Study Designs for CEQUA® (cyclosporine ophthalmic solution) 0.09% Direct Mail Campaign – Wave 4

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]

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]

CEQUA, Xiidra®, and Restasis Treatment Duration Study Design: Real-world, retrospective, longitudinal cohort study utilizing data from the Symphony Health Integrated Dataverse (IDV), a national provider-based claims database, examining time to treatment discontinuation, probability of treatment discontinuation, and treatment persistence among patients with DED treated with CEQUA (n=1846), Restasis (n=2248), or Xiidra (n=3008).[4]

2-week Corneal Staining Study Design: 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:

1. Data on file. Cranbury, NJ: Sun Pharmaceutical Industries, Inc.
2. 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.
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. Karpecki P, Barghout V, Schenkel B, et al. Real-world treatment patterns of OTX-101 ophthalmic solution, cyclosporine ophthalmic emulsion, and lifitegrast ophthalmic solution in patients with dry eye disease: a retrospective analysis. *BMC Ophthalmol.* 2023;23(1):443. doi:10.1186/s12886-023-03174-y.
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 Opththalmol.* 2022;16:4145-4151.

Current as of: August 7, 2024

PM-US-CQA-1627 08/2024