References for CEQUA® (cyclosporine ophthalmic solution) 0.09%

[a]The safety of CEQUA was evaluated in clinical trials that included 769 patients who received at least 1 dose of study treatment.[2]

Study design: In two 12-week double-masked studies, a Phase 2/3 (Study 1; N=455) and a Phase 3 (Study 2; N=744), patients were randomized 1:1:1 to receive CEQUA (0.05% or 0.09%) or vehicle control. Study 1 co-primary endpoints were change from baseline in conjunctival staining and global symptom score at Day 84. Study 2 primary endpoint was improvement of ≥10 mm in Schirmer score at Day 84. Conjunctival staining was a secondary endpoint in both studies.[1,2,6]

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. 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. 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.[3-5]

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.[4]

References:

1. 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.
2. CEQUA [package insert]. Cranbury, NJ: Sun Pharmaceutical Industries, Inc.; 2022.
3. Data on file. Cranbury, NJ: Sun Pharmaceutical Industries, Inc.
4. 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
5. 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.
6. Tauber J, Schechter BA, Bacharach J, et al. A phase II/III, randomized, double-masked, vehicle-controlled, dose-ranging study of the safety and efficacy of OTX-101 in the treatment of dry eye disease. *Clin Ophthalmol*. 2018;12:1921-1929.

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