April 27, 2021

DATA RELEASE

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

Nasdaq: ALDX

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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

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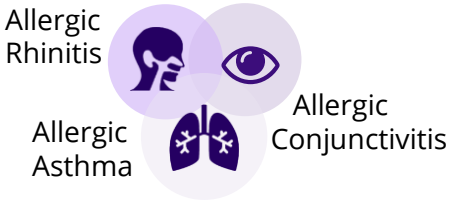
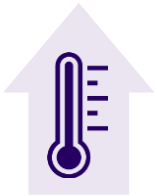
The Prevalence of Allergic Conjunctivitis is Rising



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 CO_2 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.

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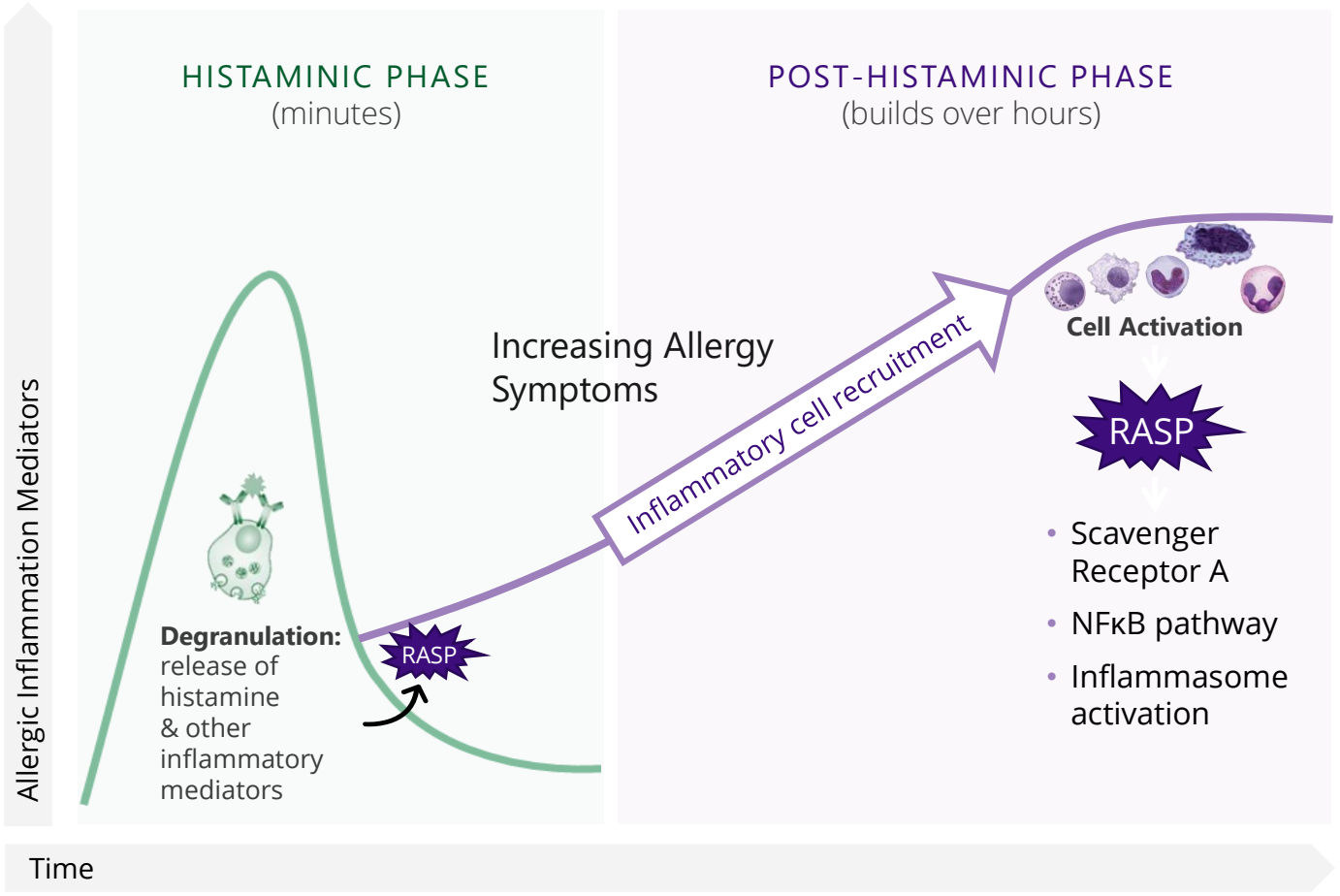
Slide sources: Ziska LH, Makra L, Harry, SK, et al. Lancet Planetary Health. 2019; Trends in prevalence and treatment of ocular allergy – Curr. Opin. Allergy Clin. Immunol. 2014 Oct; White Book on Allergy (2013 Update) ; Singh K, Axelrod S, Bielory L, J Allergy Clin Immunol. 2010; Pitt AD, Smith AF, Lindsell L, et al. Ophthal. Epidemiol. 2004.

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

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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.

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Slide source: Clantha Research

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)

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ClinicalTrials.gov Identifier: NCT04207736

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

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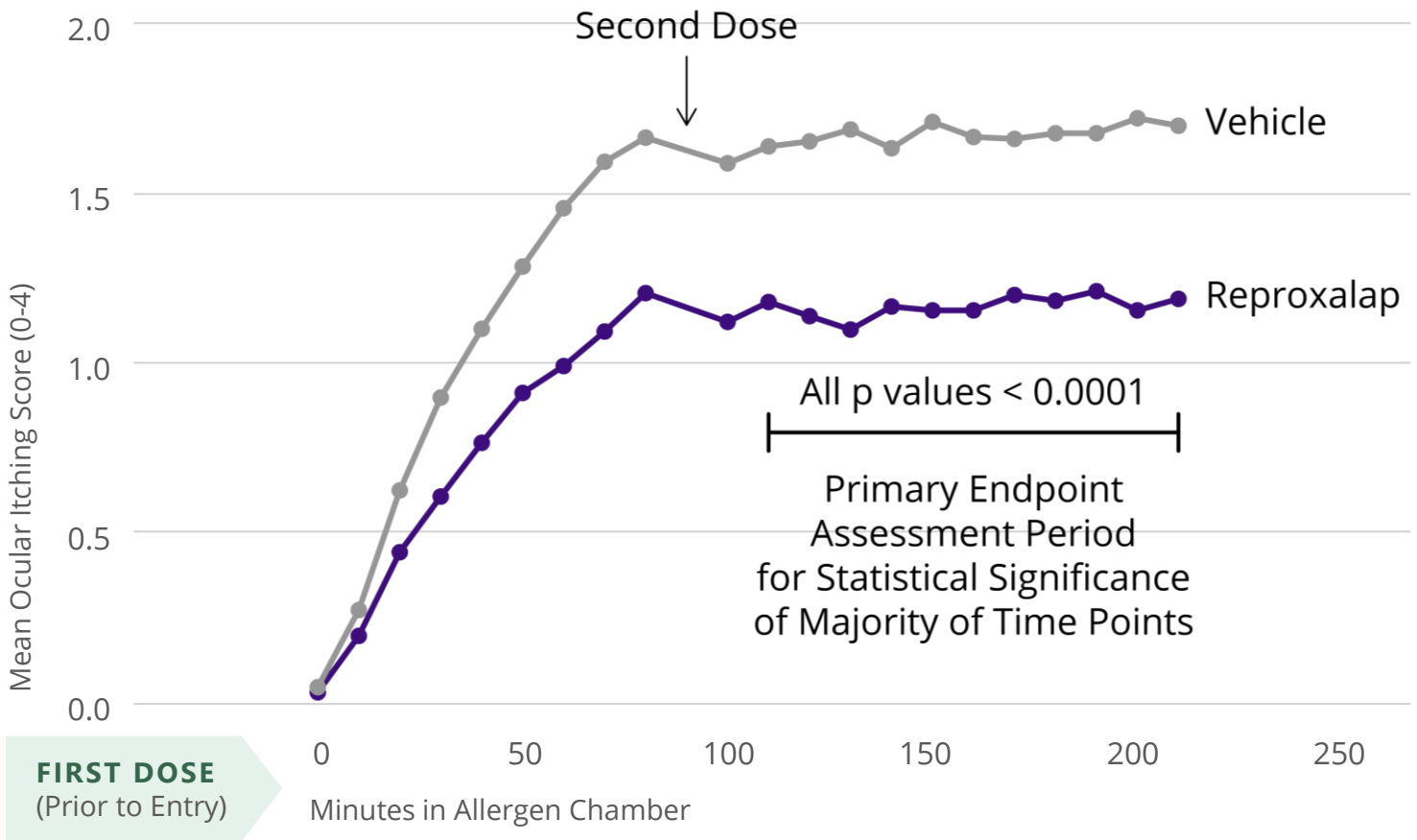
p values derived from mixed effect model of repeated measures (MMRM). Topical ocular reproxalap is an investigational drug that has been studied in over 1,200 patients with no safety concerns reported; mild instillation site discomfort is the most commonly reported adverse event in clinical trials. Slide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

Reproxalap Achieved 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.

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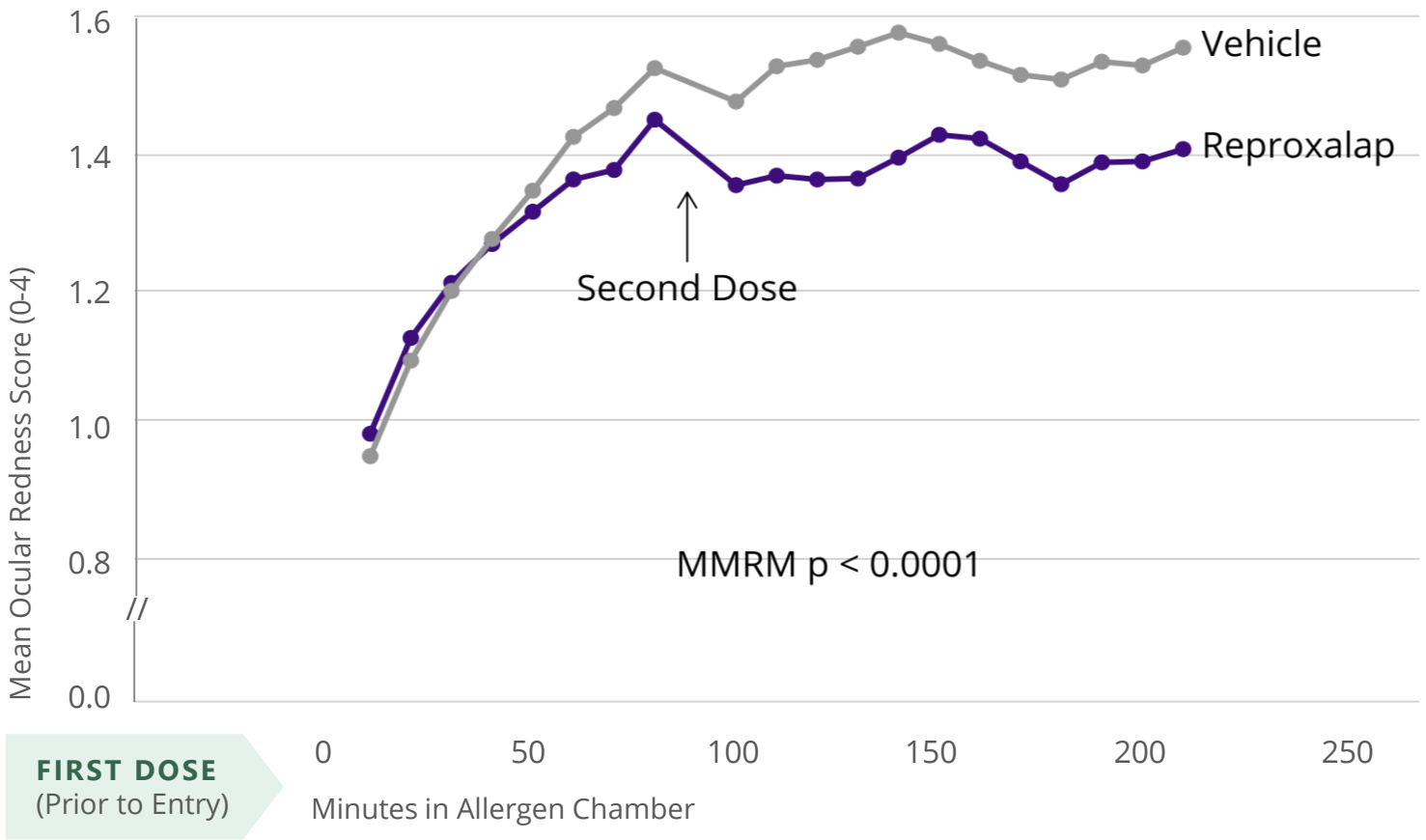
Reproxalap Achieved Key Secondary Endpoint of Reduction in Ocular Redness in the INVIGORATE Trial



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

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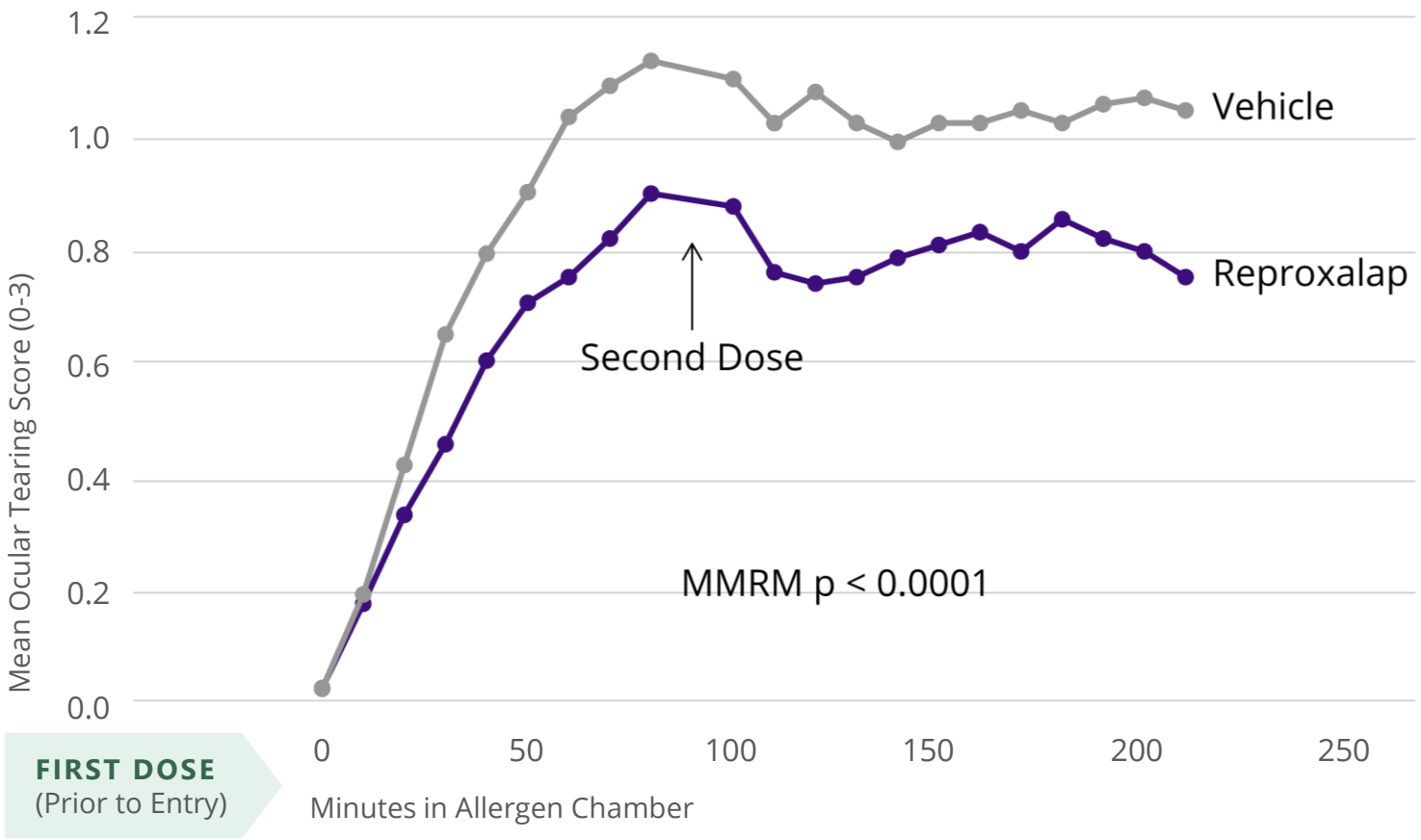
Reproxalap Achieved Secondary Endpoint of Reduction in Ocular Tearing in the INVIGORATE Trial



KEY RESULTS

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

Prophylactic and treatment effects of reproxalap demonstrated

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

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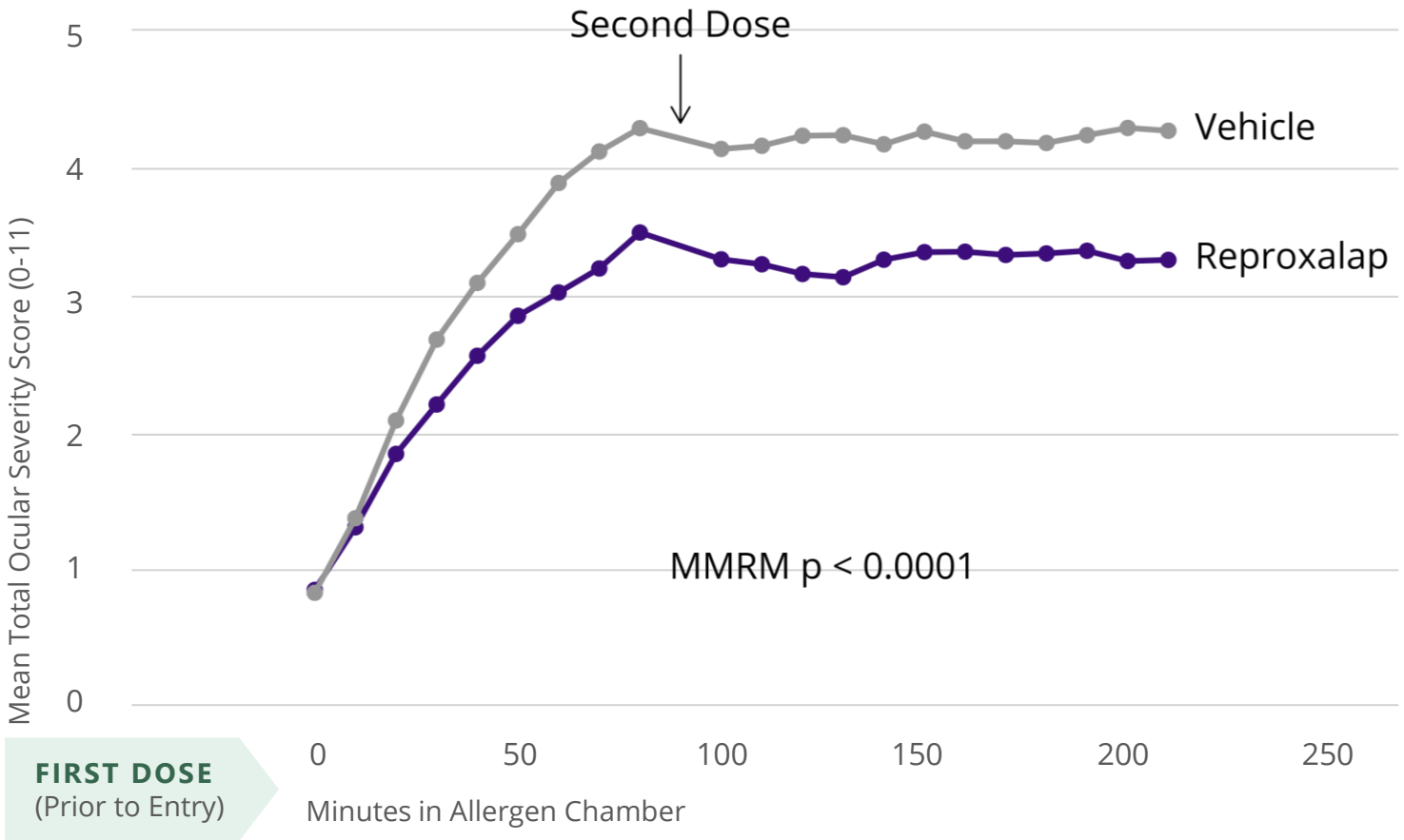
Reproxalap Achieved Secondary Endpoint of Reduction in Total Ocular Severity Score in the INVIGORATE Trial



KEY RESULTS

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

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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

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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 s the most commonly reported adverse event in clinical trials. CAC = conjunctival allergen challenge

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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."

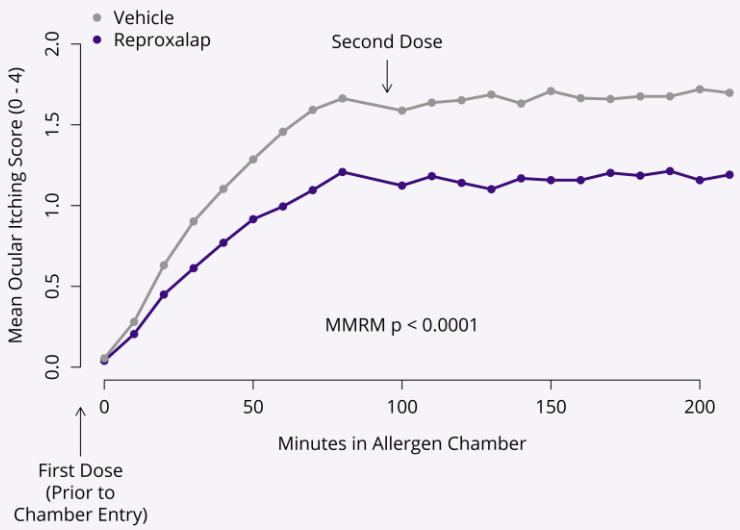
Slide sources: Concepts adapted from "The Whipsaw of Allergic Dry Eye" by Mark B. Abelson, MD and Lauren Lilyestrom in REVIEW of Ophthalmology; October 2008; and Hom MM, Nguyen AL, Bielory L. Allergic conjunctivitis and dry eye syndrome. Ann Allergy Asthma Immunol. 2012 Mar;108(3):163-6.

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

ITCHING

Allergen Chamber

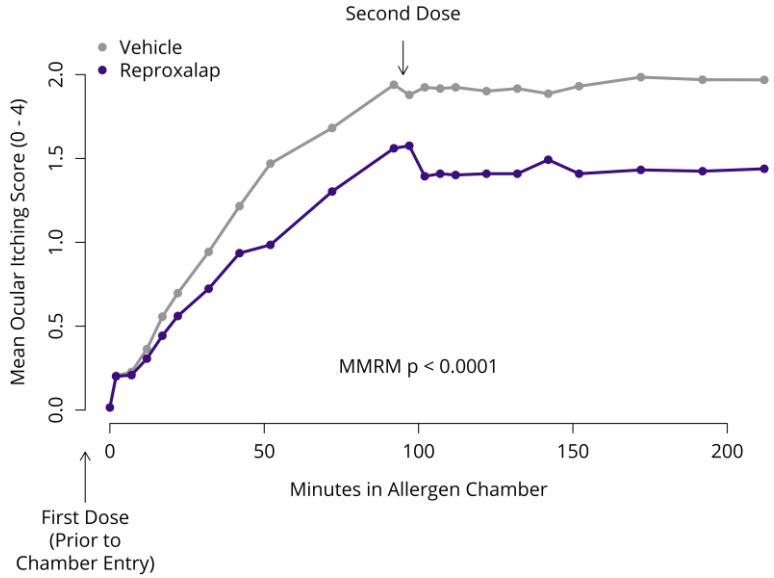
INVIGORATE Phase 3 Trial



ITCHING

Allergen Chamber

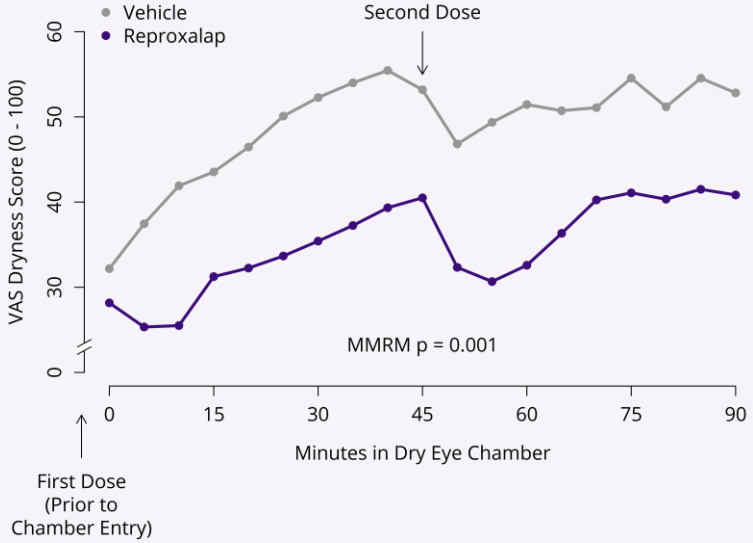
Phase 2 Trial



DRYNESS

Dry Eye Chamber

TRANQUILITY Run-In Cohort



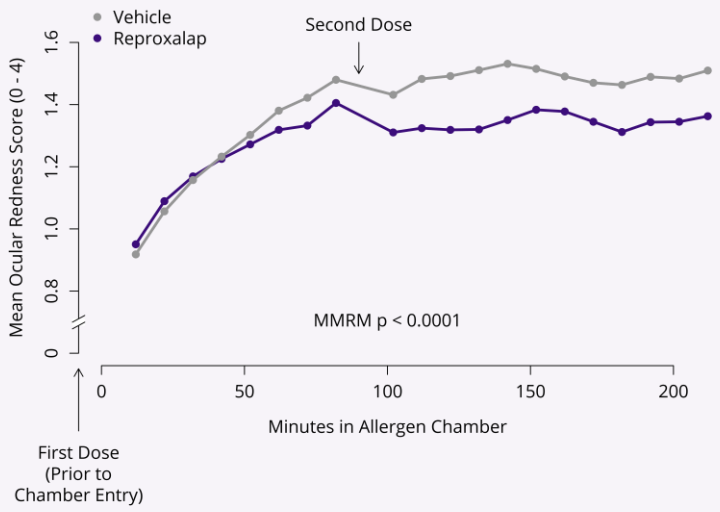
Topical ocular reproxalap is an investigational drug that has been studied in over 1,200 patients with no safety concerns reported; mild instillation site discomfort is the most commonly reported adverse event in clinical trials. Slide sources: TRANQUILITY run-in cohort results; Phase 2 Allergen Chamber 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

Allergen Chamber

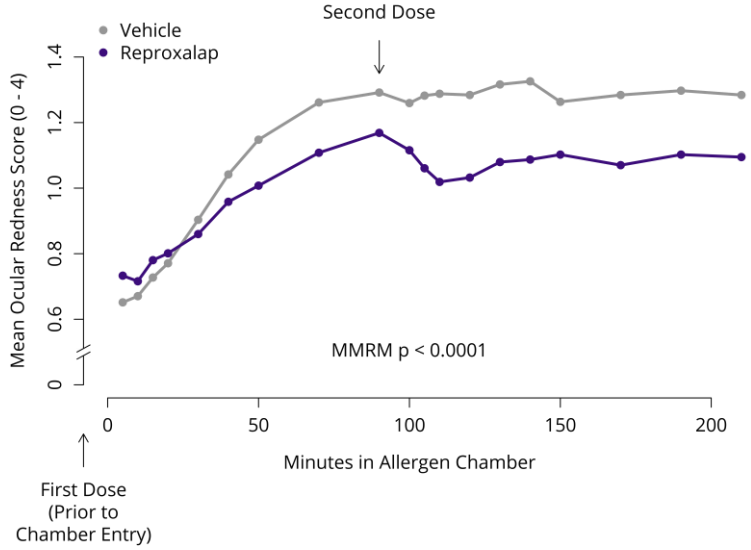
INVIGORATE Phase 3 Trial



REDNESS

Allergen Chamber

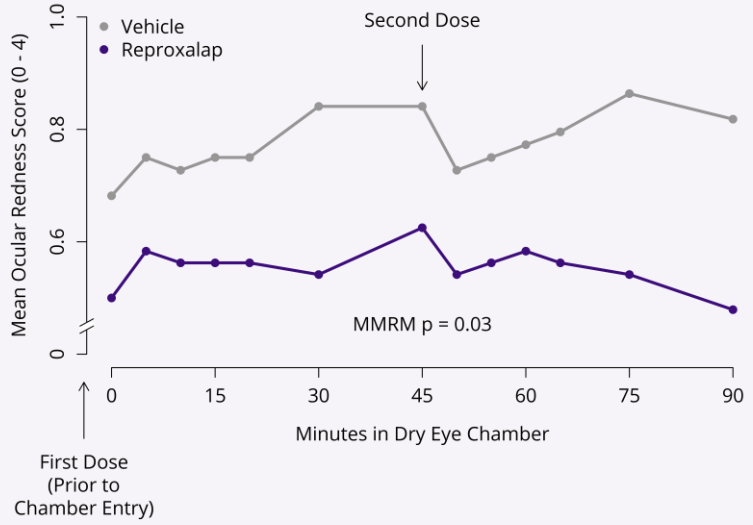
Phase 2 Trial



REDNESS

Dry Eye Chamber

TRANQUILITY Run-In Cohort



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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.

*The timing of clinical trial initiation and completion depends, in part, on restrictions related to COVID-19, the availability of clinical research facilities and staffing, the ability to recruit patients, and regulatory feedback.

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

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*Contingent on funding, regulatory review, clinical results, and other factors