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OKYO Pharma Plans Q4 2022 IND Filing of OK-101 to treat Dry Eye Disease with Subsequent Phase 2 Initiation Alongside Peptide Manufacturing Partner, AmbioPharm

- OK-101 to treat ocular diseases, including Dry Eye Disease (DED), uveitis, allergic conjunctivitis, and ocular pain.
- Successful pre-IND meeting with FDA in Q1 2022 and novel speed to market potential.
- IND filing on OK-101 to treat DED planned for Q4 2022, with first human trial designed as Phase 2 trial planned to begin in Q1 2023.
- Multibillion-dollar DED market whose medical needs remain largely unmet.
- AmbioPharm supporting OK-101 program with peptide synthesis and development.

London and New York, N.Y., and North Augusta, S.C. 30 August 2022

[OKYO Pharma Limited](#) (NASDAQ: OKYO; LSE: OKYO), a biotechnology company focused on the discovery and development of novel molecules to treat inflammatory dry eye diseases and ocular pain, **plans a Q4 2022 IND filing for OK-101** to treat dry eye disease (DED), with [AmbioPharm](#) playing a key role in peptide manufacturing and development.

[OK-101](#) is a lipid-peptide analog developed using a novel membrane-anchored peptide (MAP) technology. It consists of a 12 amino acid peptide sequence, a linker component, and an anchoring lipid domain. OK-101 is designed to increase the potency and combat ocular washout through the inclusion of the lipid 'anchor' contained in the molecule to enhance the residence time within the ocular environment. The OK-101 drug candidate displays potent anti-inflammatory activity in animal models of DED. OK-101 also reduces Corneal Neuropathic Pain (CNP) in a ciliary nerve ligation animal model of CNP. Inflammation and pain are the two main symptoms of DED, and inflammation is believed to be a major driver of the DED condition.

OK-101 has novel speed-to-market potential by skipping a Phase I trial as the drug is administered topically, and by designing its Phase 2 trial effectively as a Phase 3 registration trial. Additionally, animal studies have shown no adverse effects of the drug.

In Q1 2022, OKYO had a successful pre-IND meeting with the FDA and the FDA concurred with OKYO's plan to prespecify co-primary efficacy endpoints of DED disease in the planned Phase 2 clinical trial. The Phase 2 trial, designed as effectively a Phase 3 registration trial, if successful, **would accelerate the timeline to new drug application (NDA)**.

DED remains largely a major unmet medical need as approved drugs, to date, still leave many patients unsatisfied. Consequently, there is multi-billion-dollar market potential for an effective drug with minimal side effects to treat this disease.

AmbioPharm is supporting the OK-101 program with peptide synthesis and development. A peptide contract development and manufacturing organization (CDMO) providing cGMP peptide APIs with capabilities ranging from research to commercial scales, AmbioPharm actively engages with innovative biopharmaceutical companies in developing first-in-class, best-in-class, and breakthrough peptide technologies that utilize AmbioPharm's peptide manufacturing expertise and in-depth scientific experience in novel and conventional peptide chemistry. "The OK-101 program is a perfect fit for our dynamic business model, which helps our partners by providing high quality products and services with a highly competitive cost structure," said Michael W. Pennington, Ph.D., Chief Scientific Officer of AmbioPharm Inc.

"We are absolutely delighted to have AmbioPharm, a global leader in the synthesis of peptides and peptide analogs, manufacturing our drug candidate OK-101," said Gary S. Jacob, Ph.D., Chief Executive Officer of OKYO Pharma Ltd. "The work performed by AmbioPharm during this post-COVID 19 period to keep us on schedule with the manufacture of API went above and beyond the call of duty and was a testament to the high standards that AmbioPharm abides by."

About OKYO

OKYO Pharma Limited (NASDAQ: OKYO; LSE: OKYO) is a life sciences and biotechnology company recently listed on Nasdaq and 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.

For further information, please visit www.okyopharma.com/

About AmbioPharm

AmbioPharm, a part of the Ambio Pharmaceuticals Group, is a leading and innovation-driven company specializing in the development and manufacture of peptides and peptide-related products. With a comprehensive range of services, AmbioPharm produces custom products for research, clinical development, and commercial application to pharmaceutical and biotechnology companies worldwide.

Further information is available at www.ambiopharm.com.

Forward Looking Statements

Certain statements made in this announcement are forward-looking statements including with respect to the creation of a trading market for ADSs representing the Ordinary Shares in the United States. 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, including market conditions. We caution you therefore against relying on any of these forward-looking statements. Important factors that could cause actual results to differ materially from those in the

forward-looking statements include, without limitation, our ability to raise capital to fund continuing operations; our ability to protect our intellectual property rights; the impact of any infringement actions or other litigation brought against us; competition from other providers and products; our ability to develop and commercialize products and services; changes in government regulation; our ability to complete capital raising transactions; and other factors relating to our industry, our operations and results of operations. . 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.

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