

## **Study Designs for CEQUA® (cyclosporine ophthalmic solution) 0.09% CEQUA Wave 8 Patient Testimonials DM**

Study design: 2-week efficacy data come from a Phase 2b/3, randomized, multicenter, double-masked, vehicle-controlled, dose-ranging study in 455 patients. 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.<sup>4</sup>

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  $\geq 10$  mm in Schirmer score after 84 days of treatment. Both studies assessed corneal staining as a secondary endpoint.<sup>1,2,3</sup>

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).<sup>1,2</sup>

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.<sup>1,2</sup>

## References:

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2. 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.
3. CEQUA [package insert]. Cranbury, NJ: Sun Pharmaceutical Industries, Inc.; 2022.
4. Schechter BA, Urbietta M, Bacharach J, et al. Effect of OTX-101 in patients with dry eye disease at day 14 of treatment: ocular surface endpoint results from the phase 2b/3 clinical trial. *Clin Ophthalmol*. 2022;16:4145-4151.
5. Data on file. Cranbury, NJ: Sun Pharmaceutical Industries, Inc.

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