



September 2021

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## **CORPORATE OVERVIEW**

# Innovative Approaches to Regulating Immune Response

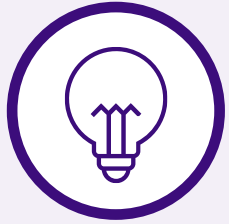
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# Compelling Value Proposition



## NOVEL SYSTEMS-BASED APPROACHES FOR IMMUNOLOGY

- Ocular and systemic RASP-inhibition represent first-in-class, pre-cytokine therapeutic approaches.
- Rare retinal disease methotrexate platform provides potential near-term, high-value commercial opportunity.



## NEAR-TERM DEVELOPMENT CATALYSTS\*

- Phase 3 TRANQUILITY and TRANQUILITY-2 results in dry eye disease expected 2H 2021.
- ADX-629 Phase 2 clinical testing results in asthma, psoriasis, and COVID-19 expected in Q4 2021 or Q1 2022.



## LARGE AND UNDERSERVED MARKET OPPORTUNITY

- Lead product candidate reproxalap targets a U.S. addressable market of >\$18B.
- Potential rapid onset and ocular redness control differentiates reproxalap in blockbuster ocular indications of dry eye disease and allergic conjunctivitis.



## SOLID CASH POSITION

- Cash, cash equivalents and marketable securities of \$249.7M as of 6/30/2021
- Cash runway through the end of 2023, based on projected operating expenses\*

# Deep and Innovative Pipeline Addressing Immunological Disease

PRODUCT CANDIDATES	DISEASE TARGETS	PRECLINICAL	PHASE 1	PHASE 2	PHASE 3
Reproxalap (ophthalmic solution)	Dry Eye Disease				
	Allergic Conjunctivitis				
ADX-2191 (intravitreal injection)	Proliferative Vitreoretinopathy*†				
	Primary Vitreoretinal Lymphoma*				
	Retinitis Pigmentosa*				
RASP-Inhibitor Discovery Platform	Multiple Immune-Mediated Retinal and Systemic Indications				
ADX-629 (oral administration)	Cytokine Release Syndrome (COVID-19)				
	Allergy (Atopic Asthma)				
	Autoimmune Disease (Psoriasis)				



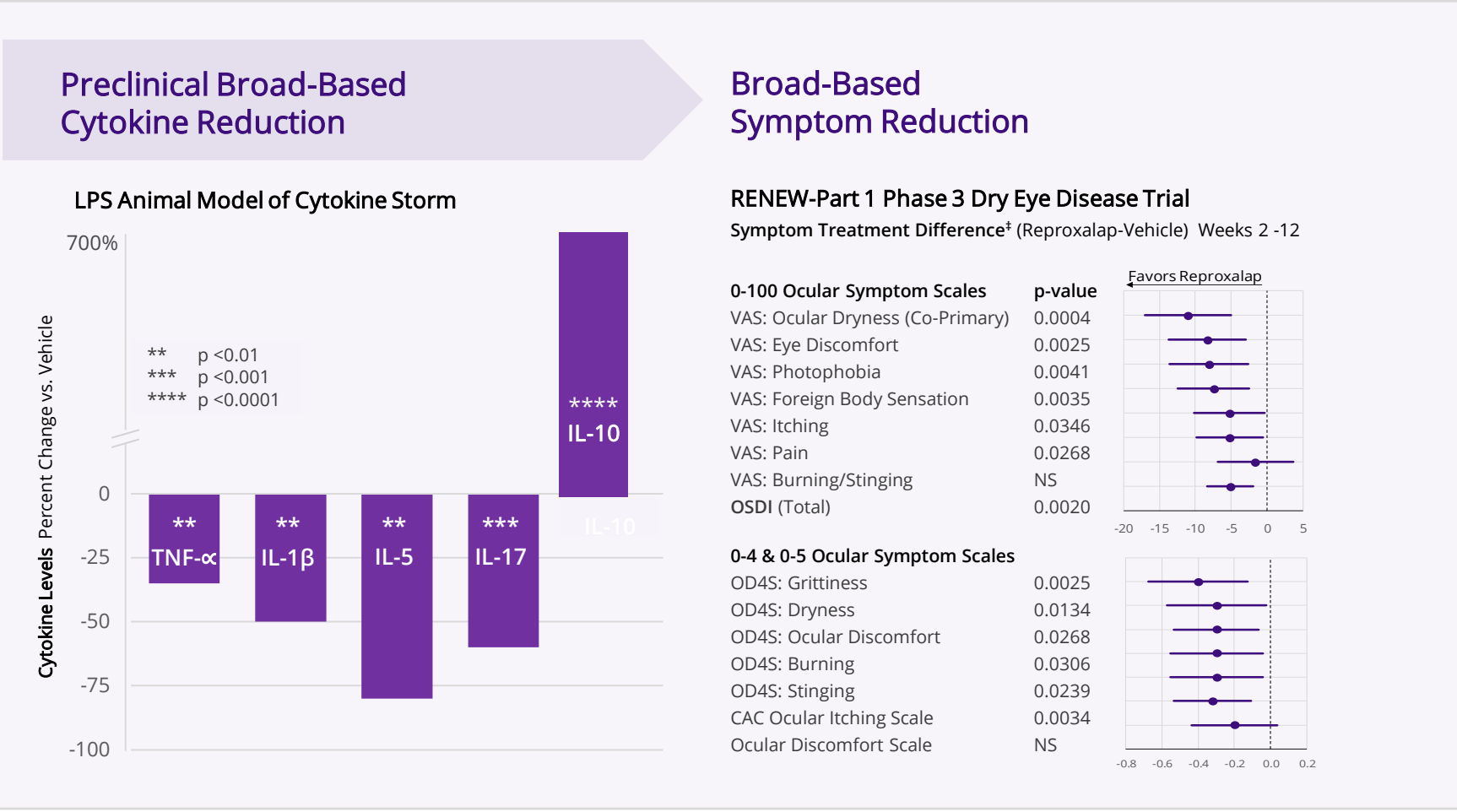
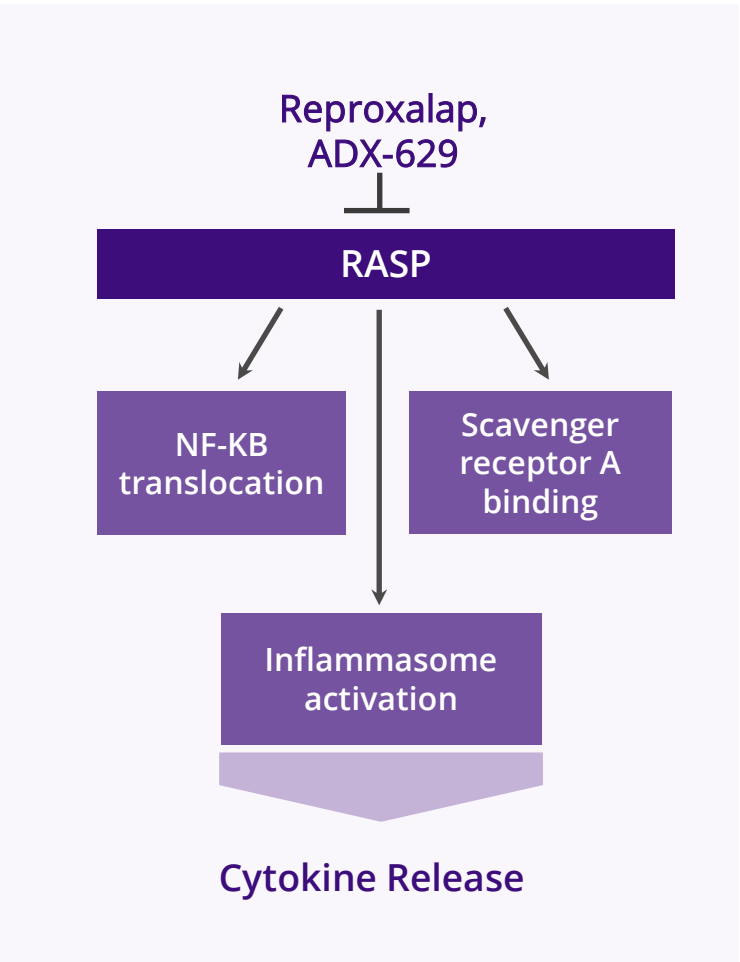
September 2021

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## **REPROXALAP AND ADX-629**

# RASP Inhibition – A First-in-Class Therapeutic Approach for Immune Modulation

# RASP Inhibition is a Pre-Cytokine, Systems-Based Approach that Has Been Clinically Validated in Late-Stage Trials



**Sources:** Cullen, et al. The Small Molecule Aldehyde Trap NS2 Exhibits Potent Anti-Inflammatory Activity in Three Murine Models of Inflammation [abstract]. In: The Journal of Allergy and Clinical Immunology. Volume 135, Issue 2, AB384, Feb 2015; Reproxalap RENEW-Part 1 clinical trial results. ‡Treatment Difference of induction-maintenance dosing, defined as the difference between the changes from baseline for the evaluated drug vs. vehicle (LS Mean Difference  $\pm$  95% CI). Ocular Dryness Score co-primary endpoint assessed in pre-specified patient population having an OD4S dryness baseline score of  $\geq$  3 (N=170). **RASP** = Reactive Aldehyde Species **VAS** = Visual Analog Scale **OSDI** = Ocular Surface Disease Index **NS** = Not Significant **OD4S** = Ocular Discomfort & 4-Symptom **CAC** = Conjunctival Allergen Challenge



# Reproxalap Activity in Ocular Inflammatory Diseases is Supported by Marquee Peer-Reviewed Publications

AMERICAN JOURNAL OF OPHTHALMOLOGY

Clinically Relevant Activity of the Novel RASP Inhibitor Reproxalap in Allergic Conjunctivitis: The Phase 3 ALLEVIATE Trial

DAVID CLARK, BILL CAVANAGH, ALAN L. SHIELDS, PAUL KARPECKI, JOHN SHEPPARD, AND TODD C. BRADY

JOURNAL OF OCULAR PHARMACOLOGY AND THERAPEUTICS

Randomized Phase 2 Trial of Reproxalap, a Novel Reactive Aldehyde Species Inhibitor, in Patients with Noninfectious Anterior Uveitis: Model for Corticosteroid Replacement

Kenneth J. Mandell,<sup>1</sup> David Clark,<sup>1</sup> David S. Chu,<sup>2</sup> C. Stephen Foster,<sup>3</sup> John Sheppard,<sup>4</sup> and Todd C. Brady<sup>1</sup>

AMERICAN JOURNAL OF OPHTHALMOLOGY

Early Onset and Broad Activity of Reproxalap in a Randomized, Double-Masked, Vehicle-Controlled Phase 2b Trial in Dry Eye Disease

DAVID CLARK, JOSEPH TAUBER, JOHN SHEPPARD, AND TODD C. BRADY

JOURNAL OF OCULAR PHARMACOLOGY AND THERAPEUTICS

A Randomized Double-Masked Phase 2a Trial to Evaluate Activity and Safety of Topical Ocular Reproxalap, a Novel RASP Inhibitor, in Dry Eye Disease

David Clark,<sup>1</sup> John Sheppard,<sup>2</sup> and Todd C. Brady<sup>1</sup>

Clinical Ophthalmology

Dovepress

open access to scientific and medical research

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ORIGINAL RESEARCH

A Post-Acute Ocular Tolerability Comparison of Topical Reproxalap 0.25% and Lifitegrast 5% in Patients with Dry Eye Disease

David McMullin<sup>1</sup>  
David Clark<sup>1</sup>  
Bill Cavanagh<sup>1</sup>  
Paul Karpecki<sup>2</sup>  
Todd C. Brady<sup>1</sup>

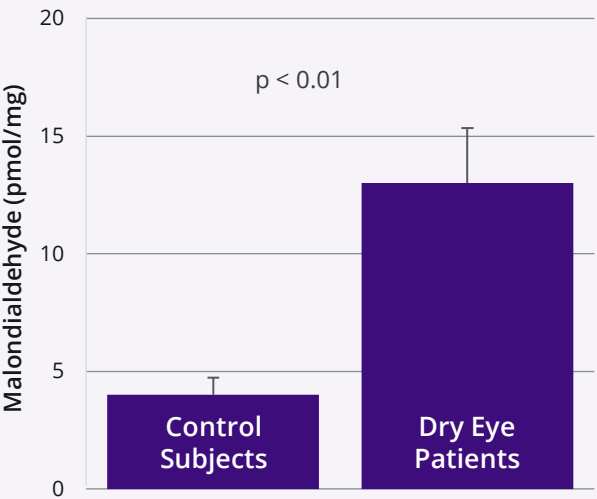
<sup>1</sup>Aldeyra Therapeutics, Inc., Lexington, MA, USA; <sup>2</sup>Kentucky Eye Institute, Lexington, KY, USA

# Reproxalap's Mechanism of Action Reduces RASP, a Potential Dry Eye Disease Biomarker

## RASP in Dry Eye Disease

RASP markers are upregulated in dry eye disease.

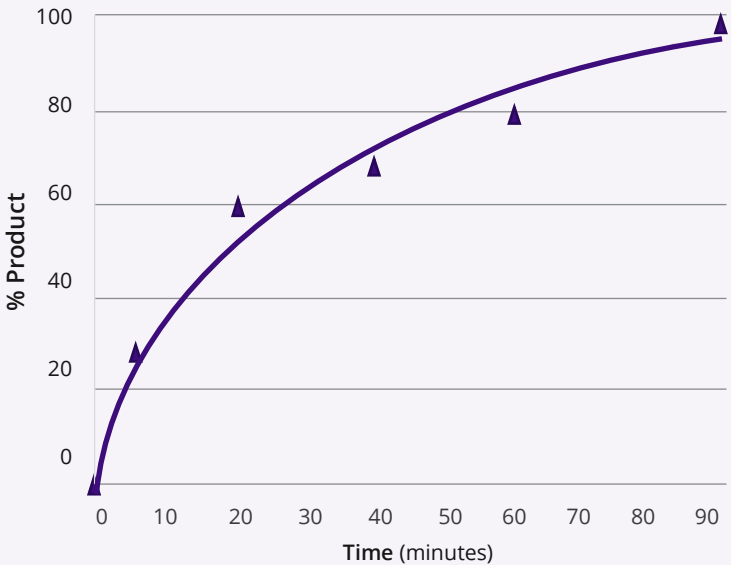
RASP levels have been shown to correlate with worsening symptoms and signs.



## REPROXALAP

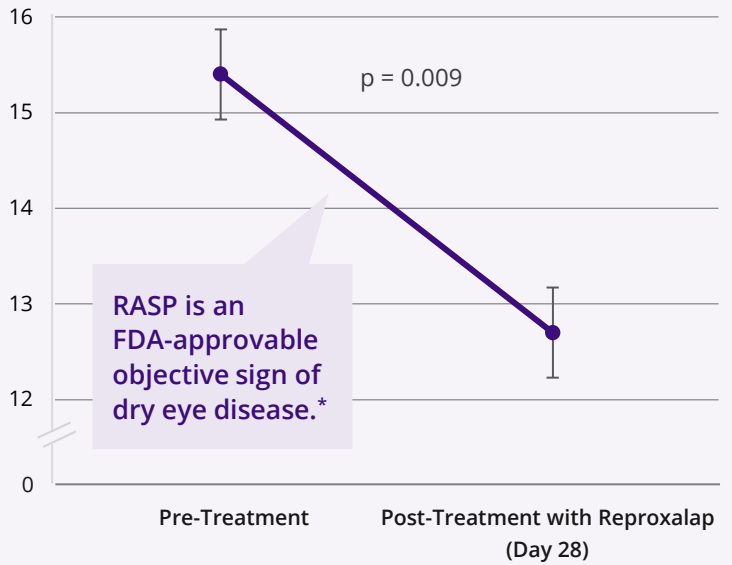
### Rapid RASP binding in vitro

In vitro Reproxalap-Malondialdehyde (MDA) adduct formation over time (% of MDA bound by reproxalap)



### Clinical reduction in RASP adducts

Phase 2a: Tear RASP Levels in Dry Eye Disease Patients (µM Malondialdehyde Adduct; Mean ± Within-Subject SEM)



**Sources:** Choi W., et al. Expression of Lipid Peroxidation Markers in the Tear Film and Ocular Surface of Patients with Non-Sjogren Syndrome: Potential Biomarkers for Dry Eye Disease. Curr Eye Res. 2016, 41(9):1143-9; Clark D, Sheppard J, Brady TC. A Randomized Double-Masked Phase 2a Trial to Evaluate Activity and Safety of Topical Ocular Reproxalap, a Novel RASP Inhibitor, in Dry Eye Disease. J Ocul Pharmacol Ther. 2021 May; 37(4):193-199; reproxalap preclinical results on file. \*Aldeyra's written meeting minutes with the FDA confirmed the use of redness or RASP as accepted objective signs for the treatment of dry eye disease. Topical ocular reproxalap has been studied in over 1,200 patients with no observed safety concerns; mild instillation site discomfort is the most commonly reported adverse event in clinical trials.



# Lead RASP Inhibitor Reproxalap, a Novel Topical Ocular Drug, Now in Two Phase 3 Programs for Ocular Inflammation

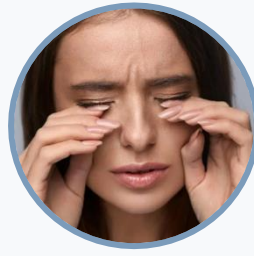
## DRY EYE DISEASE



**34 million** or more adults in the U.S.<sup>1</sup>

Often months to demonstrate even modest efficacy with current Rx

## ALLERGIC CONJUNCTIVITIS



**66 million** or more adults in the U.S.<sup>2</sup>

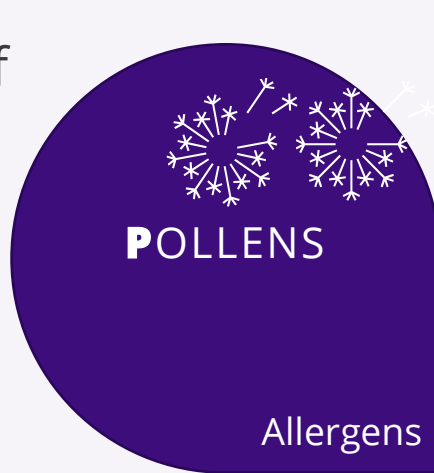
Unchecked growing disease burden and limited options beyond OTC antihistamines

Reproxalap is poised to potentially be the next novel entrant in the dry eye disease and allergic conjunctivitis markets.

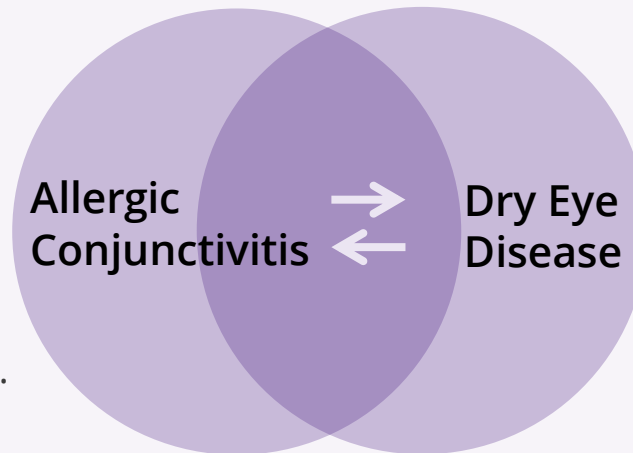
**Sources:** <sup>1</sup>Paulsen AJ, Cruickshanks KJ, Fischer ME, et al. Dry eye in the beaver dam offspring study: prevalence, risk factors, and health-related quality of life. Am J Ophthalmol. 2014;157(4):799-806. doi:10.1016/j.ajo.2013.12.023; <sup>2</sup>Singh K, Axelrod S, Bielory L. The epidemiology of ocular and nasal allergy in the United States, 1988-1994. J Allergy Clin Immunol. 2010;126(4):778-783.e6. doi:10.1016/j.jaci.2010.06.050. Topical ocular reproxalap has been studied in over 1,200 patients with no observed safety concerns; mild instillation site discomfort is the most commonly reported adverse event in clinical trials.

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

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



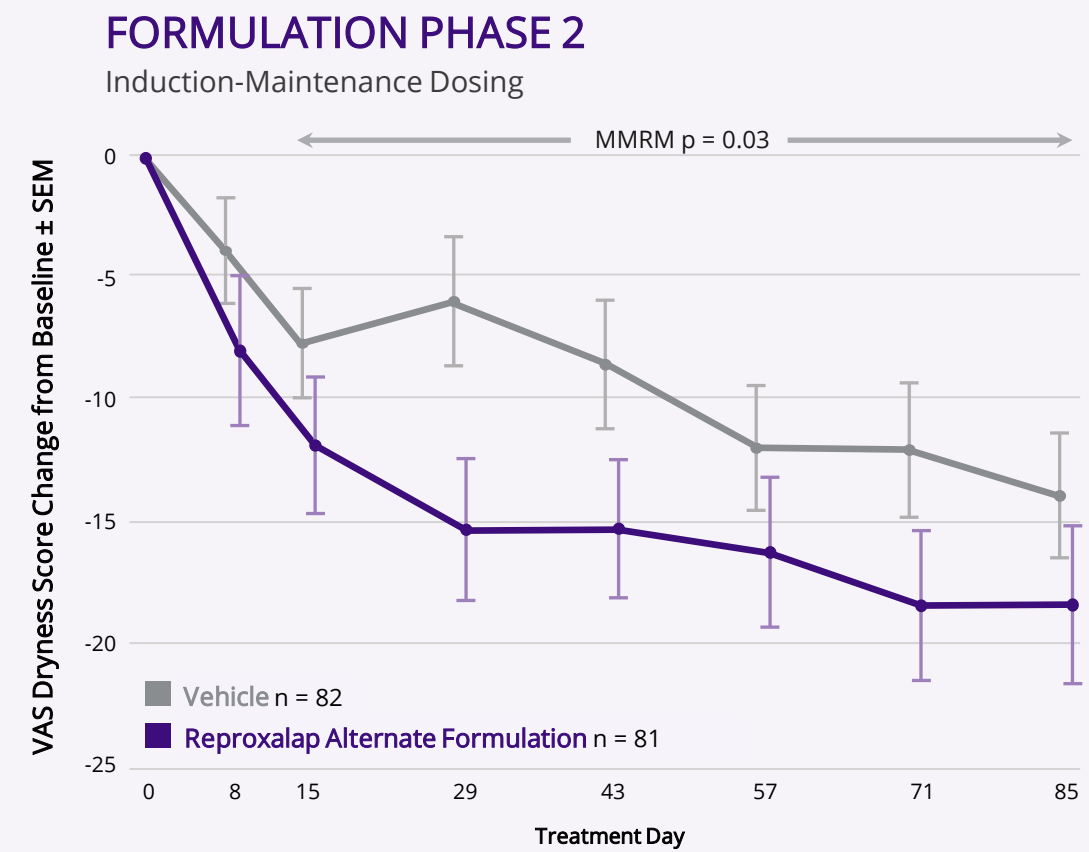
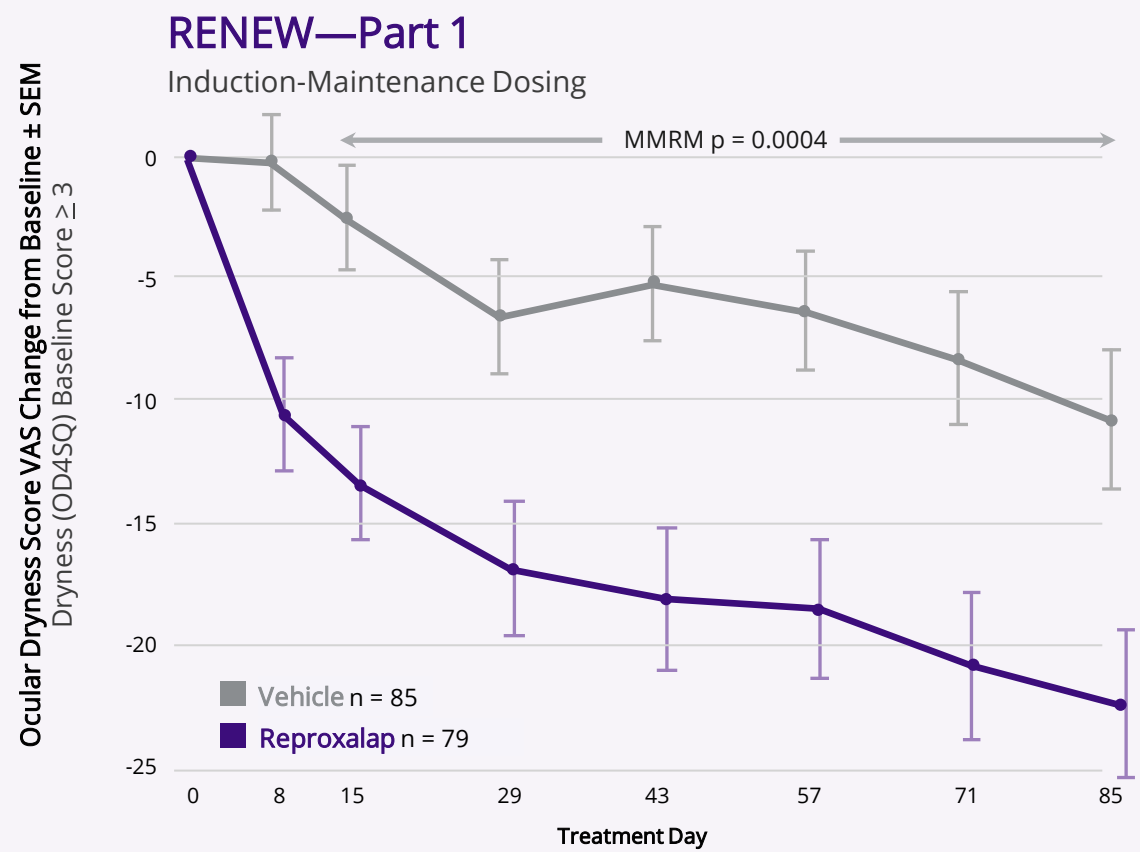
- Allergic response can compromise tear film.
- Dry eye inflammation can enhance allergic response.
- Dry, polluted environments exacerbate both conditions.



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

-Mark B. Abelson, MD et. al.

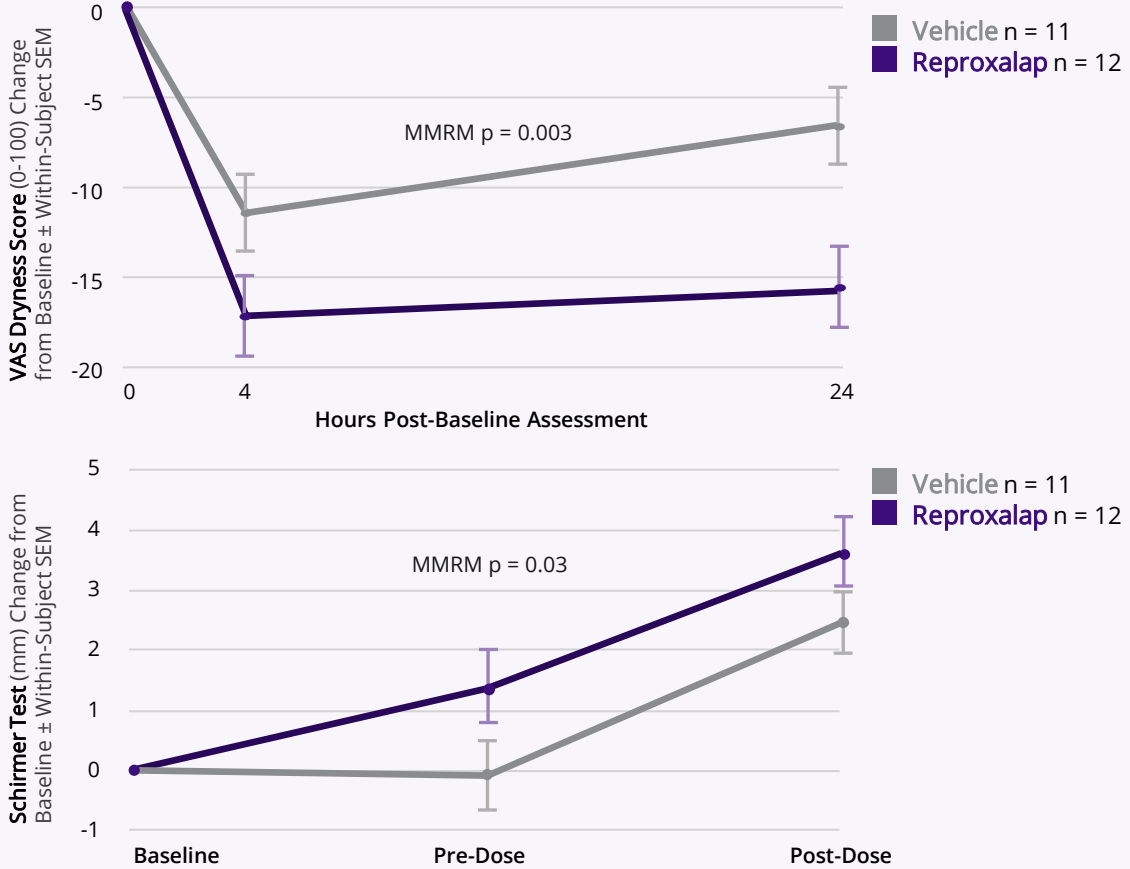
# Reproxalap Met 12-Week (Chronic) Dryness Symptom Primary Endpoint in RENEW-Part 1 and Formulation Phase 2 Clinical Trials



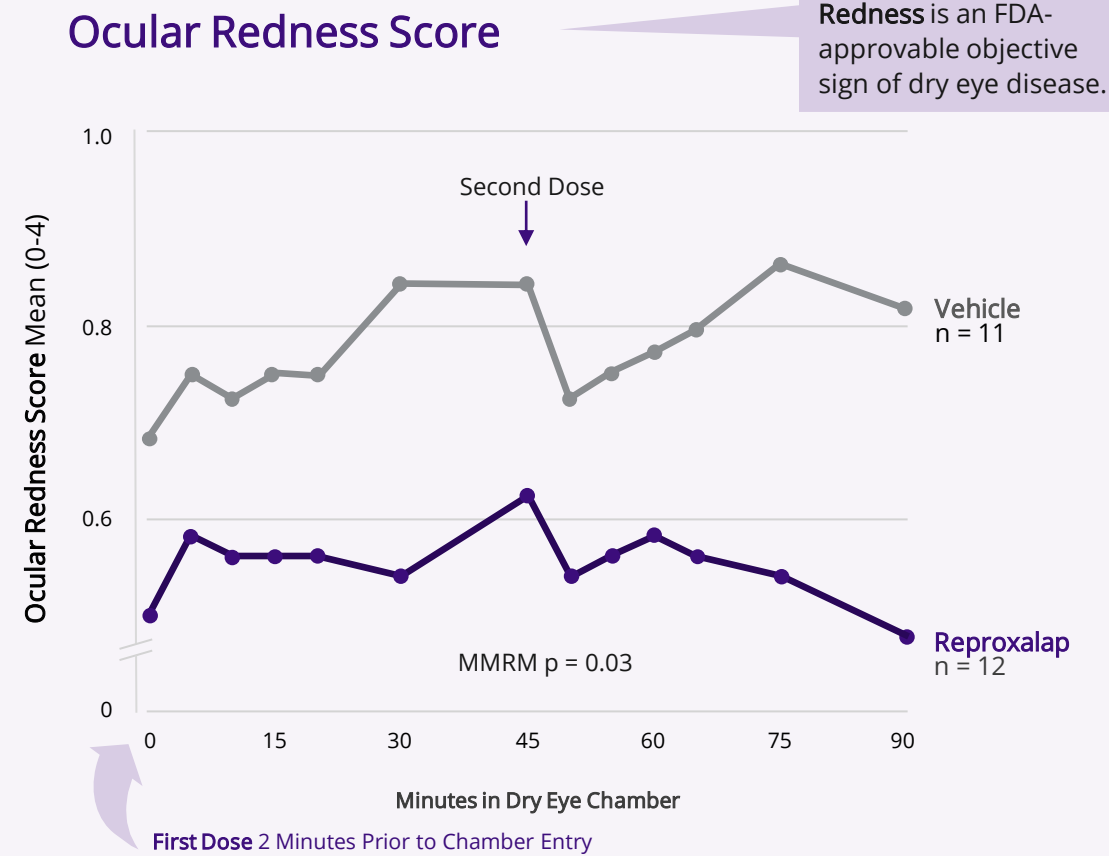
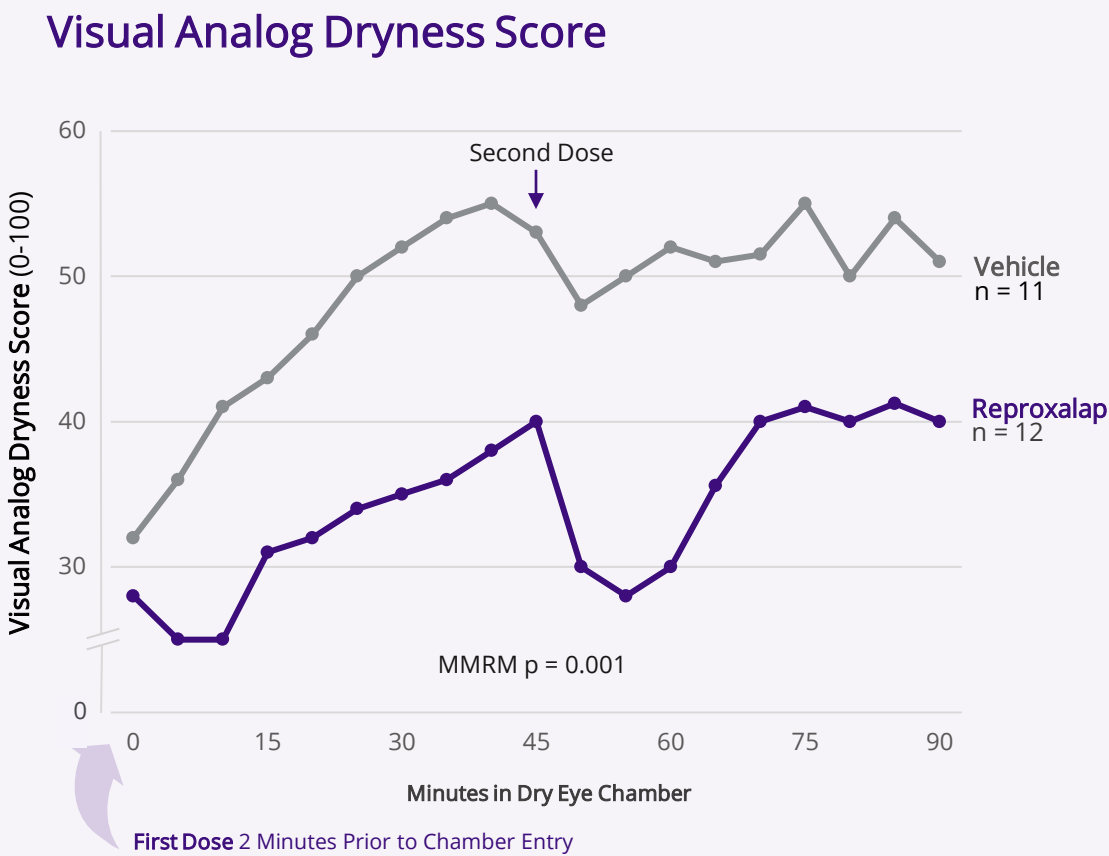
# Reproxalap Demonstrated Rapid and Broad Improvements After Only One Day of Treatment in the TRANQUILITY Run-In Cohort

A single day of dosing led to statistically significant changes in symptoms and Schirmer Test.

Dry Eye Assessment (Scale) After Environmental Dosing	Change from Baseline		p-Value
	Reproxalap n=12	Vehicle n=11	
VAS Dryness (0-100)	-26	+2	0.003
OD4S: Discomfort (0-5)	-0.7	+0.4	0.003
OD4S: Dryness (0-5)	-1.2	+0.1	0.006
OD4S: Grittiness (0-5)	-1.1	+0.1	0.006
OD4S: Burn (0-5)	-0.1	+0.8	0.07
OD4S: Sting (0-5)	-0.1	+0.4	0.23
Ocular Discomfort Scale (0-4)	-0.7	+0.4	0.07
Schirmer's Test (mm)*	+2.9	+0.7	0.03



# Phase 3 TRANQUILITY Trial Run-In Cohort: Symptom and Sign Activity Demonstrated within Minutes in a Dry Eye Chamber



Source: TRANQUILITY Run-In Cohort initial results. p values derived from MMRM of change from baseline, where baseline defined as Time 0. Topical ocular reproxalap has been studied in over 1,200 patients with no observed safety concerns; mild instillation site discomfort is the most commonly reported adverse event in clinical trials. **MMRM** = Mixed Effect Model Repeated Measures

# Phase 3 TRANQUILITY Dry Eye Disease Trial Design

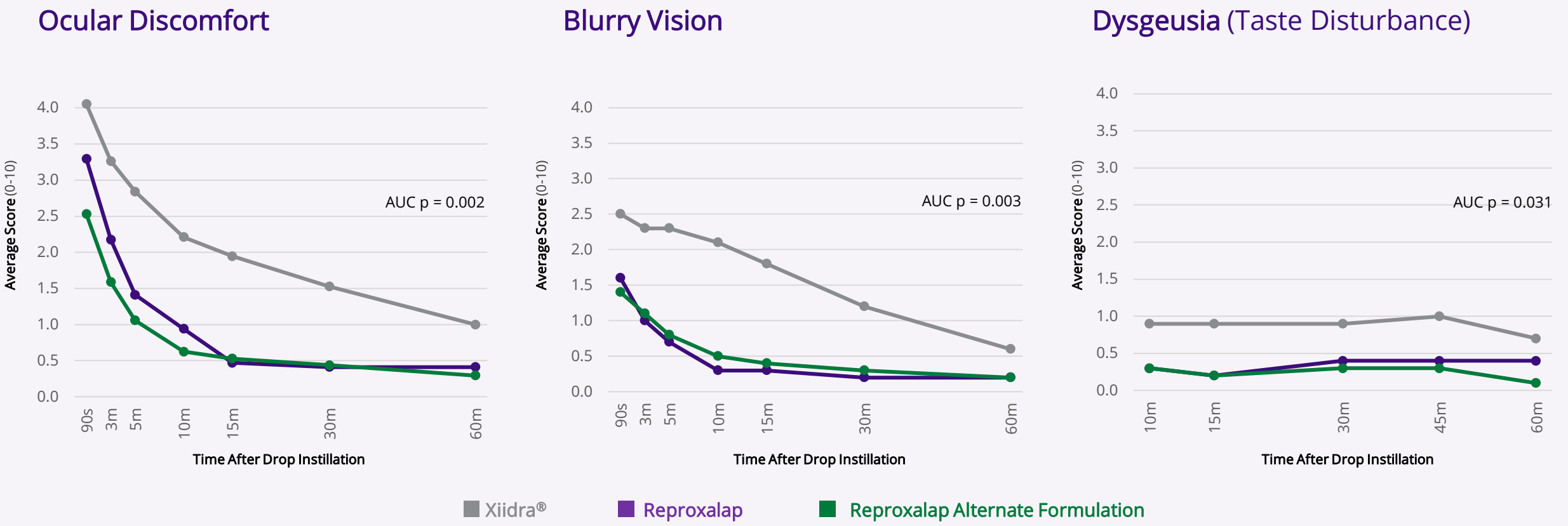
## Dry Eye Chamber Challenge Model

Design	Multi-center, randomized, double-masked, parallel group, vehicle-controlled
Dosing	Day 1: QID; Day 2 (chamber): BID
Size	~150 patients per arm; 300 patients total
Primary Endpoint	Ocular redness over 90 minutes in a dry eye chamber
Secondary Endpoints	<ul style="list-style-type: none"><li>• Tear RASP levels</li><li>• Schirmer's Test</li><li>• Dry eye symptoms</li></ul>

Results from the identical TRANQUILITY and TRANQUILITY-2 Trials are expected in Q4 2021.



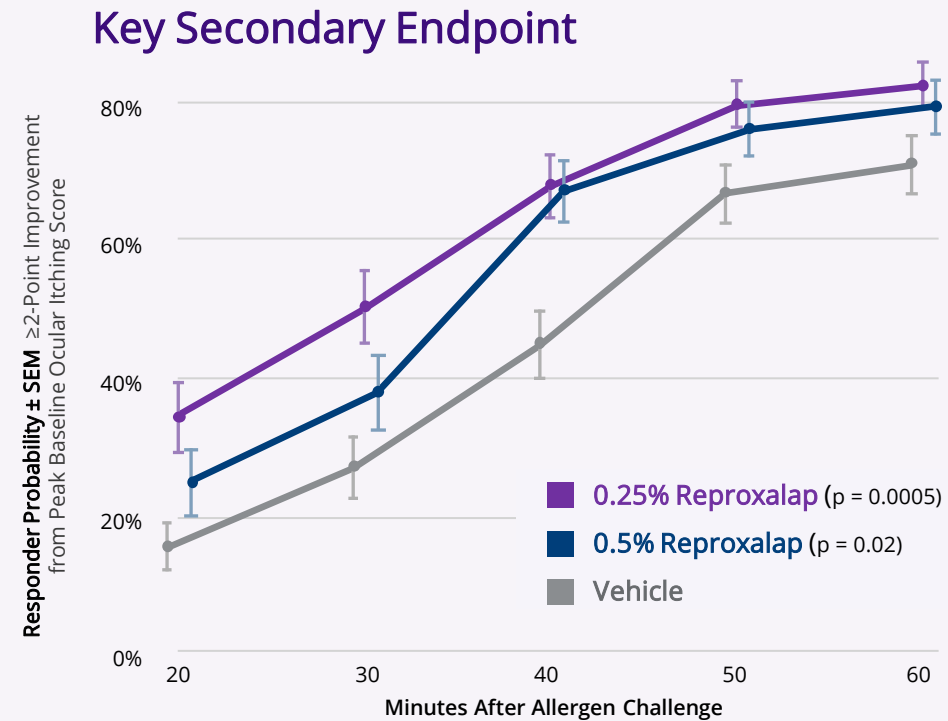
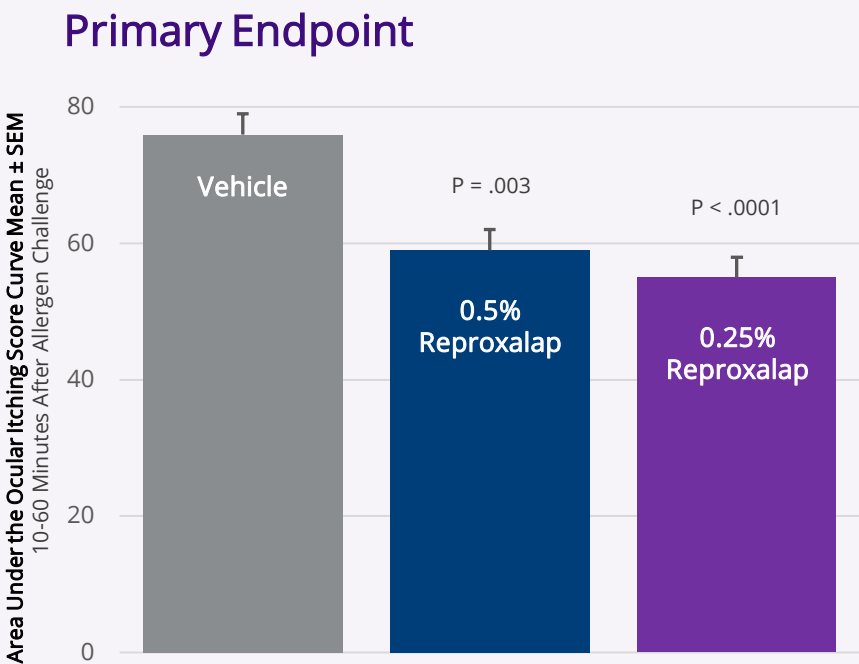
# Tolerability of Reproxalap Over One Hour Post-Instillation Significantly Improved vs. Xiidra® in Dry Eye Disease Patients



Source: Phase Xiidra® HTH Trial results. p-values represent MMRM of vehicle area under the curve vs. pooled reproxalap AUC. Topical ocular reproxalap has been studied in over 1,200 patients with no observed safety concerns; mild instillation site discomfort is the most commonly reported adverse event in clinical trials. AUC = area under the curve

# Reproxalap Achieved Primary and Key Secondary Endpoints in ALLEVIATE Phase 3 Trial in Allergic Conjunctivitis

CONJUNCTIVAL  
ALLERGEN  
CHALLENGE

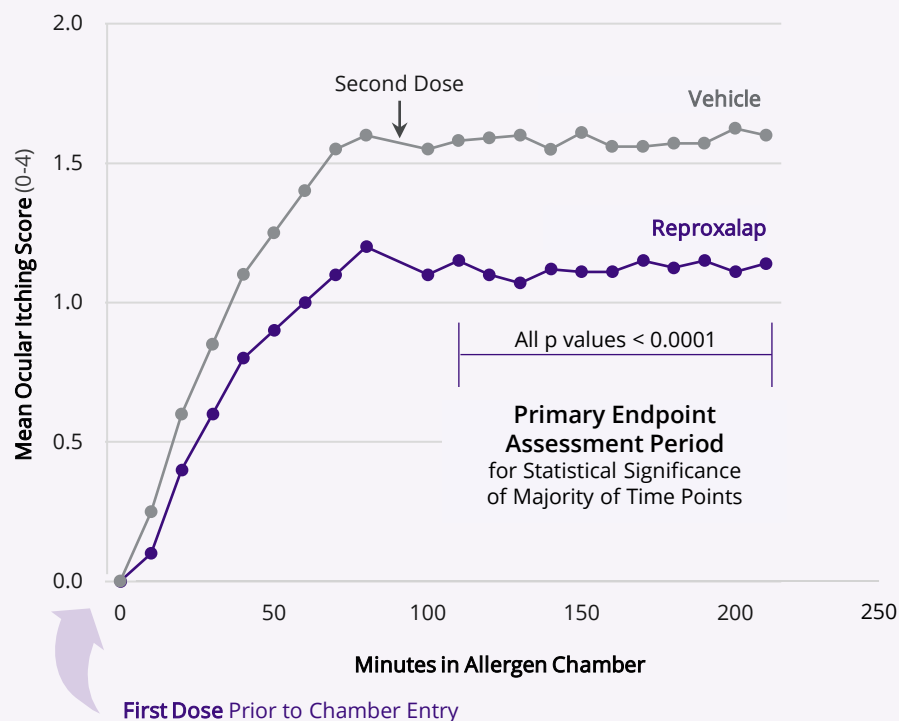


# Primary and Key Secondary Endpoints Achieved in Phase 3 INVIGORATE Allergen Chamber Trial

Prophylactic and treatment effects of reproxalap demonstrated

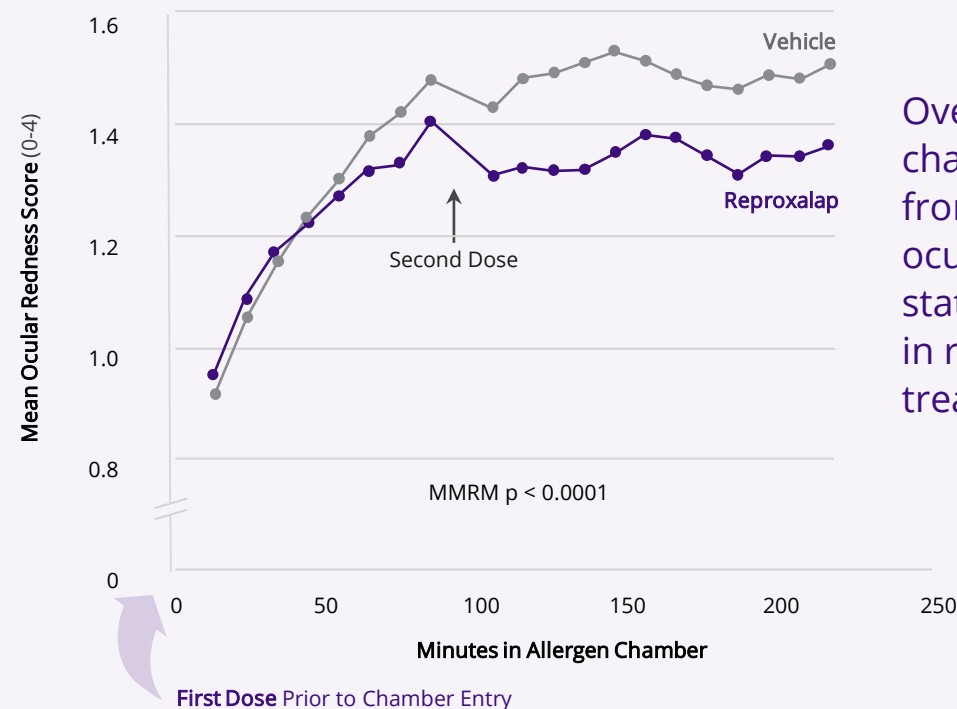
## Primary Endpoint

Reduction in Ocular Itching Over Pre-Specified Time Frame



## Key Secondary Endpoint

Reduction in Ocular Redness Over the Entire Chamber

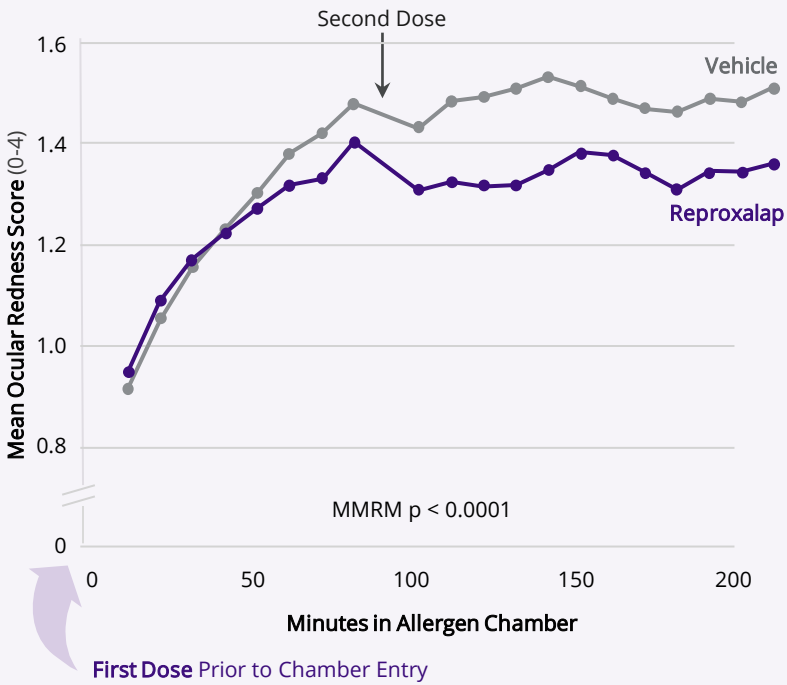


Over entire chamber, change from baseline in ocular redness statistically lower in reproxalap-treated subjects

# Reproxalap Has Demonstrated Consistent Effect on Redness Across Two Distinct Chamber Challenge Models in Ocular Surface Disease

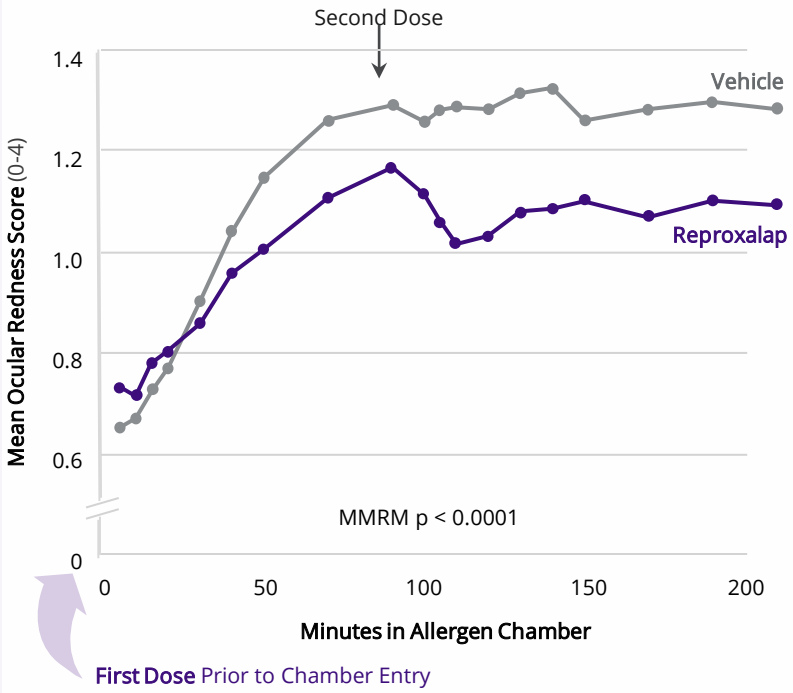
## Allergen Chamber

### INVIGORATE Phase 3 Trial



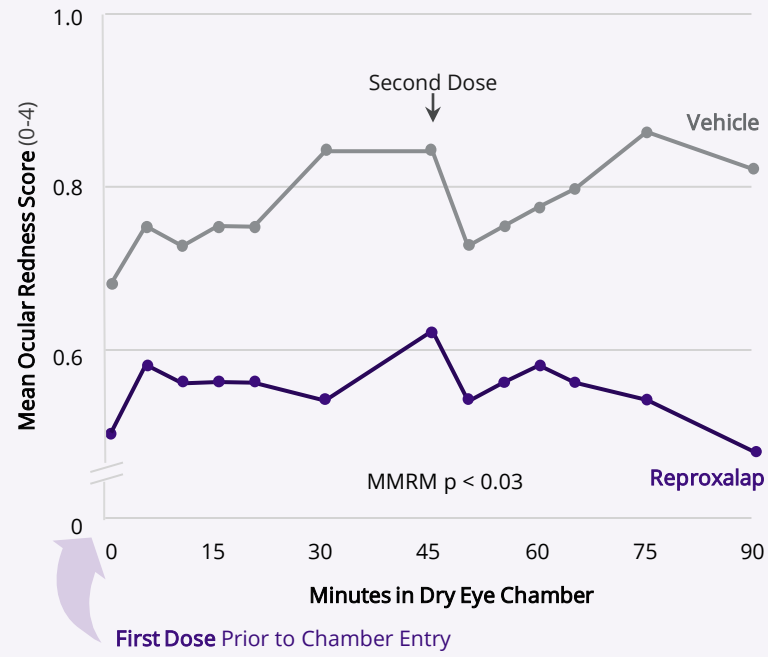
## Allergen Chamber

### Phase 2 Trial



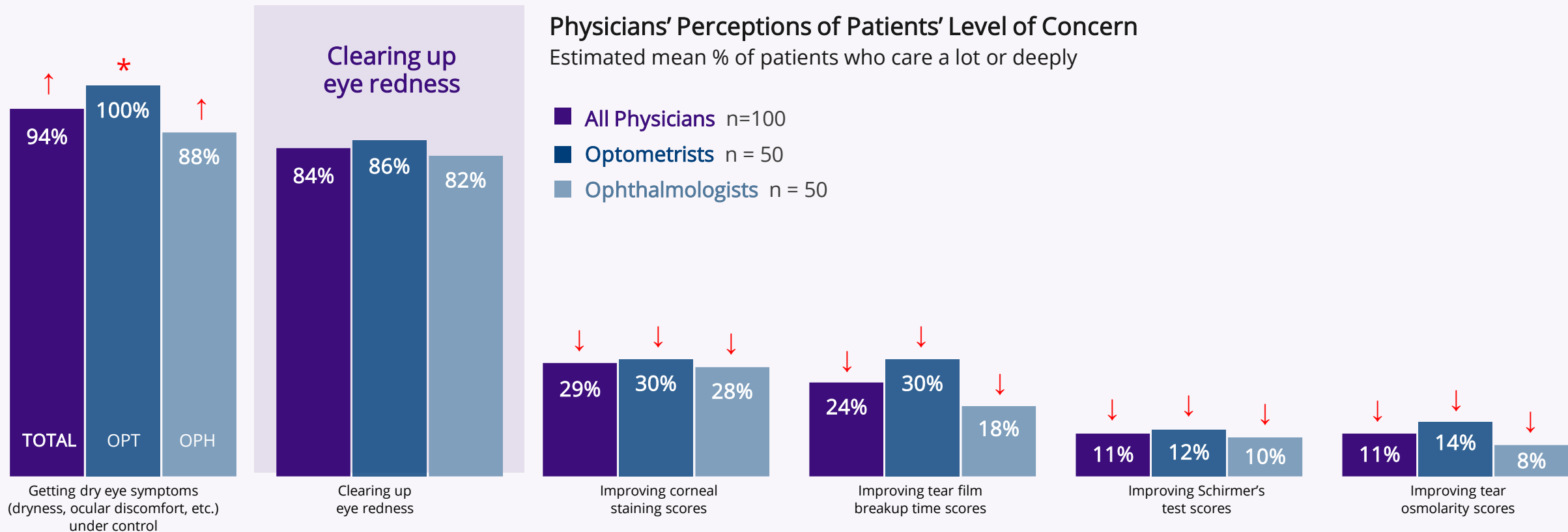
## Dry Eye Chamber

### TRANQUILITY Run-In Cohort



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

# Physicians Believe Most Patients Care More About Redness Than Other Signs of Dry Eye Disease



# Reproxalap Represents a Novel, Rapid-Onset Potential Therapeutic Approach in Dry Eye Disease

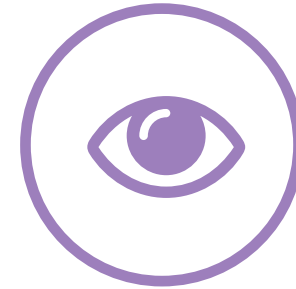
Potential advantages for patients and healthcare providers could effect a paradigm shift relative to standard of care



Rapid symptom  
improvement  
within minutes



Broad  
symptomatic  
activity



Acute  
conjunctival  
redness control



# ADX-629, A RASP Inhibitor for Oral Administration, Expands Pipeline Beyond Ocular Disease

**ADX-629 is a first-in-class**, orally available and irreversible covalent inhibitor of pro-inflammatory RASP, and potentially represents a new paradigm in the understanding and treatment of systemic immune-mediated disease.

**A comprehensive systemic disease initiative** is in process to assess the activity of ADX-629 in three types of severe inflammation: cytokine release syndrome, allergic inflammation, and autoimmune disease.

## RASP-INHIBITION IN SYSTEMIC DISEASES

### Phase 2 Proof of Concept Clinical Trials in Three Types of Severe Inflammation

- 1 Phase 2 clinical trial in COVID-19
- 2 Phase 2 allergen-challenge clinical trial in atopic asthma
- 3 Phase 2 clinical trial in psoriasis

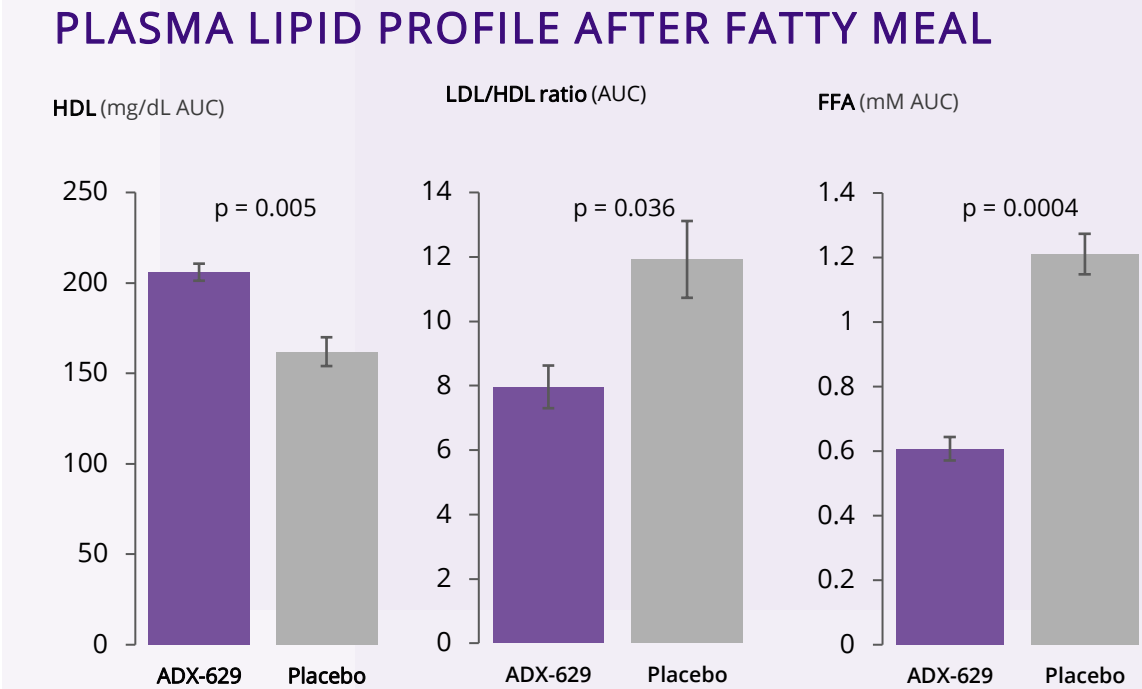
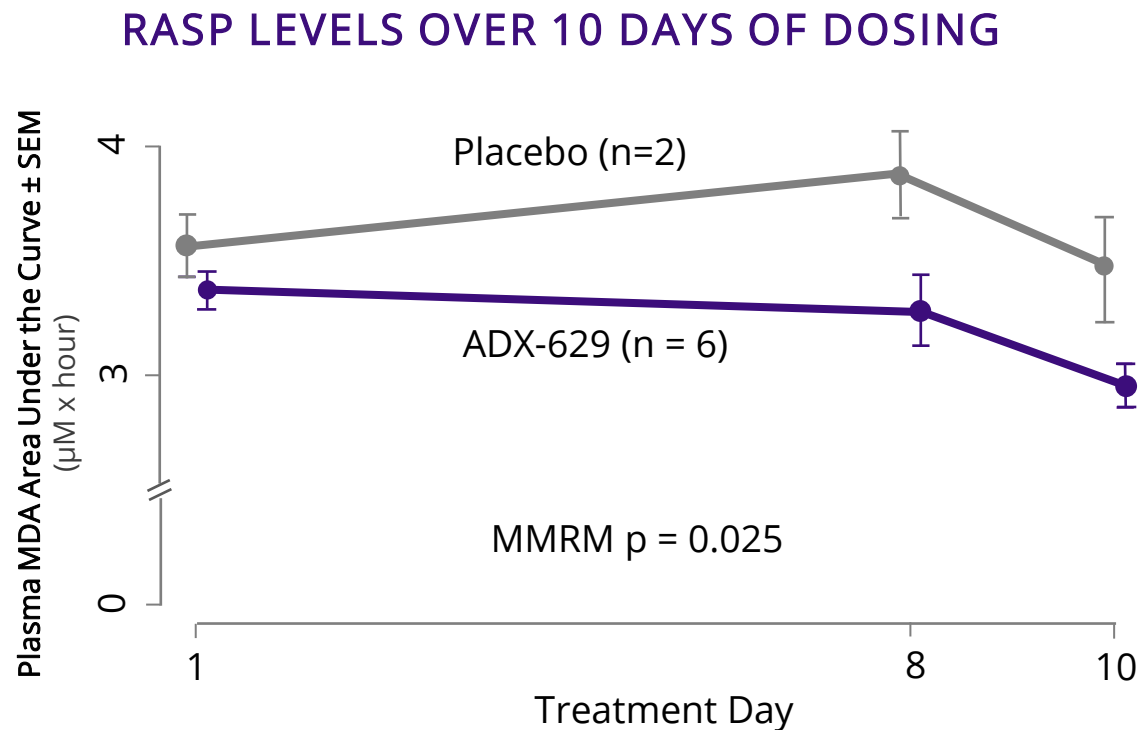
Data  
Readouts  
Expected  
in Q4 2021  
or Q1 2022

Cytokine Release Syndrome

Allergic Inflammation

Autoimmune Disease

# ADX-629 Reduced RASP vs. Placebo in Phase 1 Clinical Trial, Demonstrating Target Engagement and Improved Lipid Profiles



Source: ADX-629 Phase 1 clinical trial results. MDA = Malondialdehyde MMRM = Mixed Model Repeated Measures HDL = High-density lipoprotein LDL = Low-density lipoprotein FFA = Free fatty acids



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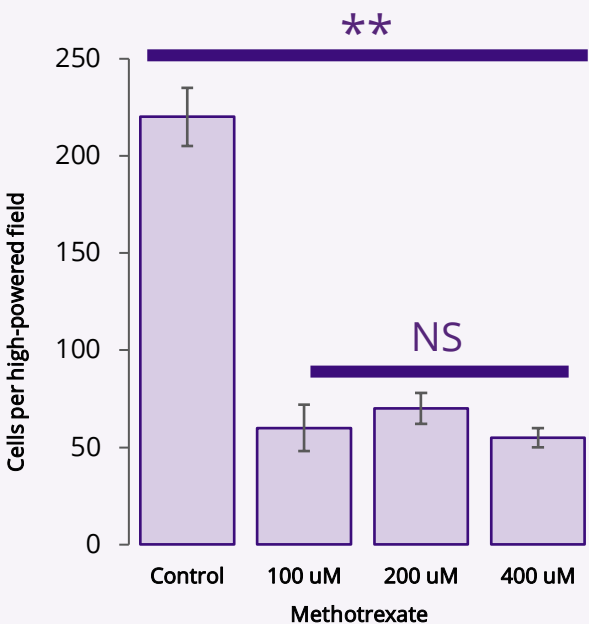
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## **ADX-2191 (METHOTREXATE FOR INTRAVITREAL INJECTION)**

# A Platform Approach to Treat Rare Immune-Mediated Retinal Diseases

# ADX-2191, a Novel Intravitreal Formulation of Methotrexate, Represents a Clinically Proven Systems Modulating Approach

## Preclinical reduction in cellular proliferation

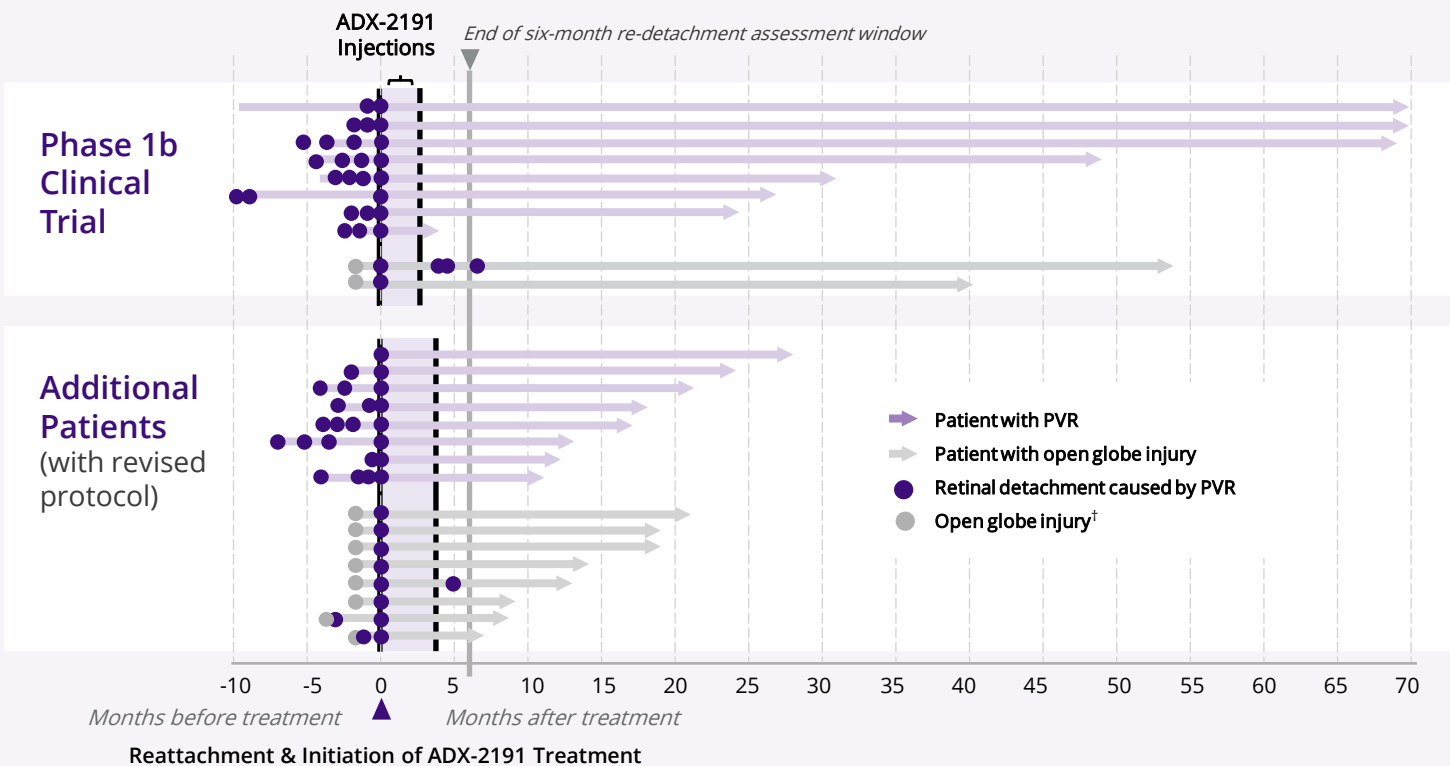


Source



## Clinical reduction in retinal detachment

Retinal Detachments Over Time by Patient



**Sources:** ADX-2191 PVR Phase 1b investigator sponsored clinical trial (n=10) results and additional in-practice use (n=16); Invest Ophthalmol Vis. Sci. 2017; 58:3940–3949. †Timing of open globe injury as shown is estimated. There is no assurance that prior results, such as signals of safety, activity or durability of effect, observed from this open label investigator sponsored trial will be replicated in more rigorous clinical trials involving ADX-2191. \*\* = p value ≤ 0.01 NS = Not Significant PVR = Proliferative vitreoretinopathy

# ADX-2191 Represents a Novel Potential Therapeutic Option For the Prevention of Proliferative Vitreoretinopathy

## PROLIFERATIVE VITREORETINOPATHY (PVR)



PVR is a **rare disease**, with ~4,000 patients per year in the U.S. and nearly twice as many in Europe and Japan combined.



Left untreated, retinal detachment due to PVR can progress to **permanent blindness**.



There is currently **no FDA- or EMA-approved therapy**.



Repeat surgery, which can lead to **vision loss**, is currently the only possible course of action.

## ADX-2191

**Granted U.S. orphan designation and FDA fast track designation for the prevention of PVR**

**Tolerability and reattachment success demonstrated in Phase 1b open-label investigator sponsored clinical trial**

**GUARD adaptive Phase 3 clinical trial for the prevention of recurrent retinal detachment due to PVR ongoing**

# ADX-2191: GUARD Trial Design in Proliferative Vitreoretinopathy

## Adaptive Phase 3 (Part 1) Clinical Trial Design

### COMPLETION OF ENROLLMENT EXPECTED IN 2021

#### Primary Objective

Evaluate efficacy of intravitreal ADX-2191 injections for prevention of recurrent retinal detachment due to PVR

#### Design

Multi-center, randomized, controlled, two- part, adaptive Phase 3 clinical trial (N $\approx$ 100)

#### Inclusion Highlights

- Recurrent retinal detachment due to PVR, or
- Retinal detachment associated with open-globe injury

#### Dosing Regimen

At surgery, weekly (x8), and then every other week (x4) intravitreal ADX-2191 injections

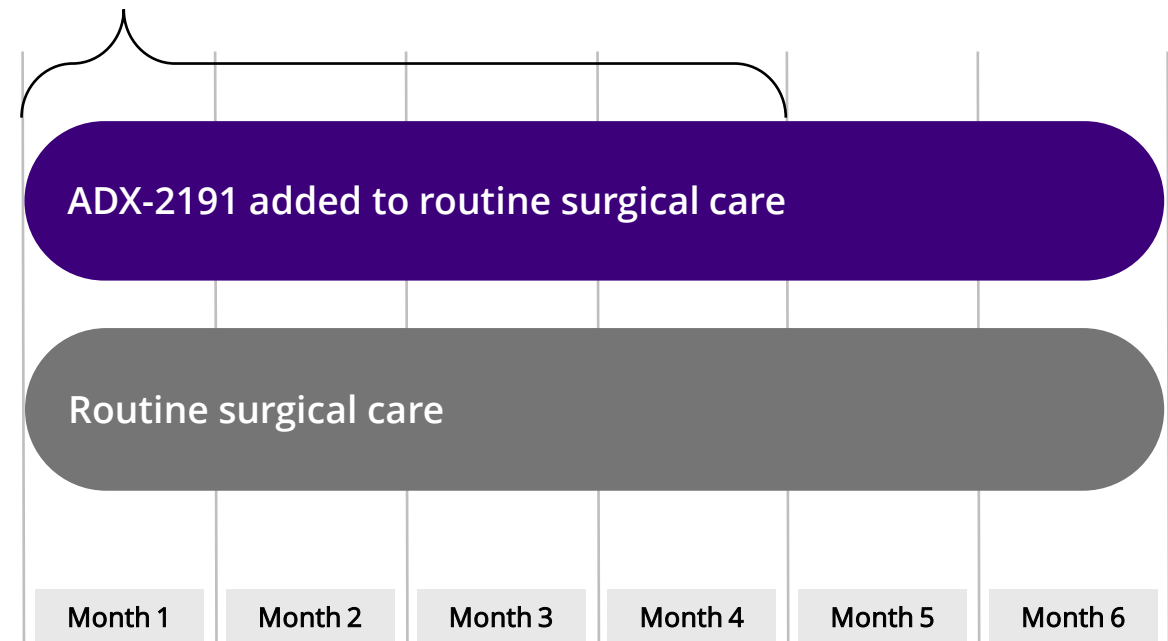
#### Endpoint

Retinal re-detachments due to PVR requiring re-operation within 6 months:

1. OCT demonstrating fovea-off retinal detachment
2. Photographic documentation retinal detachment

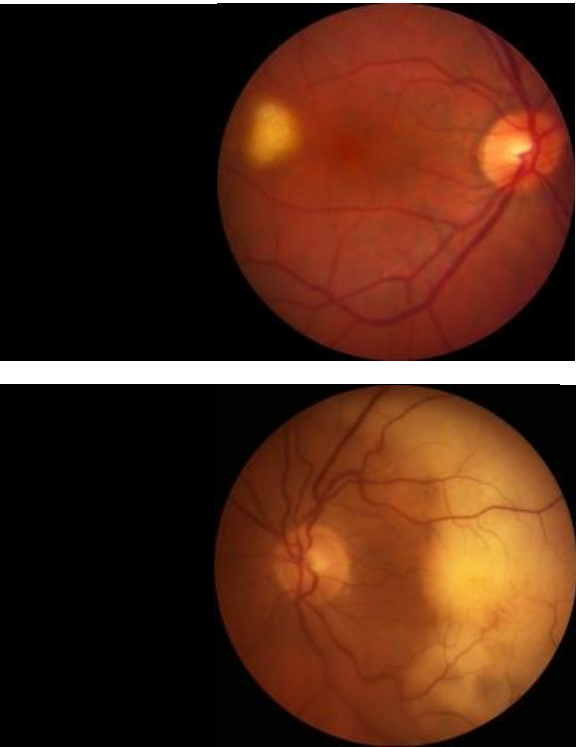
### ADAPTIVE PHASE 3 PVR CLINICAL TRIAL DESIGN: PART 1

*ADX-2191 intravitreal injections*





# ADX-2191 Has the Potential to be the Only Approved Drug for Primary Vitreoretinal Lymphoma (PVRL), a Rare but Serious Retinal Cancer



*Small (top) and large (bottom) subretinal infiltrates in patients with primary vitreoretinal lymphoma*

A rare, aggressive, high-grade cancer, PVRL arises in the vitreous and retina.

Approximately **2,900 people** in the United States suffer from PVRL.

Approximately **600 new cases** of PVRL are diagnosed in the United States per year.

**4.83 years** is the median survival for newly diagnosed patients.

The most common ocular complaints reported by patients include **blurred vision, painless loss of vision, floaters, red eye, and photophobia.**

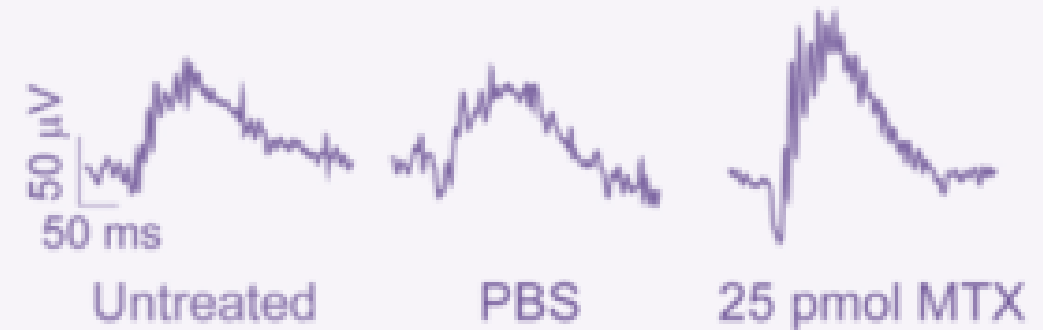
**No approved treatments** are currently available, though methotrexate represents current standard of care.

# ADX-2191 Has the Potential to be the Only Approved Drug for Retinitis Pigmentosa (RP), a Clinical Group of Rare Genetic Eye Diseases

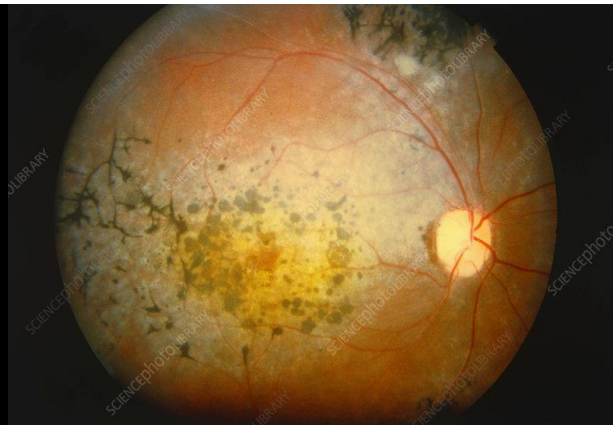
RP refers to a group of inherited retinal diseases characterized by cell death and loss of vision.

Affects an estimated 82,000-110,000 individuals in the United States, and approximately 1 in 4,000 people worldwide.

Forms of RP and related diseases include usher syndrome, Leber's congenital amaurosis, and Bardet-Biedl syndrome, among others.



Preclinical evidence suggests that methotrexate improves retinal function in a mouse model of RP.



# ADX-2191: Phase 2 Clinical Trial Design in RP

## INITIATION OF ENROLLMENT EXPECTED IN 2021\*

### Primary Objective

To evaluate the safety and efficacy of ADX-2191 in patients with RP

### Design

Single-center, open label study (N=8)

### Inclusion Highlights

Diagnosis of RP due to rhodopsin gene mutations, including P23H

### Dosing Regimen

Cohort A (N=4): Monthly injections  
Cohort B (N=4): Twice-monthly injections

### Primary Endpoint

Safety and tolerability of ADX-2191 in RP subjects

### Secondary Endpoints

1. Change in visual acuity assessed by ETDRS
2. Central retinal sensitivity assessed by MAIA microperimetry
3. Change in dark-adapted flash analyzed by ffERG
4. Change in dark-adapted retinal sensitivity
5. OCT assessment for change in central subfield foveal thickness and ellipsoid zone area/width

## RETINITIS PIGMENTOSA CLINICAL TRIAL DESIGN

### Cohort A: Monthly Intravitreal Injections



Month 1

Month 2

Month 3

### Cohort B: Twice-Monthly Intravitreal Injections



# Experienced Management Team and Board of Directors

## MANAGEMENT TEAM

**Todd Brady, M.D., Ph.D.**  
President, CEO & Director



**Joshua Reed, M.B.A.**  
Chief Financial Officer



**Stephen Machatha, Ph.D.**  
Chief Development Officer



## BOARD OF DIRECTORS

**Richard Douglas, Ph.D.** Former SVP Corporate Development at Genzyme  
Chairman

**Ben Bronstein, M.D.** Former CEO Peptimmune<sup>6</sup>

**Marty Joyce, M.B.A.** Former CFO of Serono USA

**Nancy Miller-Rich** Former SVP BD&L and Commercial Strategy at Merck

**Gary Phillips, M.D.** CEO OrphoMed

**Neal Walker, D.O.** CEO Aclaris Therapeutics

**Todd Brady, M.D., Ph.D.** CEO Aldeyra Therapeutics

# Upcoming Planned Clinical Milestones\*



Phase 3  
TRANQUILITY and  
TRANQUILITY-2 Trials  
of reproxalap in dry  
eye disease

**Top-line results  
expected in Q4 2021**



Part 1 of Phase 3  
GUARD Trial of  
ADX-2191 in  
proliferative  
vitreoretinopathy

**Completion of  
enrollment in 2021**



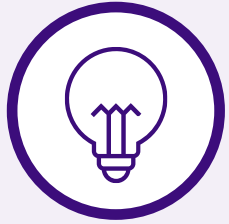
Phase 2 clinical trial  
of ADX-2191 in  
retinitis pigmentosa  
**Initiation in 2021**



Phase 2 clinical trials  
of ADX-629 in  
multiple systemic  
indications

**Top-line results  
expected in Q4 2021  
or Q1 2022**

# Compelling Value Proposition



## NOVEL SYSTEMS-BASED APPROACHES FOR IMMUNOLOGY

- Ocular and systemic RASP-inhibition represent first-in-class, pre-cytokine therapeutic approaches.
- Rare retinal disease methotrexate platform provides potential near-term, high-value commercial opportunity.



## NEAR-TERM DEVELOPMENT CATALYSTS\*

- Phase 3 TRANQUILITY and TRANQUILITY-2 results in dry eye disease expected 2H 2021.
- ADX-629 Phase 2 clinical testing results in asthma, psoriasis, and COVID-19 expected in Q4 2021 or Q1 2022.



## LARGE AND UNDERSERVED MARKET OPPORTUNITY

- Lead product candidate reproxalap targets a U.S. addressable market of >\$18B.
- Potential rapid onset and ocular redness control differentiates reproxalap in blockbuster ocular indications of dry eye disease and allergic conjunctivitis.



## SOLID CASH POSITION

- Cash, cash equivalents and marketable securities of \$249.7M as of 6/30/2021
- Cash runway through the end of 2023, based on projected operating expenses\*





September 2021

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## **CORPORATE OVERVIEW**

# Innovative Approaches to Regulating Immune Response