Study Designs for CEQUA® (cyclosporine ophthalmic solution) 0.09% Wave 9 Med Influencer DM

Phase 4 Study design: Single arm, Phase 4, 12-week, multicenter study of 124 adults with DED inadequately controlled (i.e., still symptomatic and/or exhibiting disease signs) on current Restasis therapy. The co-primary endpoints were corneal fluorescein staining (CFS) and modified Symptom Assessment in Dry Eye (mSANDE) at Week 12. Patients received 1 drop, 2X daily of CEQUA in each eye.[1-3]

Phase 4 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
4. Goldberg DF, Malhotra RP, Schechter BA, Justice A, Weiss SL, Sheppard JD. A phase 3, randomized, double-masked study of OTX-101 ophthalmic solution 0.09% in the treatment of dry eye disease. *Ophthalmology.* 2019;126(9):1230-1237
5. CEQUA [package insert]. Cranbury, NJ: Sun Pharmaceutical Industries, Inc.; 2022.

Current as of February 25, 2025

PM-US-CQA-1810 2/2025