Study Designs:

[a]**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.[1]

[b]**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).[3]

References:

1. Schechter BA, Urbieta 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.
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. 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.
4. CEQUA [package insert]. Cranbury, NJ: Sun Pharmaceutical Industries, Inc.; 2022.

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