Study Designs for CEQUA® (cyclosporine ophthalmic solution) 0.09% Nurture Campaign Non-Writers Wave 2

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.[1,2] The co-primary endpoints were corneal fluorescein staining (CFS) and modified Symptom Assessment in Dry Eye (mSANDE) at Week 12.[3] Patients received 1 drop, 2x daily of CEQUA in each eye.[2] 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.[3]

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.[5]

References:

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5. 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.
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