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

Study design: Single-arm, open-label study evaluating 60 (46 assessable) patients at 7, 14, and 28 days. The primary endpoint was change in corneal higher order aberrations measured in the central 6.0 mm of the cornea after 7, 14, and 28 days of treatment. The secondary endpoint was change in corneal staining (Oxford scale) at 7, 14, and 28 days of treatment. Exclusion criteria were similar to past studies with the exception that patients switching from another dry eye medication were not excluded.[1]

Pivotal studies 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.[2,4,5]

References

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3. Malhotra R, Devries DK, Luchs J, et al. Effect of OTX-101, a novel nanomicellar formulation of cyclosporine A, on corneal staining in patients with keratoconjunctivitis sicca: A pooled analysis of phase 2b/3 and phase 3 studies. *Cornea*. 2019;38:1259-1265.
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