



February 2023

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## **CORPORATE OVERVIEW**

# Innovative Therapeutics to Treat Immune-Mediated Diseases

# Disclaimers and Forward-Looking Statements

This presentation and various remarks which may be made during this presentation contain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and Section 21E of the Securities Exchange Act of 1934, as amended, including statements regarding Aldeyra's possible or assumed future results of operations, expenses and financing needs, business strategies and plans, statements regarding Aldeyra's future expectations, plans and prospects, including, without limitation, statements regarding: the sufficiency of the Company's cash, cash equivalents, and marketable securities, Aldeyra's belief in the adequacy of the data it has submitted or plans to submit in the NDAs for reproxalap and ADX-2191; the potential timing for FDA review of such NDAs or the potential for FDA acceptance of such NDAs; the potential for regulatory approval and commencement of commercialization of reproxalap and ADX-2191 and Aldeyra's goals as to timing; the potential profile and benefit of reproxalap in dry eye disease and its other product candidates in the indications for which they are developed; and other statements regarding the goals, opportunity and potential for reproxalap, anticipated clinical or regulatory milestones for ADX-2191 and ADX-629, including expectations regarding the results of scheduled FDA meetings, clinical trial initiations and completions and submissions to the FDA; and other statements regarding the goals, opportunity and potential for reproxalap, ADX-2191, ADX-629 and Aldeyra's other product candidates, and for Aldeyra's business, research, development and regulatory plans or expectations, political, economic, legal, social and health risks, including the COVID-19 pandemic and related public health measures and other responses to it, that may affect Aldeyra's business or the global economy, the structure, timing and success of Aldeyra's planned or pending clinical trials, expected milestones, market sizing, pricing and reimbursement, competitive position, regulatory matters, industry environment and potential growth opportunities, among other things. The results of earlier preclinical or clinical trials may not be predictive of future results. Forward-looking statements include all statements that are not historical facts and, in some cases, can be identified by terms such as "may," "might," "will," "objective," "intend," "should," "could," "can," "would," "expect," "believe," "anticipate," "project," "on track," "scheduled," "target," "design," "estimate," "predict," "contemplates," "likely," "potential," "continue," "ongoing," "aim," "plan," or the negative of these terms, and similar expressions intended to identify forward-looking statements.

Forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause Aldeyra's actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. These statements reflect Aldeyra's current views with respect to future events and are based on assumptions and subject to risks and uncertainties, including the development of, and clinical and regulatory plans or expectations for Aldeyra's investigational new drugs (including reproxalap and ADX-2191), and systems-based approaches, later developments with the FDA that may be inconsistent with Aldeyra's expectations and beliefs, including the risk that the results from earlier clinical trials, portions of clinical trials, or pooled clinical data may not accurately predict results of subsequent trials or the remainder of a clinical trial for the same or different indications, inconsistent expectations regarding FDA acceptance and review of the company's filings and submitted data sets, and Aldeyra's continuing or post-hoc review and quality control analysis of clinical data. Important factors that could cause actual results to differ materially from those reflected in Aldeyra's forward-looking statements are described in Aldeyra's most recent Annual Report on Form 10-K and Quarterly Report on Form 10-Q, as well as Aldeyra's subsequent filings with the Securities and Exchange Commission. All of Aldeyra's development plans and timelines may be subject to adjustment depending on funding, recruitment rate, regulatory review, which regulatory review timeline may be flexible and subject to change based on the regulator's workload and other potential review issues, preclinical and clinical results, and other factors any of which could result in changes to Aldeyra's development plans and programs or delay the initiation, enrolment, completion, or reporting of clinical trials.

In addition to the risks described above and in Aldeyra's other filings with the SEC, other unknown or unpredictable factors also could affect Aldeyra's results. No forward-looking statements can be guaranteed, and actual results may differ materially from such statements. The information in this presentation is provided only as of **February 16, 2023**, and Aldeyra undertakes no obligation to update any forward-looking statements contained in this presentation on account of new information, future events, or otherwise, except as required by law.

**ALDEYRA'S MISSION** is to discover and develop innovative medicines that improve the lives of patients who suffer from immune-mediated diseases.

**OUR APPROACH** is to create therapies that modulate immunological systems, instead of directly inhibiting or activating single protein targets, with the goal of optimizing multiple pathways at once while minimizing toxicity.



# Aldeyra is a Well-Capitalized Biotechnology Company with a Broad Immunology Pipeline and Near-Term Catalysts

PRODUCT CANDIDATES	DISEASE TARGETS	DEVELOPMENT STAGE	NEXT EXPECTED MILESTONE
RASP PLATFORM FOR OCULAR AND SYSTEMIC IMMUNE-MEDIATED DISEASES			
Reproxalap (ophthalmic solution)	Dry Eye Disease	NDA Review	PDUFA Date: November 23, 2023 <sup>†</sup>
	Allergic Conjunctivitis	Phase 3	2023: Final Pivotal Trial Results
ADX-629 (oral administration)	Atopic Dermatitis (Part 1)	Phase 2	2023: Trial Completions
	Chronic Cough		
	Sjögren-Larsson Syndrome**	Phase 2	2023: Trial Initiation
	Idiopathic Nephrotic Syndrome (Part 1)		
	Moderate Alcohol-Associated Hepatitis**	Phase 2	2023: Trial Initiation
RASP-Modulator Discovery Platform	Multiple Immune-Mediated Retinal and Systemic Indications	Preclinical	2023: IND Submissions
VITREOUS METHOTREXATE PLATFORM FOR RARE RETINAL INFLAMMATORY DISEASES			
ADX-2191 (intravitreal injection)	Primary Vitreoretinal Lymphoma (U.S. FDA Orphan Drug Designation)	NDA Review	Q1 2023: Acceptance of NDA Submission
	Proliferative Vitreoretinopathy (U.S. FDA Orphan Drug and Fast Track Designation)	Phase 3	H1 2023: Type C Meeting
	Retinitis Pigmentosa (U.S. FDA Orphan Drug Designation)	Phase 2	H1 2023: Trial Results

**As of 9/30/2022, cash, cash equivalents, and marketable securities were \$185.3M. Based on its current operating plans, Aldeyra believes that its existing cash, cash equivalents, and marketable securities will be sufficient to fund the Company into the second half of 2024.**



<sup>†</sup>Regulatory review timelines are flexible and subject to change based on the regulator's workload and other potential review issues. **PDUFA** = Prescription Drug User Fee Act.

**IND** = Investigational New Drug. **NDA** = New Drug Application. **\*\*Investigator sponsored.**

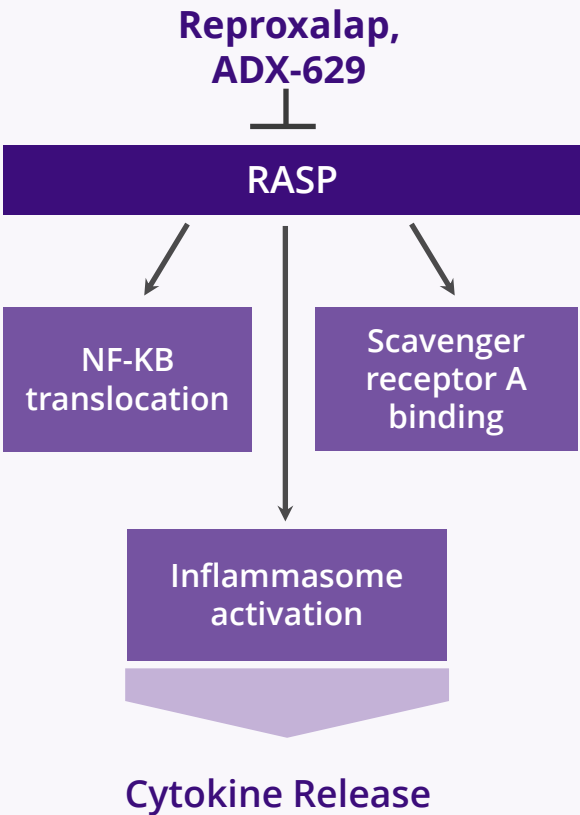


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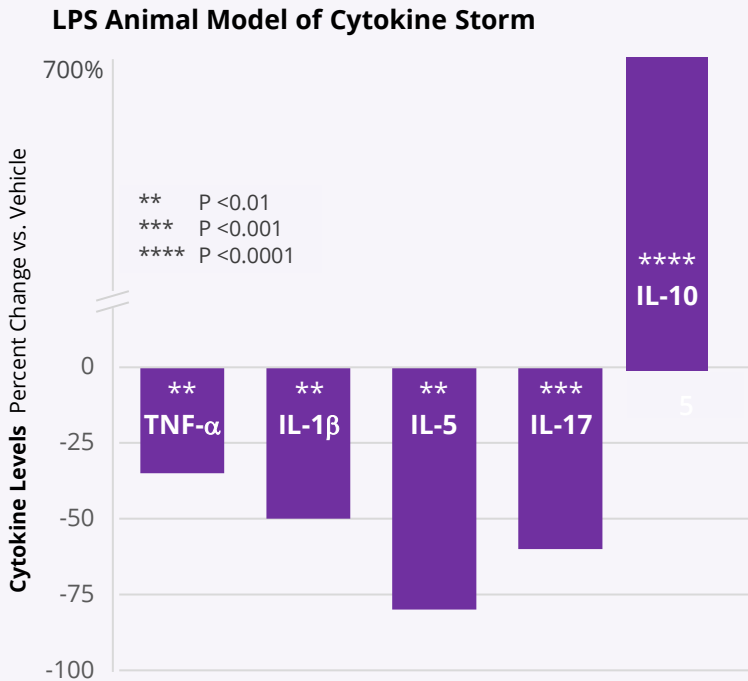
## **REPROXALAP, ADX-629, AND NOVEL RASP MODULATORS**

# Modulating RASP – A First-in-Class, Systems-Based Therapeutic Approach

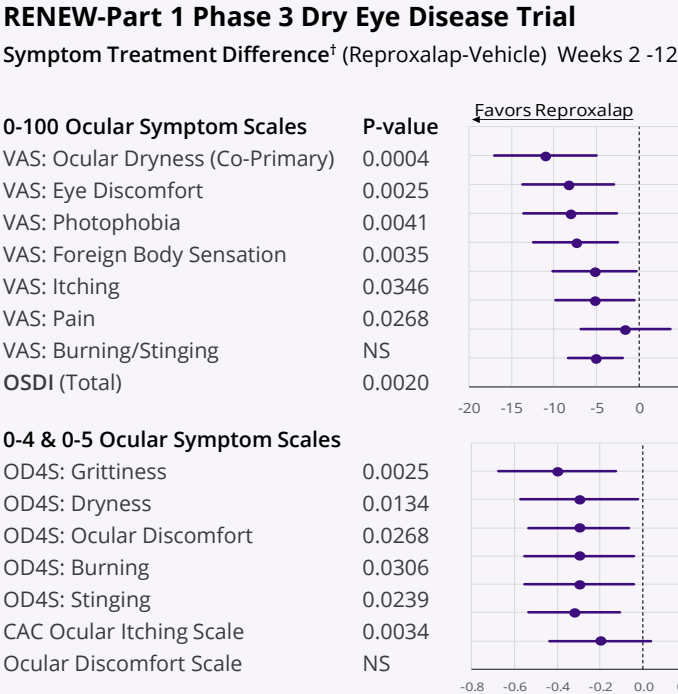
# Aldeyra is the Leading Developer of RASP Modulators: A Novel Approach Supported by Late-Stage Trials



## Preclinical Broad-Based Cytokine Reduction



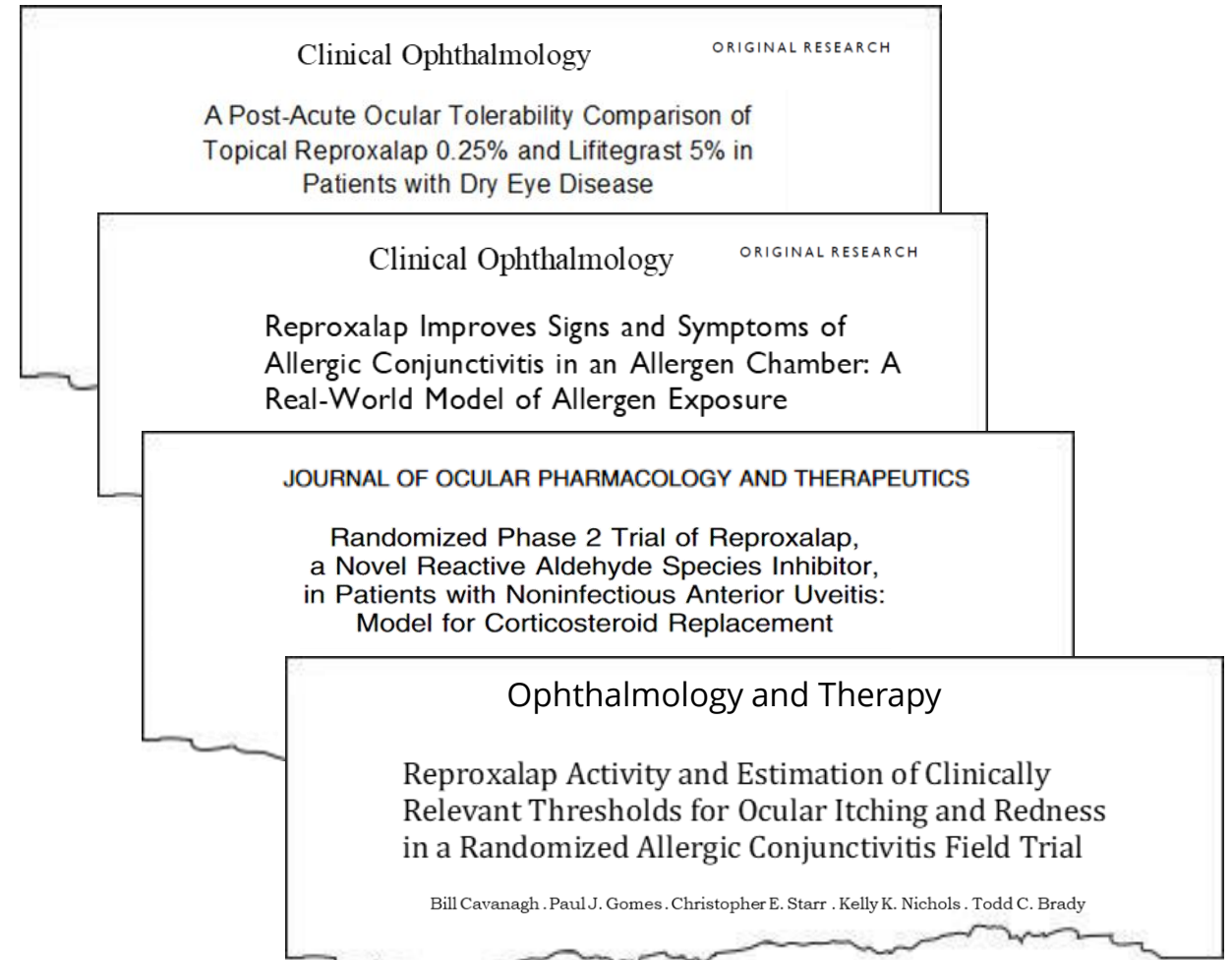
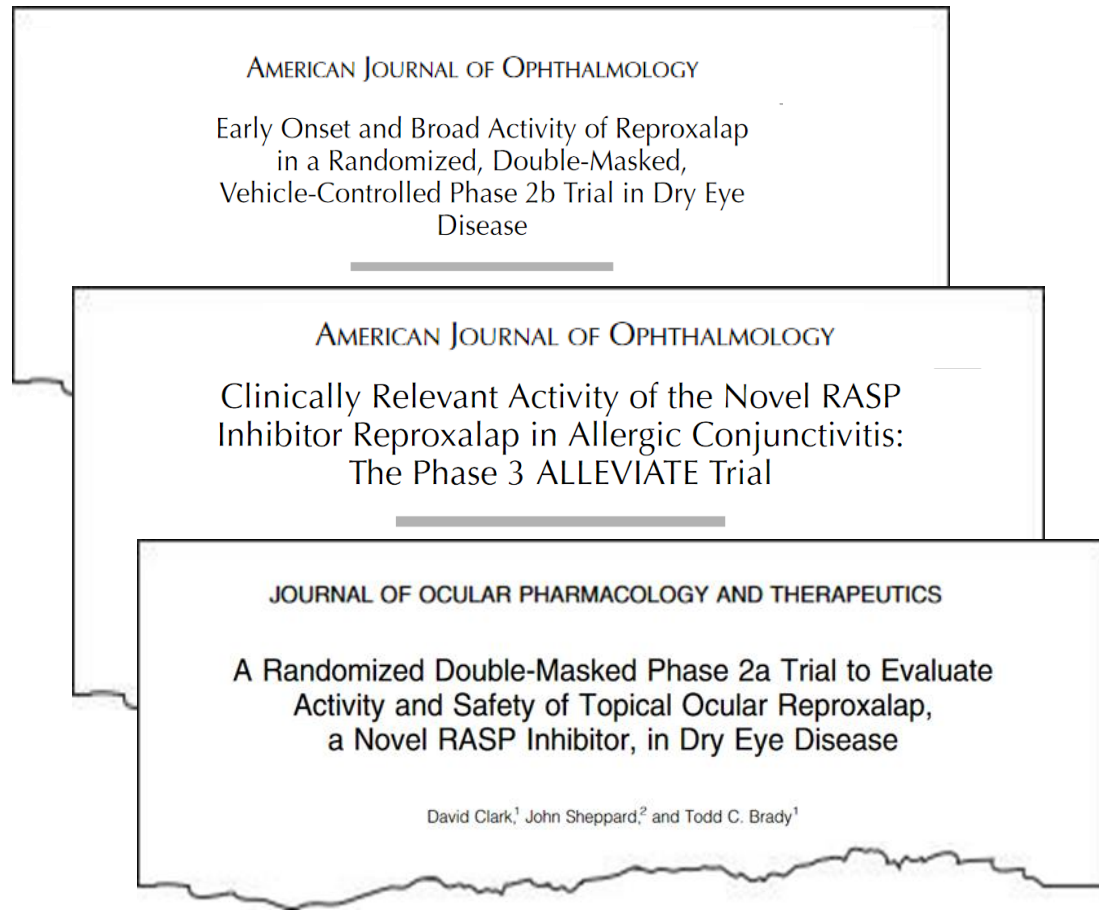
## Broad-Based Symptom Reduction



<sup>†</sup>Treatment difference of induction-maintenance dosing, defined as the difference between the changes from baseline for the evaluated drug minus vehicle (least squares mean difference ± 95% confidence interval). Ocular Dryness Score co-primary endpoint assessed in pre-specified patient population having an OD4S dryness baseline score of ≥ 3 (N=170). **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. **RASP** = reactive aldehyde species. **LPS** = lipopolysaccharide. **VAS** = visual analog scale. **OSDI** = Ocular Surface Disease Index. **NS** = not significant. **OD4SQ** = Ocular Discomfort & 4-Symptom Questionnaire. **CAC** = conjunctival allergen challenge.



# The Activity of Lead RASP Modulator Reproxalap is Supported by Marquee Peer-Reviewed Publications



# Reproxalap is in Late-Stage Development for Ocular Inflammation

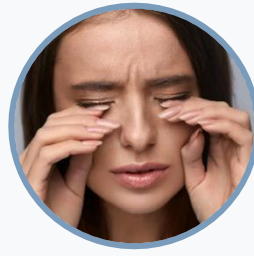
## DRY EYE DISEASE



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

Currently available topical therapy often requires months to demonstrate even modest efficacy.

## ALLERGIC CONJUNCTIVITIS



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

For patients that do not respond to over-the-counter antihistamine eyedrops, therapeutic options are limited.

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

**Sources:** <sup>1</sup>Company estimates and 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; <sup>2</sup>Company estimates and 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. Topical ocular reproxalap is an investigational new drug candidate that has been studied in more than 2,000 patients with no observed safety concerns; mild and transient instillation site irritation is the most commonly reported adverse event in clinical trials.



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

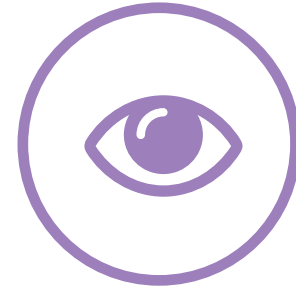
Potential advantages for patients and healthcare providers could effect a paradigm shift relative to standard of care.



Rapid symptom improvement

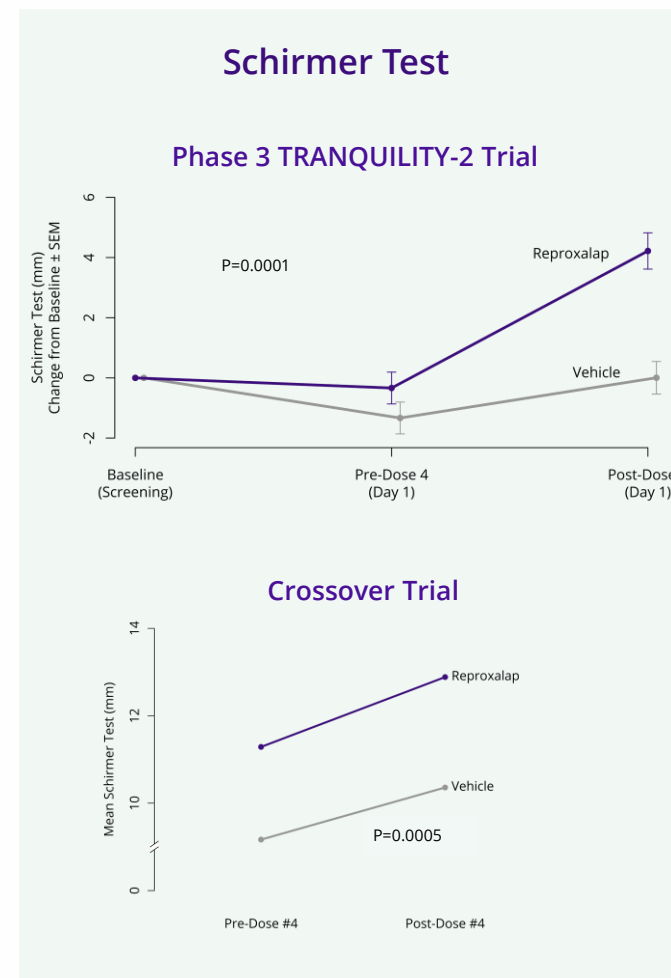
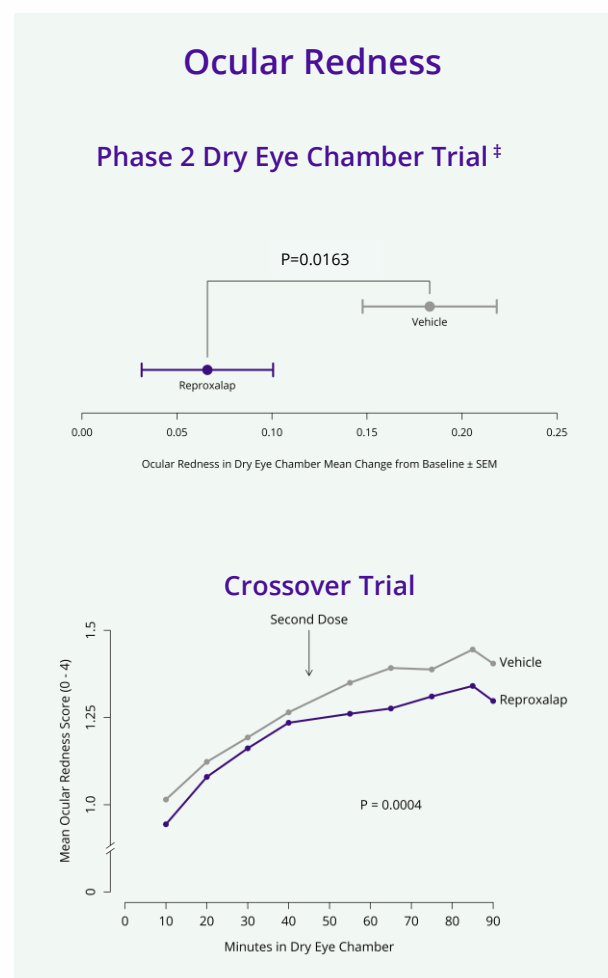
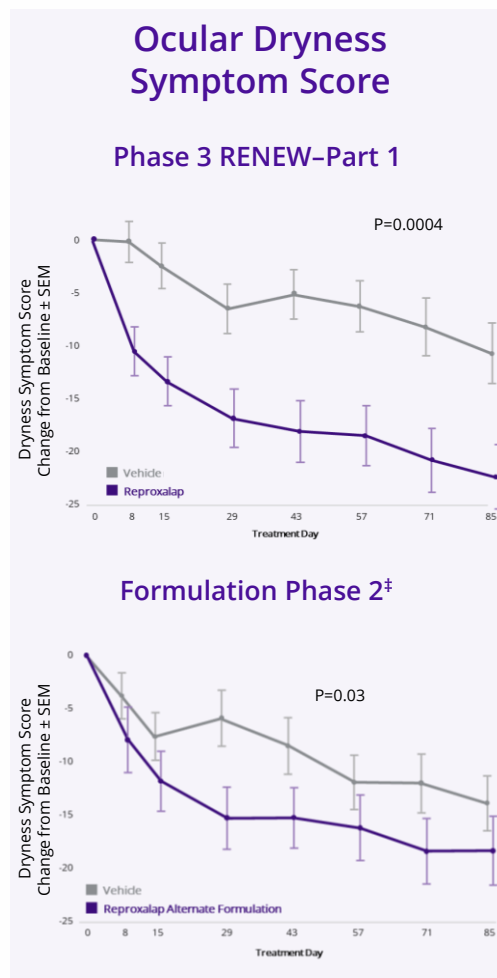


Broad symptomatic activity



Acute increase in tear production and reduction of ocular redness

# Aldeyra Has Submitted Symptom and Three Sign Endpoints for Satisfaction of Dry Eye Disease NDA Efficacy Requirements†



### ≥10 mm Schirmer Test Responder Analysis

Phase 3 TRANQUILITY-2 Trial

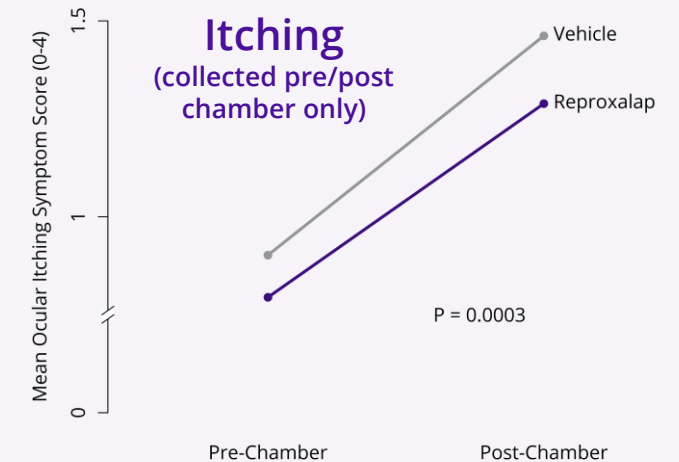
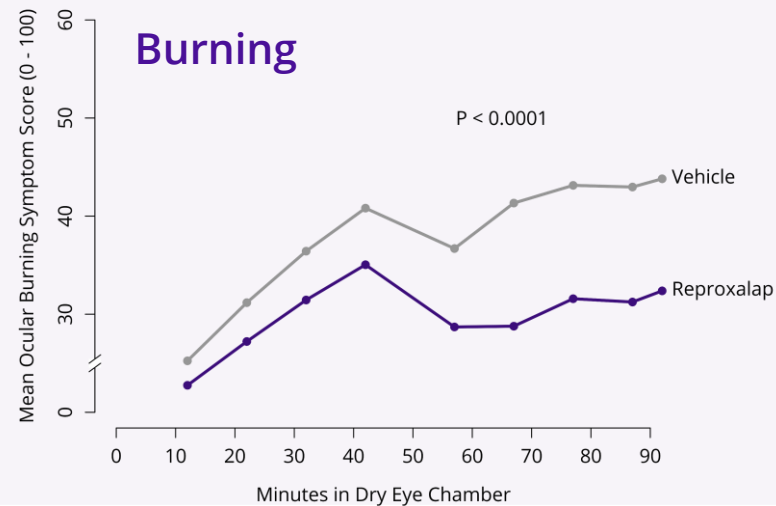
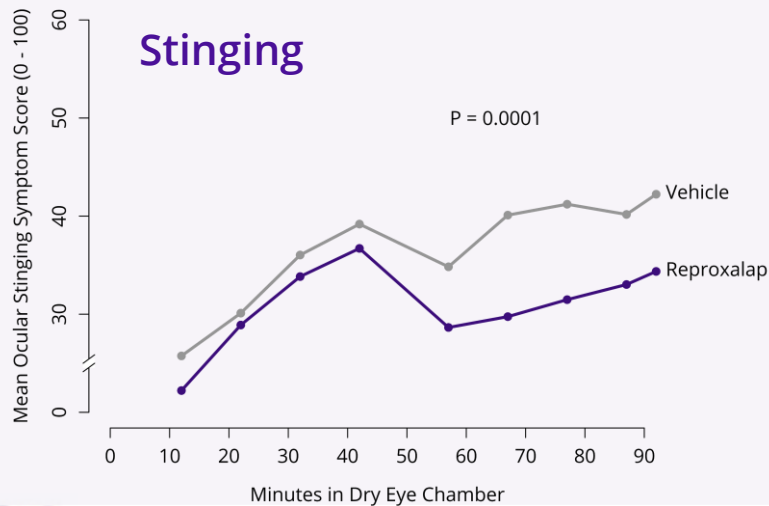
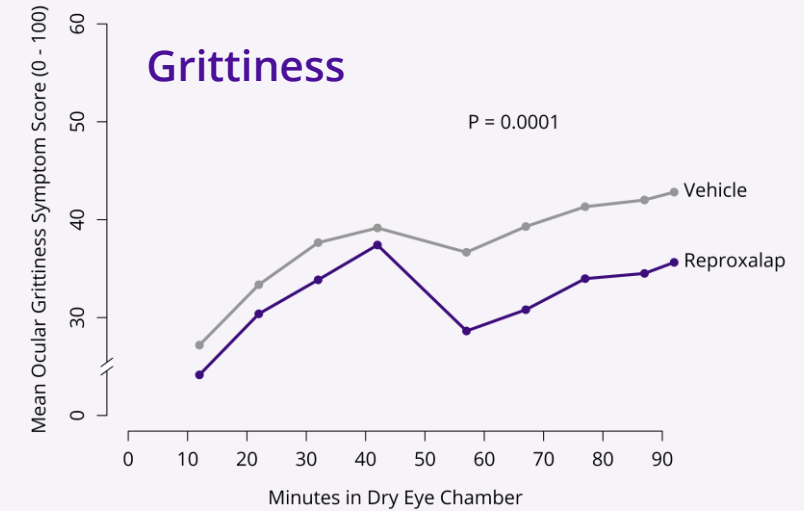
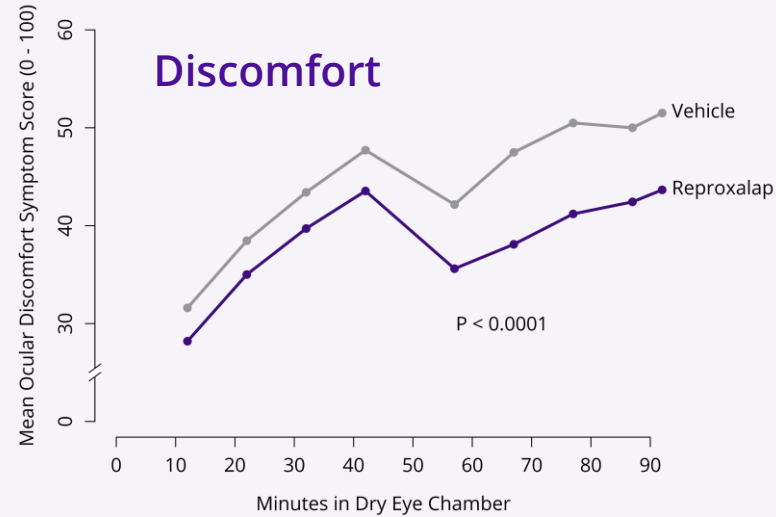
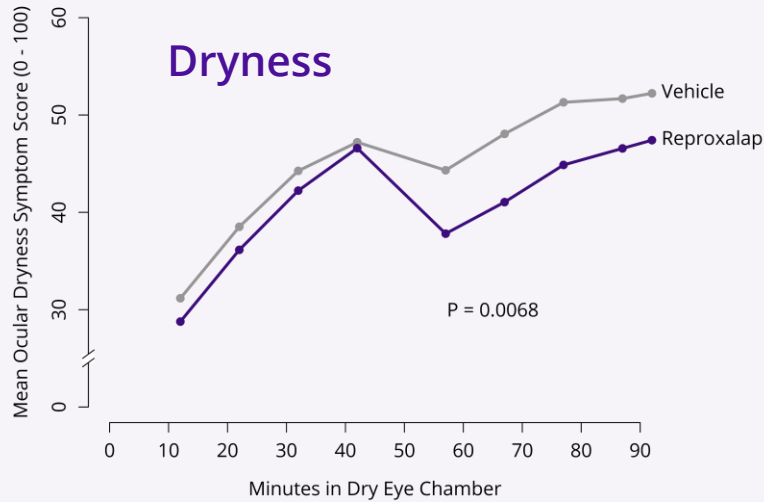
Change from Baseline	
Odds ratio	2.625
P value versus vehicle	<0.0001

Crossover Trial	
Raw Score	
Odds ratio	1.551
P value versus vehicle	0.0361

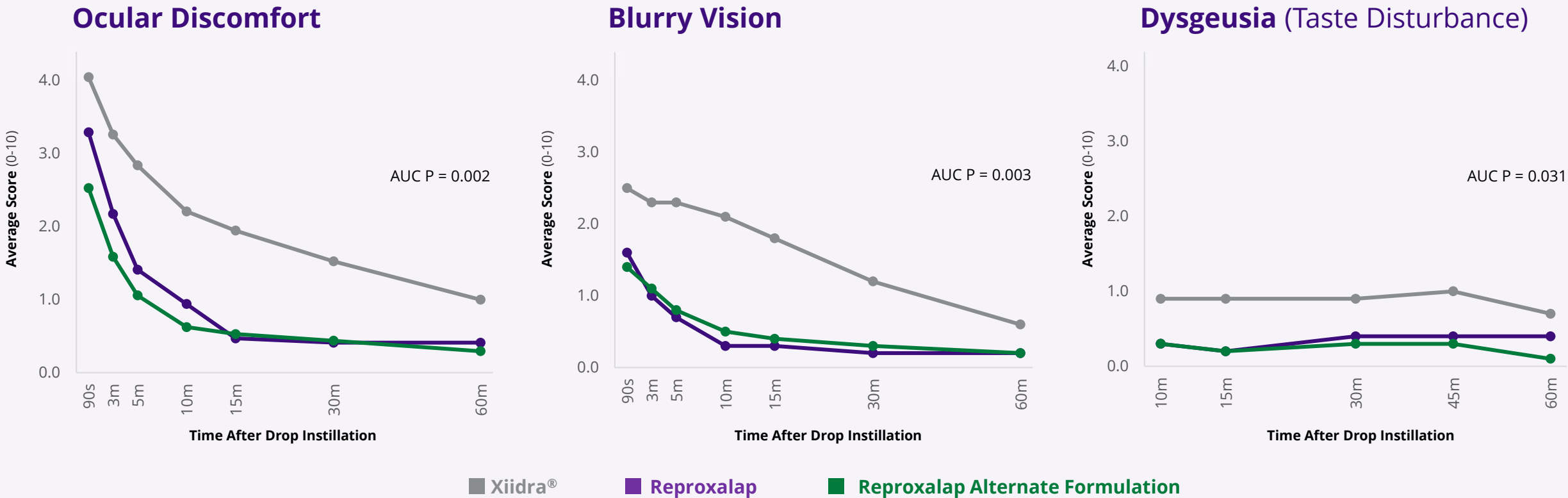
†The NDA submission includes a combination of primary, secondary, multiplicity-adjusted, and nominal P-value endpoints. ‡Adequate and well-controlled Phase 2 or Phase 3 clinical trials can be submitted as pivotal. **Sources:** Clinical trial results on file. **SEM** = standard error of the mean. Topical ocular reproxalap is an investigational drug candidate that has been studied in more than 2,000 patients with no observed safety concerns; mild and transient instillation site irritation is the most commonly reported adverse event in clinical trials.

# In the Dry Eye Disease Crossover Trial, All Assessed Symptom Endpoints Were Achieved



P values derived from mixed effect model of repeated measures of change from baseline. **Source:** Dry eye disease crossover clinical trial results on file. Topical ocular reproxalap is an investigational new drug candidate that has been studied in more than 2,000 patients with no observed safety concerns; mild and transient instillation site irritation is the most commonly reported adverse event in clinical trials.

# Tolerability of Reproxalap Was Statistically Superior to That of Xiidra® in a Post-Acute Ocular Tolerability Clinical Trial

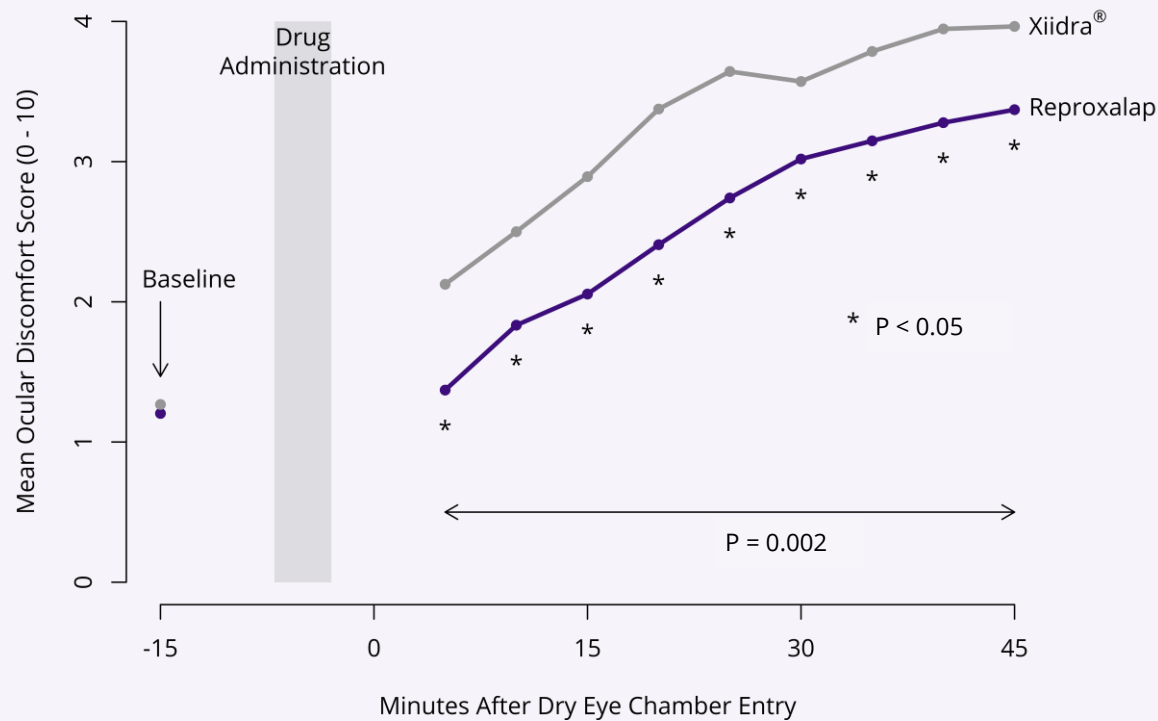


**Source:** McMullin D, Clark D, Cavanagh B, Karpecki P, Brady TC. A Post-Acute Ocular Tolerability Comparison of Topical Reproxalap 0.25% and Lifitegrast 5% in Patients with Dry Eye Disease. Clin Ophthalmol. 2021 Sep 22;15:3889-3900. **AUC** = area under the curve. P-values represent comparison of vehicle area under the curve vs. pooled reproxalap AUC. Topical ocular reproxalap is an investigational new drug candidate that has been studied in more than 2,000 patients with no observed safety concerns; mild and transient instillation site irritation is the most commonly reported adverse event in clinical trials.

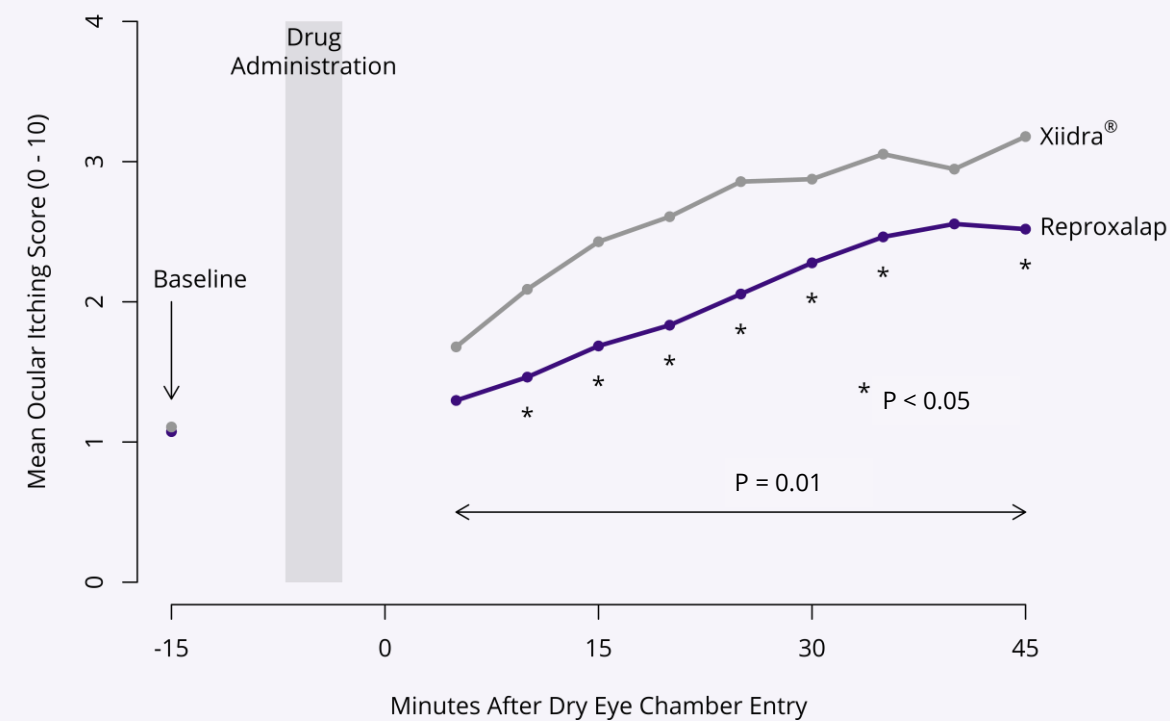


# Patient-Reported Ocular Discomfort and Ocular Itching Were Statistically Lower with Reproxalap than with Xiidra® in a Phase 2 Dry Eye Chamber Clinical Trial

Ocular Discomfort



Ocular Itching



**Source:** Clinical trial results on file. Topical ocular reproxalap is an investigational new drug candidate that has been studied in more than 2,000 patients with no observed safety concerns; mild and transient instillation site irritation is the most commonly reported adverse event in clinical trials.



# The Reproxalap Clinical Package is Believed to Represent the Most Comprehensive Dry Eye Disease NDA Submission<sup>†</sup> to Date

- The NDA is supported by previously announced safety and efficacy results from five adequate and well-controlled clinical trials encompassing data for ocular dryness symptom score, ocular redness, Schirmer test, and Schirmer test  $\geq 10$  mm responder analysis.
- The NDA includes activity ranging from within minutes of drug administration to up to 12 weeks of treatment, crossover and parallel-group clinical trial designs, and assessment in dry eye chamber challenge and natural environment settings.
- On February 7, Aldeyra announced that the FDA accepted the NDA for reproxalap and assigned a PDUFA date of November 23, 2023<sup>‡</sup>. If approved, reproxalap has the potential to be the first dry eye disease drug with at least two labeled objective signs, and the only topical ocular drug with evidence of activity within minutes of dosing.

<sup>†</sup>The NDA submission includes a combination of primary, secondary, multiplicity-adjusted, and nominal P-value endpoints. Topical ocular reproxalap is an investigational new drug candidate that has been studied in more than 2,000 patients with no observed safety concerns; mild and transient instillation site irritation is the most commonly reported adverse event in clinical trials.

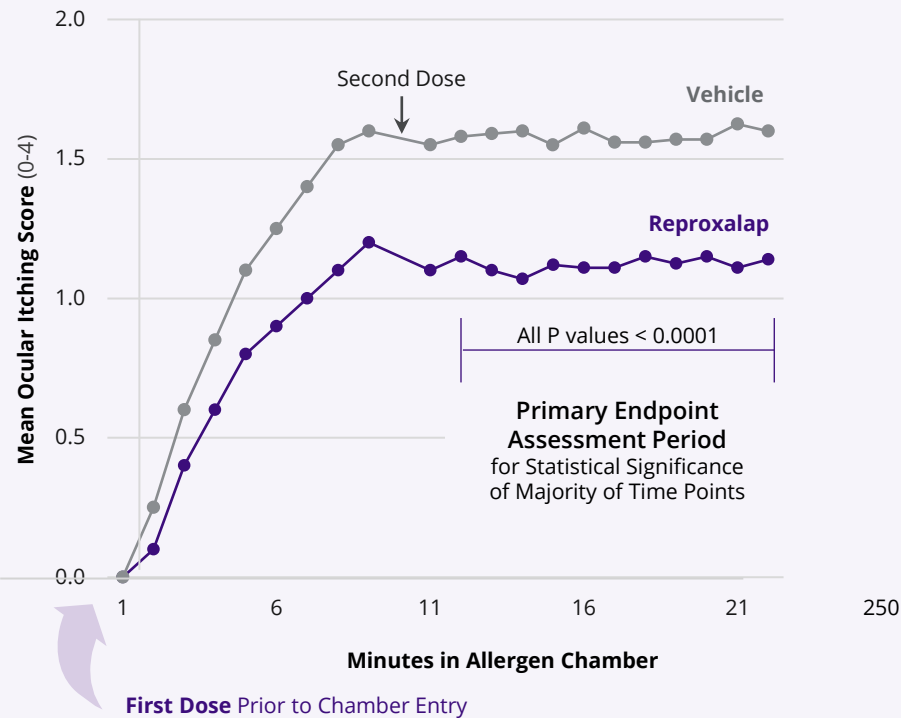
<sup>‡</sup>Regulatory review timelines are flexible and subject to change based on the regulator's workload and other potential review issues.

# Aldeyra is One Pivotal Trial Away from Potential NDA Submission of Reproxalap for Allergic Conjunctivitis<sup>†</sup>

## The Phase 3 INVIGORATE Allergen Chamber Trial

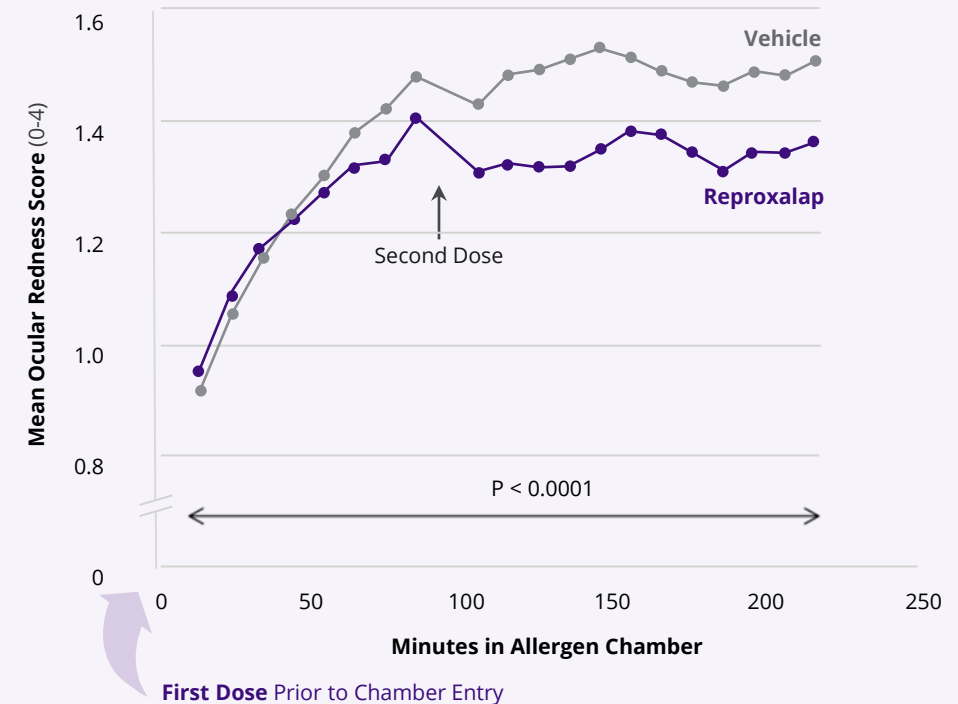
### Primary Endpoint

Reduction in Ocular Itching Over Pre-Specified Time Frame



### Key Secondary Endpoint

Reduction in Ocular Redness Over the Entire Chamber



<sup>†</sup>NDA submission requirements depend, in part, on clinical results, enrollment, and regulatory feedback. **Source:** INVIGORATE clinical trial results. Topical ocular reproxalap is an investigational new drug candidate that has been studied in more than 2,000 patients with no observed safety concerns; mild and transient instillation site irritation is the most commonly reported adverse event in clinical trials.

# The Phase 3 INVIGORATE-2 Trial is Designed to be Substantially Identical to INVIGORATE

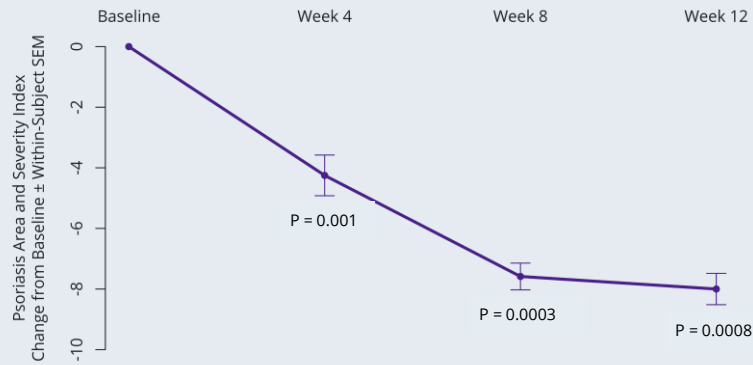
- Results are expected 2023.
- Enrollment criteria, endpoints, trial design, and study conduct are substantially identical to INVIGORATE.
- Based on data from INVIGORATE, simulation modeling indicates that more than 90% of outcomes achieved for the primary endpoint of patient-reported ocular itching.

<b>Design</b>	Randomized, double-masked, crossover, vehicle-allergen chamber exposure to aerosolized pollen over hours
<b>Dosing</b>	0.25% reproxalap or vehicle  One dose just prior to chamber entry, one dose 90 minutes after chamber entry
<b>Size</b>	Approximately 50 patients
<b>Primary Endpoint</b>	Patient-reported ocular itching score
<b>Key Secondary Endpoint</b>	Investigator-assessed ocular redness score

# ADX-629, a RASP Modulator for Oral Administration, Is a First-in-Class Pharmacologic Approach with Activity in Phase 2 Clinical Trials



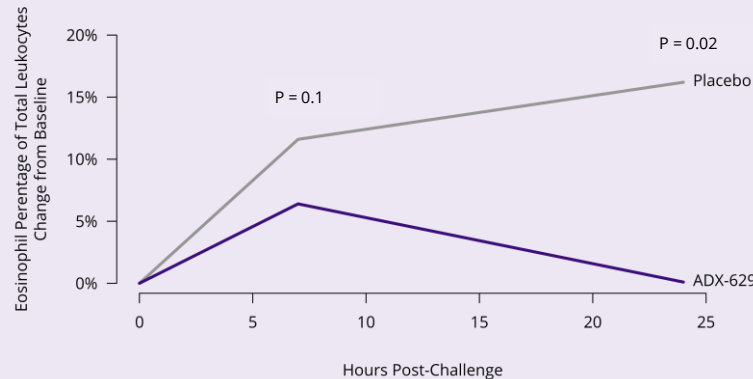
## Autoimmune Disease: Psoriasis



**SEM** = standard error of the mean. P values derived from mixed model for repeated measures analysis of comparison to 0 (no change).



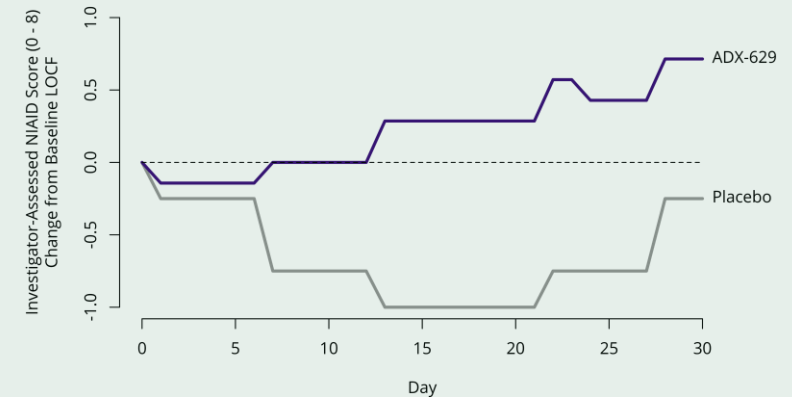
## Allergic Inflammation: Asthma



P values are derived from mixed model for repeated measures analysis of placebo group comparison to 0 (no change).



## Infectious Disease: COVID-19



**NIAID** = National Institute of Allergy and Infectious Diseases.  
**LOCF** = Last Observation Carried Forward.

# New Clinical Development Indications for ADX-629 Feature Multiple Systemic Diseases Associated with RASP



## Moderate Alcohol-Associated Hepatitis

~**12M adults** in the U.S. have alcohol-associated liver disease.

In a Phase 2 clinical trial, ADX-629 **reduced dermal flushing** and **improved balance time** following alcohol intoxication.



## Chronic Cough

**Approximately 13M adults in the U.S.**, and up to 10% of people worldwide, have chronic cough.

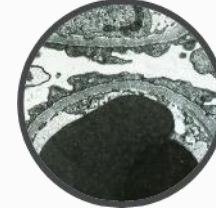
**RASP are increased** in the lungs of patients with chronic cough.<sup>†</sup>



## Sjögren-Larsson Syndrome

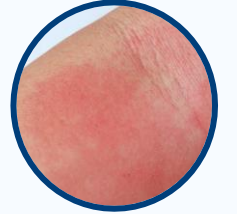
Sjögren-Larsson Syndrome is an autosomal recessive neurocutaneous **inborn error of metabolism** preventing degradation of fatty aldehydes.

**Approximately 1,300 U.S. patients** are impacted.



## Idiopathic Nephrotic Syndrome

Idiopathic nephrotic syndrome is comprised of a broad group of **renal inflammatory diseases**, including minimal change disease, and is characterized by edema, proteinuria, and hypoalbuminemia.



## Atopic Dermatitis

Atopic dermatitis is a **chronic hypersensitivity condition** that is characterized by dry, itchy, and inflamed skin, and **commonly affects children and adults**.



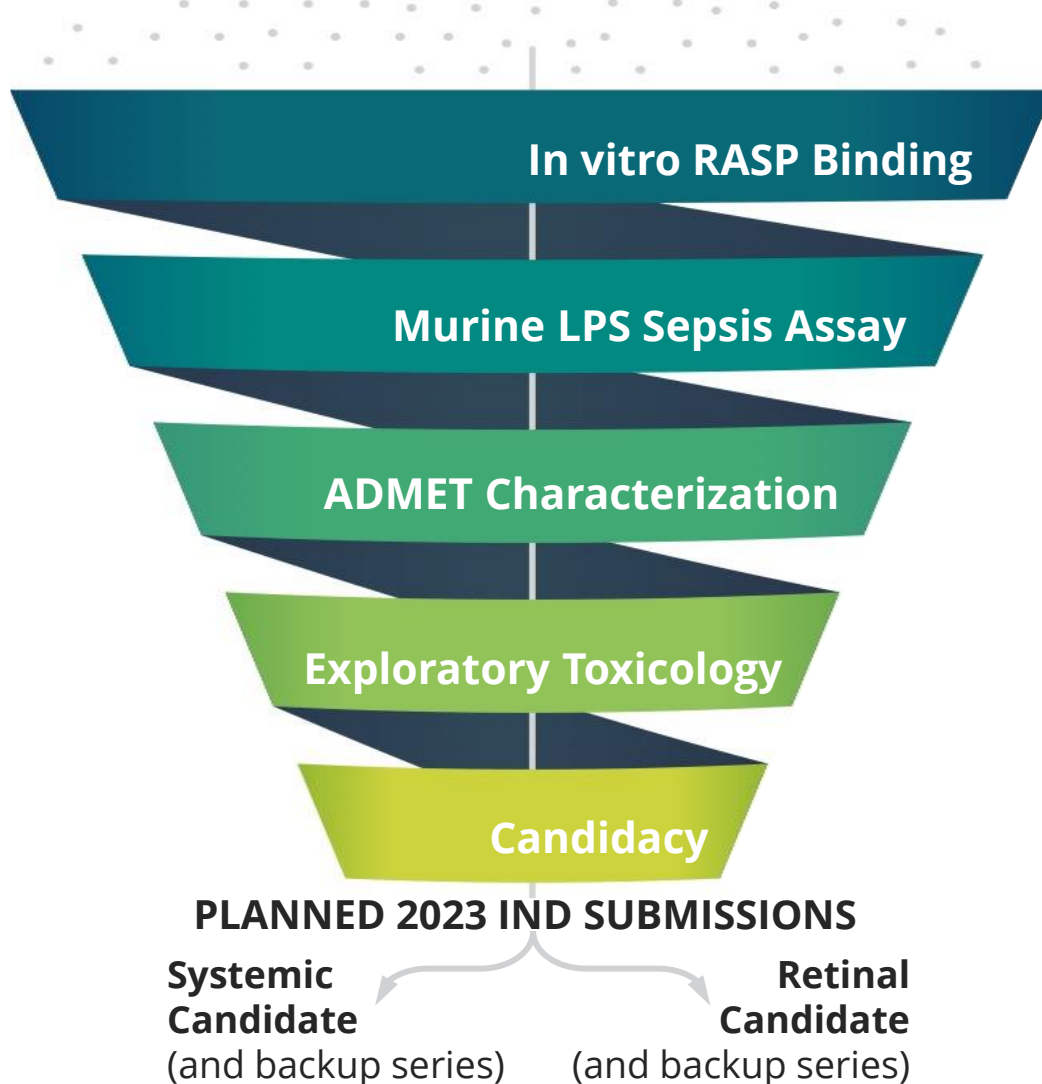
# ADX-629 Phase 2 Trials Represent Varied Designs

INDICATION	PLANNED DESIGN	PLANNED ENDPOINTS	UPCOMING MILESTONE <sup>†</sup>
<b>Chronic Cough</b>	Multicenter, placebo-controlled, crossover, days, ~50 patients	Cough frequency, symptoms	Completion H1 2023
<b>Sjögren-Larsson Syndrome<sup>‡</sup></b>	Single-center, open-label, 12 weeks, up to 10 patients	Plasma biomarkers, magnetic resonance quality of life	Completion 2023
<b>Idiopathic Nephrotic Syndrome</b>	Multicenter, placebo-controlled, two-part, parallel-group, 12 weeks, 5 patients (Part 1)	Relapse (corticosteroid dependency,	Part 1 Completion 2023
<b>Moderate Alcohol-Associated Hepatitis<sup>‡</sup></b>	Single-center, placebo-controlled, two-part, parallel-group, 6 weeks, 10 patients (Part 1)	MELD/Lille scores, liver function tests, survival	Initiation 2023
<b>Atopic Dermatitis</b>	Multicenter, placebo-controlled, two-part, parallel-group, 12 weeks, 10 patients (Part 1)	Investigator Global Assessment, Eczema Area Severity Index scores	Part 1 Completion 2023



<sup>†</sup>Timing depends, in part, on the availability of clinical research facilities and staffing, the ability to recruit patients, and regulatory feedback. <sup>‡</sup>Investigator sponsored.  
**MELD** = Model for End-Stage Liver Disease.

# New Candidates for Systemic and Retinal Diseases Expected to be Advanced to Clinical Trials in 2023



Aldeyra has developed the leading RASP modulation discovery platform.

**LPS** = lipopolysaccharide

**ADMET** = absorption, distribution, metabolism, excretion, and toxicity

**IND** = Investigational New Drug



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## **ADX-2191 (METHOTREXATE INJECTION, USP) FOR INTRAVITREAL ADMINISTRATION**

# A Platform Approach to Treat Rare Inflammatory Retinal Diseases

# ADX-2191, an Investigational Vitreous-Compatible Formulation of Methotrexate, Represents a Platform Approach for Rare Retinal Diseases

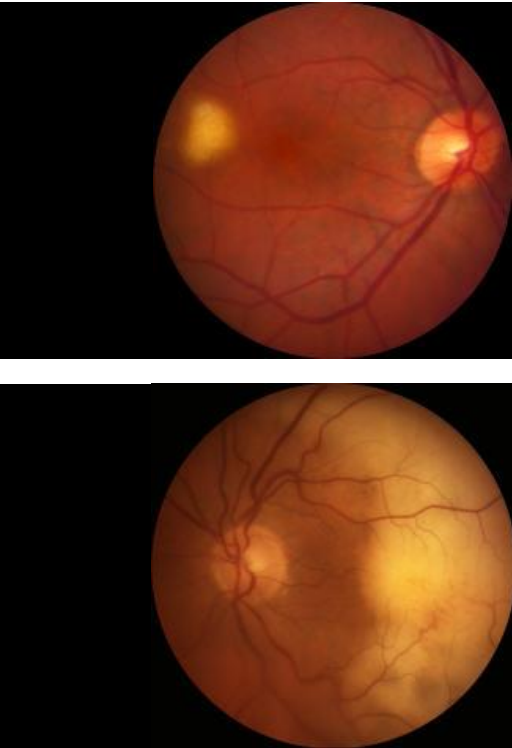
ADX-2191 (methotrexate injection, USP) is the first sterile, non-compounded formulation of methotrexate designed to meet the unique requirements of intravitreal administration for specific rare retinal diseases, including primary vitreoretinal lymphoma and proliferative vitreoretinopathy.

The ADX-2191 intravitreal formulation is designed to be vitreous-compatible and optimized for excipient composition, viscosity, density, tonicity, pH, active ingredient concentration, and volume of administration.

ADX-2191 has received U.S. FDA Orphan Drug Designation for proliferative vitreoretinopathy, primary vitreoretinal lymphoma, and retinitis pigmentosa.



# ADX-2191 Has the Potential to be the First 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 **300-600 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.

**U.S. FDA Orphan Drug Designation** received in July 2021.

**NDA Submitted; Acceptance of NDA Expected in Q1 2023**



# If Approved, ADX-2191 will be the First cGMP Manufactured Methotrexate Drug Product for Intravitreal Administration

- Aldeyra submitted an NDA for ADX-2191 (methotrexate injection, USP) for the treatment of primary vitreoretinal lymphoma in Q4 2022.
- The NDA submission is supported by a combination of published literature on the safety and efficacy of methotrexate for the treatment of primary vitreoretinal lymphoma and safety data from the recently completed Phase 3 GUARD Trial of ADX-2191 for the prevention of proliferative vitreoretinopathy.
- As part of the NDA submission, Aldeyra requested Priority Review Designation, which reduces the review period during which the FDA aims to take action on an NDA to within 6 months, compared to 10 months under standard review.



# 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.



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 one of the main courses of action.

## ADX-2191

ADX-2191 was granted **U.S. FDA Orphan Drug Designation** and **U.S. FDA Fast Track Designation** for the prevention of PVR, and **EU Orphan Medicinal Product Designation** for the treatment of retinal detachment.

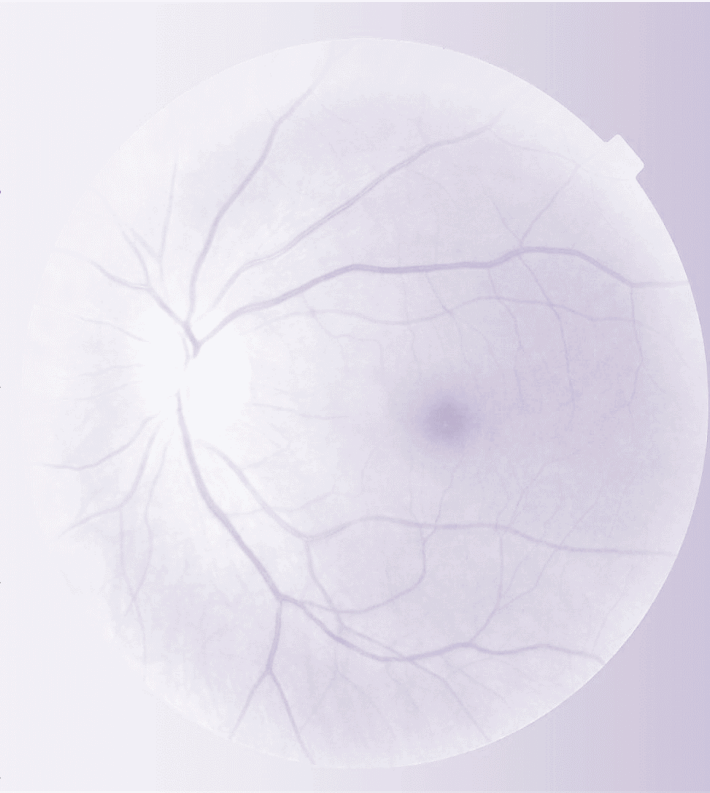
**Tolerability and reattachment success was demonstrated** in the Phase 3 GUARD trial.

**Published clinical data support the use of methotrexate** for the prevention of recurrent retinal detachment due to PVR.

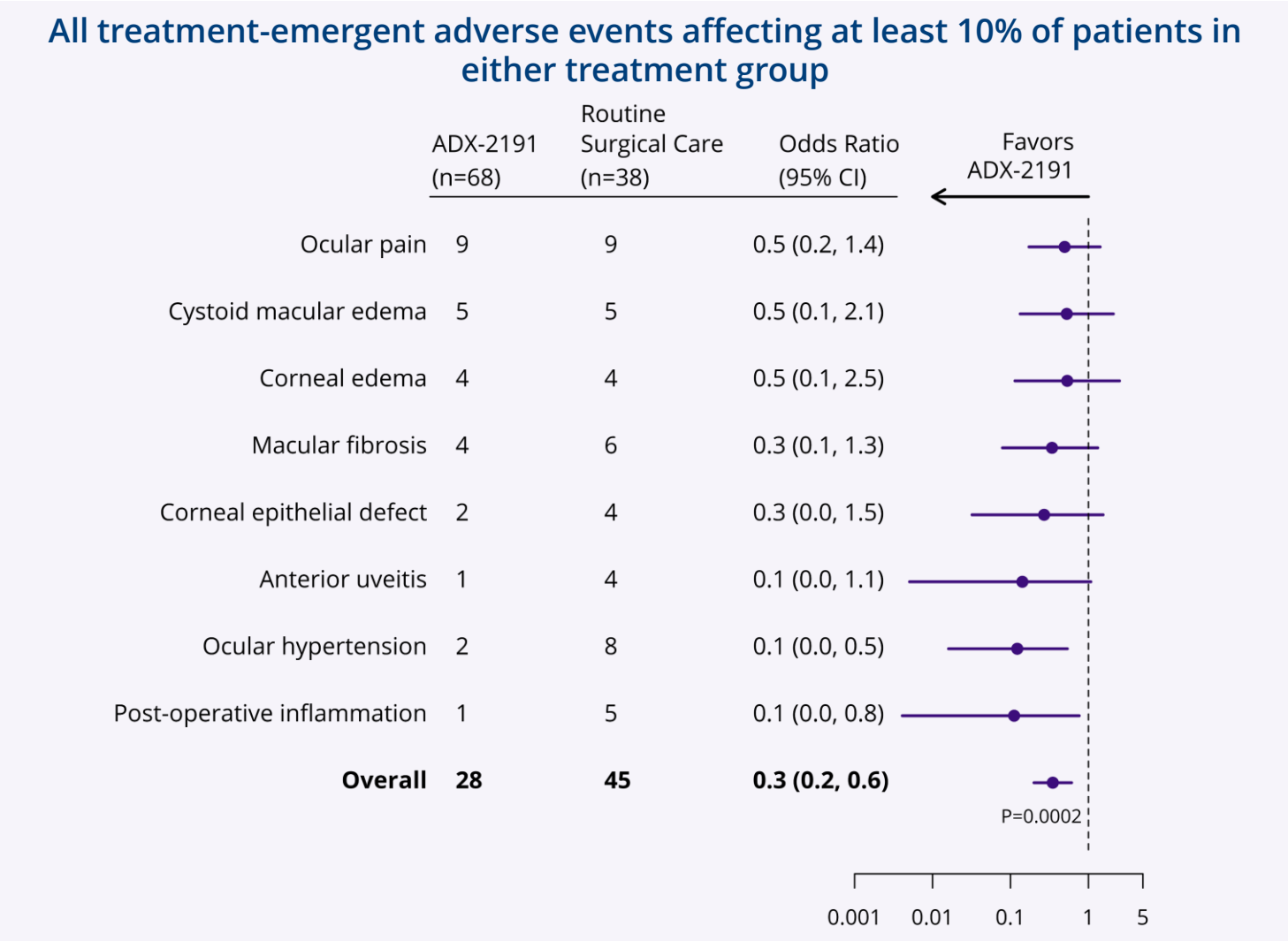
**Type C Meeting with the FDA Planned in H1 2023**

# In the Phase 3 GUARD Trial of ADX-2191 in PVR, the Primary Endpoint Was Achieved

	ADX-2191 (n=68)	Historical Control <sup>†</sup> (n=292)
Patients with retinal detachment within months of surgery	16	113
Odds ratio (95% CI) vs. historical control	0.49 (0.26, 0.89)	
P value vs. historical control*	0.024	



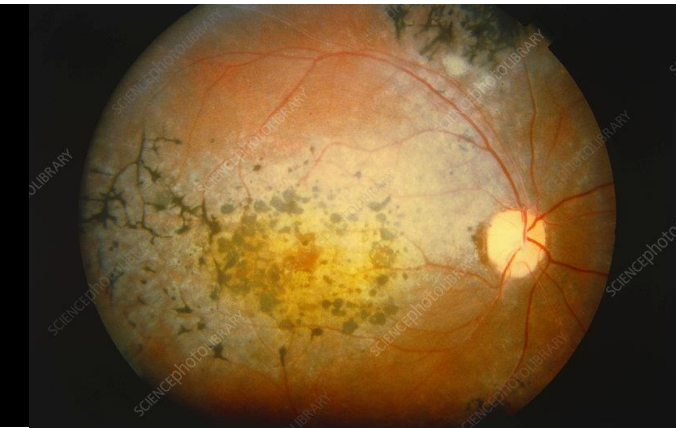
# ADX-2191 Was Numerically Favored Over Routine Surgical Care for Key Safety Endpoints



CI = confidence interval. P value derived from random effect meta-analysis. ADX-2191 (methotrexate injection, USP) for intravitreal administration is an investigational drug candidate. The most common adverse event associated with ADX-2191 administration was punctate keratitis, a well-known side effect of intravitreal methotrexate.

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

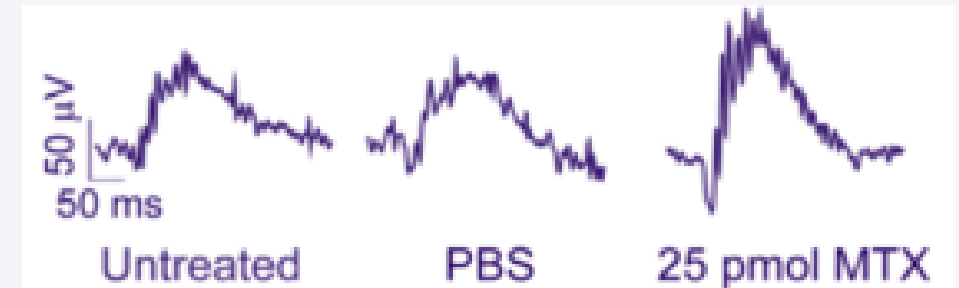
RP refers to a group of inherited retinal diseases characterized by cell death and loss of vision.



**Affects an estimated 82,000 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.

**U.S. FDA Orphan Drug Designation** received in August 2021



**Preclinical evidence in a P23H rhodopsin mutation mouse model of RP suggests that methotrexate improves retinal function.**

**Phase 2 Clinical Trial Results Expected H1 2023**



# ADX-2191: Phase 2 Clinical Trial Design in Retinitis Pigmentosa

## 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



**Bruce Greenberg, C.P.A.**  
VP of Finance, Interim Chief  
Financial Officer, and Treasurer



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



## BOARD OF DIRECTORS

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

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

**Marty Joyce** Former CFO of Serono USA

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

**Gary Phillips, M.D.** CBO Anaveon AG

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

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

# Upcoming Planned Clinical Milestones



## **Dry Eye Disease**

PDUFA date of November 23, 2023<sup>†</sup>

## **Allergic Conjunctivitis**

Phase 3 INVIGORATE 2 trial results expected 2023<sup>‡</sup>



## **Primary Vitreoretinal Lymphoma**

Acceptance of NDA submission expected Q1 2023

## **Proliferative Vitreoretinopathy**

Planned Type C meeting with FDA in H1 2023 to discuss completion of clinical development

## **Retinitis Pigmentosa**

Phase 2 clinical trial results expected in H1 2023<sup>‡</sup>



## **Atopic Dermatitis (Part 1), Chronic Cough, Idiopathic Nephrotic Syndrome (Part 1), and Sjögren-Larsson Syndrome\***

Completion of Phase 2 clinical trials expected in 2023<sup>‡</sup>

## **Moderate Alcohol-Associated Hepatitis\***

Initiation of Phase 2 clinical trial expected in 2023<sup>‡</sup>

# We Are Creating What We Believe Are Best-in-Class Therapeutic Platforms for Modulation of Inflammatory Disease

**Unparalleled drug discovery and development engine targeting RASP, with multiple early and late-stage milestones expected over the next two years<sup>†</sup>**

- The FDA has accepted the dry eye disease NDA for reproxalap, and has assigned a PDUFA date of November 23, 2023.<sup>‡</sup>
- ADX-629 is advancing to Phase 2 trials in five new indications.
- New compounds for systemic and retinal disease are expected to begin clinical trials in 2023.

**Novel intravitreal methotrexate formulation with orphan drug status in three rare retinal diseases**

- ADX-2191 could be the first approved therapy for primary vitreoretinal lymphoma, proliferative vitreoretinopathy, and retinitis pigmentosa.
- Acceptance of NDA submission for ADX-2191 in primary vitreoretinal lymphoma is expected in Q1 2023.



<sup>†</sup>Timing depends, in part, on the availability of clinical research facilities and staffing, the ability to recruit patients, and regulatory feedback. <sup>‡</sup>Regulatory review timelines are flexible and subject to change based on the regulator's workload and other potential review issues. **NDA** = New Drug Application.



February 2023

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## **CORPORATE OVERVIEW**

# Innovative Therapeutics to Treat Immune-Mediated Diseases