Final audited results for the year ended 31 March 2022

OKYO Pharma Limited (the "Company") is pleased to announce its final audited results for the year ended 31 March 2022.

Summary of OKYO-101 studies during the last year

- OK-101 is designed to target a chemokine-like receptor 1, or CMKLR1, which is a G protein-coupled receptor, or GPCR, expressed on macrophages, monocytes, plasmacytoid/myeloid dendritic cells, natural killer cells and nonhemopoietic cell types, such as endothelial and epithelial cells. Activation of CMKLR1 by its endogenous peptide ligand chemerin is known to modulate inflammation, but natural ligands for CMKLR1 have short half-lives due to rapid inactivation.
- A major issue with topical administration of any drug designed for treating DED is the requirement that the drug have adequate drug 'residence' time at the ocular site. The drug candidates we have developed are designed to combat washout by including a lipid 'anchor' within the candidate drug molecule to enhance the residence time of the drug in the eye. We refer to our candidates for DED as "lipidated-chemerin" analogues to highlight this pharmacologic characteristic.
- Animals induced with scopolamine to generate acute DED showed a statistically significant increase in corneal permeability relative to naïve non-stressed animals. The addition of cyclosporine to scopolamine-induced DED animals showed a statistically significant reduction of permeability ($p \leq 0.001$). Notably, OK-101 demonstrated a dramatic reduction of DED-induced corneal permeability as well ($p \leq 0.001$).
- OK-101 was topically administered to mice in comparison to the positive control gabapentin which was administered via intraperitoneal injection. Pain relief was evaluated by an eye-wipe count, and OK-101 was shown to reduce corneal pain similar to that of gabapentin, a commonly used oral drug for neuropathic pain. Notably, the drug concentration of OK-101 used in this study was identical to that used in mouse models of DED that demonstrated ocular anti-inflammatory activity. OK-101 had no effect on corneal epithelial integrity compared to gabapentin or balanced salt solution.
- A separate series of experiments was also performed to evaluate ocular tolerance of OK-101 in rabbits via repeated ocular instillation followed by clinical ophthalmic observations. Rabbit ocular tolerance tests on OK-101 showed no adverse signs such as inflammation, chemosis or hyperemia and no signs of local irritation.
- During the fourth quarter of 2021 we successfully manufactured a 200-gram batch of OK-101 drug substance needed for the IND-enabling studies.
- On February 15, 2022, we announced the successful completion of the pre-IND meeting facilitated by Ora with the FDA regarding development plans for OK-101 to treat DED. Both nonclinical and clinical development milestones were covered in the pre-IND meeting, with the FDA agreeing that our first human trial would be a Phase 2 safety and efficacy trial in DED patients.

Summary of OKYO-201 studies during the last year

- OK-201 is designed to activate a human MAS-Related G Protein-coupled Receptor (MRGPR), which is a promising analgesic target. This receptor is expressed mainly in sensory neurons and is involved in the perception of pain. Activation of MRGPR by BAM peptide inhibits pain by modulating Ca2+ influx.
- On April 28, 2021, we announced positive results of OK-201, a non-opioid analgesic drug candidate delivered topically, 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.

Future strategy of OKYO-101

- To support our work, we signed an agreement on April 13, 2021 with Ora, Inc., or Ora, a major clinical research organization ("CRO"), specializing in ophthalmic drug development.
- Based on the results from earlier DED animal model studies that have been performed with OK-101 as well as the additional animal study showing the potential of OK-101 to reduce corneal neuropathic pain, we are moving forward with plans to file an IND to treat DED in the fourth quarter of 2022.
- Followed by the subsequent initiation of a Phase 2 trial of OK-101 to treat DED patients in the first quarter of 2023.

- Once we are clinically evaluating OK-101 to treat dry eye, we will also undertake the plan to explore the drug candidate's potential to suppress the inflammation associated with uveitis and allergic conjunctivitis. In support of this plan, we will be exploring preclinical development of OK-101 for the uveitis indication by first establishing 'proof-of-concept' for this indication utilizing animal model studies of anterior uveitis to evaluate the potential of OK-101 to suppress the inflammation associated with uveitis.
- We also plan on conducting 'proof-of-concept' studies using OK-101 for the treatment of chronic and seasonal allergic conjunctivitis using a conjunctival allergen challenge animal model to investigate the potential of OK-101 to suppress the inflammation associated with allergic conjunctivitis.

Future strategy of OKYO-201

Over the next year, we have decided to maintain this drug candidate at the exploratory level.

Financial Highlights

- Total comprehensive loss of £3,976k (2021: £2,994k)
- Cash balance at 31 March 2022 £2,056k (31 March 2021: £4,992k)

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