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A Phase 2 Exploratory Study of a Novel Interleukin-1 Receptor Inhibitor (EBI-005) in the Treatmentof Moderate-to-Severe Allergic Conjunctivitis.

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Abstract

OBJECTIVES:

Many allergic conjunctivitis (AC) patients are inadequately treated with conventional therapies or require steroids. EBI-005was developed to address the late phase allergic response. This study's objectives were to evaluate two adapted clinical models for this indication and to assess safety and biological activity of EBI-005 in AC.

METHODS:

In this randomized, double-masked, vehicle-controlled study, 159 subjects with moderate-to-severe AC were randomized to topical EBI-005 (5 mg/mL) or vehicle control given 3 times per day and repeatedly challenged with allergen using an adaptation of 2 clinical models of AC. Subjects were assigned to repetitive aerosolized challenge in an allergy chamber (Environmental Exposure Chamber, EEC), or repetitive challenges with a direct conjunctival allergen challenge (Conjunctival Allergen Provocation Test, CAPT).

RESULTS:

In the EEC, the prespecified primary endpoint of ocular itching was not met. In the CAPT, EBI-005-treated subjects showed clinically meaningful, statistically significant improvements in ocular itching compared with vehicle control at the final 2 efficacy time points, visit 6 (P=0.033) and visit 7 (P=0.046). EBI-005-treated subjects showed statistically significant improvement compared with vehicle control for ocular tearing (P=0.027 and P=0.044) and nasal symptoms (P=0.004 and P=0.011) at visit 6 and visit 7. EBI-005 was well tolerated.

CONCLUSIONS:

These results support use of an adapted, multiple-challenge, direct conjunctival allergen model to assess efficacy of EBI-005 in late phase AC. In the CAPT, EBI-005 showed statistically significant improvements in clinically meaningful symptoms (ocular itching, tearing, and nasal symptoms) at multiple time points for moderate-to-severe AC subjects.