THIS ANNOUNCEMENT CONTAINS INSIDE INFORMATION FOR THE PURPOSES OF ARTICLE 7 OF REGULATION 2014/596/EU WHICH IS PART OF DOMESTIC UK LAW PURSUANT TO THE MARKET ABUSE (AMENDMENT) (EU EXIT) REGULATIONS (SI 2019/310) ("UK MAR"). UPON THE PUBLICATION OF THIS ANNOUNCEMENT, THIS INSIDE INFORMATION (AS DEFINED IN UK MAR) IS NOW CONSIDERED TO BE IN THE PUBLIC DOMAIN.

Okyo Pharma Limited
Interim Results for the Six Months Ending 30 September 2022

London and New York, NY, December 30, 2022 OKYO Pharma Limited (LSE: OKYO, NASDAQ: OKYO), an ophthalmology-focused bio-pharmaceutical company developing OK-101 to treat Dry Eye Disease (DED) to address the significant unmet need in this multi-billion-dollar market, today announces its interim results for the six months ended 30 September 2022.

Clinical Updates:

OK-101

During the past six months the Group's primary focus has been centered on accomplishing the filing of the investigational new drug (IND) application with the FDA on OK-101 to treat DED.

During this period, the Group completed the following:

- topical formulation of the OK-101 drug product as well as initial stability studies
- finalized the bioanalytical method development to support the OK-101 clinical program
- batch manufacture of cGMP OK-101 for clinical trials
- toxicokinetic method development
- toxicology studies in rabbits and dogs

Both nonclinical and clinical development plans on OK-101 were reviewed with the FDA in an earlier Pre-IND meeting in February 2022 facilitated by OKYO's contract research organization, Ora Inc, with the FDA agreeing to a first-in-human Phase 2 trial in DED patients. The 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.

After considerable effort over the past 18 months, the Group announced on 21 November 2022 the filing of an IND on OK-101 with FDA to treat DED patients. On December 22, 2022 the Group announced that it had received FDA IND clearance for its planned Phase 2 trial in DED, which it expects to initiate in Q1 2023. The study has been designed in conjunction with, and will be managed and monitored by Ora Inc, well known for its leadership of ophthalmic clinical trial activities. The Phase 2 trial is expected to be completed in 6-9 months from enrollment of the first patient.

OK-201:

On 6 August 2019, a collaborative agreement was signed with Pedram Hamrah, MD, Professor of Ophthalmology at Tufts University School of Medicine, Boston, MA to evaluate the Group's BAM8-22 analogues, including OK-201, as non-opioid analgesics to suppress corneal neuropathic pain using a mouse ocular pain model developed in Dr. Hamrah's laboratory. Neuropathic corneal pain is a severe, chronic and debilitating disease with no FDA approved commercially available treatments currently available for this condition.

On 28 April 2021 the company announced positive results of OK-201, a non-opioid analgesic drug candidate delivered topically in Dr. Hamrah's mouse neuropathic corneal pain model, as a potential drug to treat acute and chronic ocular pain. Importantly, OK-201 demonstrated a reduced corneal pain response equivalent to that of gabapentin, a commonly used oral drug for neuropathic pain. These observations demonstrated preclinical 'proof-of-concept' for the topical administration of OK-201 as a potential non-opioid analgesic for ocular pain.

Although the results with OK-201 were encouraging, due to subsequent success obtained with OK-101 in follow-on animal model studies utilizing the same mouse neuropathic corneal pain model, the company decided at the end of 2021 to pause further development of OK-201 to treat ocular neuropathic pain, and to turn its full attention to the development of OK-101 to treat DED.

During the past six months the Group has halted any further work on OK-201 as it focuses its full energies on obtaining IND clearance for OK-101 during the fourth quarter of 2022. This IND filing was successfully cleared and announced on 22 December 2022.

Financial Highlights:

- Total assets of £1.6 million (31 March 2022: £3.3 million)
- Cash on hand of £0.6 million (31 March 2022: £2.1 million)
- During the financial period under review, the Company reported a total comprehensive loss of £4.6 million (compared to total comprehensive loss of £1.8 million for the six months ending September 30 2021)

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.

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