OKYO Pharma Announces First-Patient First-Visit for Phase 2 Trial Evaluating Efficacy and Safety of OK-101 in Patients with Dry Eye Disease

- Trial designed with pre-specified primary efficacy endpoints discussed previously with FDA
- If successful, this phase 2 trial may serve as one of the two required phase 3 studies necessary to support FDA approval
- Top-line data from trial anticipated before end of 2023

London and New York, NY, May 2, 2023 – OKYO Pharma Limited (LSE: OKYO; NASDAQ: OKYO), an ophthalmology-focused bio-pharmaceutical company which is developing OK-101 to treat dry eye disease to address the significant unmet need in this multi-billion-dollar market, is pleased to announce that the first patient has been screened for its phase 2, multi-center, randomized, double–blinded, placebo-controlled trial, evaluating the efficacy and safety of OK-101 ophthalmic solution in subjects with dry eye disease (DED).

"The initiation of this trial of topically applied OK-101 to treat dry eye disease marks a significant step for the company as we have been laser focused on moving this drug candidate into clinical trials over the last 18 months," said Gary S. Jacob, Ph.D., CEO of OKYO Pharma. "Importantly, this first clinical study is designed to include pre-specified primary efficacy endpoints which are the hallmark of phase 3 registration trials, and the results from this trial are anticipated before the end of this year. The drug has been shown in pre-clinical studies to have potent anti-inflammatory and neuropathic corneal pain activities, and we are eager to evaluate its potential benefits in the clinic."

"One of the most exciting aspects of this innovative clinical program is that we can get a rapid and informative answer on both safety and efficacy of OK-101 by the end of the year," said Gabriele Cerrone, Executive Chairman and Founder of OKYO Pharma. "Furthermore, positive results would allow us to expedite the program towards FDA approval by leveraging results from this phase 2 dry eye trial in lieu of one of the two required phase 3 trials needed to support U.S. marketing authorization. OKYO remains well-positioned as novel ophthalmic compounds in large markets represent promising acquisition targets as evidenced by the recent $5.9 billion Iveric deal."

Dry eye disease is a common condition that occurs when an individual's tears are unable to adequately lubricate the eyes. This condition affects approximately 49 million people in the U.S. alone and has been a difficult one to positively diagnose and to treat due to the multifactorial nature of the condition. A number of contributing factors can lead to this condition, including age, sex, certain medical conditions, reduced tear production and tear film dysfunction. Tear film instability typically leads to inflammation and damage to the ocular surface.

About the Phase 2 Trial Design

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 3 cohorts of 80 patients. Participants will be selected based on specific inclusion and exclusion criteria. The three cohorts will be comprised of one cohort treated with placebo, a second cohort treated with a low

dose of OK-101, and the third cohort receiving a higher dose of OK-101. The drug and placebo will be administered in both eyes twice daily for 12 weeks. The duration of a patient's treatment will be approximately 14 weeks, including a 2-week run-in period and 12 weeks of treatment. The protocol for the study includes two prespecified primary endpoints and a number of secondary endpoints. Further details regarding the specifics of the trial are posted on the ClinicalTrials.gov public website (ClinicalTrials.gov Identifier: NCT05759208).

About OKYO

OKYO Pharma Limited (LSE: OKYO; NASDAQ: OKYO) is a life sciences company admitted to listing on NASDAQ and on the standard segment of the Official List of the UK Financial Conduct Authority and to trading on the main market for listed securities of London Stock Exchange plc. OKYO is 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

About OK-101

OK-101 is a lipid conjugated chemerin peptide antagonist 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 corneal neuropathic pain; 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.

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

The person who arranged for the release of this announcement on behalf of the Company was Gary S. Jacob, Ph.D., Chief Executive Officer of OKYO.

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