OKYO Pharma Ltd. (OKYO)

Overweight

FDA Affirms Streamlined Phase 3 Design; Potential For Single-Trial Registration

CONCLUSION

This morning, OKYO announced positive feedback from a Type D meeting with the FDA, resulting in a streamlined Phase 3 design for urcosimod in neuropathic corneal pain (NCP), with Ph3 trial now expected to initiate in 2H26. The newly unveiled NEPTUNE trial represents a meaningful simplification vs the previously disclosed Phase 2b/3 design (3 arms, ~150 patients, 12-week dosing regimen), instead advancing directly into a single dose concentration, 2-arm pivotal study (0.05% urcosimod vs placebo, 2:1 randomization, ~111 patients) that the FDA has indicated could support a single-trial registration pathway. We view this as a significant de-risking event that reduces trial complexity and cost, and also provides a clear regulatory path for urcosimod.

- **Phase 3 trial design simplification.** The prior Phase 2b/3 plan called for 3 arms (placebo, 0.025%, 0.05%) and ~150 patients dosed over 12 weeks. NEPTUNE instead drops the low-dose arm entirely, uses only the 0.05% dose that showed a strong Ph2a signal (5.5-point VAS improvement vs 2.75 for placebo, with 75% of per-protocol patients with >80% VAS pain reduction), and reduces enrollment to ~111 patients in a 2:1 randomization. The new trial design should lower trial costs, with OKYO on track to initiate NEPTUNE in 2H26. The trial should also improve odds of success.

- **Single-trial registration potential is a win.** The planned NEPTUNE trial was designed as a pivotal study that could support a potential single-trial registration, contingent on successful results and continued FDA review. We'd flag this as the primary swing factor for the stock, where a clean NEPTUNE readout likely triggers NDA-enabling discussions without a second confirmatory trial, materially compressing time-to-filing versus prior expectations (previously 1H27 topline / EOP2 meeting ~YE27 under the old 3-arm design). OKYO is also pursuing Breakthrough Therapy Designation (BTD), which would layer on more frequent/senior FDA interaction and potential rolling review.

- **What to watch for next:** (1) further characterization of the statistical and powering assumptions at n=111 and with more patient numbers at the 0.05% concentration than the previous design; (2) formal trial initiation and site activation cadence into 2H26; (3) BTD decision timing; and (4) balance sheet updates – management notes a "strong balance sheet" supporting direct advancement into Phase 3, but we'll want visibility on runway through topline data.

COMPANY DESCRIPTION

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

PRICE: US$1.75
TARGET: US$7.00
Our $7 PT is based on a DCF through 2035E(15% discount rate) and assumes ~ $328Min peak risk-adjusted Urcosimod sales in Neuropathic Corneal Pain, Post Surgery and Dry Eye Disease, in both the US and EU.

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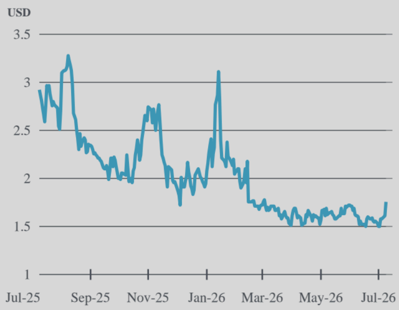
RISKS TO ACHIEVEMENT OF PT & RECOMMENDATION

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

Price Performance - 1 Year



Source: Bloomberg

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