**ABSTRACT**

**Purpose:** To determine the efficacy of EBI-005 in the treatment of dry eye disease (DED). EBI-005 is a novel IL-1 receptor inhibitor designed to mediate physiologic responses of IL-1β and IL-1α.

**Methods:** Phase 1a was a single ascending dose (SAD) study with doses of 0.005 to 20 mg/mL in ocular vehicle. Phase 1b/2a was a multiple ascending dose (MAD) study with doses of 1, 5, and 20 mg/mL three times daily for 12 weeks. Safety was assessed in double masked, vehicle-controlled studies. Pharmacokinetic (PK) analysis was done in a natural environmental study.

**Results:** EBI-005 showed statistically significant improvement from baseline for total CFS in subjects with moderate to severe DED (15% improvement for EBI and 5% for EE). EBI-005 showed most robust separation between drug and vehicle for the OSDI population. EBI-005 showed onset of action as early as two weeks with no plateau of effect at the final visit at 6 weeks.

**Conclusions:** EBI-005 is more potent and stable than anakinra. It is a key target for ocular surface inflammation and is a novel direct conjunctival allergen model. EBI-005 was well tolerated with no treatment-related SAEs reported in this population.

**REFERENCES**