to differ materially from those expressed or forecasted in the forward-looking statements. The Company cautions security holders and prospective security holders not to place undue reliance on these forward-looking statements, which reflect the view of the Company only as of the date of this announcement. The forward-looking statements made in this announcement relate only to events as of the date on which the statements are made. The Company will not undertake any obligation to release publicly any revisions or updates to these forward-looking statements to reflect events,

circumstances, or unanticipated events occurring after the date of this announcement except as required by law or by any appropriate regulatory authority.

For further information, please visit the Company's website at [www.okyopharma.com](http://www.okyopharma.com)

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