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A Phase 2 Clinical Trial of Topical Ocular Reproxalap, a Novel RASP Inhibitor, in an Allergen Chamber Model of Allergic Conjunctivitis

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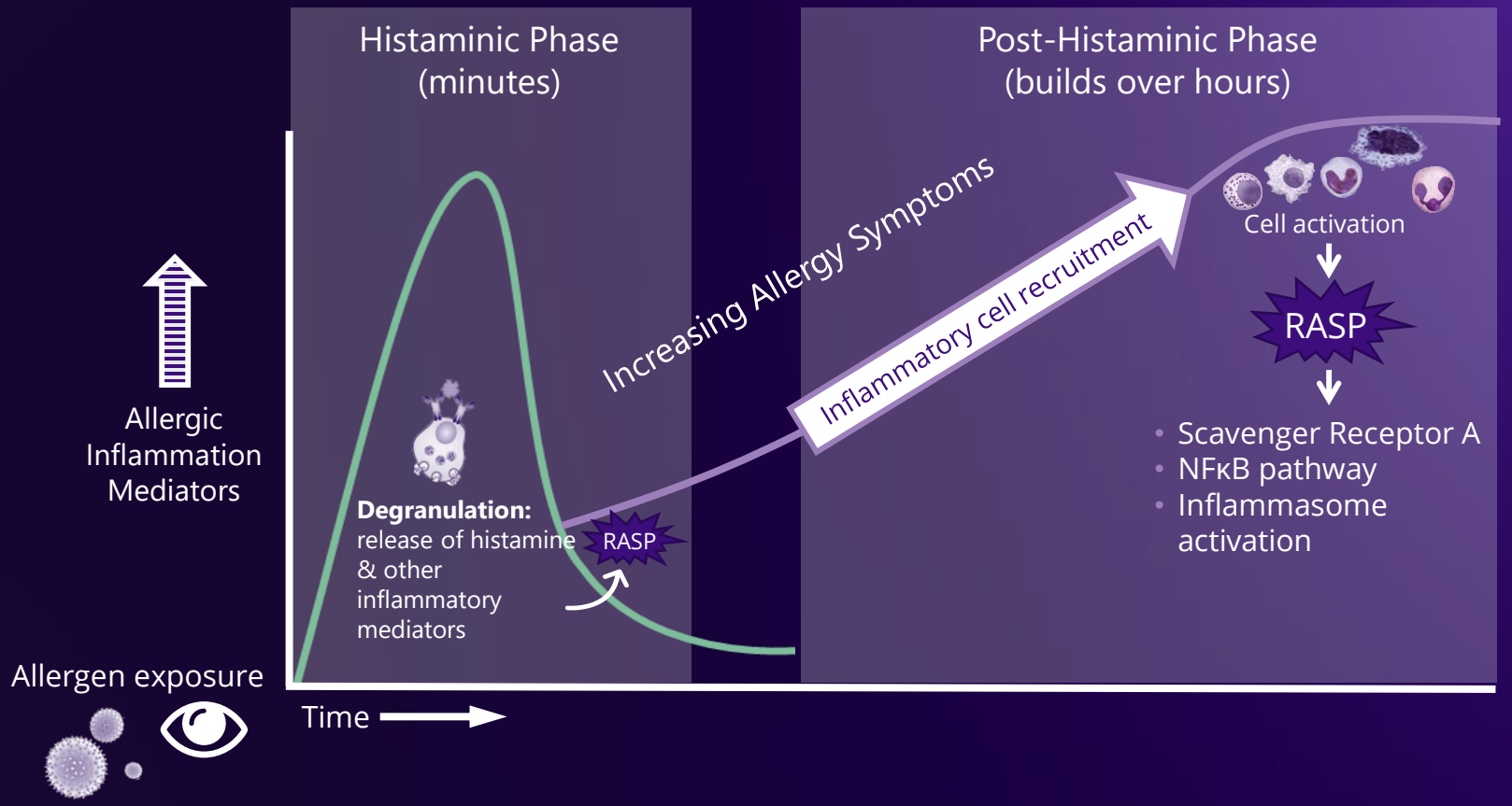
Nasdaq: ALDX

Financial Disclosures

- Drs. Soo, Gow, Clark, and Brady: Employees of Aldeyra Therapeutics
- Dr. Salapatek: Employee of Cliantha Research

Reproxalap's Novel Mechanism of Action Has The Potential to Provide Differentiated Activity Versus Antihistamines



Reproxalap

- Reproxalap irreversibly inhibits RASP, limiting allergic inflammation.
- Reproxalap has the potential to be uniquely effective in post-histaminic allergy, which affects all allergic conjunctivitis patients.

RASP = Reactive Aldehyde Species

The Allergen Chamber:
A Demanding Real-World Drug Assessment in Allergic Conjunctivitis

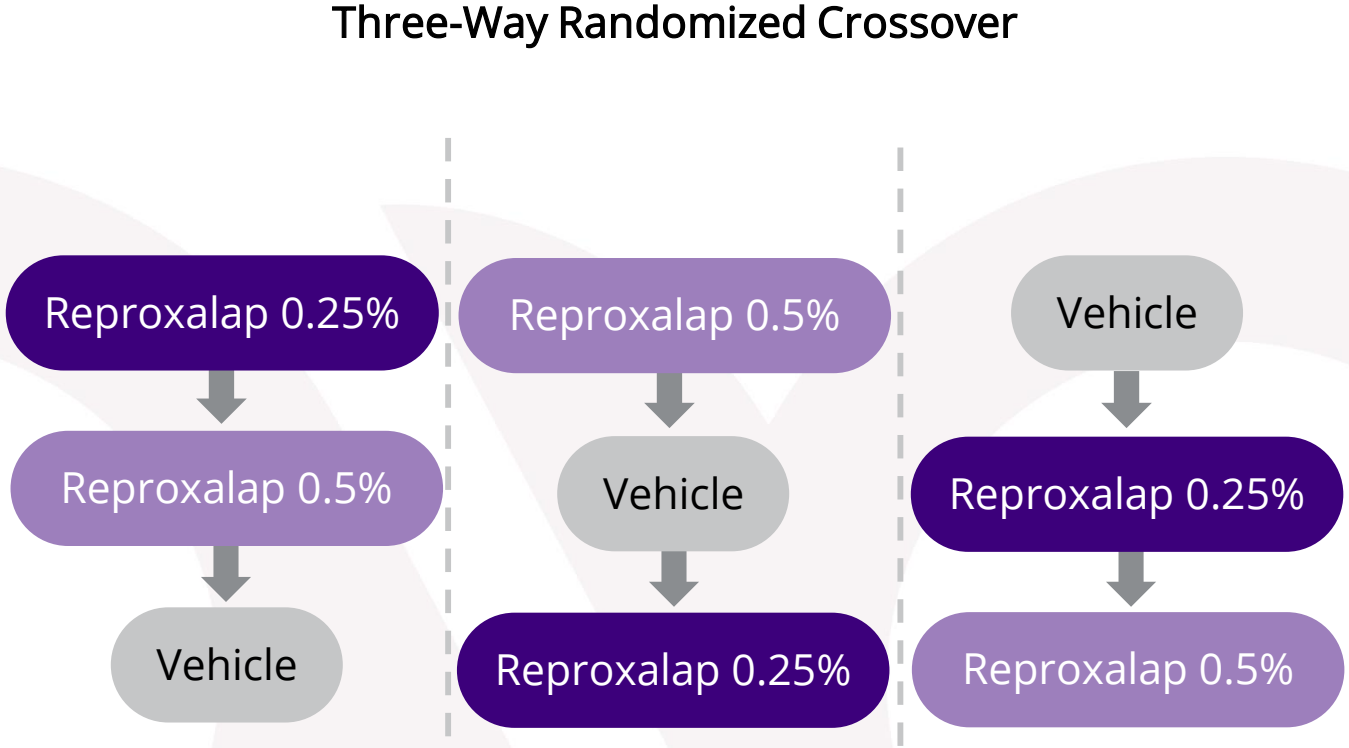
- To our knowledge, no late-stage investigational allergic conjunctivitis drug has been rigorously tested in an allergen chamber.
- The allergen chamber enables a controlled, environmental allergen exposure that mimics real-world exposure to airborne allergens.
- Subjects are exposed to a naturalistic level of allergen continuously for approximately 3.5 hours.
- Subject-reported ocular itch and tearing scores, and investigator-assessed redness scores, are obtained approximately every 10 minutes.
- Drug or vehicle is administered prior to allergen exposure and at 90 minutes, when peak symptoms typically occur.
- The chamber allows for detailed assessment of prophylaxis and treatment with unparalleled standardization.

Source: Cliantha Research

aldeyra

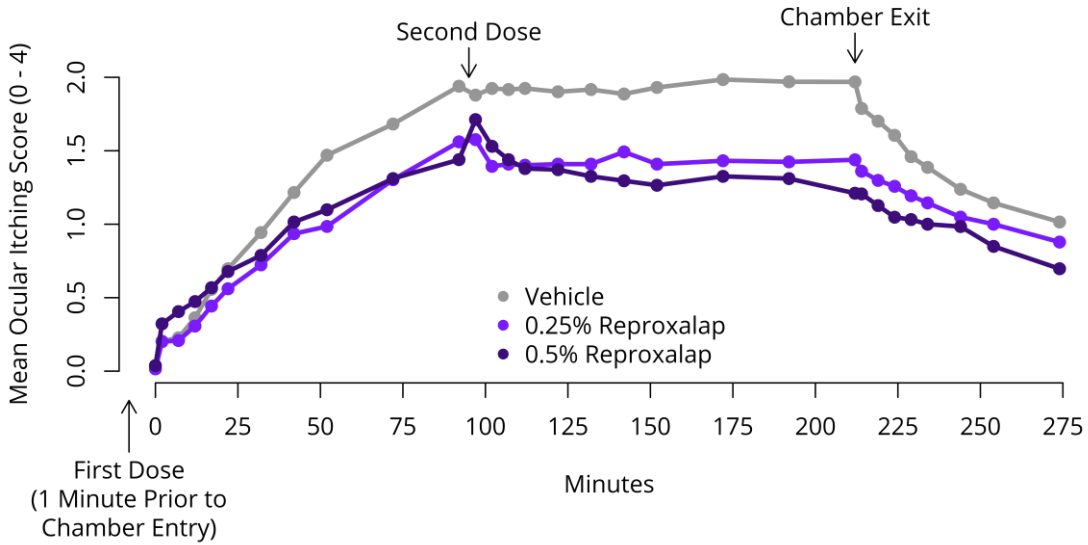
Reproxalap Allergen Chamber Clinical Trial Design*

- **Primary objective:**
  - Evaluate efficacy of reproxalap ophthalmic solution vs. vehicle to confirm dosing regimen and sample size for Phase 3 clinical testing
- **Inclusion/exclusion criteria:**
  - History of moderate to severe allergic conjunctivitis to ragweed pollen
  - Itching score of ≥ 2.5 or redness score ≥ 2 in baseline chamber test
- **Endpoints:**
  - Patient-reported ocular itch score and tearing score
  - Investigator-assessed ocular redness score
  - Total ocular symptom score

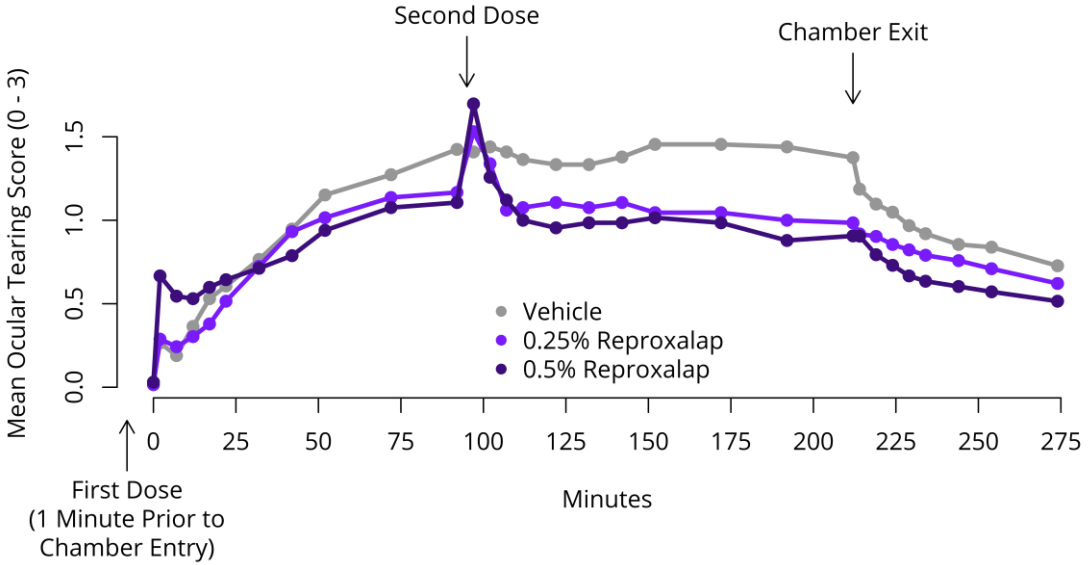


*The reproxalap allergen chamber clinical trial was a Phase 1/2 methods development study. Further information can be found on www.clinicaltrials.gov: Trial #NCT03709121.

Reproxalap Demonstrated Prophylaxis and Treatment of Subject-Reported Ocular Itching and Tearing in Allergen Chamber



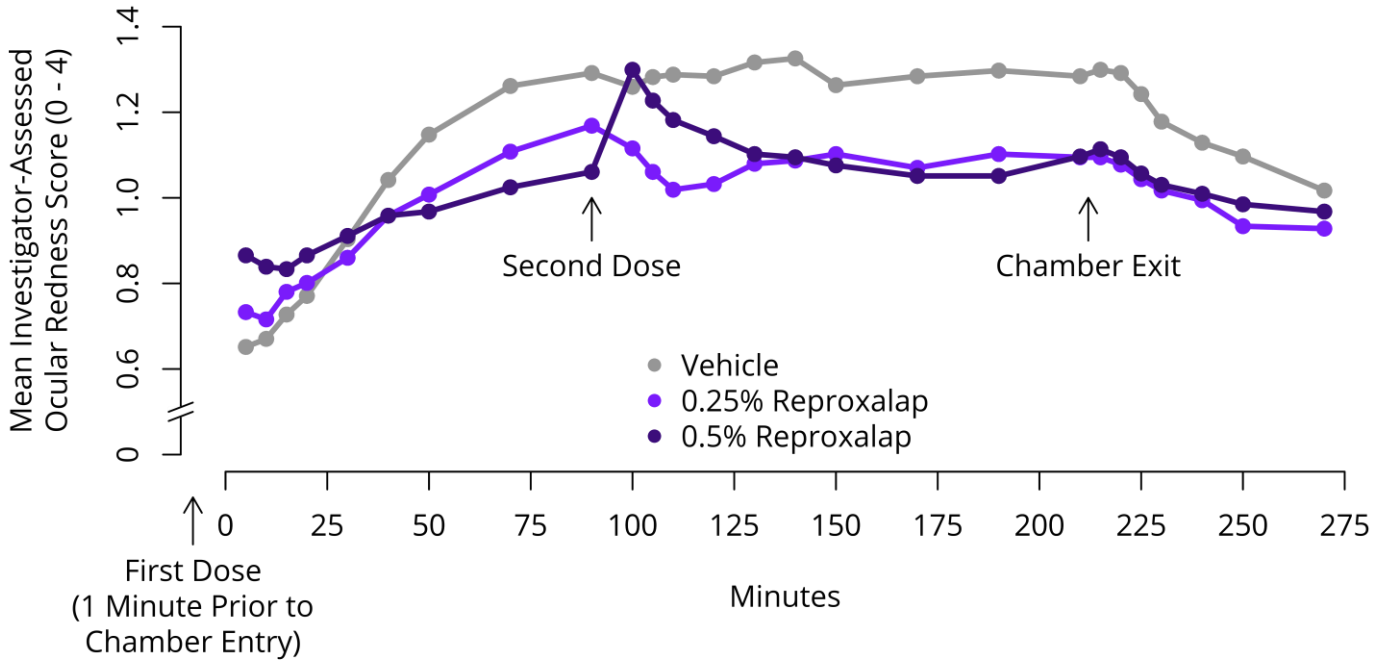
Comparison	P Value
0.5% vs. Vehicle	<0.0001
0.25% vs. Vehicle	<0.0001



Comparison	P Value
0.5% vs. Vehicle	<0.0001
0.25% vs. Vehicle	<0.0001

P values derived from Mixed-Effect Model for Repeated Measures.

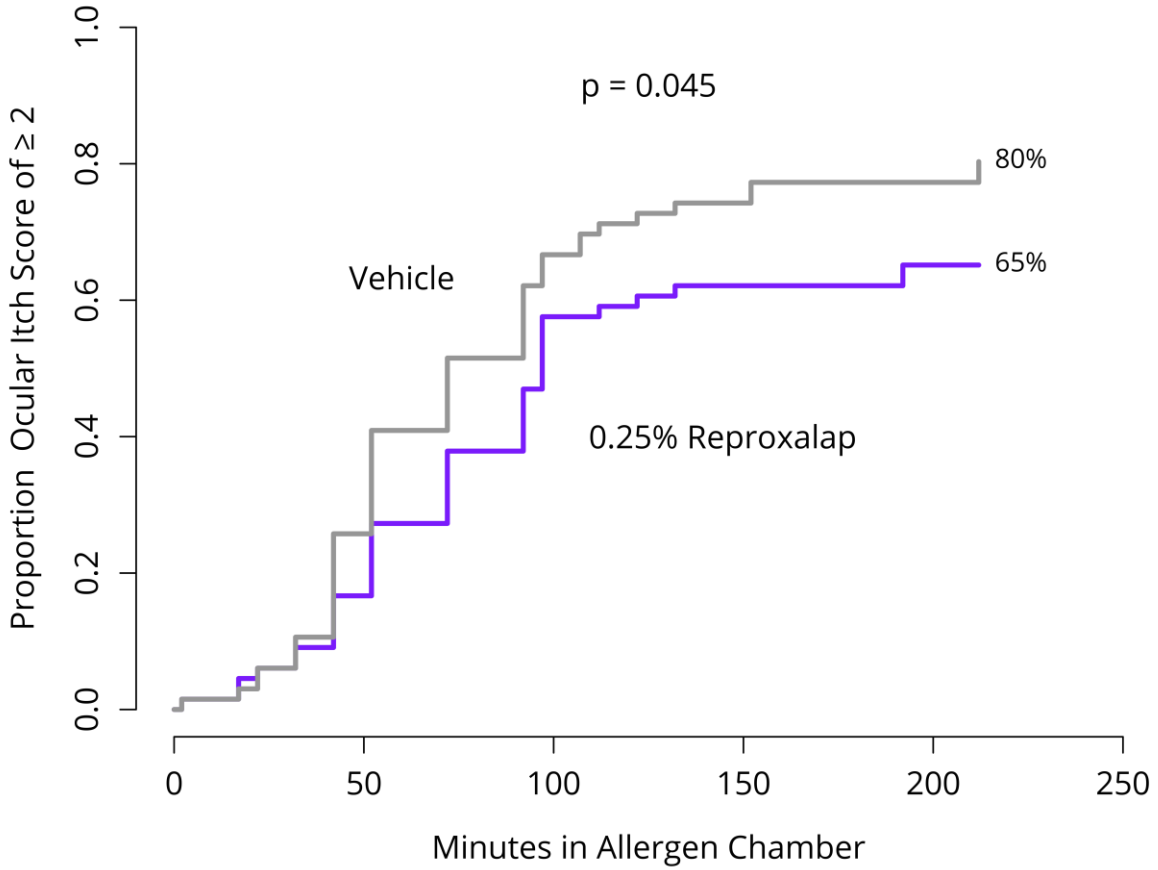
Reproxalap Demonstrated Prophylaxis and Treatment of Investigator-Assessed Ocular Redness in Allergen Chamber

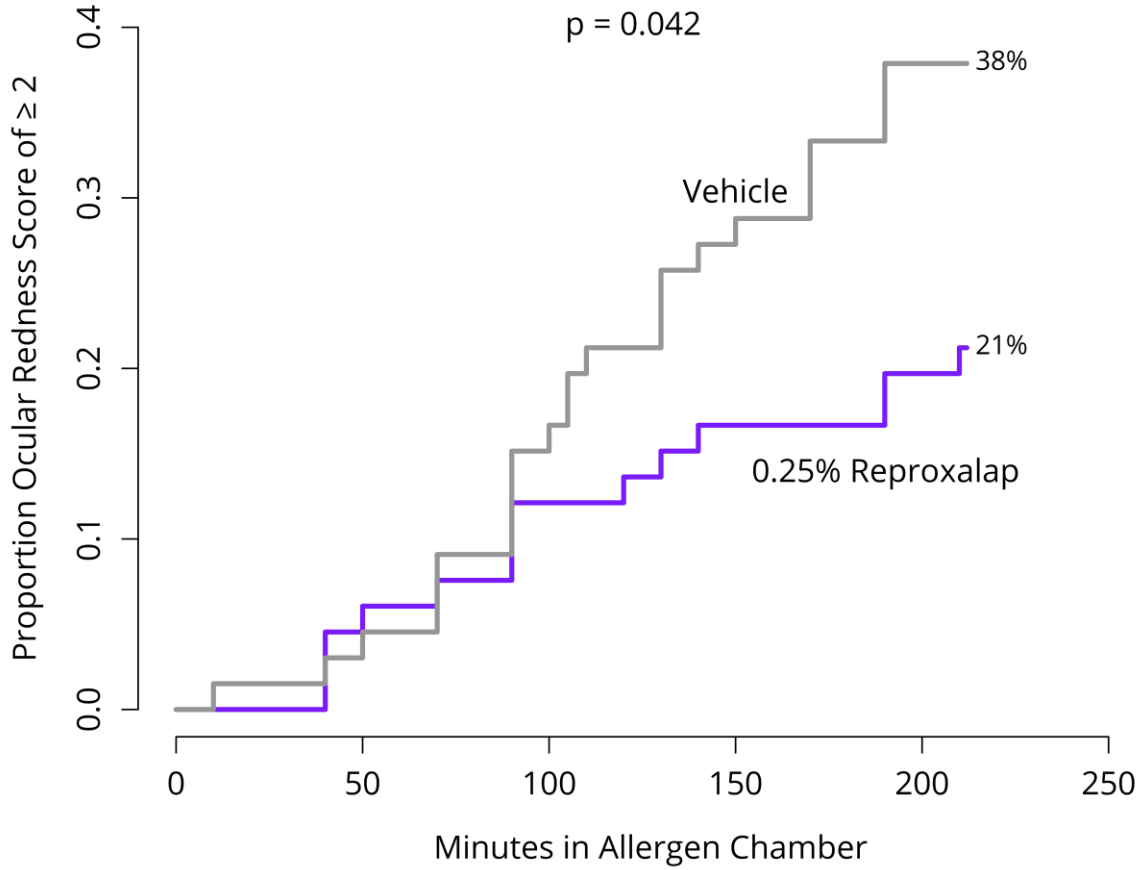


Comparison	P Value
0.5% vs. Vehicle	<0.0001
0.25% vs. Vehicle	<0.0001

P values derived from Mixed-Effect Model for Repeated Measures.

Clinical Relevance of Changes in Ocular Itching and Redness for 0.25% Reproxalap Was Confirmed with Time to Event Analyses





Patient-reported ocular itching score and investigator-assessed ocular redness score range 0 to 4.
P values derived from log-rank test.

Reproxalap Was Generally Well Tolerated and No Safety Concerns Were Noted

- 66 of 70 enrolled subjects completed all three treatments.
- No safety or tolerability concerns were evident.
- Transient instillation site irritation was observed, consistent with prior reproxalap clinical trials.
- No clinically relevant findings on safety assessments were observed:
  - Visual acuity
  - Intraocular pressure
  - Slit lamp biomicroscopy
  - Dilated fundoscopy

Conclusions

- Reproxalap is a novel immune-modulating reactive aldehyde species (RASP) inhibitor, which targets the post-histaminic allergic phase of allergic conjunctivitis.
- Relative to vehicle, 0.25% and 0.5% reproxalap demonstrated statistically superior prophylaxis and treatment of ocular itching, tearing, and redness in a real-world model of allergen exposure.
- The activity of the two concentrations of reproxalap was similar.
- No safety or tolerability concerns were evident.
- The 0.25% concentration of reproxalap was advanced to the Phase 3 INVIGORATE allergen chamber trial.