OK-101 First-in-Human Trial planned as Phase 2 Trial incorporating Primary Efficacy Endpoints covering Signs and Symptoms of Dry Eye Disease

London and Boston, MA, February 15, 2022 – OKYO Pharma Limited (LSE: OKYO; OTCQB: EMMLF), a biotechnology company focused on the discovery and development of novel molecules to treat inflammatory dry eye diseases and ocular pain, today announced the successful completion of a pre-IND (Investigational New Drug) meeting with the U.S. Food and Drug Administration (FDA) regarding the development plans for OK-101 to treat dry eye disease (DED).

Both nonclinical and clinical development milestones were covered in the Pre-IND meeting facilitated by Ora Inc., with the FDA providing guidance on the proposed phase 2 trial in DED patients. FDA concurred with OKYO's decision to designate co-primary efficacy endpoints covering both a sign and a symptom of dry disease in the clinical protocol of the trial.

"We are thrilled to have clear guidance from the FDA regarding our plans for the clinical development path for OK-101 to treat DED," said Gary S. Jacob Ph.D., CEO of OKYO Pharma. "We believe that the successful outcome of the pre-IND meeting with FDA will accelerate OKYO's previously forecasted timeline for an NDA filing and commercialization of the drug. The fact that we are designating efficacy endpoints as primary endpoints in this first-in-human trial is highly significant. Should our upcoming trial meet its prespecified primary endpoints, this would be an important step in reducing the timeline to a new drug application (NDA) filing with the FDA."

"FDA's valuable feedback has confirmed the first-in-human study design to determine the safety and efficacy of OK-101 for the treatment of dry eye. Ora is looking forward to initiating the trial with OKYO and evaluating this innovative therapy to potentially help millions of patients suffering from this debilitating disease." said George Ousler, Senior Vice President for Ora.

"We are on track with our pre-IND work on OK-101 and are planning to file the IND to treat DED in Q3/Q4 2022, followed by the planned commencement of a Phase 2 trial in DED patients in Q4 2022," said Raj Patil Ph.D., CSO of OKYO Pharma. "We believe that OK-101 can provide a new way to treat DED patients who are presently not well served by drugs currently approved for treating dry eye disease."

OK-101 is a lipidated chemerin peptide agonist of the ChemR23 G-protein coupled receptor which is typically found on immunological cells of the eye responsible for the inflammatory response. 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 drug molecule to enhance the residence time of OK-101 within the ocular environment.

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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Notes for Editors:

About OKYO

OKYO Pharma Limited (LSE: OKYO; OTCQB: EMMLF) is a life sciences and biotechnology company admitted to listing 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 ocular neuropathic pain.

About OK-101

OK-101 is a lipidated chemerin peptide antagonist of the ChemR23 G-protein coupled receptor which is typically found on immunological 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.

About Ora®, Inc.

Ora is the world's leading full-service ophthalmic drug and device development firm with offices in the United States, Europe, and Asia. For over 40 years, we have proudly helped our clients earn more than 50 product approvals. We support a wide array of organizations, from start-ups to global pharmaceutical and device companies, to efficiently bring their new products from concept to market. We bring together the world's most extensive and experienced team of ophthalmic experts, R&D professionals, and management executives to maximize the value of new product initiatives. For more information, please visit www.oraclinical.com

About Dry Eye Disease

Dry eye disease is a multifactorial disease that results in ocular discomfort and tear film instability that can lead to ocular surface damage. It is often a chronic problem, particularly in older adults, and is expected to become even more prevalent with the aging population and increased use of digital screens such as computers and smart phones. Despite new product approvals, dry eye disease remains a significant unmet medical need and is one of the leading causes for patient visits to eye care specialists. Novel therapies that improve the signs and symptoms of dry eye disease will be beneficial to dry eye patients.

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.