Study Designs for CEQUA® (cyclosporine ophthalmic solution) 0.09% Phase 4 Blitz Campaign 2024 – Wave 1

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.[1]

Enrolled patients were selected by their doctors based on: Clinical diagnosis of DED and treatment on Restasis for ≥3 months; BCVA of ≥20/200; mSANDE score of ≥40; total CFS ≥6 or CFS in an individual zone ≥2 at baseline.[3]

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]

References:

1. 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.
2. Data on file. Cranbury, NJ: Sun Pharmaceutical Industries, Inc.
3. Effect of CEQUA in Subjects with Dry Eye Disease, ClinicalTrials.gov identifier NCT04357795. Updated Sept 09, 2022. Accessed August 29, 2023. https://www.clinicaltrials.gov/study/NCT04357795

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