



April 27, 2021

DATA RELEASE

Top-Line Results from the Phase 3 INVIGORATE Trial in Allergic Conjunctivitis



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Top-Line Results from Phase 3 INVIGORATE Clinical Trial of Reproxalap in Allergic Conjunctivitis

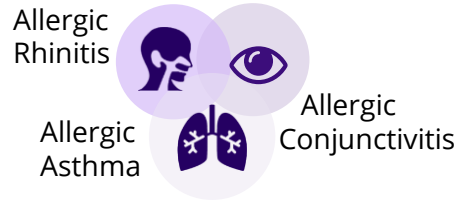
Statistical Significance Achieved for:

- Primary Endpoint of Ocular Itching at All Prespecified Timepoints ($p < 0.0001$)
- Key Secondary Endpoint of Reduction in Ocular Redness ($p < 0.0001$)
- Secondary Endpoints of Ocular Tearing ($p < 0.0001$) and Total Ocular Severity Score ($p < 0.0001$)

Results Consistent with Phase 3 ALLEVIATE Allergic Conjunctivitis Clinical Trial and Previous Chamber Results in Phase 2 Allergic Conjunctivitis Trial and Run-In Cohort of Phase 3 TRANQUILITY Dry Eye Disease Trial

Reproxalap Potentially Represents the First **New Allergic Conjunctivitis Therapeutic Mechanism** in Decades

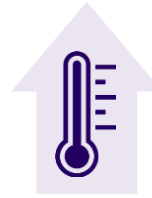
The Prevalence of Allergic Conjunctivitis is Rising



Allergic diseases are **hyperendemic** and prevalence is increasing.



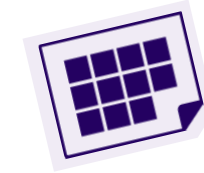
Allergic conjunctivitis affects **more than 1 billion people worldwide**, including 100 million in the U.S.



Temperatures and CO₂ levels are **rising**.



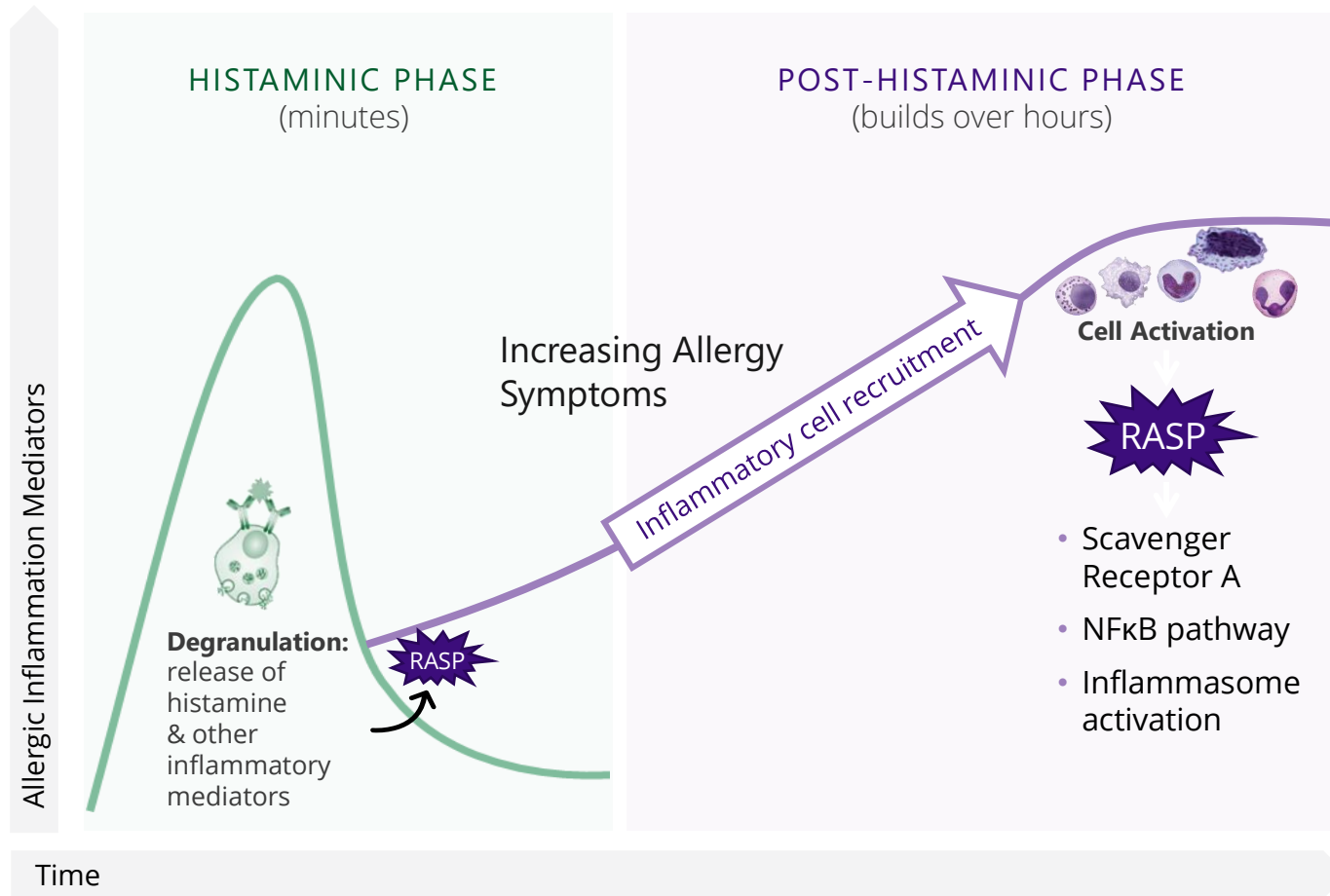
Pollen is spreading to new areas.



Allergy seasons are getting **longer and more severe**.

Millions of patients continue to suffer, and new treatments are needed.

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



REPROXALAP

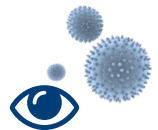
Irreversibly inhibits RASP, limiting allergic inflammation

Potential to provide **differentiated activity** in post-histaminic allergy, which affects all allergic conjunctivitis patients

Potential to represent an important **alternative to topical corticosteroids**, which can lead to ocular toxicity

Potential to represent **one of the first new therapeutic mechanisms for allergic conjunctivitis in decades**

Topical ocular reproxalap is an investigational drug that has been studied in over 1,200 patients with no safety concerns reported; mild instillation site discomfort is the most commonly reported adverse event in clinical trials. RASP = reactive aldehyde species



ALLERGEN
EXPOSURE

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.
- allows for detailed assessment of prophylaxis and treatment with unparalleled standardization.



Subjects are exposed to naturalistic **moderate to high levels of ragweed pollen** continuously for approximately 3.5 hours.

- Drug or vehicle is administered prior to allergen exposure and at 90 minutes, when peak symptoms typically occur.
- Subject-reported ocular itching and tearing scores, and investigator-assessed ocular redness scores, are obtained approximately every 10 minutes.

The Phase 3 INVIGORATE Allergic Conjunctivitis Trial Design

Design

Randomized, two-way crossover, vehicle-controlled, double-masked allergen chamber challenge

Chamber Exposure & Dosing Schedule

- 3.5 hours continuous allergen exposure
- First dose just before chamber entry
- Second dose 90 minutes after entry (peak allergy symptoms)

Inclusion/Exclusion Criteria

- History of moderate to severe allergic conjunctivitis to ragweed pollen
- Itching score of ≥ 2.5 and redness score ≥ 2 in baseline chamber assessment

Primary Endpoint

Statistical significance in patient-reported ocular itching (0-4 scale) at a majority of 11 timepoints between 110 and 210 minutes

Key Secondary Endpoint

Change from baseline in investigator-assessed ocular redness (0-4 scale) over the duration of the allergen chamber

Secondary Endpoints

- Patient-reported ocular tearing score (0-4 scale)
- Total ocular severity score (11-point composite of itching, tearing, and redness)

The INVIGORATE Trial Achieved All Primary and Secondary Endpoints

Primary Endpoint Achieved

Statistically significant improvement vs. vehicle ($p < 0.0001$) over all 11 prespecified timepoints of patient-reported ocular itching score from 110-210 minutes in the allergen chamber

Key Secondary Endpoint Achieved

Statistically significant improvement vs. vehicle ($p < 0.0001$) on key secondary endpoint of investigator-assessed ocular redness over the duration of the allergen chamber

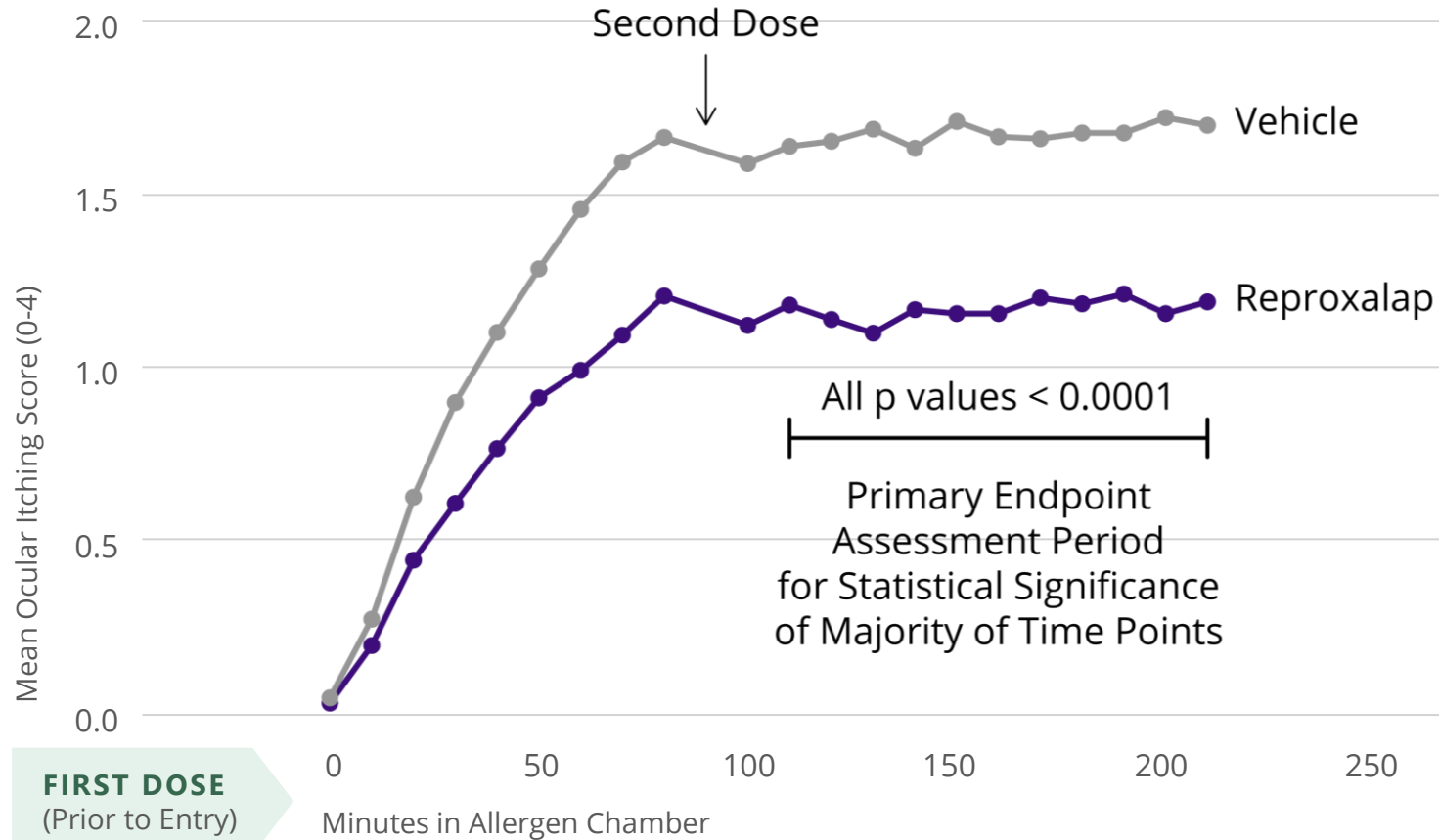
Both Secondary Endpoints Achieved

Statistically significant improvement vs. vehicle on secondary endpoints of patient-reported ocular tearing and total ocular severity score achieved ($p < 0.0001$ for both endpoints) over the duration of the allergen chamber

No Observed Safety or Tolerability Concerns

95 subjects enrolled, 89 of whom completed both treatments; no discontinuations due to adverse events

Reproxalap Achieved Primary Endpoint of Reduction in Ocular Itching in the INVIGORATE Trial



KEY RESULTS

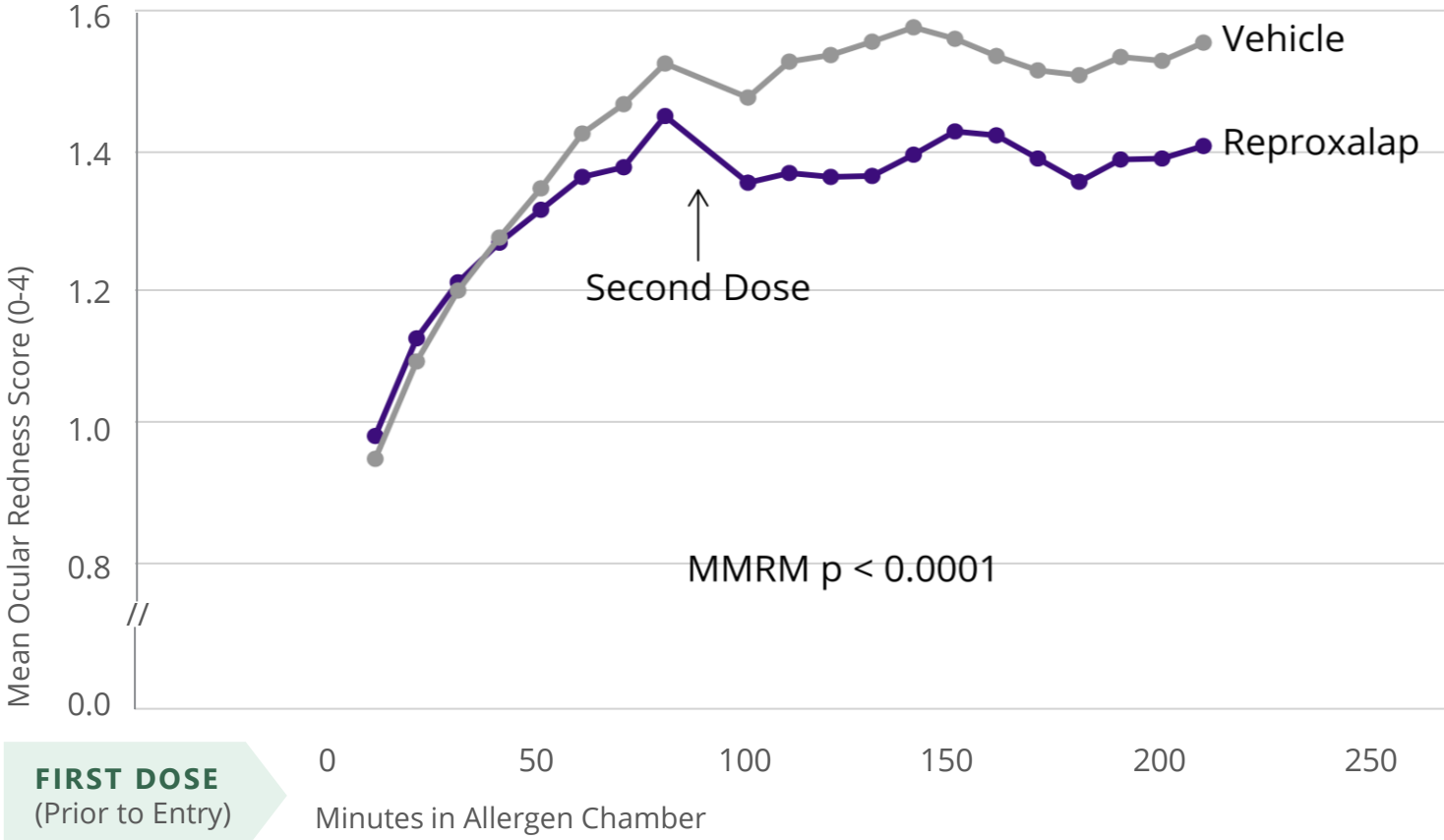
Primary endpoint of statistical significance for majority of timepoints **achieved** over prespecified time frame of 110-210 minutes after allergen chamber entry

All timepoints within 110-210 minutes **statistically significant** in favor of reproxalap ($p < 0.0001$ for each timepoint)

Prophylactic and treatment effects of reproxalap demonstrated

Topical ocular reproxalap is an investigational drug that has been studied in over 1,200 patients with no safety concerns reported; mild instillation site discomfort is the most commonly reported adverse event in clinical trials. Slide source: INVIGORATE Phase 3 results.

Reproxalap Achieved Key Secondary Endpoint of Reduction in Ocular Redness in the INVIGORATE Trial



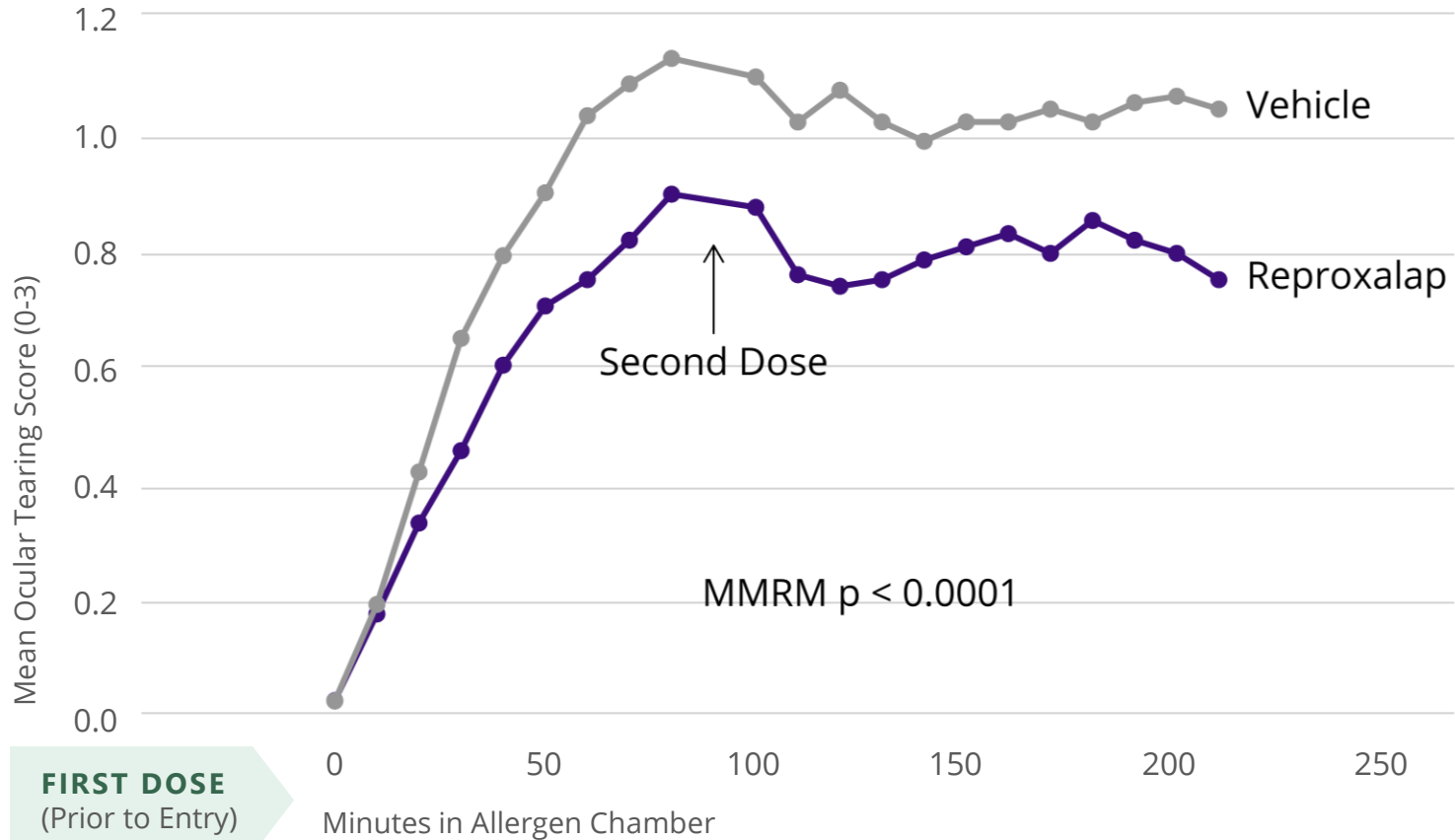
KEY RESULTS

Key secondary endpoint of statistical significance over the entire chamber achieved ($p < 0.0001$)

Prophylactic and treatment effects of reproxalap demonstrated

Topical ocular reproxalap is an investigational drug that has been studied in over 1,200 patients with no safety concerns reported; mild instillation site discomfort is the most commonly reported adverse event in clinical trials. Slide source: Reproxalap INVIGORATE Phase 3 results. MMRM = mixed effect model of repeated measures

Reproxalap Achieved Secondary Endpoint of Reduction in Ocular Tearing in the INVIGORATE Trial



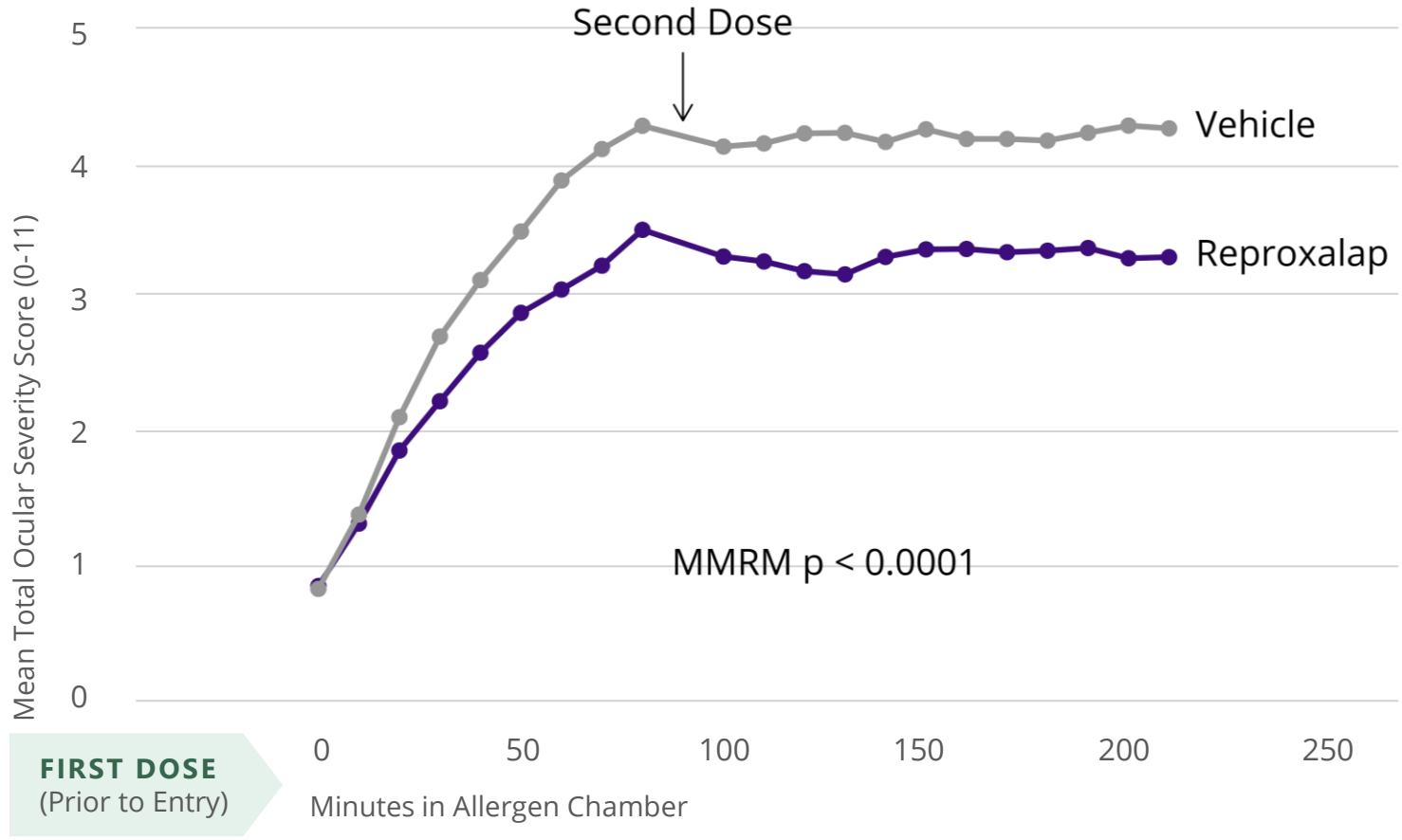
KEY RESULTS

Secondary endpoint of statistical significance over the entire allergen chamber **achieved** ($p < 0.0001$)

Prophylactic and treatment effects of reproxalap demonstrated

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Reproxalap Achieved Secondary Endpoint of Reduction in Total Ocular Severity Score in the INVIGORATE Trial



KEY RESULTS

Secondary endpoint of statistical significance over the entire allergen chamber **achieved** ($p < 0.0001$)

Prophylactic and treatment effects of reproxalap demonstrated

Topical ocular reproxalap is an investigational drug that has been studied in over 1,200 patients with no safety concerns reported; mild instillation site discomfort is the most commonly reported adverse event in clinical trials. Slide source: INVIGORATE Phase 3 results. MMRM = mixed effect model of repeated measures

Reproxalap Was Generally Well Tolerated and No Safety Concerns Were Observed in the INVIGORATE Trial

NO observed safety or tolerability concerns

NO discontinuations due to adverse events

Consistent with other topically administered drugs, most common treatment-emergent events related to transient instillation site discomfort

NO observed clinically significant findings on safety assessments, including:

- visual acuity
- intraocular pressure
- slit lamp biomicroscopy
- dilated fundoscopy

Topical ocular reproxalap is an investigational drug that has been studied in over 1,200 patients with no safety concerns reported; mild instillation site discomfort is the most commonly reported adverse event in clinical trials. Source: INVIGORATE Phase 3 results. MMRM = mixed effect model of repeated measures

TOPICAL OCULAR REPROXALAP

administered to more than

1,200 patients

ACROSS

14 clinical trials

Reproxalap Has Demonstrated Consistent Success Across a Robust Clinical Development Program in Allergic Conjunctivitis

Conjunctival Allergen Challenge

PHASE 2a		
100 patients	30 minutes post CAC	0.5% vs vehicle

PHASE 2b		
154 patients	60 minutes post CAC	0.1% and 0.5% vs vehicle

Phase 3 ALLEVIATE Trial		
318 patients	60 minutes post CAC	0.25% and 0.5% vs vehicle

Allergen Chamber

Phase 2 Allergen Chamber Trial		
66 patients (crossover)	3.5 hours in chamber	0.25% and 0.5% vs vehicle

Phase 3 INVIGORATE Trial		
95 patients (crossover)	3.5 hours in chamber	0.25% vs vehicle

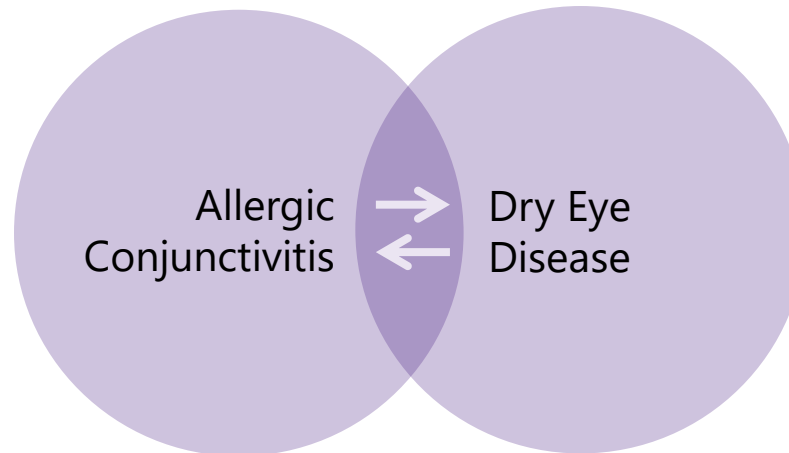
Topical ocular reproxalap is an investigational drug that has been studied in over 1,200 patients with no safety concerns reported; mild instillation site discomfort is the most commonly reported adverse event in clinical trials. CAC = conjunctival allergen challenge

Allergic Conjunctivitis and Dry Eye Disease Are Interrelated Inflammatory Ocular Surface Diseases

The Three **P's** of Ocular Surface Inflammation



- Allergic response can compromise tear film
- Dry eye oxidative stress can enhance allergic response
- Dry, polluted environments exacerbate both conditions



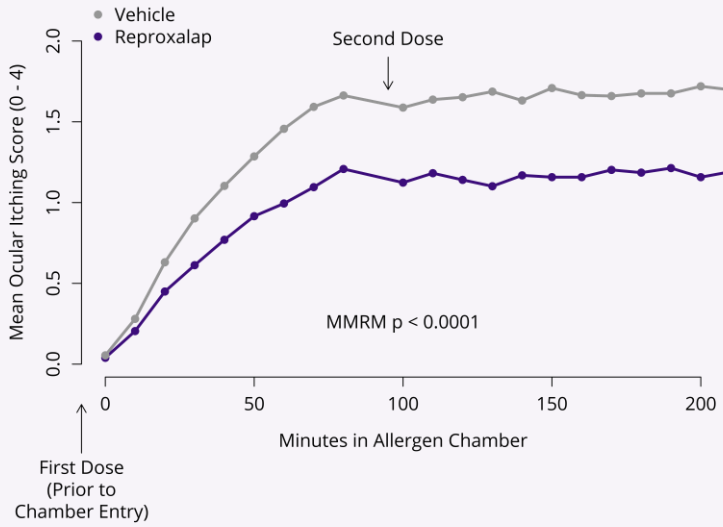
“The clear interaction of allergy, dry eye and environmental irritants makes untangling their etiology in prevalence studies difficult.”

Reproxalap Has Demonstrated Consistent Improvement in Symptoms Across Two Distinct Chamber Challenge Models of Ocular Surface Disease

ITCHING



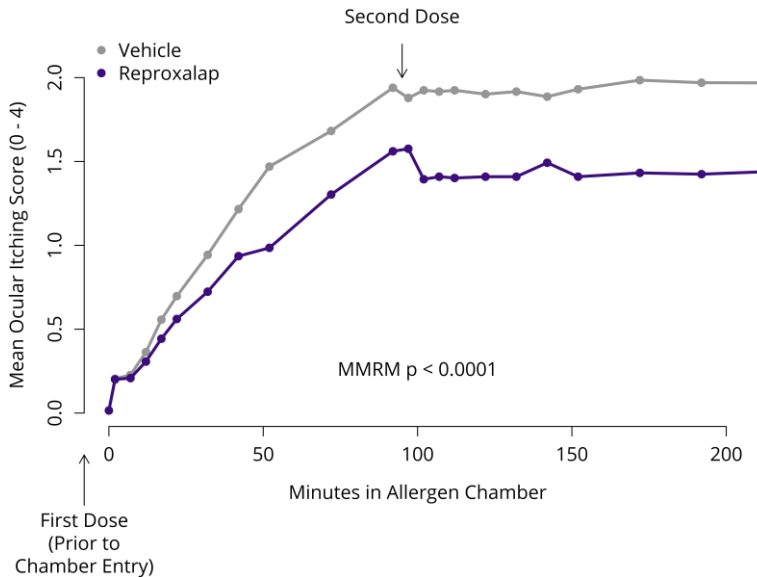
INVIGORATE Phase 3 Trial



ITCHING



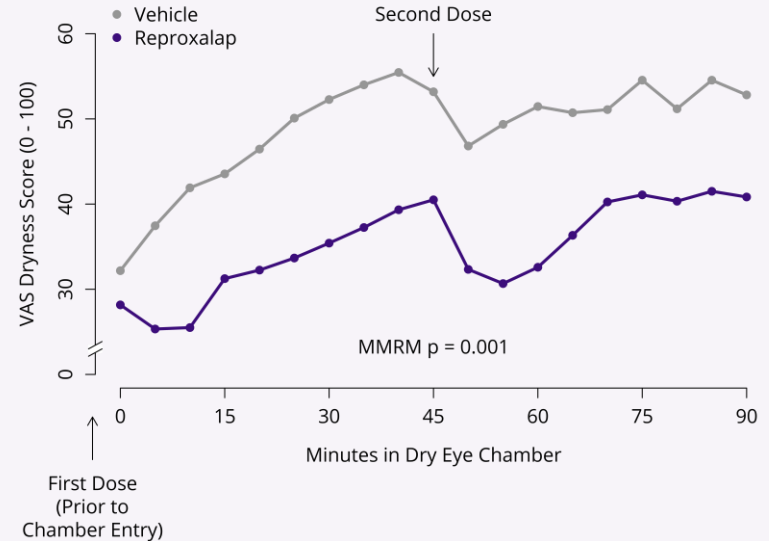
Phase 2 Trial



DRYNESS



TRANQUILITY Run-In Cohort



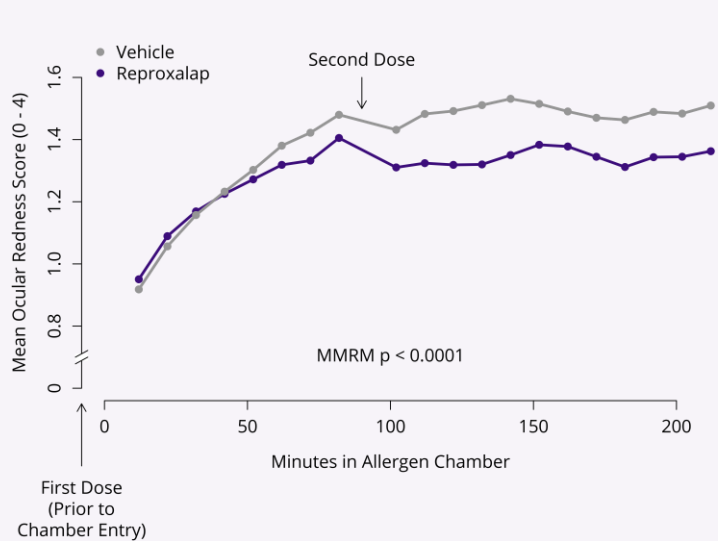
Topical ocular reproxalap is an investigational drug that has been studied in over 1,200 patients with no safety concerns reported; mild instillation site discomfort is the most commonly reported adverse event in clinical trials. Slide sources: TRANQUILITY run-in cohort results; Phase 2 Allergen Chamber clinical trial for 0.25% reproxalap (ClinicalTrials.gov #NCT03709121), INVIGORATE Phase 3 results. VAS = Visual Analog Scale, MMRM = mixed effect model of repeated measures

Reproxalap Has Demonstrated Consistent Reduction of Ocular Redness Across Two Distinct Chamber Challenge Models of Ocular Surface Disease

REDNESS



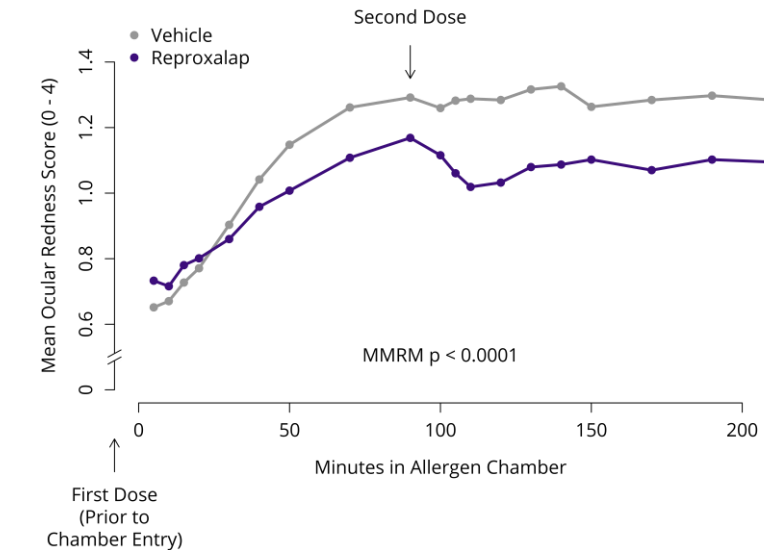
INVIGORATE Phase 3 Trial



REDNESS



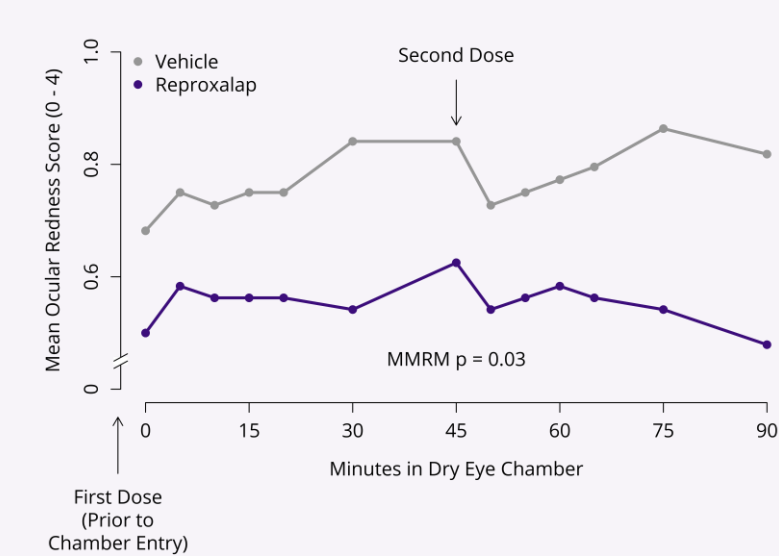
Phase 2 Trial



REDNESS



TRANQUILITY Run-In Cohort



Upcoming Expected Reproxalap Development Milestones*



Reproxalap
dry eye disease
**Phase 3 TRANQUILITY
main cohort initiation
H1 2021**



Reproxalap
allergic conjunctivitis
**Phase 3 INVIGORATE
top-line results
H1 2021**



Reproxalap
dry eye disease
**Phase 3 TRANQUILITY
and TRANQUILITY-2 top-
line results
H2 2021**

Aldeyra plans to meet with the U.S. FDA in the second half of 2021 to discuss the INVIGORATE results and the potential submission of a New Drug Application.

A New Paradigm for the Treatment of Anterior Ocular Inflammation: A Potential Single Approach for Dry Eye Disease and Allergic Conjunctivitis*

Dry Eye Disease

REPROXALAP 0.25%



Rapid symptom and redness improvement within minutes



Broad and durable symptom control

Allergic Conjunctivitis

REPROXALAP 0.25%



Clinically significant and durable symptom response across two models of ocular allergy



Potentially the first new allergic conjunctivitis therapeutic mechanism in decades