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**OKYO Pharma Limited**

**("OKYO" or the "Company")**

## **OKYO Pharma Announces U.S. IND Filing on OK-101 for the Treatment of Dry Eye Disease**

*-OK-101 first-in-human Phase 2 trial will incorporate primary and secondary efficacy endpoints characterizing signs and symptoms of Dry Eye Disease-*

**London and Boston, MA, November 21, 2022** – 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, today announced that it filed an Investigational New Drug (IND) application with the U.S. Food and Drug Administration (FDA) for the development of OK-101 to treat dry eye disease (DED).

Both nonclinical and clinical development plans on OK-101 were reviewed with the FDA in an earlier Pre-IND meeting facilitated by OKYO's contract research organization, Ora Inc, with the FDA agreeing to a first-in-human Phase 2 trial in DED patients. FDA also concurred with OKYO's plans for designating primary and secondary efficacy endpoints covering both a sign and a symptom of DED in the trial's clinical protocol.

"The filing of this IND with FDA is a key step for OKYO as we advance our plan to open a Phase 2 trial in DED patients in the first quarter of 2023," said Gary S. Jacob, Ph.D., CEO of OKYO Pharma. "We were pleased with the clear guidance we received from the FDA Pre-IND meeting earlier in the year. The fact that we are designating primary and secondary efficacy endpoints in this first-in-human trial is highly significant as should our upcoming trial of OK-101 meet its prespecified primary endpoint, it could accelerate the timeline to a new drug application (NDA) filing with the FDA."

"FDA's earlier feedback from the Pre-IND meeting confirmed our plans for the first-in-human study design to determine the safety and efficacy of OK-101 for the treatment of dry eye," said George Ousler, Senior Vice President for Ora. "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."

"The successful filing of this IND on OK-101 has been a central and critical goal for the company this past year," said Raj Patil, Ph.D., CSO of OKYO Pharma. "We are excited to be moving this

drug into clinical trials early next year and believe that OK-101 can provide a new way to treat DED patients who are presently not well-served by currently approved drugs.”

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 has been shown to produce anti-inflammatory and neuropathic pain-reducing activities in mouse models of DED and corneal neuropathic pain, respectively, 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; 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](http://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.

### **About Ora<sup>®</sup>, 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](http://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](http://www.okyopharma.com).