



March 2020

CORPORATE REVIEW

A New Paradigm for the Treatment of Immune-Mediated Diseases

Nasdaq: ALDX
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Mission and Value Proposition

Developing Next-Generation Medicines to Improve the Lives of Patients with Immune-Mediated Diseases



DEEP AND INNOVATIVE PIPELINE

- RASP-inhibition represents first-in-class therapeutic approach.
- ADX-2191 is the first potential approved therapy for PVR.



NEAR-TERM DEVELOPMENT CATALYSTS

- INVIGORATE Phase 3 clinical trial is ongoing.
- GUARD Phase 3 clinical trial is ongoing.



SIGNIFICANT MARKET OPPORTUNITY

- Reproxalap targets an U.S. addressable market of >\$20B.
- ADX-2191 represents a potential therapeutic breakthrough.



SOLID CASH POSITION

- Cash, cash equivalents and marketable securities were \$73.4 million as of December 31, 2019.



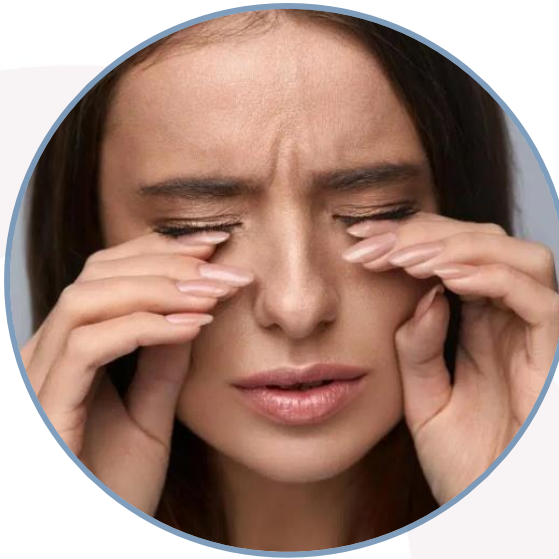
Three Late-Stage Ocular Programs Targeting Significant Unmet Needs

Dry Eye Disease



Often months to demonstrate even modest efficacy with current Rx

Allergic Conjunctivitis



Unchecked growing disease burden and limited options beyond OTC/Rx antihistamines

Proliferative Vitreoretinopathy



No approved therapy

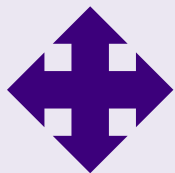
Our Lead Programs Represent Compelling Commercial Opportunities

Dry Eye Disease

Reproxalap 0.25%



Early and consistent symptom and sign improvements in clinical trials*



Broad symptom and sign improvements in clinical trials*

**RENEW-Part 1 Phase 3
Completed December 2019**

Allergic Conjunctivitis

Reproxalap 0.25%



Clinically significant and durable symptom response in allergen chamber trial



Active in post-histaminic allergy, for which no drug is approved

**INVIGORATE Phase 3
Initiated January 2020**

Proliferative Vitreoretinopathy

ADX-2191



Potential therapeutic breakthrough for PVR
✓ U.S. orphan designation
✓ FDA fast track designation



Reattachment success and tolerability demonstrated in Phase 1b clinical trial**

**GUARD Phase 3 - Part 1
Initiated December 2019**



March 2020

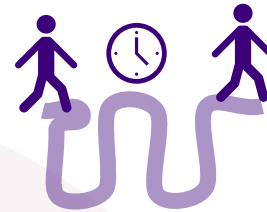
CORPORATE REVIEW

Reproxalap For The Treatment Of Dry Eye Disease

Dry Eye Disease Is a Persistently Disturbing and Inadequately Treated Condition



34 million or more **adults in the U.S.** suffer from dry eye disease.



Current Rx options **may require up to six weeks or longer** to achieve even modest efficacy.



Only 5% of diagnosed dry eye disease patients **utilize current Rx treatments.**



Between 50% and 80% of Rx treated dry eye disease **patients drop off of therapy** between their second and third refill.

The dry eye disease patient population is underserved, and novel therapies are in demand.

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

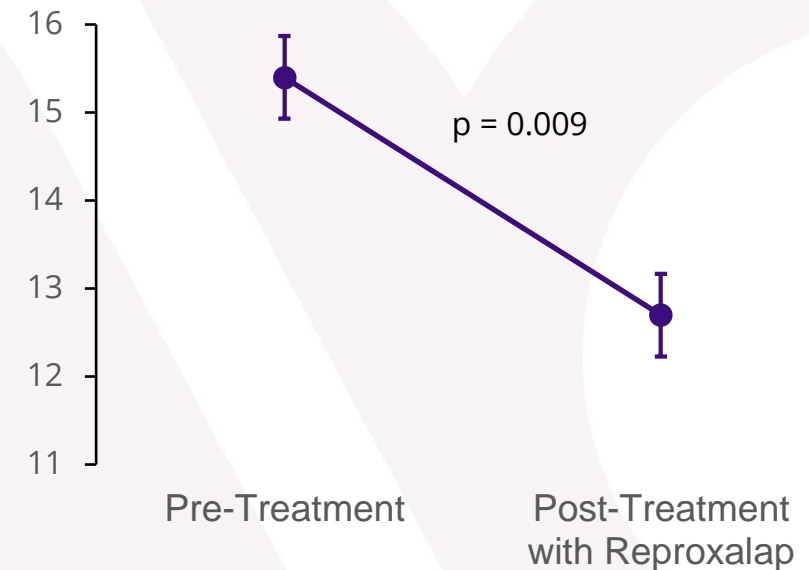
RASP in Dry Eye Disease

- RASP markers are upregulated in patients with dry eye disease.
- RASP accumulation leads to changes in tear film and triggers an inflammatory response that can lead to acute and chronic inflammation.
- RASP levels have been shown to correlate with worsening of dry eye disease symptoms and signs.
- **To our knowledge, reproxalap is the first dry eye disease drug to show biomarker changes correlated with clinical efficacy.**

Reproxalap

- In a Phase 2a clinical trial, **reproxalap significantly reduced RASP adduct levels.**

Tear RASP Levels in Dry Eye Disease Patients
(μM Malondialdehyde Adduct; Mean \pm Within-Subject SEM)



Reproxalap Dry Eye Disease Clinical Development Program Overview

DRY EYE DISEASE

✓

PHASE 2a – Efficacy/safety of two concentrations (0.1%, 0.5%)		
51 patients	4 weeks	DED symptoms and signs

✓

PHASE 2b – Efficacy/safety of two concentrations (0.1%, 0.25%) vs. vehicle		
300 patients	12 weeks	DED symptoms and signs

✓

Drop Experience – Reproxalap (0.25%) vs. Xiidra®		
19 patients	1 hour post-dosing	Drop experience in DED patients

✓

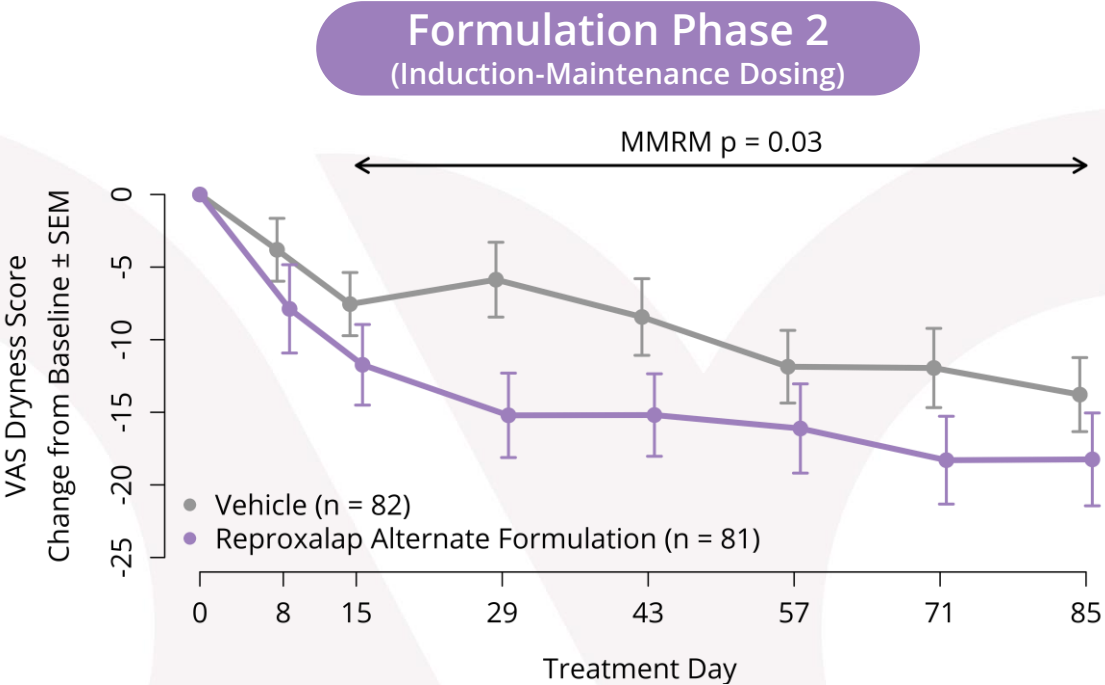
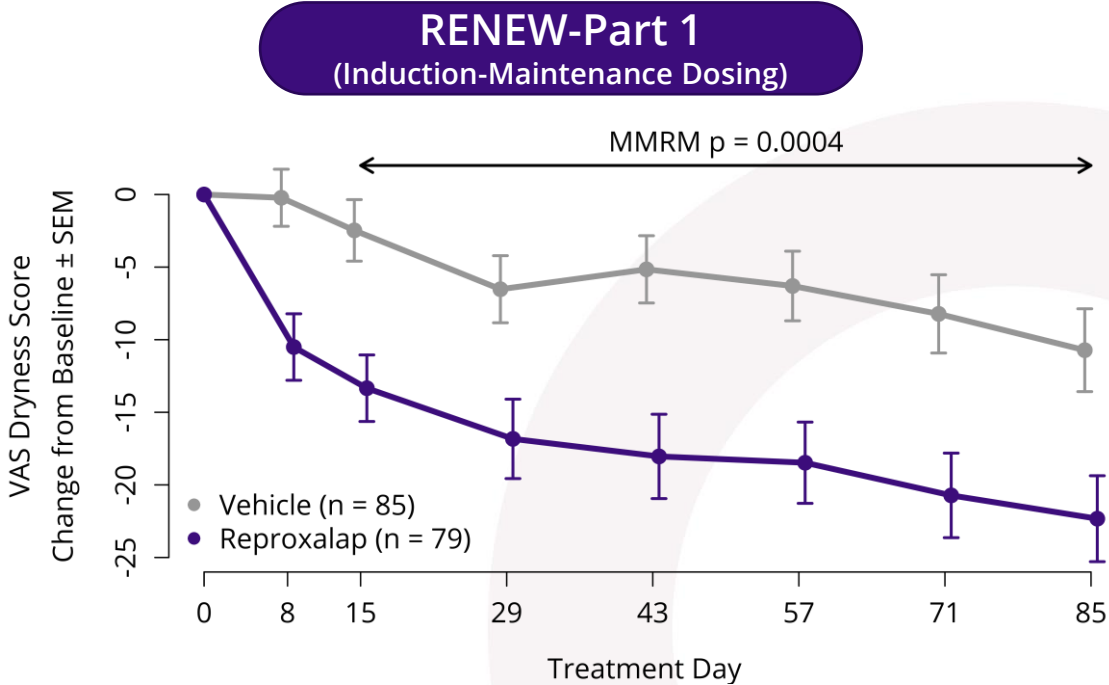
RENEW-Part 1 – Two-part adaptive Phase 3; Efficacy/safety (0.25%) vs. vehicle		
422 patients	12 weeks	Constant vs. induction/maintenance dosing*

✓

Formulation PHASE 2 – Efficacy/safety of alternate (0.25%) formulation vs. vehicle		
206 patients	12 weeks	Induction / maintenance dosing*

Reproxalap Met Dryness Symptom Primary Endpoint in RENEW-Part 1 and Formulation Phase 2 Clinical Trial

Ocular Dryness Score (VAS) Change From Baseline
Dryness (OD4SQ) Baseline Score ≥ 3

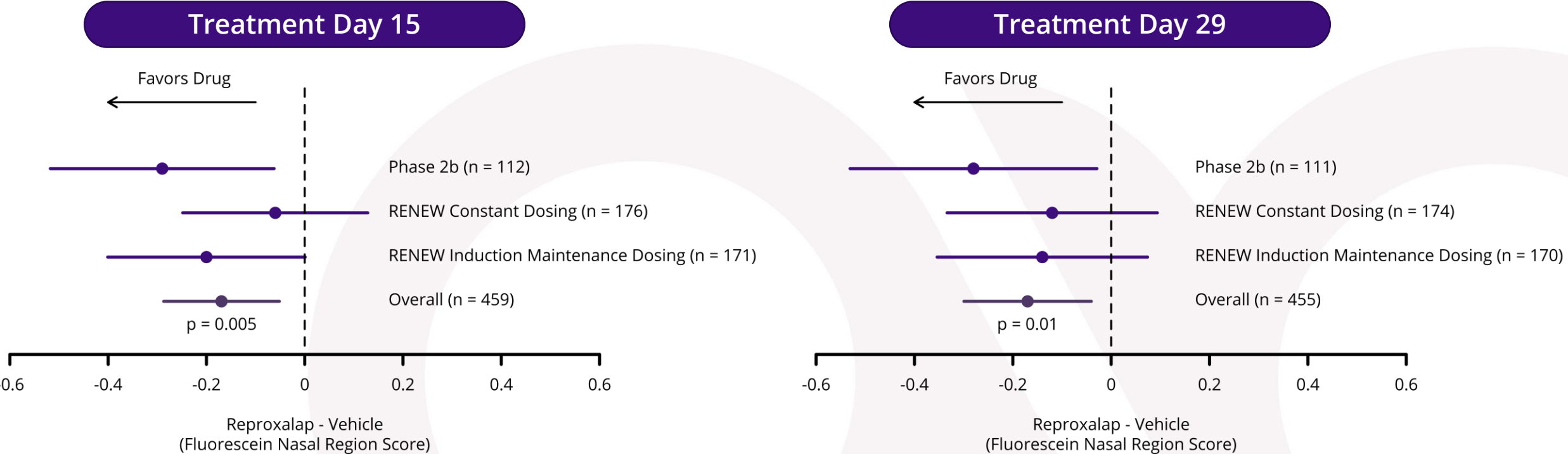


Topical ocular reproxalap has been studied in over 1,100 patients with no observed safety concerns; mild instillation site irritation is the most commonly reported adverse event in clinical trials.
Source: Reproxalap RENEW-Part 1 and Formulation Phase 2 DED clinical trial results.

OD4SQ = Ocular Dryness 4-Symptom Questionnaire
VAS = Visual Analog Scale
MMRM = Mixed Effect Model Repeated Measures

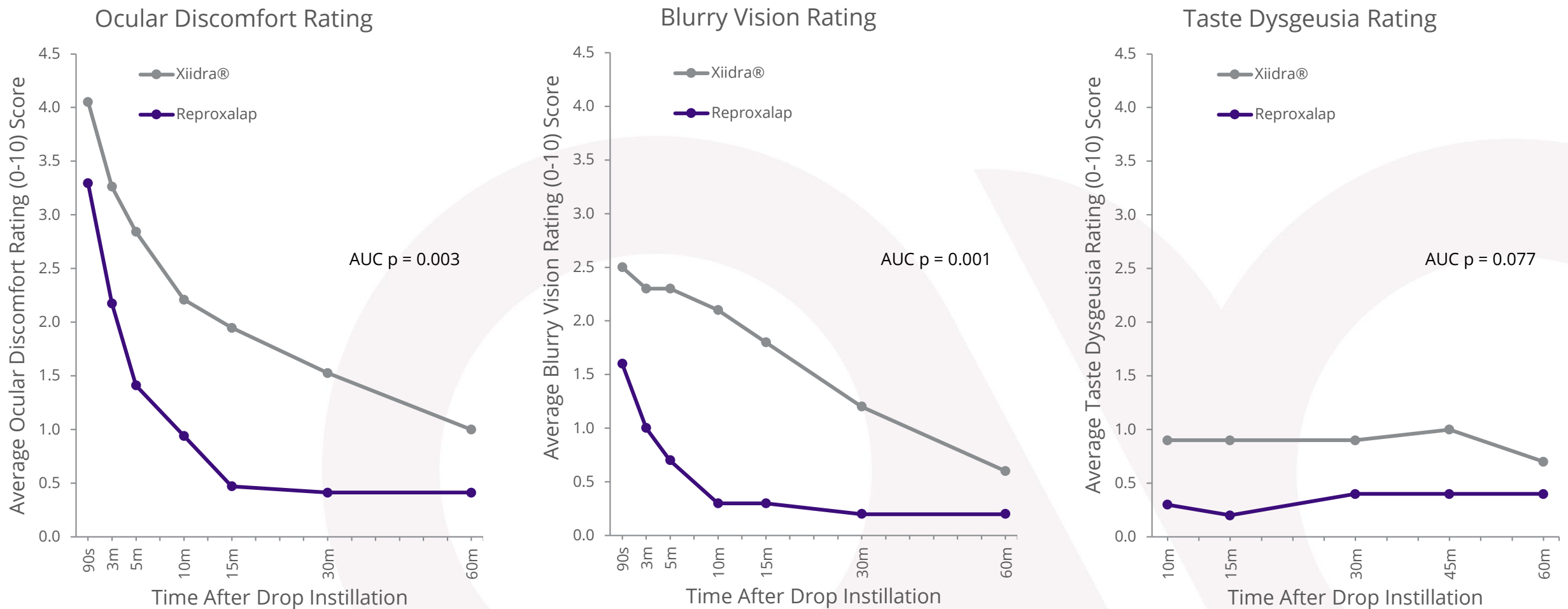
Data from RENEW-Part 1 and Phase 2b Clinical Trial Suggest Rapid and Potent Ocular Staining Control Relative to Vehicle

Fluorescein Staining (Nasal Region) Treatment Difference (Drug-Vehicle)
Baseline Score ≥ 2



Patient n values shown represent the total of drug and vehicle patients. Topical ocular reproxalap has been studied in over 1,100 patients with no observed safety concerns; mild instillation site irritation is the most commonly reported adverse event in clinical trials. Source: Reproxalap RENEW-Part 1 and Phase 2b DED clinical trial results.

Reproxalap Drop Experience Compares Favorably Versus Xiidra® Over One Hour Post-Instillation in Dry Eye Disease Patients



Reproxalap in Dry Eye Disease

- Reproxalap has met the pre-specified symptom endpoint in RENEW-Part 1 and Formulation Phase 2 clinical trials.
- Combined data from RENEW-Part 1 and Phase 2b clinical trial suggest rapid and potent activity vs. vehicle in ocular dryness and fluorescein staining.
- Tolerability of Reproxalap over one hour post-instillation statistically superior to Xiidra® in dry eye disease patients.
- Subsequent development plans are contingent on FDA feedback.



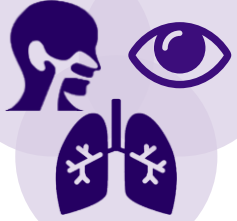
March 2020

CORPORATE REVIEW

Reproxalap For The Treatment Of Allergic Conjunctivitis

The Prevalence and Economic Burden of Allergic Conjunctivitis is Rising

Allergic Rhinitis



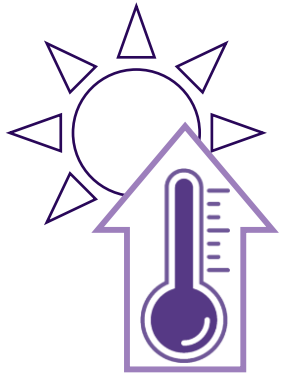
Allergic Conjunctivitis

Allergic Asthma

Allergic diseases are hyperendemic and prevalence is increasing.



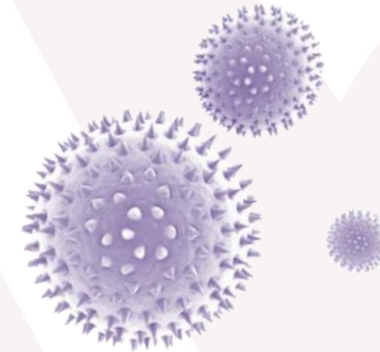
Allergic conjunctivitis affects **more than 1 billion people worldwide**, including 100 million in the U.S..



Temperatures and CO₂ levels are rising.



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



Pollen is spreading to **new areas.**

Millions of patients continue to suffer and new treatments are needed

Physicians and Patients Say That Currently Available Allergic Conjunctivitis Treatments Are Inadequate



66 million or more **people** in the U.S. suffer from allergic conjunctivitis.



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



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



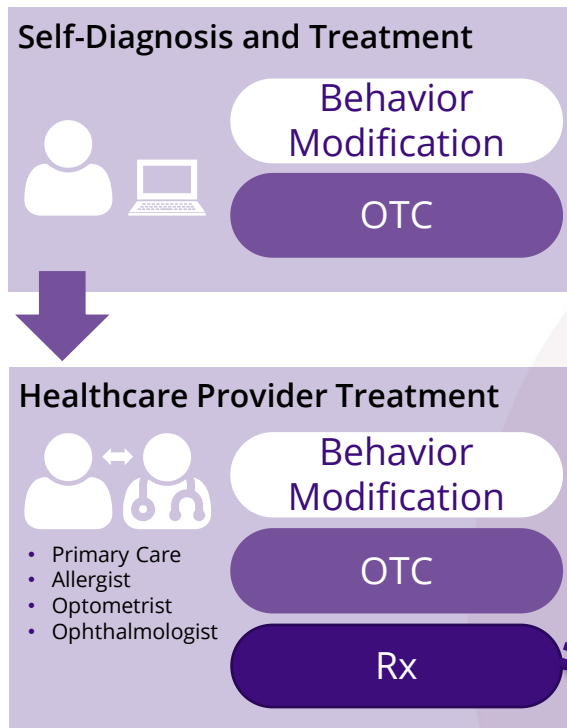
1 in 4

Nearly **1 in 4** of allergic conjunctivitis patients are using corticosteroid and/or NSAID eye drops.*

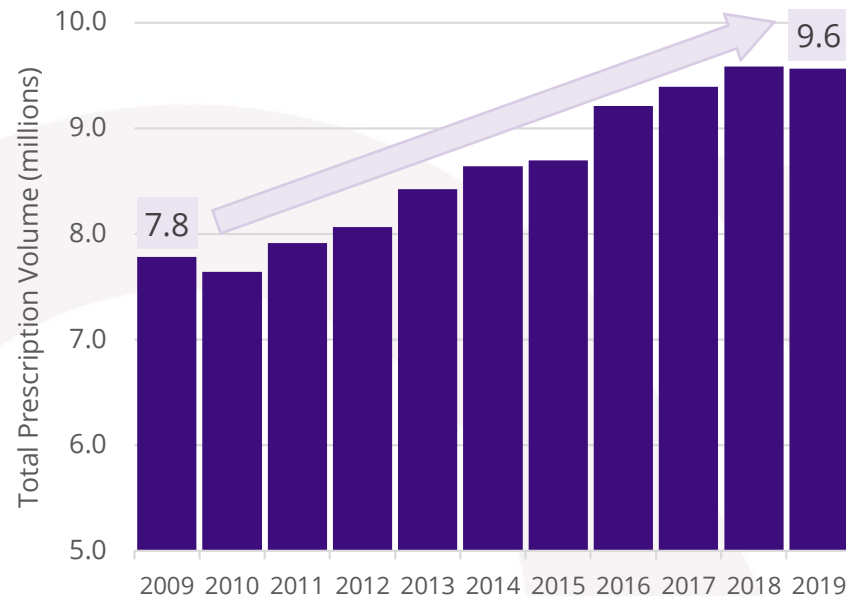
The allergic conjunctivitis patient population is underserved, and novel therapies are in demand.

Allergic Conjunctivitis Prescription Volume Has Grown 3x Faster Than the General Population Over the Past Ten Years

Allergic Conjunctivitis Patient Journey



Allergic Conjunctivitis Total Prescriptions (TRx) United States



- Antihistamines available OTC
- No novel Rx launches
- Minimal promotion

TRx Demand Outpacing Population Growth

Allergic conjunctivitis **prescription volume** has grown 3x faster than the U.S. population.

2.1%

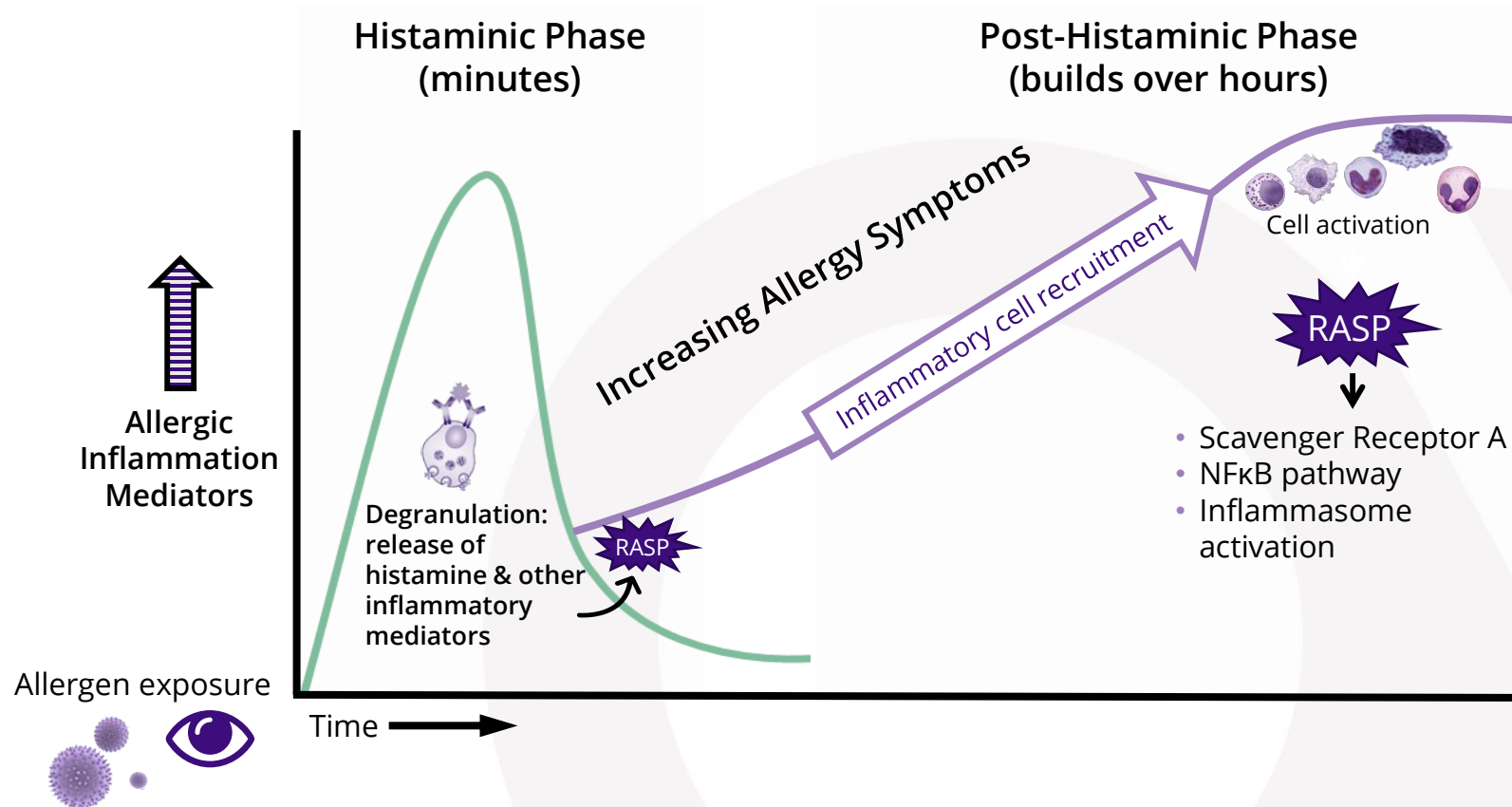
U.S. Allergic conjunctivitis TRx 10 year CAGR

vs.

0.7%

U.S. population 10 year CAGR

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

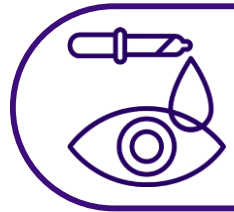


Reproxalap

- Reproxalap irreversibly inhibits RASP, limiting allergic inflammation.
- Reproxalap has the potential to provide differentiated activity in post-histaminic allergy, which affects all allergic conjunctivitis patients.

Reproxalap Has The Potential to be the First Novel Allergic Conjunctivitis New Drug Application in Decades

Reproxalap's Phase 3 Program Utilizes Two Allergic Conjunctivitis Clinical Models



Conjunctival Allergen Challenge

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

60 minutes post allergen exposure evaluated

ALLEVIATE

Positive Results Announced March 2019



Allergen Chamber

Investigator monitors and assists patients in a controlled allergen chamber.

3.5 hours of continuous allergen exposure evaluated

INVIGORATE

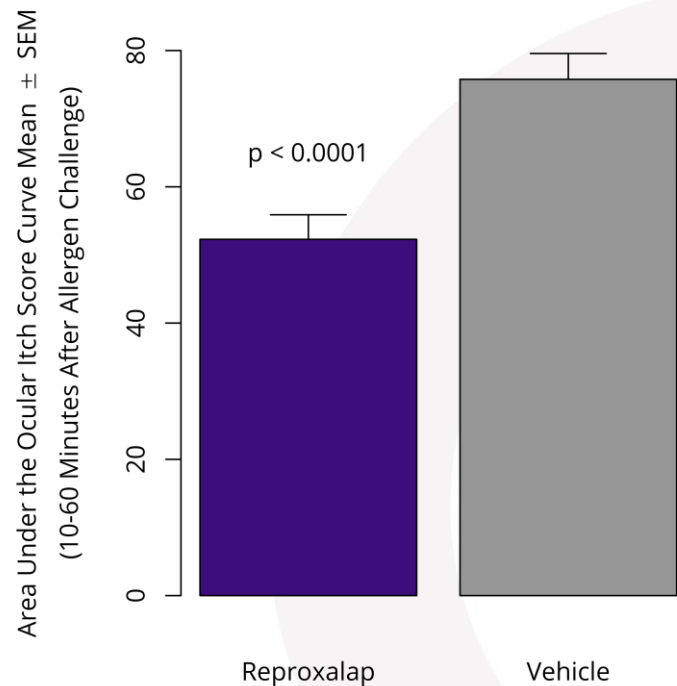
Initiated January 2020

- ✓ Supported by positive allergen chamber trial results

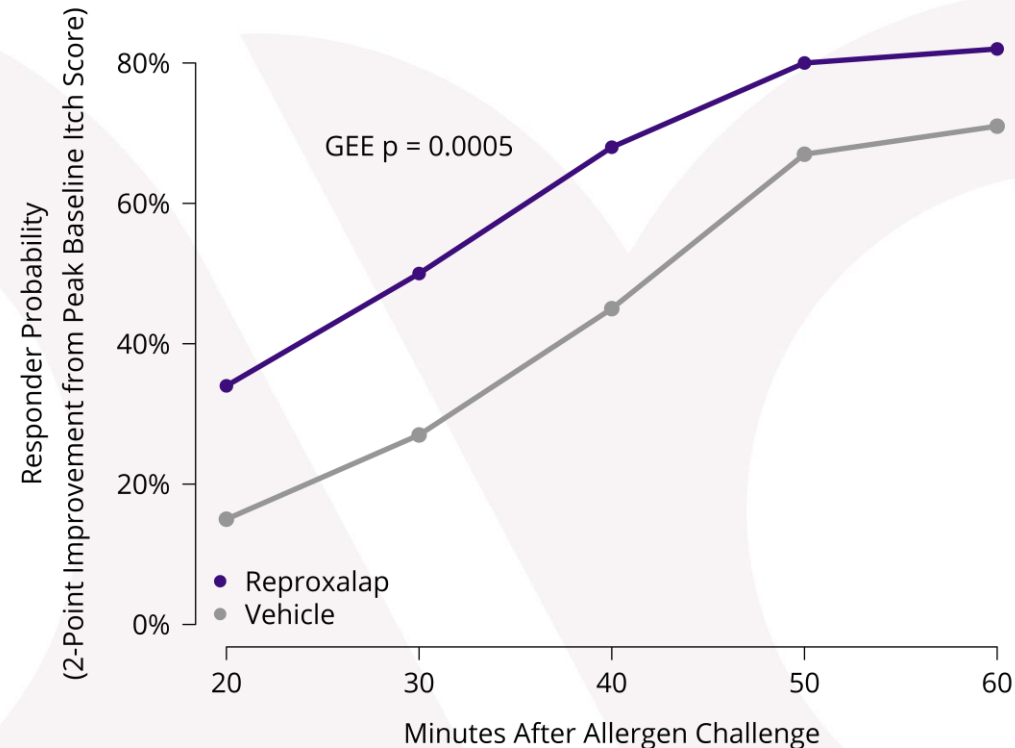
Reproxalap Demonstrated Greater and More Durable Clinical Responses than Vehicle Group in ALLEVIATE Phase 3 Clinical Trial



Total Ocular Itch Score (Area Under the Curve):
10 to 60 Minutes After Conjunctival Allergen Challenge



Probability of Two-Point Response - Ocular Itching Score:
20 to 60 Minutes After Conjunctival Allergen Challenge



Topical ocular reproxalap has been studied in over 1,100 patients with no observed safety concerns reported; mild instillation site irritation is the most commonly reported adverse event in clinical trials.
Source: Reproxalap ALLEVIATE Phase 3 clinical trial results; Ocular itch scale 0 (no itch) to 4 (incapacitating itch).

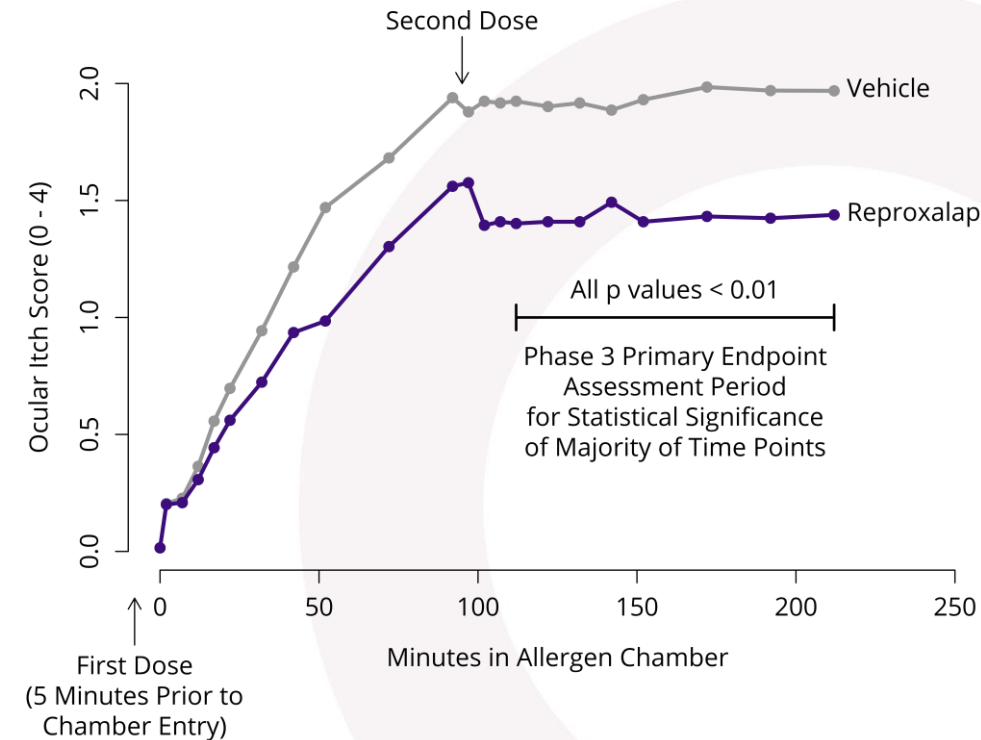
SEM = Standard error of the mean
GEE = Generalized estimating equation analysis

Reproxalap Demonstrated Durable Allergic Ocular Itch and Redness Reduction in Allergen Chamber Clinical Model

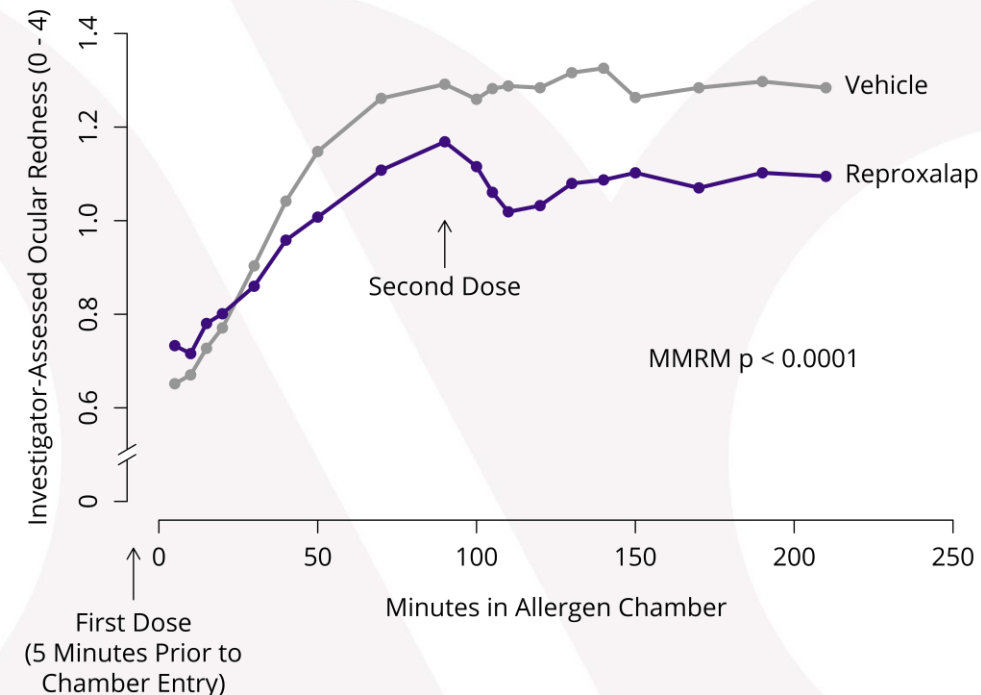


Allergen Chamber

Ocular Itching Score:
During 3.5 Hours of Allergen Exposure



Ocular Redness Score:
During 3.5 Hours of Allergen Exposure

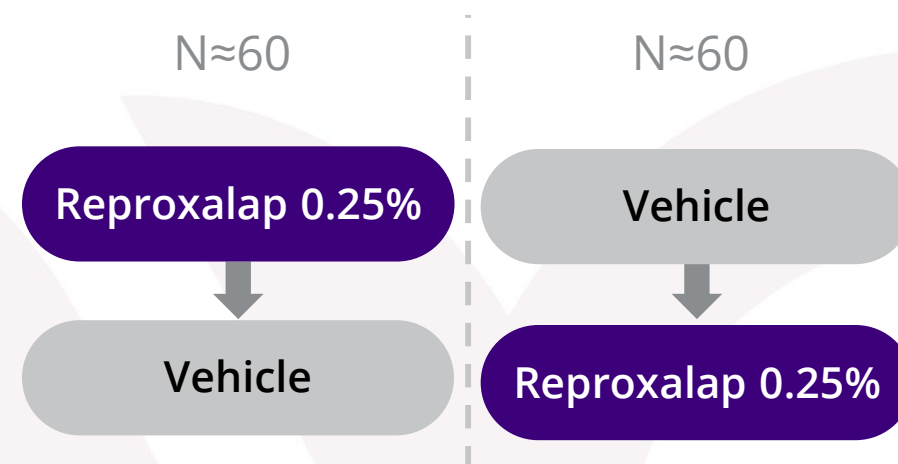


Topical ocular reproxalap has been studied in over 1,100 patients with no observed safety concerns reported; mild instillation site irritation is the most commonly reported adverse event in clinical trials.
Source: Reproxalap allergen Chamber Phase 1/2 clinical trial results; Ocular itch scale 0 (no itch) to 4 (incapacitating itch); Ocular redness scale (0-4).

The INVIGORATE Phase 3 Clinical Trial Design

- **Primary endpoint:**
 - Statistical significance in ocular itch (0-4 scale) at a majority of eleven time points between 110 and 210 minutes
- **Secondary endpoints:**
 - Investigator-assessed ocular redness score
 - Patient-reported ocular tearing score
 - Total ocular symptom score
- **Inclusion/exclusion criteria:**
 - History of moderate to severe allergic conjunctivitis to ragweed pollen
 - Itching score of ≥ 2.5 or redness score ≥ 2 in baseline chamber test
- **Chamber exposure and dosing schedule:**
 - 3.5 hours continuous allergen exposure
 - First dose 5 minutes before chamber entry
 - Second dose 90 minutes after entry (when non-treated patients reach peak allergy symptoms)

Two-Way Randomized Crossover



Expected H2 2020 Study Completion

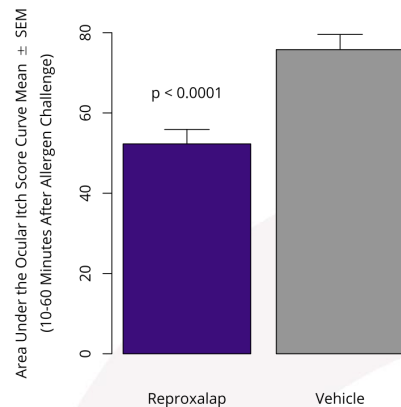
Reproxalap Has Demonstrated Reduction in Ocular Itch Across Four Independent Clinical Models

ALLERGIC CONJUNCTIVITIS



Conjunctival Allergen Challenge

Total Ocular Itch Score (Area Under the Curve):
10 to 60 Minutes After Conjunctival Allergen Challenge

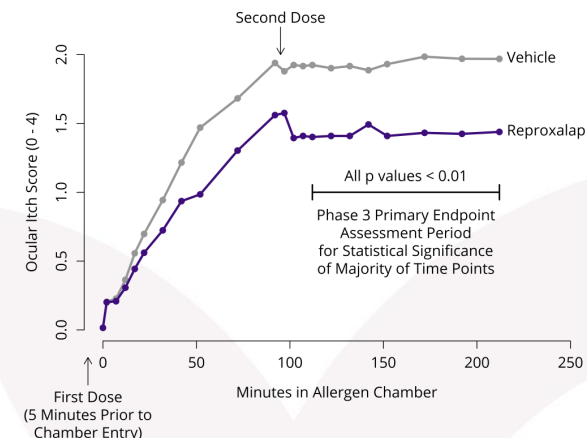


ALLERGIC CONJUNCTIVITIS



Allergen Chamber

Ocular Itching Score
During 3.5 Hours of Allergen Exposure

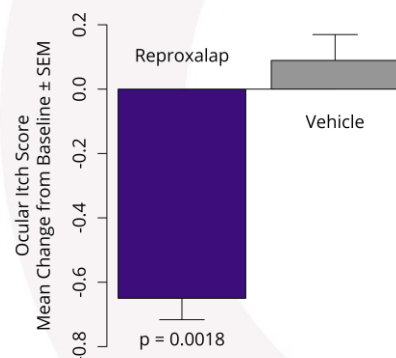


ALLERGIC CONJUNCTIVITIS



Allergen Field Study

Ocular Itch (0-4) Change From Baseline
On Highest Pollen Days*

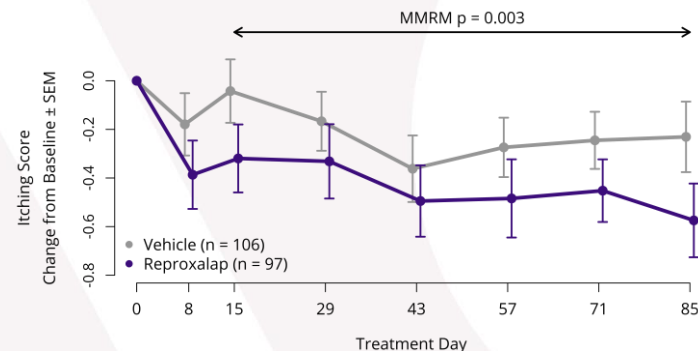


DRY EYE DISEASE

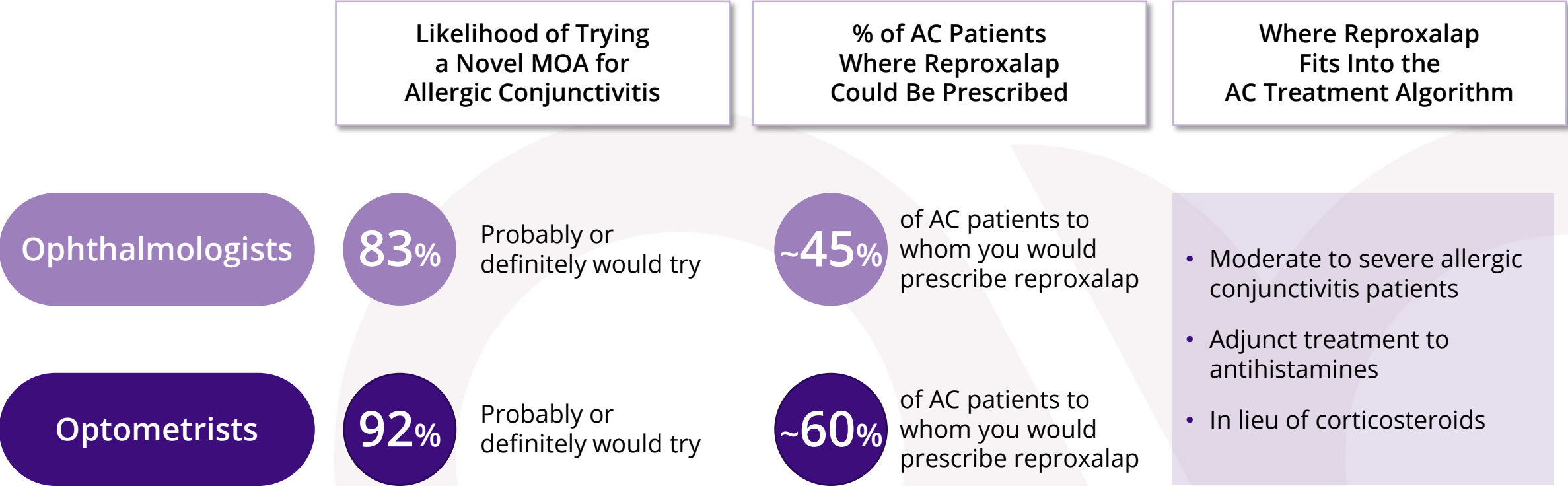


DED Field Study

CAC Ocular Itching Score Change From Baseline



Reproxalap Has the Potential to Be the First Novel Drug For Allergic Conjunctivitis in Decades, Representing A Unique Market Opportunity



Reproxalap in Allergic Conjunctivitis

- Reproxalap has demonstrated robust drug activity in multiple late-stage allergic conjunctivitis clinical trials (conjunctival allergen challenge and allergen chamber).
- Reproxalap allergic conjunctivitis clinical trial results to date demonstrate:
 - Rapid and durable onset of activity;
 - Clinically relevant improvements in allergic itch; and
 - Novel mechanism of action that is differentiated relative to currently available treatment options.
- Reproxalap has the potential to be the first novel drug for allergic conjunctivitis in decades, representing a unique market opportunity.
- INVIGORATE Phase 3 clinical trial ongoing; completion expected H2 2020.



March 2020

CORPORATE REVIEW

ADX-2191 For The Treatment Of Proliferative Vitreoretinopathy

ADX-2191 Represents a Novel Approach and Potential Therapeutic Breakthrough in Proliferative Vitreoretinopathy Treatment

Proliferative vitreoretinopathy

ADX-2191

4,000
U.S.

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**.



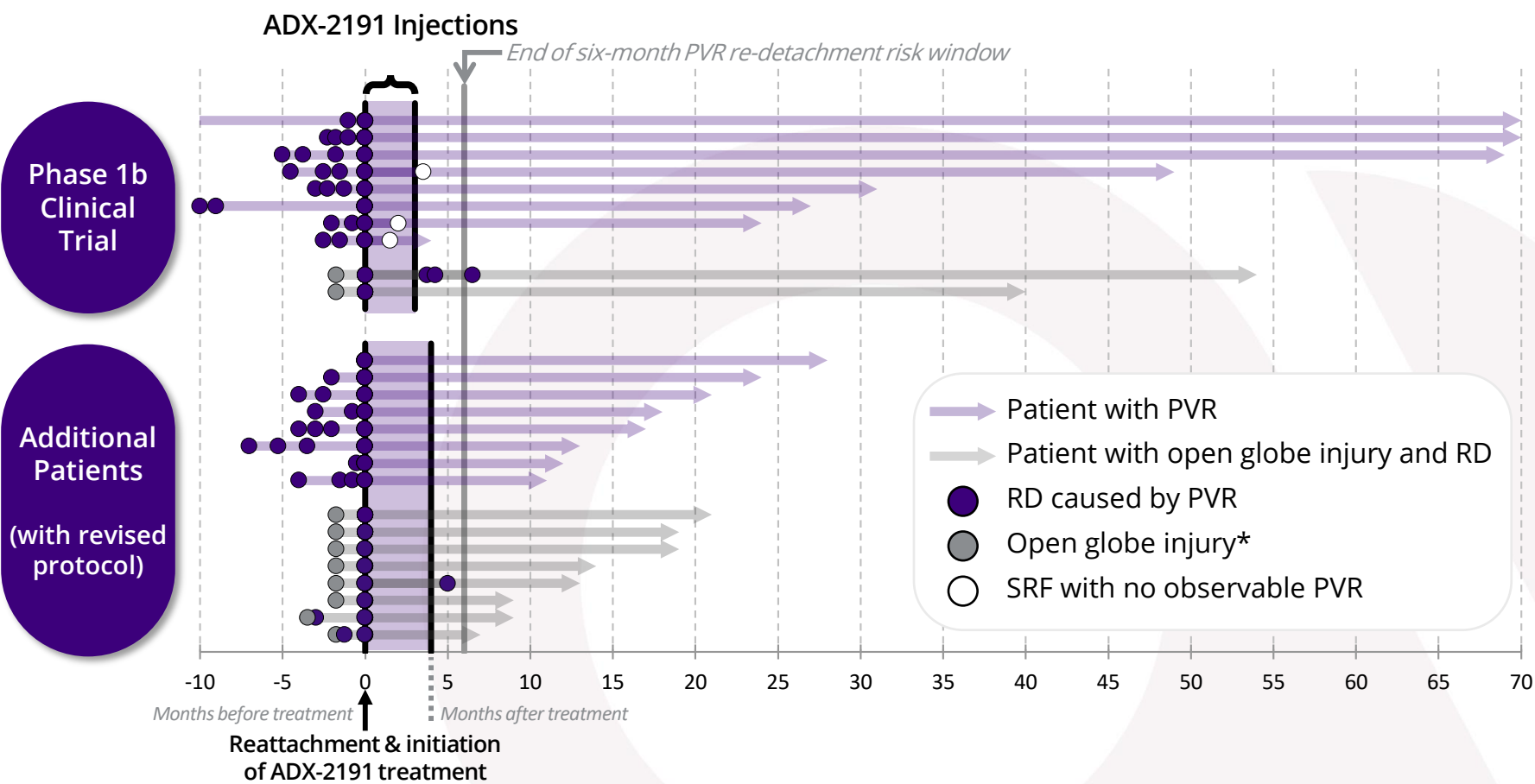
Repeat surgery, which can lead to **vision loss**, is currently the only possible course of action.

ADX-2191

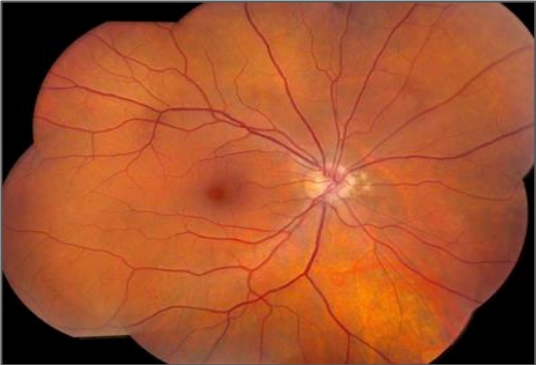
- A potential therapeutic breakthrough in PVR treatment
- **Granted U.S. orphan designation** for the prevention of PVR
- **Granted FDA fast track designation** for the prevention of PVR
- **Tolerability and reattachment success** during study period **demonstrated in Phase 1b** open-label investigator sponsored clinical trial
- **GUARD adaptive Phase 3 clinical trial initiated December 2019**

ADX-2191 Reduced Recurrent Retinal Detachment in Investigator Sponsored Phase 1b Clinical Trial and in Additional In-Practice Use

Retinal Detachments Over Time by Patient



Normal Retina



Retinal Detachment Due to PVR



*Timing of open globe injury as shown is estimated. Typically 6-8 weeks prior to reattachment & initiation of ADX-2191. 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. Source: ADX-2191 PVR Phase 1b investigator sponsored clinical trial (n=10) results and additional in-practice use (n=16)

ADX-2191: GUARD Trial Design in Proliferative Vitreoretinopathy

Adaptive Phase 3 (Part 1) Clinical Trial Design

- **Primary objective:**

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

- **Design:**

- Multi-center, randomized, controlled, two- part, adaptive Phase 3 clinical trial

- **Inclusion highlights:**

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

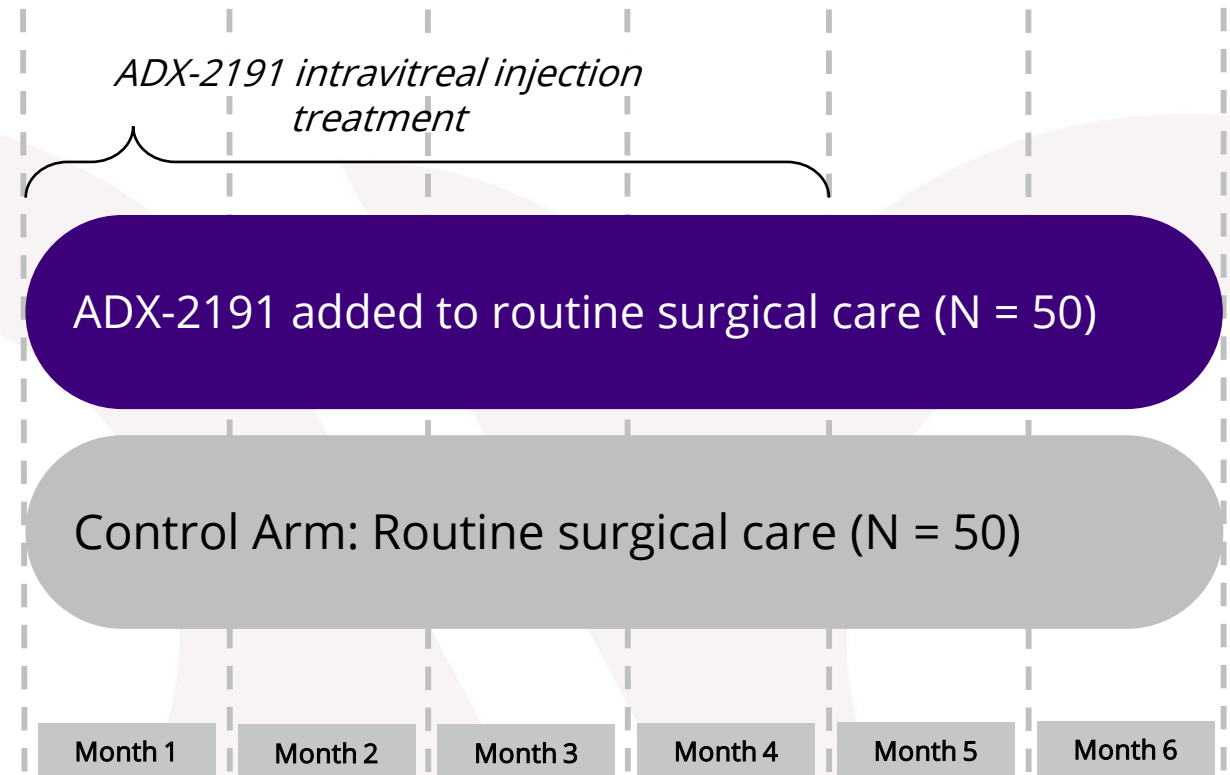
- **Dosing regimen:**

- 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



Initiated December 2019



March 2020

CORPORATE REVIEW

An Innovative Platform for Ocular and Systemic Immune-Mediated Diseases

Nasdaq: ALDX
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Innovative Pipeline Addressing Immune-Mediated Diseases

Disease Area	Compound	Mechanism	Indication	Preclinical	Phase 1	Phase 2	Phase 3
Ocular Diseases	Reproxalap	RASP	Dry Eye Disease				
			Allergic Conjunctivitis				
	ADX-2191	DHFR	Proliferative Vitreoretinopathy				
			Ocular Lymphoma				
	ADX-103/10X	RASP	Retinal Disease				
	Undisclosed	RASP	Ocular Inflammatory Diseases		Research Collaboration (undisclosed)		
Systemic Diseases	ADX-1612	CHP	Ovarian Cancer	Investigator-Sponsored Trial			
	ADX-629	RASP	Autoimmune / Inflammatory Disease				

Upcoming Development Milestones

- Reproxalap dry eye disease subsequent development plans following FDA feedback H2 2020
- Reproxalap allergic conjunctivitis INVIGORATE Phase 3 study completion H2 2020
- ADX-2191 proliferative vitreoretinopathy GUARD Phase 3 - Part 1 clinical trial progress update H2 2020
- ADX-629 SAD/MAD Phase 1 clinical trial results Q2 2020 (single and multiple ascending dose)

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

David McMullin, M.B.A.
Chief Commercial Officer

James Gow, M.D.
SVP Clinical Development

Stephen Machatha, Ph.D.
SVP Technical Operations



Board of Directors

Richard Douglas, Ph.D.
CHAIRMAN

Ben Bronstein, M.D.

Marty Joyce, M.B.A.

Nancy Miller-Rich

Gary Phillips, M.D.

Jesse Treu, Ph.D.

Neal Walker, D.O.

Todd Brady, M.D., Ph.D.

Former SVP Corporate Development at Genzyme

Former CEO Peptimmune⁷

Former CFO of Serono USA

CEO M-R Associates

CEO OrphoMed

Domain Associates

CEO Aclaris Therapeutics

CEO Aldeyra Therapeutics

1. Acquired by Xanthus/Antisoma
2. Acquired by Schwarz/UCB
3. Acquired by Takeda
4. Acquired by Ligand

5. Acquired by Merck
6. Acquired by Alexion
7. Acquired by Genzyme



A New Paradigm for the Treatment of Immune- Mediated Diseases