Study Designs for CEQUA® (cyclosporine ophthalmic solution) 0.09% CEQUA White Space NPP DM Wave 2

Phase 4 study design: Single arm, Phase 4, 12-week, multicenter study of 124 adults with DED inadequately controlled (i.e., still symptomatic and/or exhibiting disease signs) on current Restasis® therapy. The co-primary endpoints were corneal fluorescein staining (CFS) and modified Symptom Assessment in Dry Eye (mSANDE) at Week 12. Patients received 1 drop, 2X daily of CEQUA in each eye.[1-3]

Phase 4 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.[3]

NCELL® Technology study design: Ocular tissue distribution of cyclosporine was evaluated in a total of 26 female New Zealand White rabbits that received a single dose (administered to both eyes) of vehicle, cyclosporine 0.05% or 0.1% with NCELL® Technology, or a commercially available cyclosporine 0.05% emulsion (Restasis®, Allergan). Pharmacokinetic parameters for cyclosporine exposure were assessed in tears, whole blood, and ocular tissues.[2,4]

References:

1. Johnston, J. Effect of OTX-101 0.09% on corneal staining and SANDE scores in patients with dry eye disease uncontrolled on cyclosporine ophthalmic emulsion 0.05%. Abstract presented at American Academy of Optometry 2023; October 12, 2023; New Orleans, LA.
2. Data on file. Cranbury, NJ: Sun Pharmaceutical Industries, Inc.
3. Effect of CEQUA in Subjects with Dry Eye Disease, ClinicalTrials.gov identifier NCT04357795. Updated Sept 09, 2022. Accessed August 29, 2023. https://www.clinicaltrials.gov/study/NCT04357795
4. US Patent 9,937,225 B2.
5. Cholkar K, Gilger BC, Mitra AK. Topical, aqueous, clear cyclosporine formulation design for anterior and posterior ocular delivery. *Transl Vis Sci Technol*. 2015;4(3):1-16.
6. Mandal A, Bisht R, Rupenthal ID, Mitra A. Polymeric micelles for ocular drug delivery: from structural frameworks to recent preclinical studies. *J Control Release*. 2017;248:96-116.

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