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

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, logitudinal cohort study utilizing data from the Symphony Health Integrated Dataverse (IDV), a national provider-based claims database, examining time to treat 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]

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.[6] The co-primary endpoints were corneal fluorescein staining (CFS) and modified Symptom Assessment in Dry Eye (mSANDE) at Week 12.[7] Patients received 1 drop, 2x daily of CEQUA in each eye.[6]

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.
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.[7]

References:

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