

OKYO Pharma Ltd. (OKYO)

Overweight

First Patients Enrolled in NEPTUNE Ph3 in Neuropathic Corneal Pain

CONCLUSION

This morning, OKYO announced first patient enrollment in the NEPTUNE Ph3 trial of urcosimod in neuropathic corneal pain (NCP), consistent with mgmt.'s timeline of early Oct. Recall that during a Type B meeting, the company aligned with the FDA on Week 12 VAS pain reduction as the primary endpoint and indicated that a 2 point improvement vs. placebo could be clinically meaningful and potentially support approval. The key question is whether the efficacy signal from the small Ph2 study can be replicated in NEPTUNE, particularly given the challenges of identifying and enrolling patients with true NCP. Topline data are currently guided for Dec. '27. Separately, mgmt. plans to use this week's AAO meeting to build awareness of NCP and OKYO, as broader disease recognition remains important to identifying currently underdiagnosed NCP patients.

- **Pivotal Ph3 begins enrolling.** Before the market opened, OKYO announced that the first patients have enrolled in its NEPTUNE Ph3 study of urcosimod for NCP. The study will enroll ~111 patients with moderate-to-severe disease, defined by baseline VAS pain scores ≥ 5 , and randomize them 2:1 to urcosimod (0.05%) or placebo. During a recent Type B meeting, the FDA aligned on Week 12 VAS pain reduction as the primary endpoint and a 2 point placebo adjusted improvement as clinically meaningful and potentially sufficient to support approval. The study is powered at 90%, with a prespecified p-value threshold of 0.025; a p-value ≤ 0.001 could support approval based on a single pivotal study. The design focuses on the subgroup that showed the strongest Ph2 signal, including an ~3.5 point placebo adjusted benefit among just 8 patients with baseline VAS scores of ≤ 5 . Enrollment is targeted to complete around June '27, with topline data expected around Dec. '27 (note [here](#)).
- **Specialist site selection may improve enrollment quality.** Mgmt. plans to recruit through a concentrated network of 13 experienced NCP centers, including 8 in the US and 5 in Europe, with sites selected partly based on having pre-screened patients available. Additionally, mgmt. is using screening tools to distinguish true NCP from nonspecific ocular pain. We think this targeted approach should improve the likelihood of enrolling patients with NCP, rather than ocular pain from other causes
- **BTD feedback and new epidemiology data are the next near term updates.** Mgmt. expects FDA feedback on its BTD application around mid Oct. During our recent investor meetings with mgmt., the team estimated a greater than 50% chance of receiving the designation, while acknowledging that the limited clinical experience is a key constraint (note [here](#)). Separately, OKYO plans to use this week's AAO meeting to build awareness of NCP and expects prevalence and TAM analyses with Verana and Komodo toward YE26. Currently, OKYO estimates the US prevalence of NCP is $>200K$ but $<1M$, with an internal estimate of ~500K patients. These analyses could help clarify the commercial opportunity in a condition that mgmt. believes is substantially underdiagnosed, though the market remains unvalidated.

COMPANY DESCRIPTION

OKYO is developing a first-in-class chemerin receptor agonist for Neuropathic Corneal Pain (NCP).

PRICE: US\$1.47

TARGET: US\$7.00

Our \$7 PT is based on a DCF through 2035E(15% discount rate) and assumes ~\$328Min peak risk-adjusted Uracosimod sales in Neuropathic Corneal Pain, Post Surgery and Dry Eye Disease, in both the US and EU.

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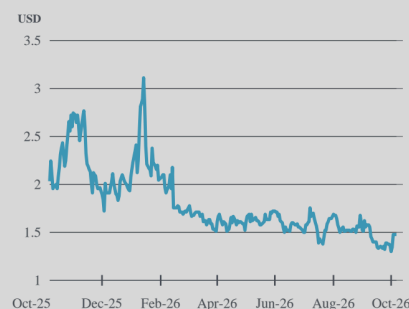
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Risks include clinical, regulatory, commercial, financing and IP.

Price Performance - 1 Year



Source: Bloomberg

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