Study Designs for CEQUA® (cyclosporine ophthalmic solution) 0.09% Leave Behind

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.[1]

1 month corneal staining study design: CEQUA was studied in two 12-week, randomized, multicenter, double-masked, vehicle-controlled studies. Patients were randomly assigned to treatment and dosed twice a day. Study 1 included 455 patients (152 received CEQUA) and Study 2 included 744 patients (371 received CEQUA). The co-primary endpoints for Study 1 were conjunctival staining and global symptom scores (change from baseline to Day 84). The primary endpoint for Study 2 was percentage of eyes demonstrating an improvement of ≥10 mm in Schirmer score after 84 days of treatment. Both studies assessed corneal staining as a secondary endpoint.[2-4]

Staining in each region of the conjunctiva was evaluated using a score ranging from 0 (no staining) to 3 (severe staining). Staining in each region of the cornea was evaluated using a score ranging from 0 (no staining) to 4 (severe staining).[2,3]

Patients were excluded from the studies if they experienced prior treatment failure with cyclosporine 0.05% or used the therapy within 3 months prior to screening. Use of artificial tears was not allowed during the studies. The mean age was 59 years (range, 18-90 years). Eighty-three percent of patients were female.[2,3]

Median 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).[5]

References:

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2. 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.
3. 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.
4. CEQUA [package insert]. Cranbury, NJ: Sun Pharmaceutical Industries, Inc.; 2022.
5. 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.

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