Study Designs for CEQUA® (cyclosporine ophthalmic solution) 0.09% 2024 Direct Mail Campaign Wave 5 – NCELL® Technology

NCELL Technology Study Design: Ocular tissue distribution of cyclosporine was evaluated in a total of 26 female New Zealand White rabbits that received a single dose (administered to both eyes) of vehicle, cyclosporine 0.05% or 0.1% with NCELL Technology, or a commercially available cyclosporine 0.05% emulsion (Restasis®, Allergan). Pharmacokinetic parameters for cyclosporine exposure were assessed in tears, whole blood, and ocular tissues.[1,2]

2-week Corneal Staining Study Design: Phase 2b/3, randomized, multicenter, double-masked, vehicle-controlled, dose-ranging study. The co-primary efficacy endpoints were mean reduction in total conjunctival staining score and mean reduction in global symptom score at Day 84. Conjunctival and corneal staining were assessed at baseline and Days 14, 28, 42, 56, and 84/early discontinuation. Conjunctival staining was assessed in 6 conjunctival zones 1–4 minutes after instilling 1 drop of 1% lissamine green. Corneal staining was evaluated in 5 corneal regions 2–2.5 minutes after instilling 1 drop of 0.5% fluorescein.[3]

CEQUA Switch Efficacy Study Design: Single arm, Phase 4, 12-week, multicenter study of 124 adults with DED inadequately controlled (ie, still symptomatic and/or exhibiting disease signs) on current Restasis® therapy.[1,4] The co-primary endpoints were corneal fluorescein staining (CFS) and modified Symptom Assessment in Dry Eye (mSANDE) at Week 12.9 Patients received 1 drop, 2x daily of CEQUA in each eye.[4] Among the secondary endpoints, patients were asked which treatment they prefer for the management of dry eye.

Exclusions: Previous history of failure on Restasis; discontinued/switched to a different immunomodulatory; allergic conjunctivitis; stable dose for ≥3 months of immunomodulators, antihistamines, cholinergics, antimuscarinics, phenothiazines, retinoids, or any systemic or topical corticosteroids.[5]

References:

1. Data on file. Cranbury, NJ: Sun Pharmaceutical Industries, Inc.
2. US Patent 9,937,225 B2.
3. Schechter BA, Urbieta M, Bacharach J, et al. Effect of OTX-101 on patients with dry eye disease at day 14 of treatment: ocular surface endpoint results from the phase 2b/3 clinical trial. *Clin Ophthalmol*. 2022;16:4145-4151.
4. Johnston, J. Effect of OTX-101 0.09% on corneal staining and SANDE scores in patients with dry eye disease uncontrolled on cyclosporine ophthalmic emulsion 0.05%. Abstract presented at American Academy of Optometry 2023; October 12, 2023; New Orleans, LA.
5. Effect of CEQUA in Subjects with Dry Eye Disease, ClinicalTrials.gov identifier NCT04357795. Updated February 2024. Accessed August 29, 2023. https://www.clinicaltrials.gov/study/NCT04357795

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