



October 31, 2019

DATA RELEASE

Allergic Conjunctivitis Allergen
Chamber Clinical Methods Trial
Expanded Data Release



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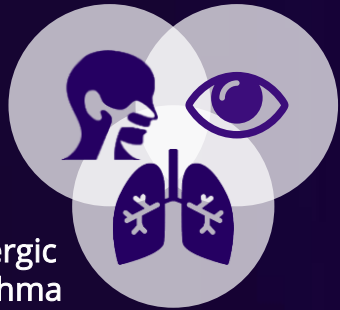
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The Prevalence and Economic Burden of Allergic Conjunctivitis is Rising

Allergic Rhinitis



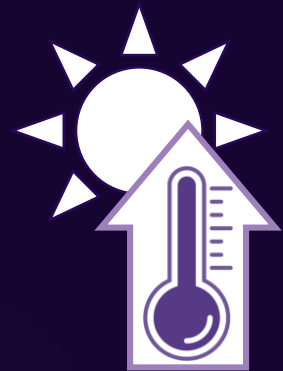
Allergic Conjunctivitis

Allergic diseases are hyperendemic and prevalence is increasing



Allergic conjunctivitis affects more than 1 billion people worldwide, including 100 million in the U.S.

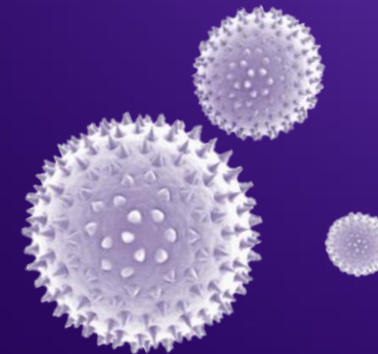
Allergic Asthma



Temperatures and CO₂ levels are rising



Allergy seasons are getting longer and more severe



Pollen is spreading to new areas

Millions of patients continue to suffer and new treatments are needed

Physicians and Patients Say That Currently Available Treatments Are Inadequate



Up to 30 million of allergic conjunctivitis sufferers in the U.S. do not respond adequately to or are dissatisfied with antihistamines



Antihistamines are not effective in an estimated 24% of treated allergic conjunctivitis patients



Many allergic conjunctivitis patients make significant sacrifices due to lack of drug activity

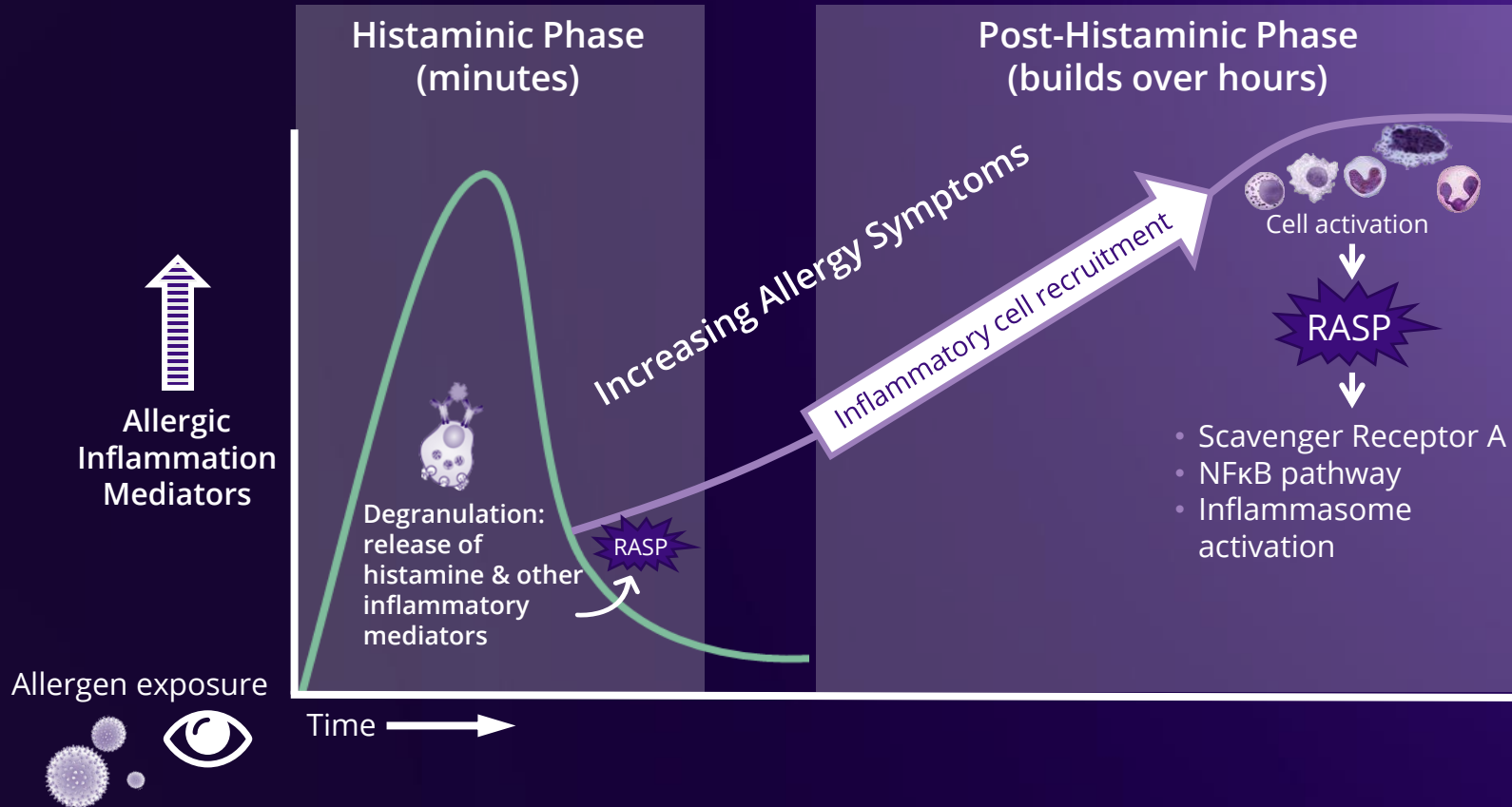


Nearly 1 in 5 of allergic conjunctivitis patients are using corticosteroid and/or NSAID eye drops*

The allergic conjunctivitis patient population is underserved, and novel therapies are in demand.

*IQVIA analysis of diagnosed AC patients utilizing topical ocular Rx treatments.
Source: Aldeyra internal estimates based on primary and secondary market research; published literature

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.

The Allergen Chamber is Designed to Mimic Real-World Exposure to Airborne Allergens With Control and Consistency

Clinical Model Comparison For Allergic Conjunctivitis Clinical Trial Design



Patients administer drug at home during allergy season and maintain a journal.

- ✓ Real-world exposure to allergen
- ✓ Repeated exposure to allergen throughout study
- ✗ Uncontrolled allergen content and concentration
- ✗ Variable participant behavior



Investigator administers one drop of allergen mixture on to conjunctiva and records results.

- ✓ Specified allergen content and concentration
- ✓ Participants observed and assisted by investigator
- ✗ Artificial allergen exposure
- ✗ Single exposure limitation



Investigator monitors and assists patients in a controlled allergen chamber.

- ✓ Real-world exposure to allergen
- ✓ Specified allergen content and concentration
- ✓ Repeated exposure to allergen throughout study
- ✓ Participants observed and assisted by investigator
- ✓ Assessment of prophylaxis and treatment

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

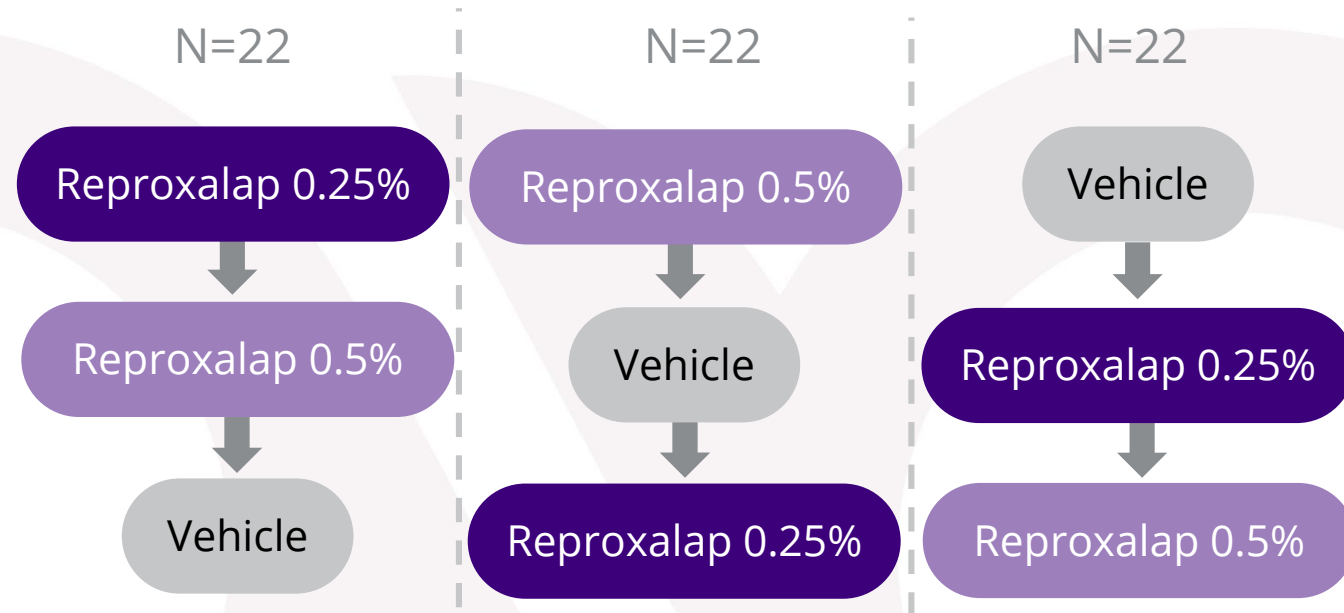
- To our knowledge, no late-stage investigational allergic conjunctivitis drug has been rigorously tested in an allergen chamber.
- The allergen chamber enables a controlled, environmental allergen exposure that mimics real-world exposure to airborne allergens.
- Subjects are exposed to allergen continuously 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.



Reproxalap Allergen Chamber Clinical Trial Design*

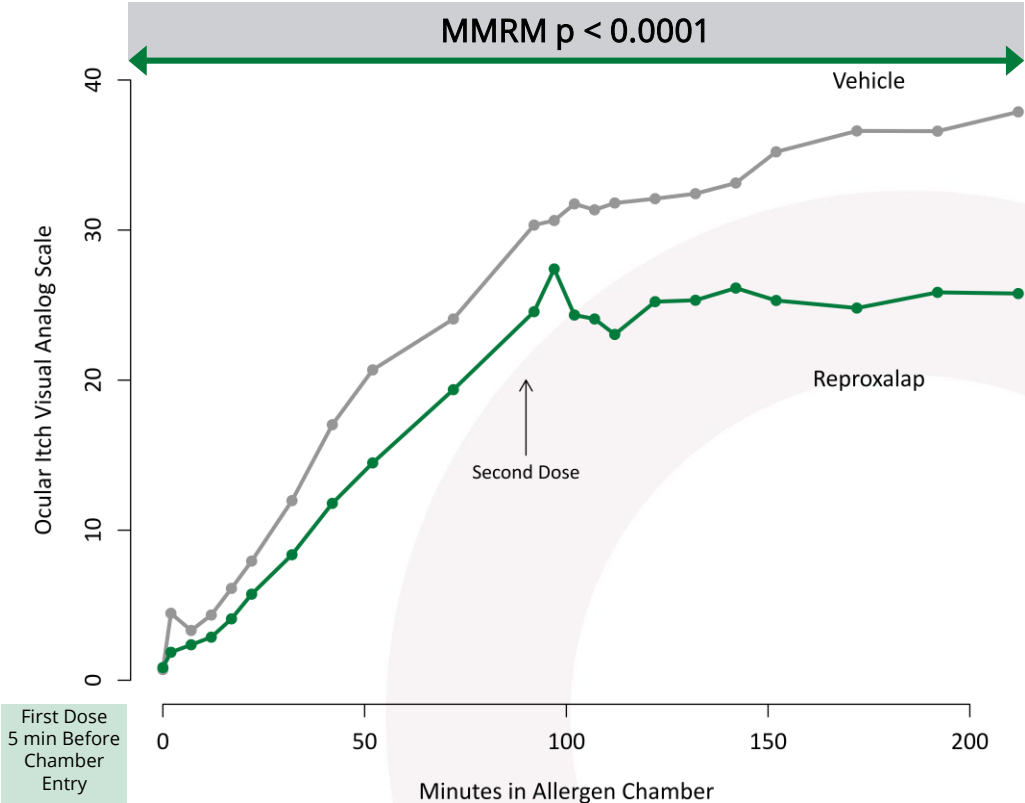
- **Primary objective:**
 - Evaluate efficacy of reproxalap ophthalmic solution vs. vehicle to confirm dosing regimen and sample size for Phase 3 clinical testing
- **Inclusion/exclusion criteria:**
 - History of moderate to severe allergic conjunctivitis to ragweed pollen
 - Itching score of ≥ 2.5 or 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

Three-Way Randomized Crossover



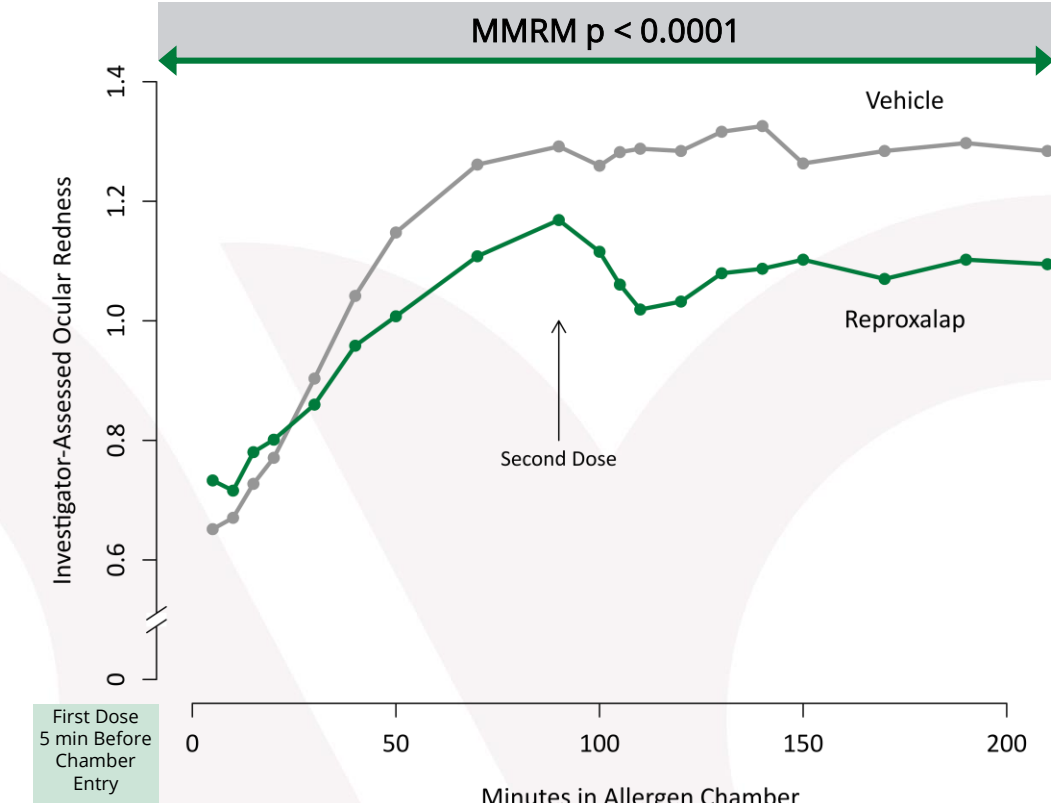
Reproxalap Showed Greater and More Durable Clinical Responses Than Vehicle in Allergen Chamber Clinical Trial

Ocular Itch Score (0-100) During 3.5 Hours of Allergen Exposure



Statistically significant reduction in ocular itch vs. vehicle for more than three hours of exposure to allergen

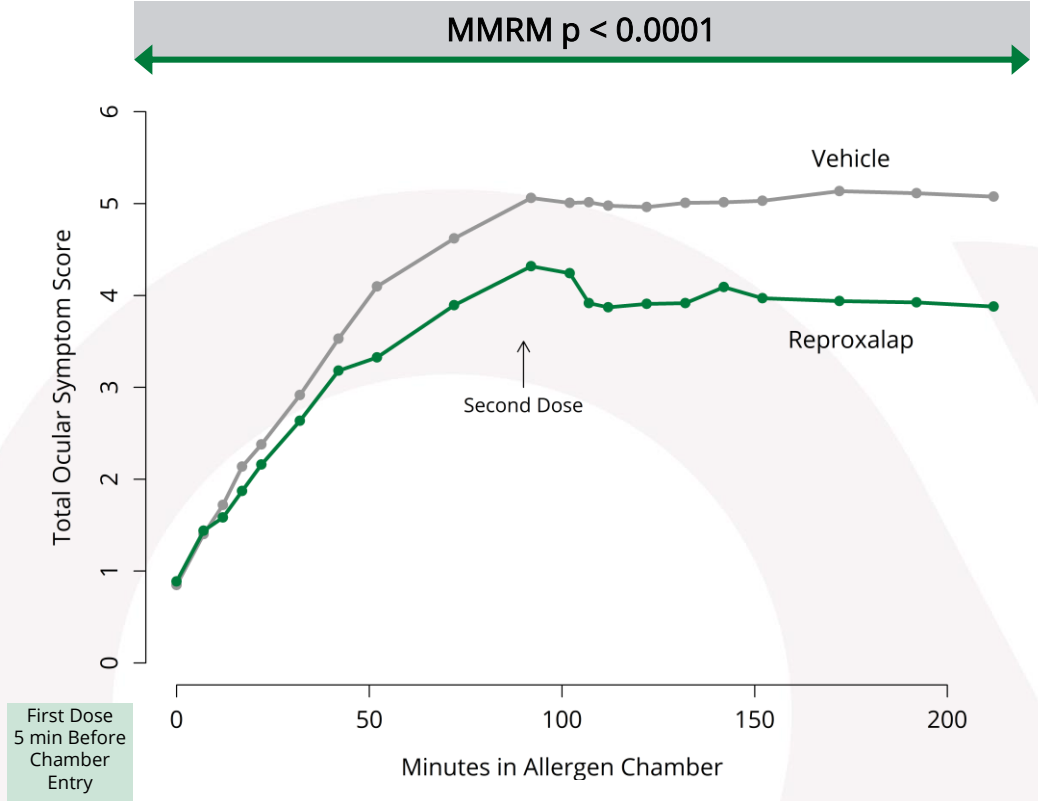
Ocular Redness Score (0-4) During 3.5 Hours of Allergen Exposure



Statistically significant reduction in ocular redness vs. vehicle for more than three hours of exposure to allergen

Reproxalap Demonstrated Prophylactic and Treatment Activity in Allergen Chamber Clinical Trial

Total Ocular Symptom Score (0-11 scale) During 3.5 Hours of Allergen Exposure



Statistically significant reduction in all assessed ocular symptoms and signs (itch, redness, and tearing) for more than three hours of exposure to allergen

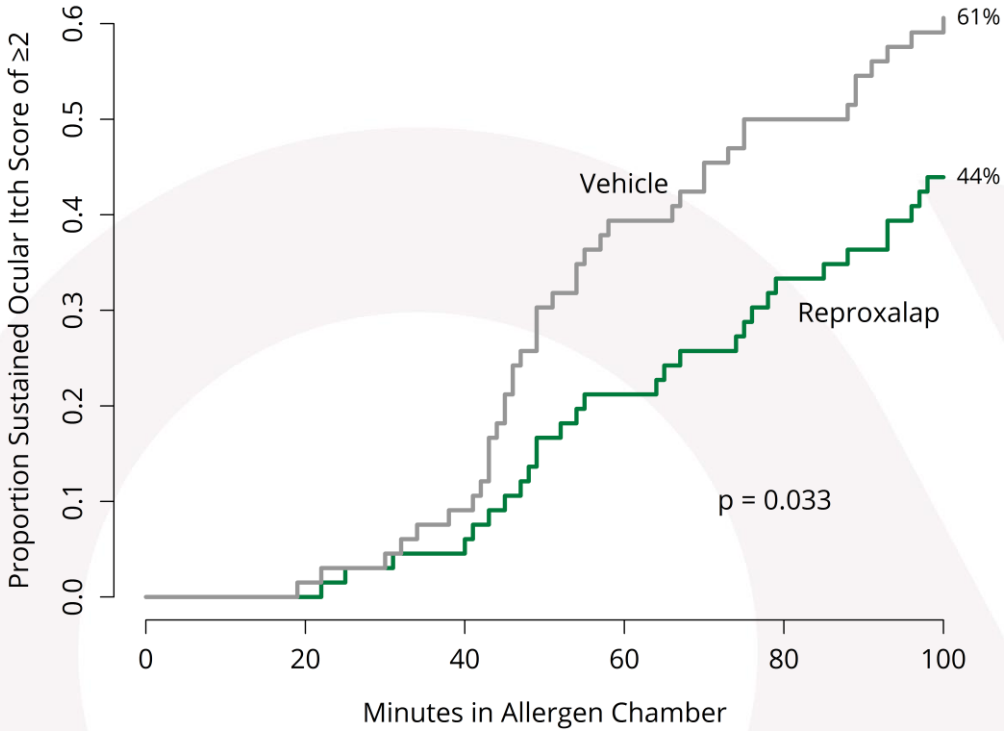


Source: Aldeyra Therapeutics allergen chamber clinical trial – reproxalap 0.25% (ClinicalTrials.gov #NCT03709121); n=66

MMRM = Mixed Effect Model Repeated Measures 10

Relative to Vehicle Treatment, Fewer Reproxalap-Treated Subjects Reached Sustained Ocular Itch Scores ≥ 2 in Allergen Chamber Clinical Trial

Proportion of Subjects with Sustained Ocular Itch Scores ≥ 2 (0-4 Scale)



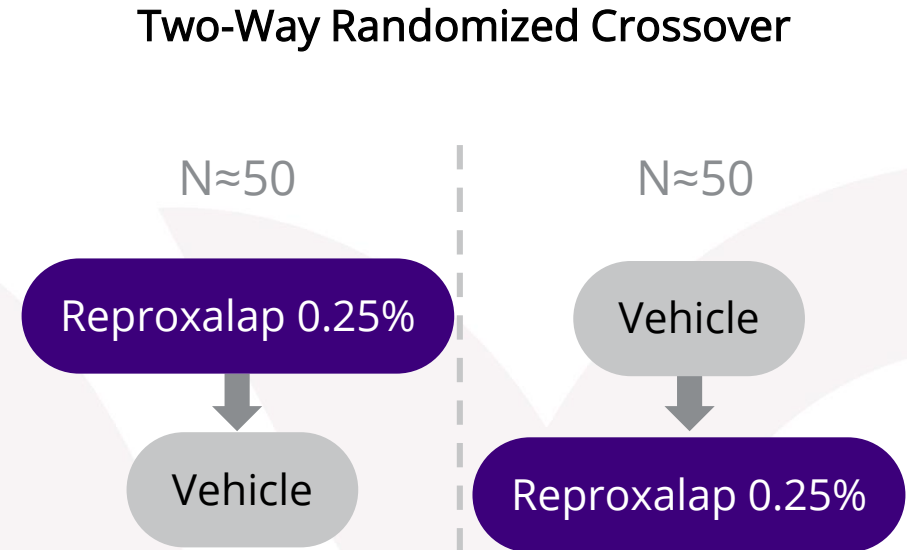
Development of sustained ocular itch scores of greater than or equal to 2 (scale 0 – 4) was slower and less frequent in reproxalap-treated subjects than in vehicle-treated subjects, supporting the clinical relevance of the itch score results.

Reproxalap Was Generally Well Tolerated and No Safety Concerns Were Observed in Allergen Chamber Clinical Trial

- No observed safety or tolerability concerns
- Most common treatment-emergent event was transient instillation site irritation
- No observed findings on safety assessments:
 - Visual Acuity (ETDRS chart)
 - Intraocular pressure (contact tonometry)
 - Slit lamp biomicroscopy
 - Dilated fundoscopy
- Topical ocular reproxalap has now been administered to over 1,000 patients across twelve clinical trials.

The INVIGORATE Phase 3 Clinical Trial Design

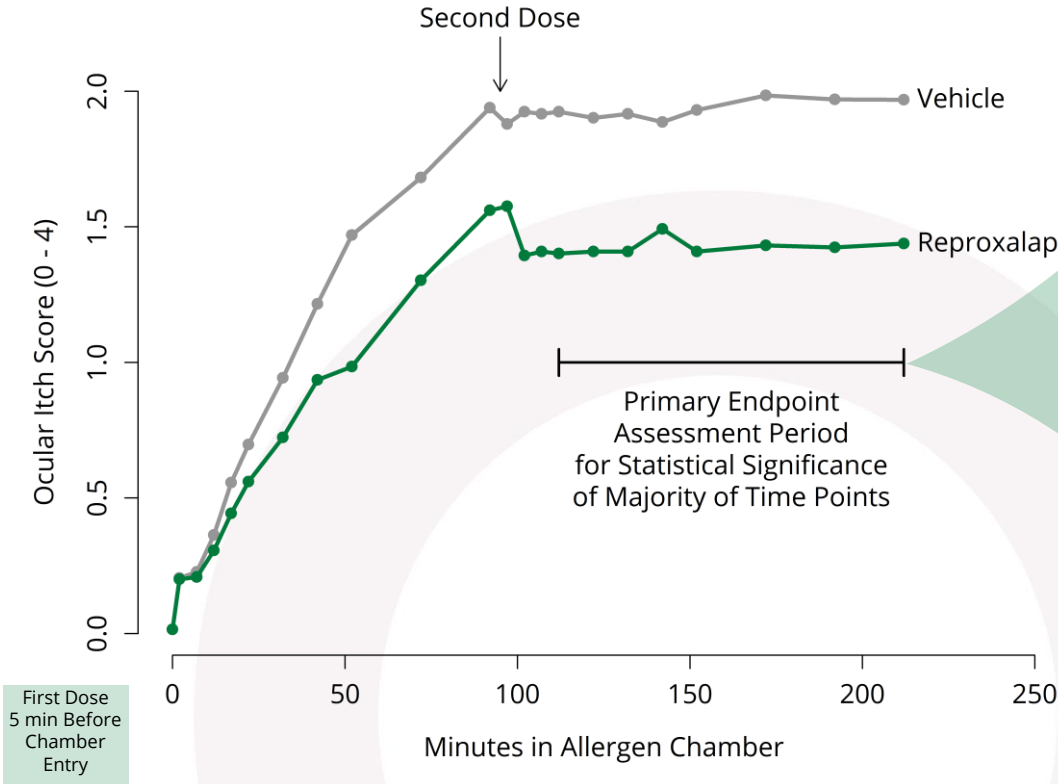
- **Primary endpoint:**
 - Statistical significance in ocular itch (0-4 scale) at a majority of eleven time points between 110 and 210 minutes
- **Secondary endpoints:**
 - Investigator-assessed ocular redness score
 - Patient-reported ocular tearing score
 - Total ocular symptom score
- **Inclusion/exclusion criteria:**
 - Same as prior allergen chamber trial
- **Dosing schedule and chamber exposure:**
 - Same as prior allergen chamber trial



Agreement on trial design and primary endpoint reached with FDA on October 1, 2019.

Confirmed INVIGORATE Phase 3 Primary Endpoint Achieved in Allergen Chamber Clinical Trial*

Ocular Itching Score (0-4) During 3.5 Hours of Allergen Exposure



Allergen chamber time point	p value
112	0.0002
122	0.0004
132	0.0002
142	0.0044
152	0.0001
172	<0.0001
192	<0.0001
212	0.0002

All time points from 110 to 210 minutes were statistically significant in allergen chamber trial.



*The safety and efficacy results of later phase or subsequent clinical trials may not confirm the results of earlier trials; p-value derived from Mixed effect Model Repeat Measurement (MMRM) time point analyses.

Source: Aldeyra Therapeutics allergen chamber clinical trial – reproxalap 0.25% (ClinicalTrials.gov #NCT03709121); n=66

INVIGORATE Phase 3 Trial Design And Primary Endpoint Confirmed

Positive Allergen Chamber Clinical Trial Results

- Reproxalap showed greater and durable clinical responses vs. vehicle
 - Statistically significant reduction in ocular itch ($p < 0.0001$), ocular redness ($p < 0.0001$), and total ocular symptoms score ($p < 0.0001$)
- Reproxalap demonstrated prophylaxis and treatment activity for more than three hours of continuous allergen exposure
- Clinical relevance of itch score results supported by responder analysis
 - Less frequent development of sustained ocular itch score ≥ 2 in reproxalap-treated subjects vs. vehicle (0-4 scale)

INVIGORATE Phase 3 Clinical Trial

- Design and primary endpoint agreement with FDA on October 1, 2019
 - Dosing schedule and chamber exposure same as prior allergen chamber trial
 - Phase 3 primary endpoint defined as statistical significance in ocular itching at a majority of time points over a pre-specified range
- Confirmed primary endpoint achieved in prior allergen chamber clinical trial*

Expected to initiate H1 2020

Upcoming and Recently Achieved Development Milestones: Novel Approaches to Address Immune-Mediated Disease*

○ = Ocular Diseases
○ = Systemic Diseases

✓ Reproxalap allergic conjunctivitis design for INVIGORATE Phase 3 confirmed October 2019

○ ADX-2191 proliferative vitreoretinopathy GUARD Phase 3 - Part 1 clinical trial initiation Q4 2019

○ ADX-1612 post-transplant lymphoproliferative disorder Phase 2 clinical trial initiation H2 2019

○ Reproxalap dry eye disease RENEW Phase 3 - Part 1 completion Q4 2019

NEW ○ Reproxalap allergic conjunctivitis INVIGORATE Phase 3 initiation H1 2020

✓ ADX-629 systemic Phase 1 clinical trial initiation H2 2019

✓ Reproxalap Sjögren-Larsson Syndrome RESET Phase 3 - Part 1 completion Q2 2019

✓ Positive reproxalap allergic conjunctivitis allergen chamber trial top-line results

✓ Reproxalap dry eye disease RENEW Phase 3 - Part 1 clinical trial initiation April 2019

✓ Positive reproxalap allergic conjunctivitis ALLEVIATE Phase 3 trial results March 2019