

Safety and Efficacy of Topical Ophthalmic MIM-D3, a Novel TrkA Receptor Agonist, in a Phase 2 Clinical Trial for the Treatment of Dry Eye

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Purpose: To assess the safety and efficacy of 1% and 5% MIM-D3 Ophthalmic Solutions compared to placebo for the treatment of the signs and symptoms of dry eye.

Methods: A multi-center, randomized, double-masked, placebo-controlled study included a 7-day run-in period and 28 days of BID dosing. For screening purposes, at Visits 1 and 2 subjects were exposed to the Controlled Adverse Environment (CAE) Model. Subjects were dosed BID with artificial tears between Visits 1 and 2. Eligible subjects had sufficient dry eye signs and symptoms pre-CAE at both visits as well as exacerbation in fluorescein corneal staining and ocular symptoms with CAE exposure. Patients were randomized (1:1:1): 1%, 5%, or placebo. Symptoms were recorded daily. CAE exposure was repeated at Days 14 and 28 to assess treatment efficacy. **Results:** In patients with moderate signs and symptoms of dry eye (n=150) both doses showed significantly less fluorescein staining than placebo after 28 days of treatment.

Improvements in staining were observed in the post-CAE and changes from pre- to post-CAE analyses. Fluorescein staining in the 1% arm were significantly lower than in the placebo arm for the inferior, temporal, nasal, total cornea, conjunctiva and whole eye assessments (p=0.0039 to 0.0422). The mean dryness score in the symptom diaries over the 28-day treatment period demonstrated a treatment effect for both MIM-D3 groups with the 5% arm being significantly lower than the placebo arm (p=0.0342). In a subgroup defined by higher symptom scores during the run-in period, significant treatment effects for dryness (1% p=0.0150, 5% p=0.0637) and worst symptom (1% p=0.0368, 5% p=0.0533) were noted. Both doses of MIM-D3 were safe and well tolerated. **Conclusions:** Topical ophthalmic MIM-D3 showed robust protection against the exacerbation of signs in the CAE model, and patient reported diary symptoms in the environment, with a favorable safety profile. MIM-D3 demonstrates promising results as a novel treatment for dry eye disease and will be further evaluated in a multi-center Phase 3 trial.