



February 2020

CORPORATE REVIEW

A New Paradigm for the Treatment of Immune-Mediated Diseases

Nasdaq: ALDX
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Our Mission and Value Proposition

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



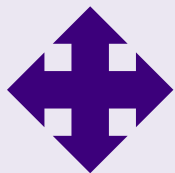
Our Lead Programs Represent Compelling Commercial Opportunities

Dry Eye Disease

Reproxalap 0.25%



Early and consistent symptom and sign improvements in RENEW-Part 1 top-line results



Broad symptom and sign improvements in RENEW-Part 1 top-line results

**RENEW-Part 2 Phase 3
Initiation H1 2020**

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**



February 2020

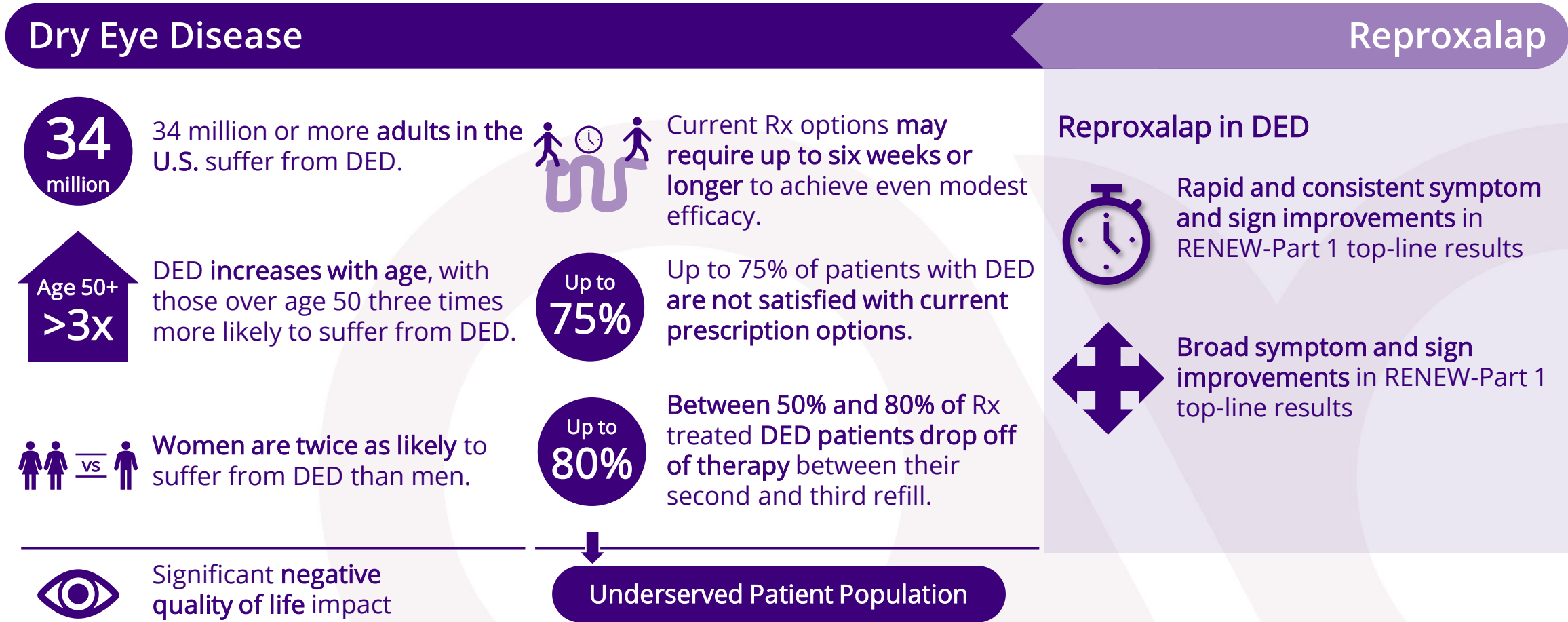
CORPORATE REVIEW

Ocular Disease Area

- **DRY EYE DISEASE**
- ALLERGIC CONJUNCTIVITIS
- PROLIFERATIVE VITREORETINOPATHY

Reproxalap Represents a New Approach for Dry Eye Disease

– A Persistently Disturbing And Inadequately Treated Condition



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

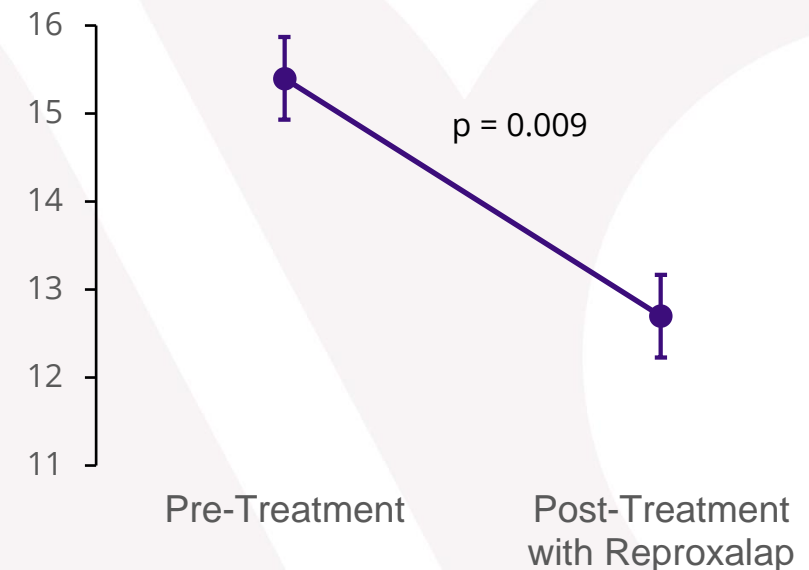
RASP in Dry Eye Disease

- 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 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

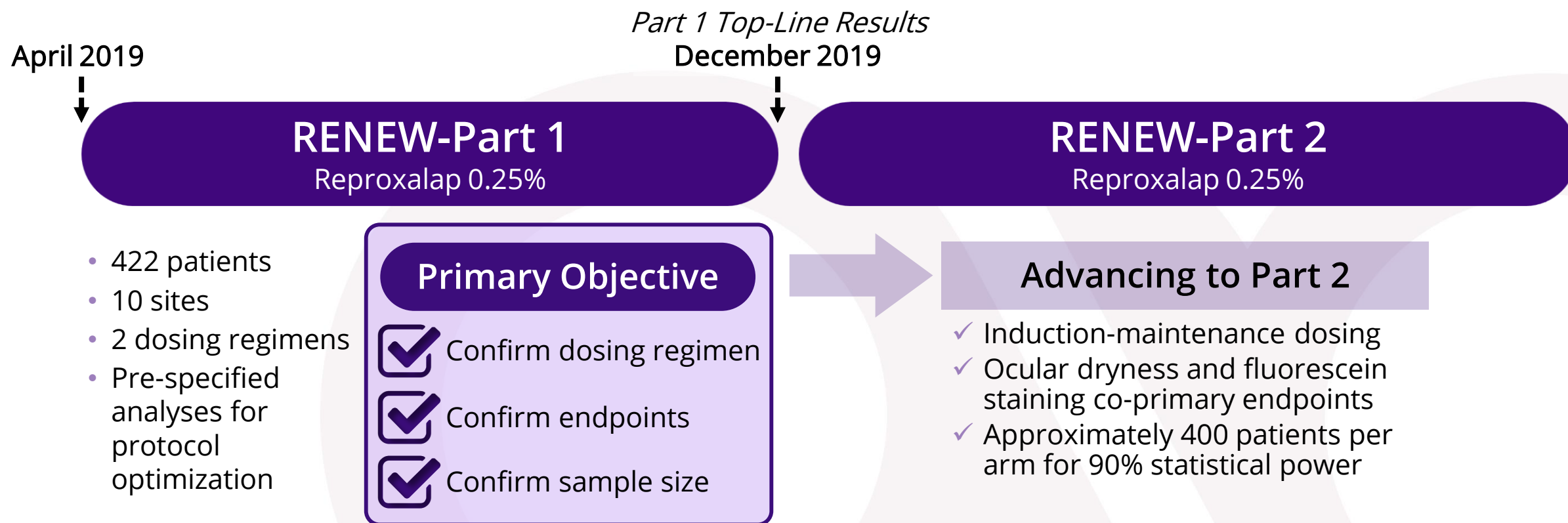
- In a Phase 2a clinical trial, **reproxalap significantly reduced RASP adduct levels.**

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



The RENEW Trial in Dry Eye Disease

RENEW: An Ongoing Adaptive Two-Part, Multi-Center, Randomized, Vehicle-Controlled, Double-Masked, Parallel-Group Phase 3 Clinical Trial

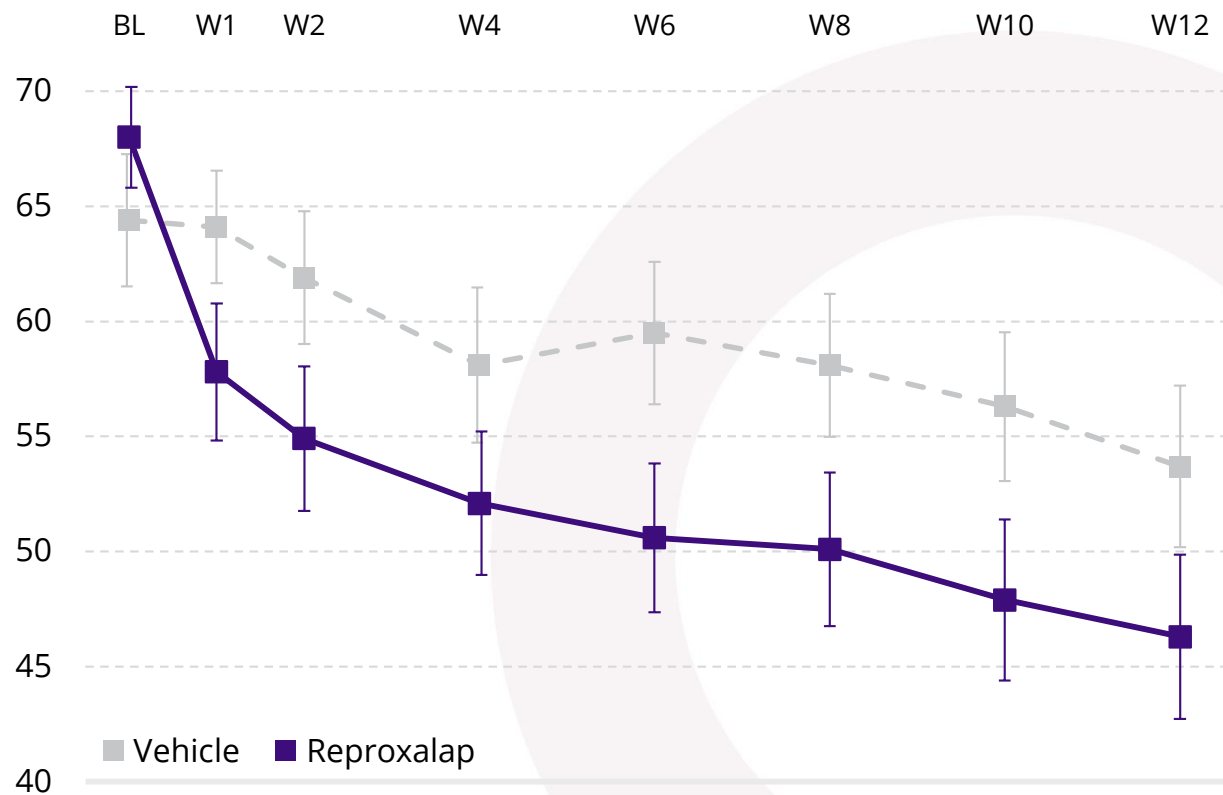


Further information can be found on www.clinicaltrials.gov: Trial #NCT03879863.

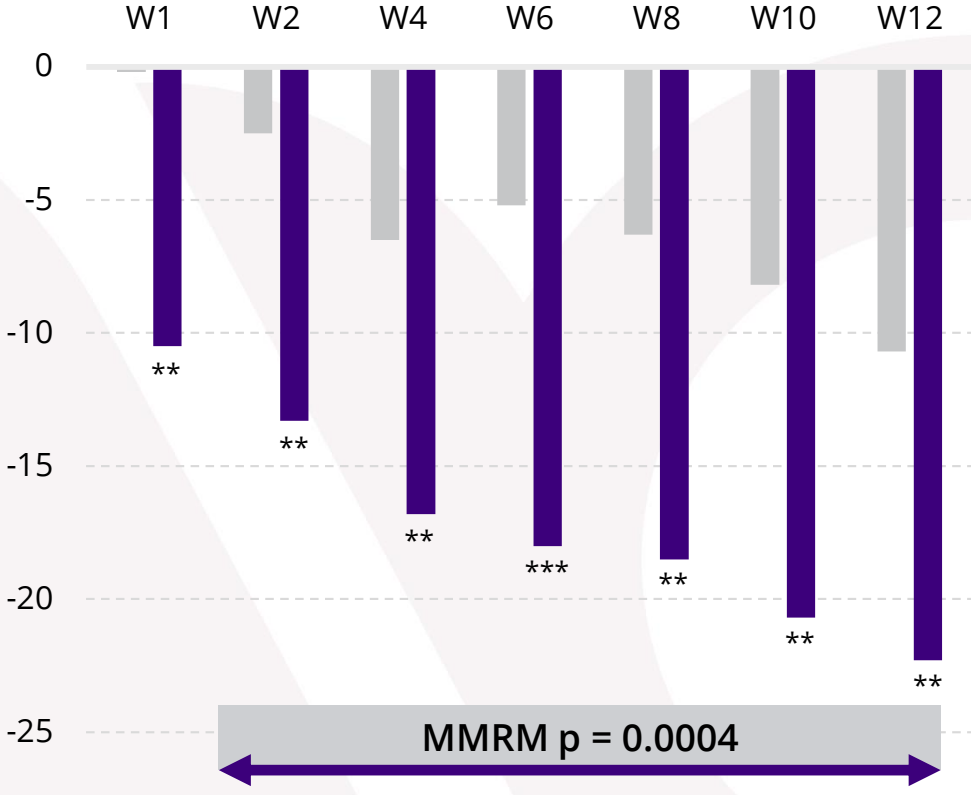
Reproxalap Demonstrated Rapid and Durable Improvement in Co-Primary Endpoint of Ocular Dryness Score in RENEW-Part 1

Co-Primary Symptom Endpoint for RENEW

Ocular Dryness Score (VAS)[†]
Baseline and Weeks 1 to 12; ± Standard Error of the Mean



Ocular Dryness Score (VAS)[†] Change From Baseline
Weeks 1 to 12



MMRM p = 0.0004

p<0.01 *p<0.001

VAS = Visual Analog Scale

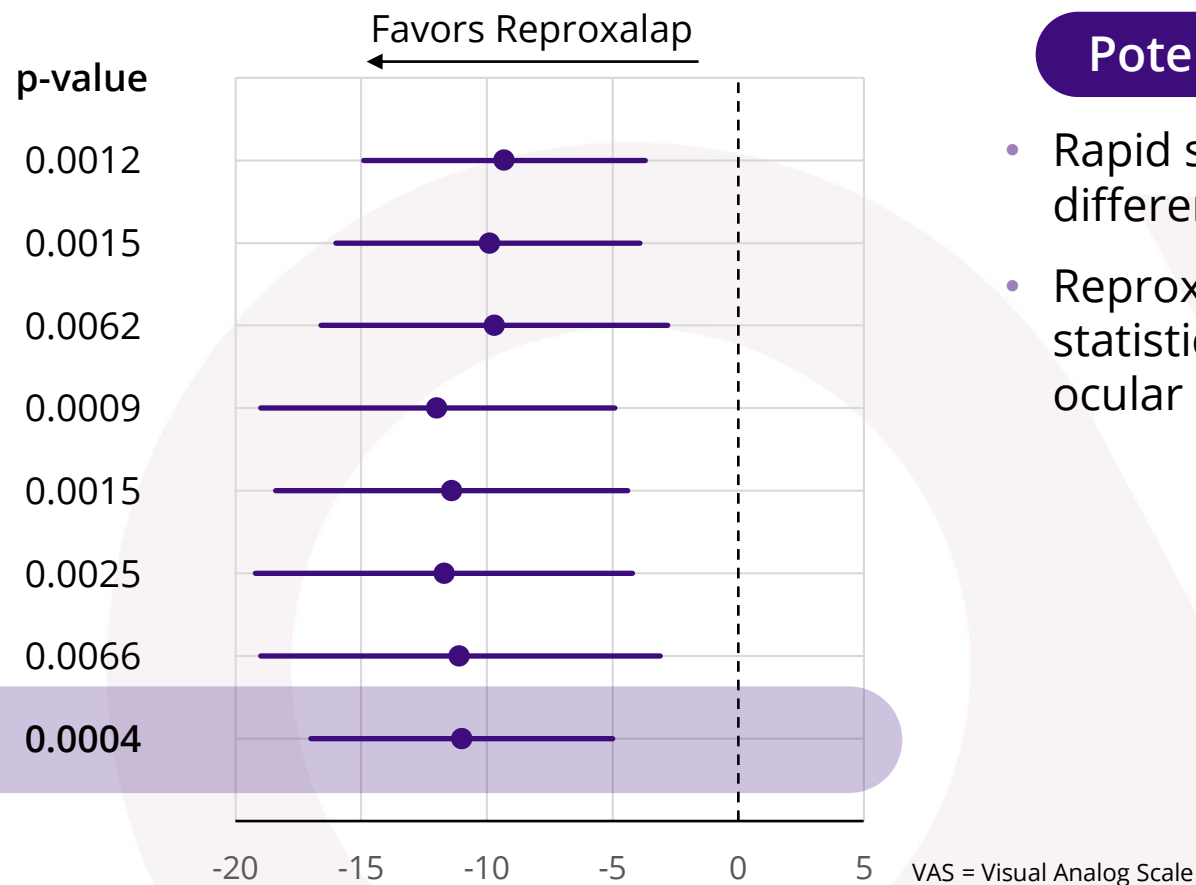
BL = Baseline; W = Week

MMRM = Mixed Effect Model Repeated Measures

[†]Ocular Dryness Score co-primary endpoint assessed in pre-specified patient population having an ocular dryness (Ocular Dryness 4-Symptom) baseline score of ≥ 3 (N=170). Topical ocular reproxalap has been studied in over 1,100 patients thus far with no observed safety concerns; mild instillation site irritation is the most commonly reported adverse event in clinical trials.
Source: RENEW-Part 1 induction-maintenance top-line results

Reproxalap Demonstrated Highly Statistically Significant Reductions in Ocular Dryness in RENEW-Part 1

Ocular Dryness Score (VAS) Treatment Difference (Reproxalap-Vehicle)*



Potential Competitive Advantages[†]

- Rapid symptom improvement supports differentiated product profile.
- Reproxalap demonstrated large and statistically significant improvements in ocular dryness at every time point.

[†]Pending clinical data, regulatory discussions, payor negotiations, competition, potential legislative changes, and other factors, which may not be in Aldeyra's control.

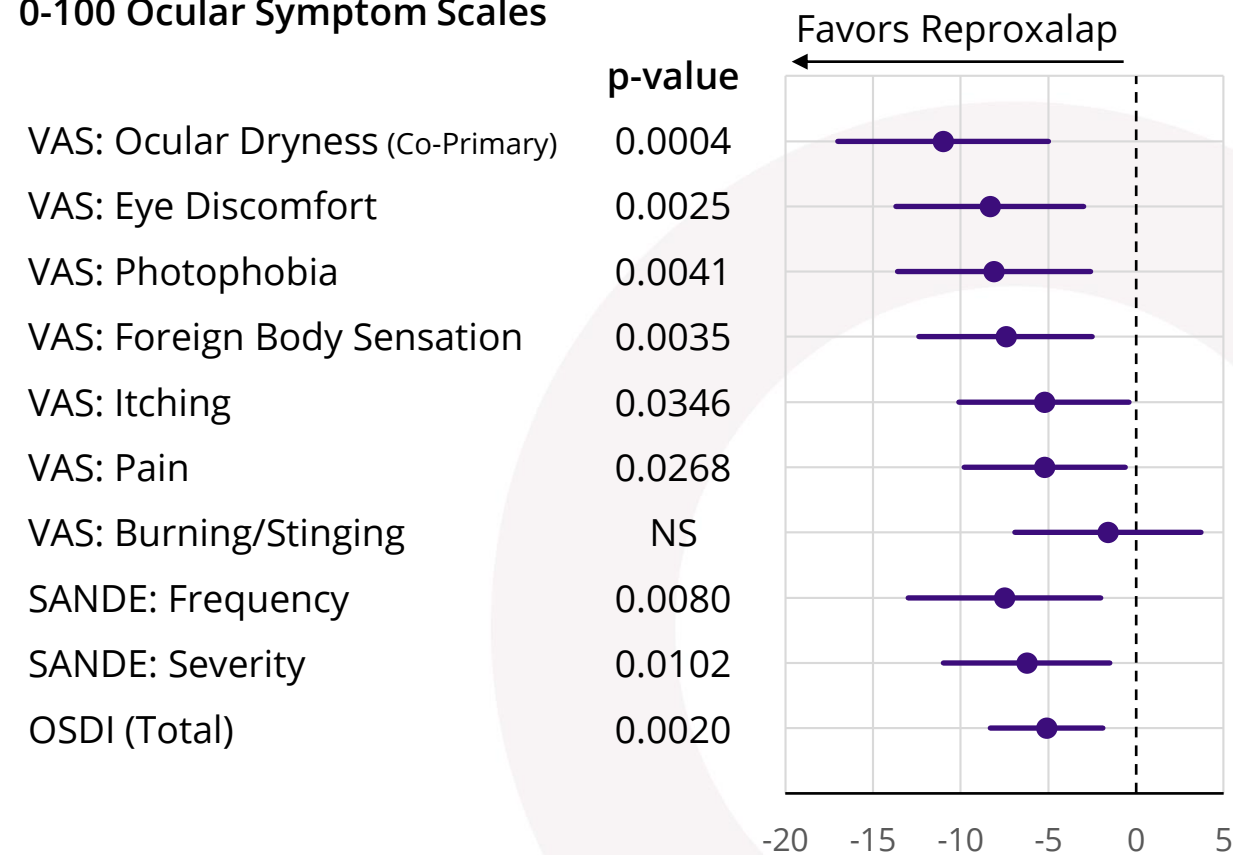
*Treatment Difference defined as the difference between the changes from baseline for the evaluated drug vs. vehicle (LS Mean Difference \pm 95% CI). Topical ocular reproxalap has been studied in over 1,100 patients thus far with no observed safety concerns; mild instillation site irritation is the most commonly reported adverse event in clinical trials. Ocular Dryness Score co-primary endpoint assessed in pre-specified patient population having an OD4S dryness baseline score of ≥ 3 (N=170).

Source: RENEW-Part 1 induction-maintenance top-line results

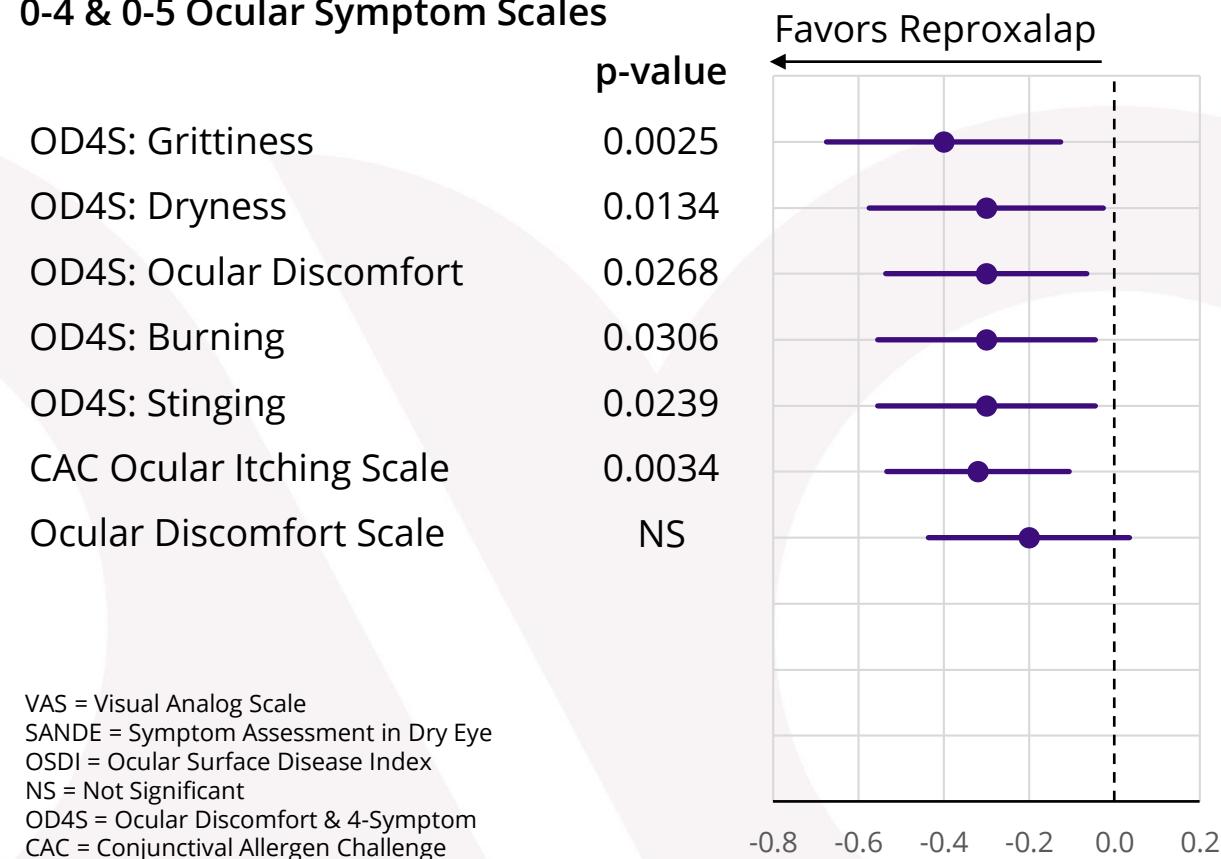
Reproxalap Demonstrated Broad Statistically Significant Symptom Improvement in RENEW-Part 1

Symptom Treatment Difference* (Reproxalap-Vehicle) Over Weeks 2 to 12

0-100 Ocular Symptom Scales



0-4 & 0-5 Ocular Symptom Scales

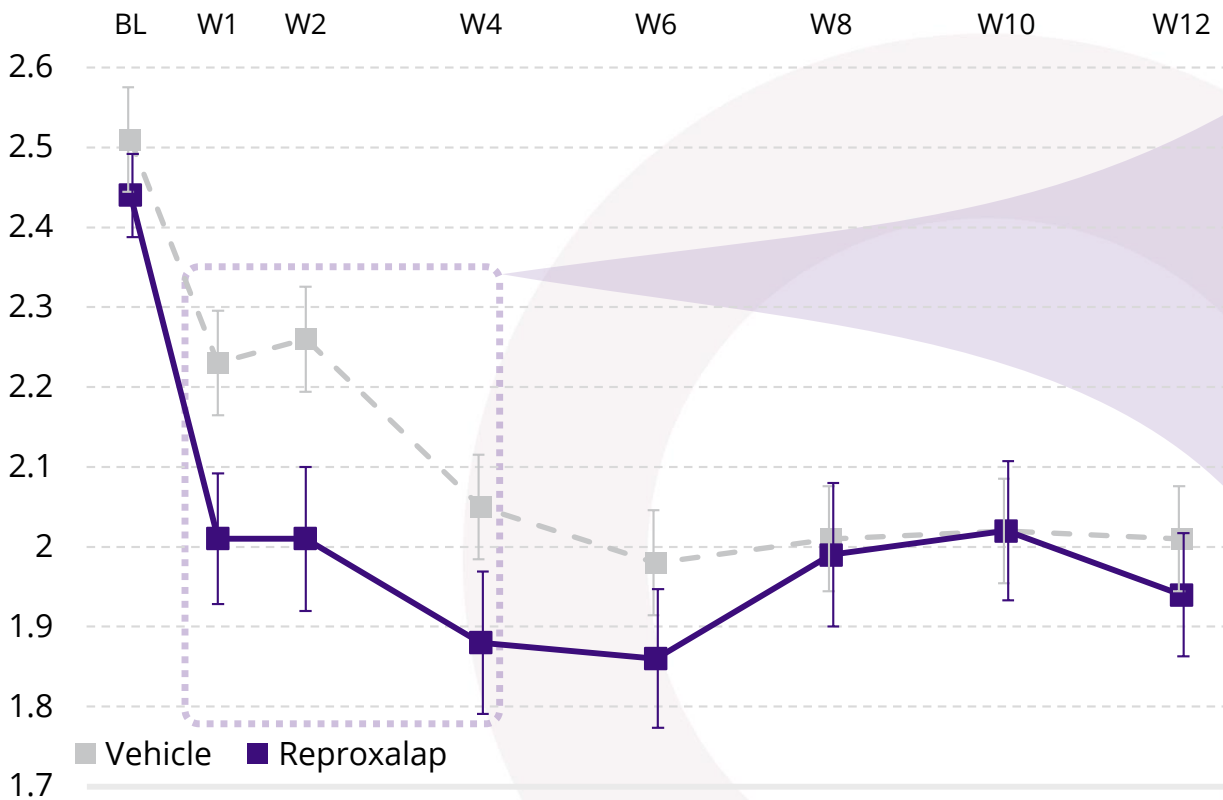


VAS = Visual Analog Scale
 SANDE = Symptom Assessment in Dry Eye
 OSDI = Ocular Surface Disease Index
 NS = Not Significant
 OD4S = Ocular Discomfort & 4-Symptom
 CAC = Conjunctival Allergen Challenge

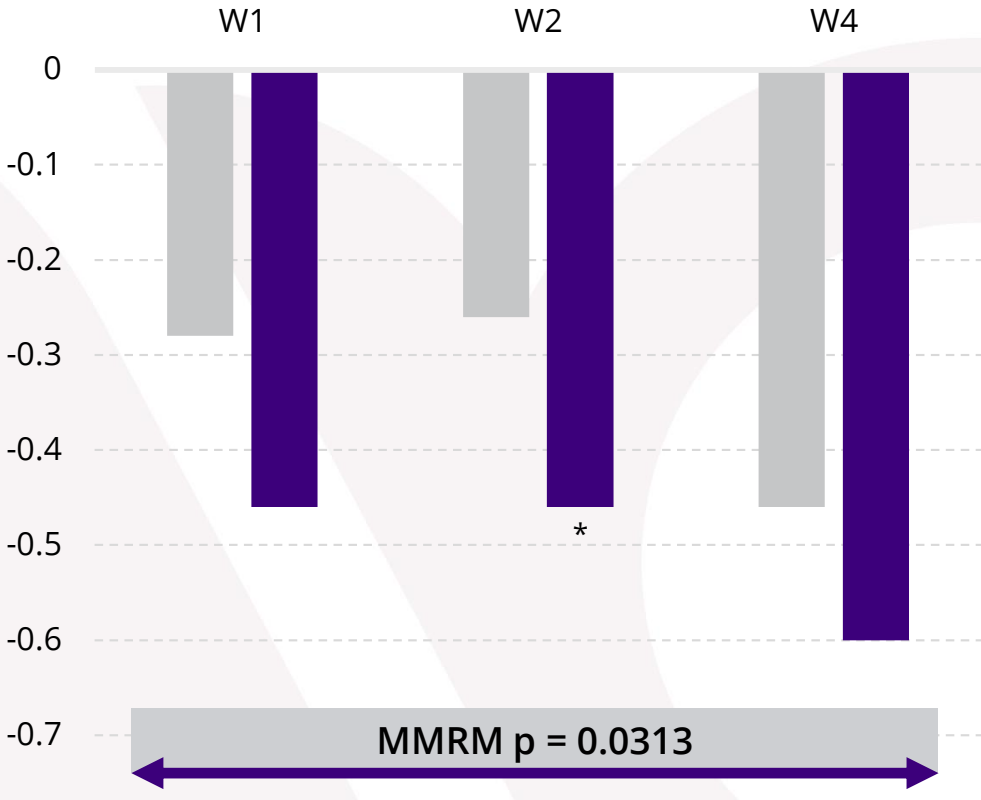
Reproxalap Demonstrated Rapid Improvement in Co-Primary Endpoint of Fluorescein Staining Score in RENEW-Part 1

Co-Primary Sign Endpoint for RENEW

Fluorescein Staining: Nasal Region† (0-4)
Baseline and Weeks 1 to 12; ± Standard Error of the Mean



Fluorescein Staining: Nasal Region† Change From Baseline
Weeks 1 to 4



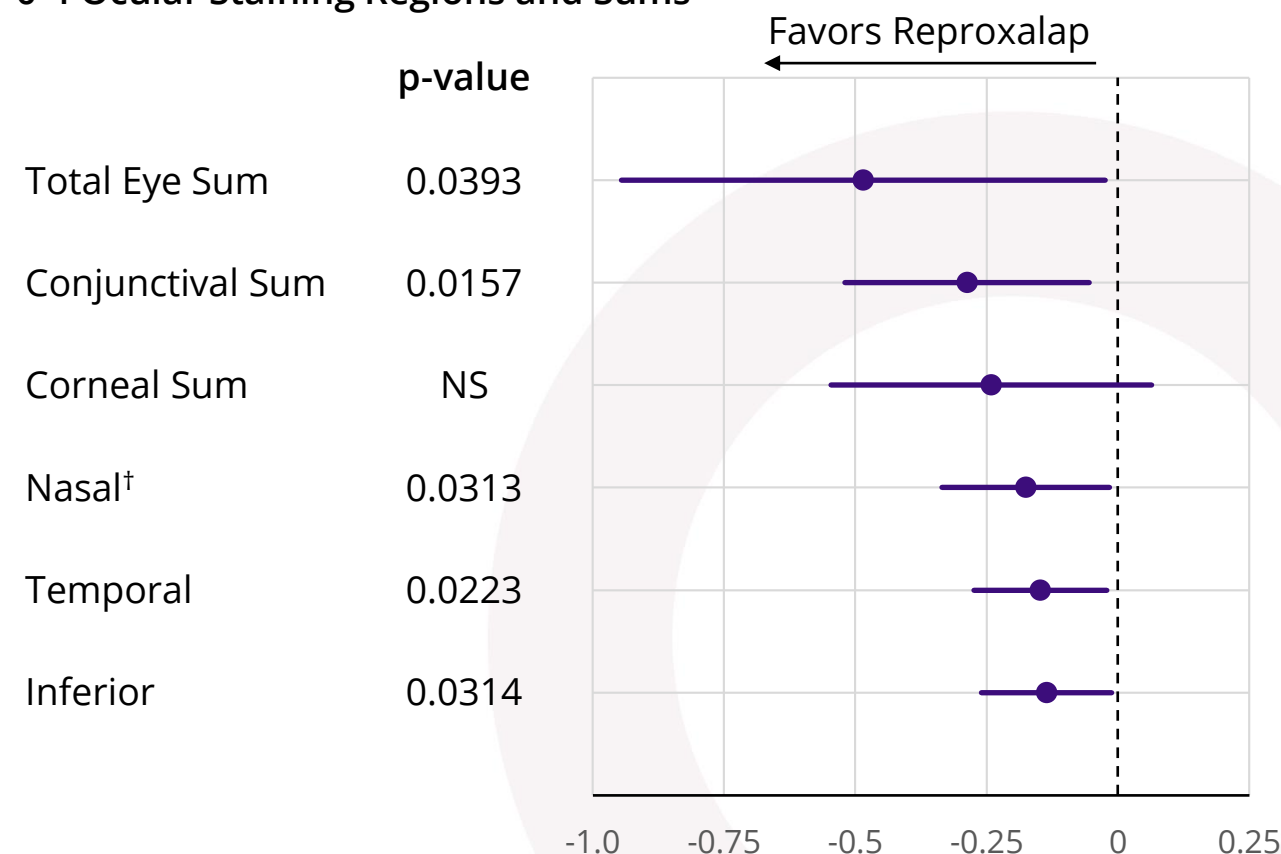
†Fluorescein Staining co-primary endpoint assessed in pre-specified patient population having a nasal region baseline score of ≥ 2 (N=179). Topical ocular reproxalap has been studied in over 1,100 patients thus far with no observed safety concerns; mild instillation site irritation is the most commonly reported adverse event in clinical trials.
Source: RENEW-Part 1 induction-maintenance top-line results

MMRM p = 0.0313
*p<0.05
BL = Baseline; W = Week
MMRM = Mixed Effect Model Repeated Measures (across 12 weeks)

Reproxalap Demonstrated Rapid and Broad Staining Improvements in RENEW-Part 1

Fluorescein Staining Treatment Difference (Reproxalap-Vehicle) Over Weeks 1 to 4*

0-4 Ocular Staining Regions and Sums



Potential Competitive Advantages†

- Rapid sign improvement supports differentiated product profile.
- Reproxalap demonstrated statistically significant improvements over vehicle in majority of regions over Weeks 1 to 4.
- Reproxalap demonstrated substantial improvements at Week 1, with near-peak difference from vehicle achieved by Week 4.

Total Eye Sum = All five regions
Conjunctival Sum = Nasal + Temporal
Corneal Sum = Inferior + Central + Superior

†Pending clinical data, regulatory discussions, payor negotiations, competition, potential legislative changes, and other factors, which may not be in Aldeyra's control.

*Treatment Difference defined as the difference between the changes from baseline for the evaluated drug vs. vehicle (LS Mean Difference ± 95% CI). Topical ocular reproxalap has been studied in over 1,100 patients thus far with no observed safety concerns; mild instillation site irritation is the most commonly reported adverse event in clinical trials.

†Fluorescein Staining co-primary endpoint assessed in pre-specified patient population having a nasal region baseline score of ≥ 2 (N=179).

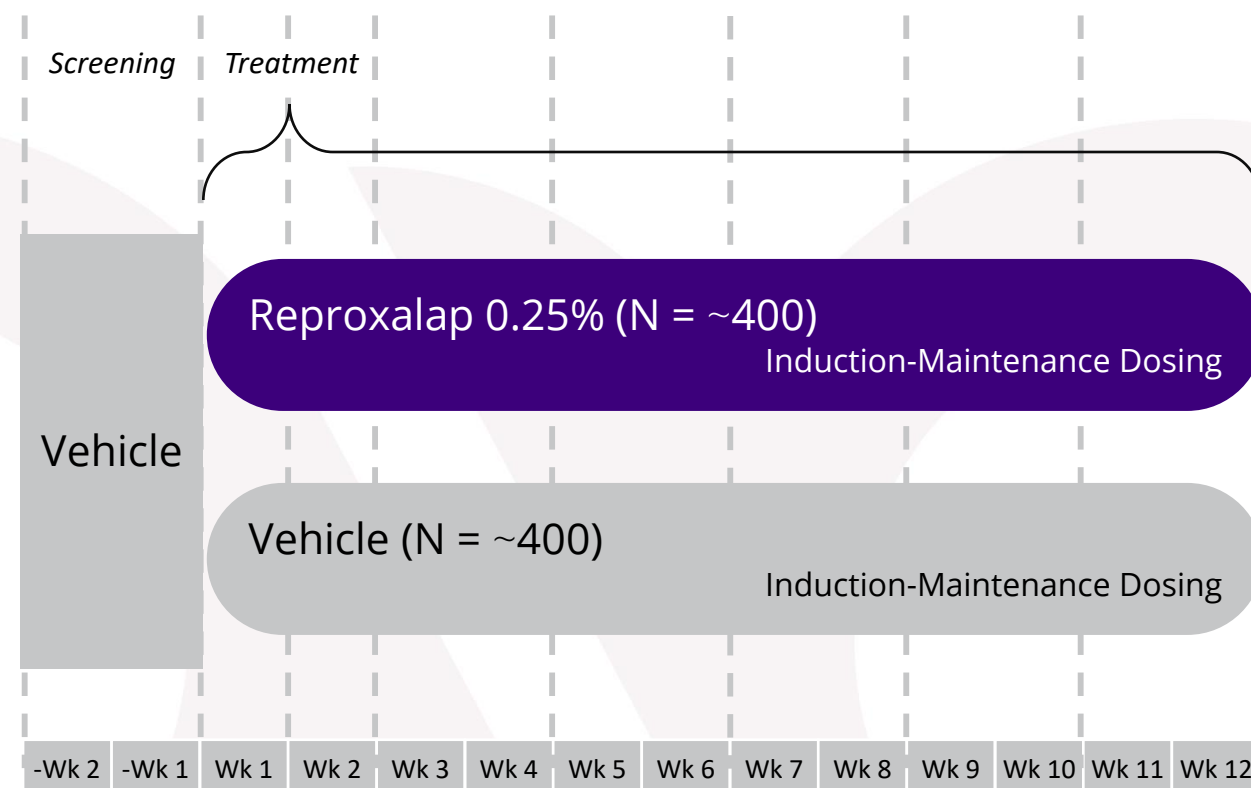
Source: RENEW-Part 1 induction-maintenance top-line results

RENEW-Part 2 Clinical Trial Design

- **RENEW-Part 2 primary objective:**
 - Evaluate efficacy of reproxalap ophthalmic solution (0.25%) vs. vehicle for the symptoms and signs of dry eye disease
- **RENEW-Part 2 inclusion/exclusion criteria:**
 - Same as used for RENEW-Part 1
 - Moderate to severe dry eye disease
- **RENEW co-primary endpoints:**
 - Ocular dryness score (0-100mm VAS)
 - Fluorescein nasal region staining
- **RENEW analysis strategy:**
 - Mixed Model Repeated Measures (MMRM)
 - Pre-specified patient populations
 - Ocular dryness score (OD4S): baseline score of ≥ 3
 - Fluorescein nasal region staining: baseline score ≥ 2

Expected to initiate H1 2020

RENEW Phase 3 Dry Eye Disease Clinical Trial: Part 2



Further information can be found on [www.clinicaltrials.gov](https://www.clinicaltrials.gov/ct2/show/study/NCT03879863): Trial #NCT03879863.



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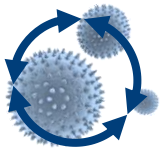
CORPORATE REVIEW

Ocular Disease Area

- DRY EYE DISEASE
- **ALLERGIC CONJUNCTIVITIS**
- PROLIFERATIVE VITREORETINOPATHY

Reproxalap Represents a New Approach for Allergic Conjunctivitis – A Burdensome and Growing Disease with Unmet Medical Need

Allergic Conjunctivitis



Allergy seasons are getting **longer and more severe** with pollen spreading to new areas.



AC prescription volume is growing approx. 4x faster than the U.S. population.*

30
million

Up to 30 million of AC sufferers in the U.S. **do not respond** adequately to or are dissatisfied with antihistamines.



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

24%

Antihistamines are not **effective** in an estimated 24% of treated AC patients.†



1 in 5

Nearly 1 in 5 of AC patients are using corticosteroid and/or NSAID eye drops**.

Underserved Patient Population



Growing and burdensome unmet medical need

Reproxalap

Reproxalap in AC

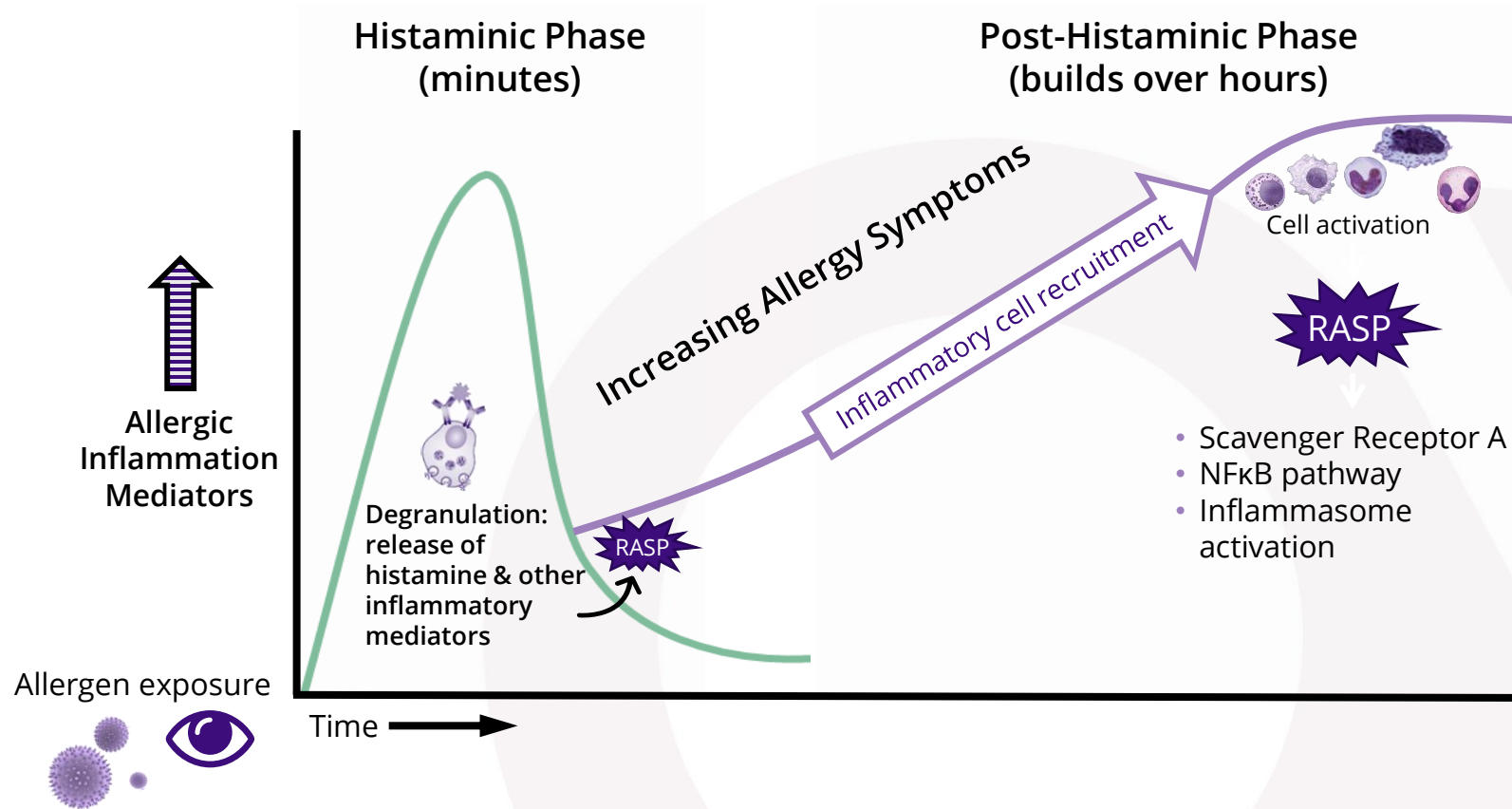


Clinically significant and durable symptom response in ALLEVIATE Phase 3 and allergen chamber clinical trials



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

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

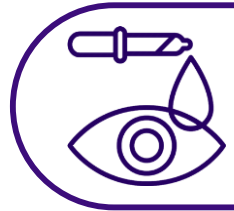


Reproxalap

- 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

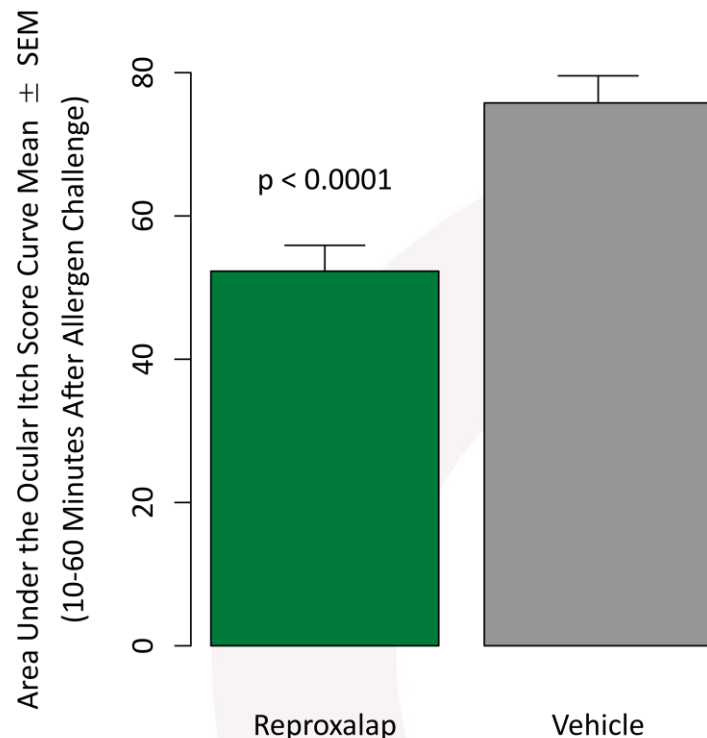
Initiated January 2020

- ✓ Supported by positive allergen chamber trial results

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

Primary Endpoint

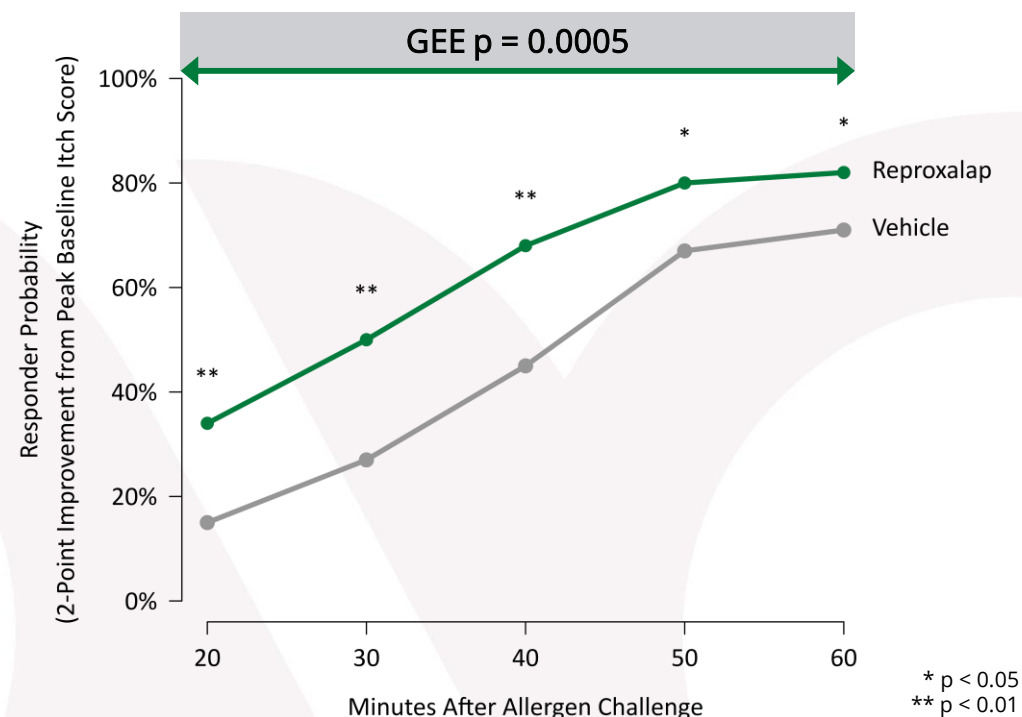
Area Under the Curve: Ocular Itch Score (0-4) 10 to 60 Minutes After Conjunctival Allergen Challenge



Improvement in itch score over one hour after allergen exposure statistically greater for reproxalap vs. vehicle

Key Secondary Endpoint

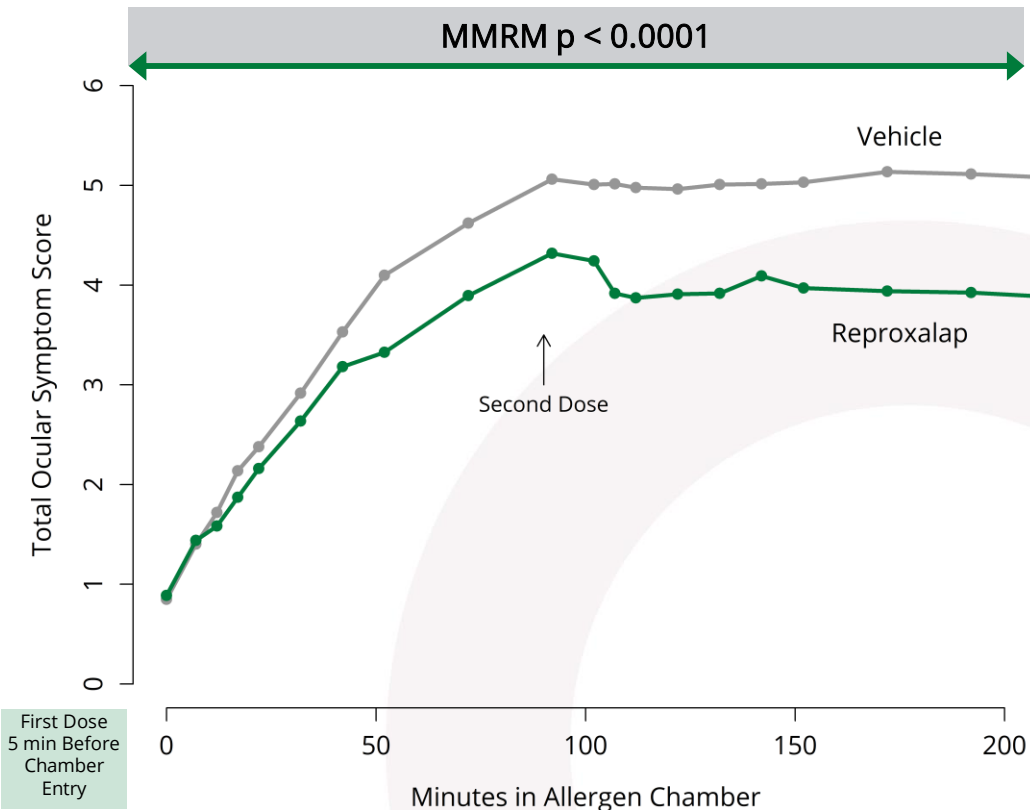
Probability of Two-Point Response: Ocular Itch Score (0-4) 20 to 60 Minutes After Conjunctival Allergen Challenge



Clinically significant response rate of reproxalap statistically higher than that of vehicle

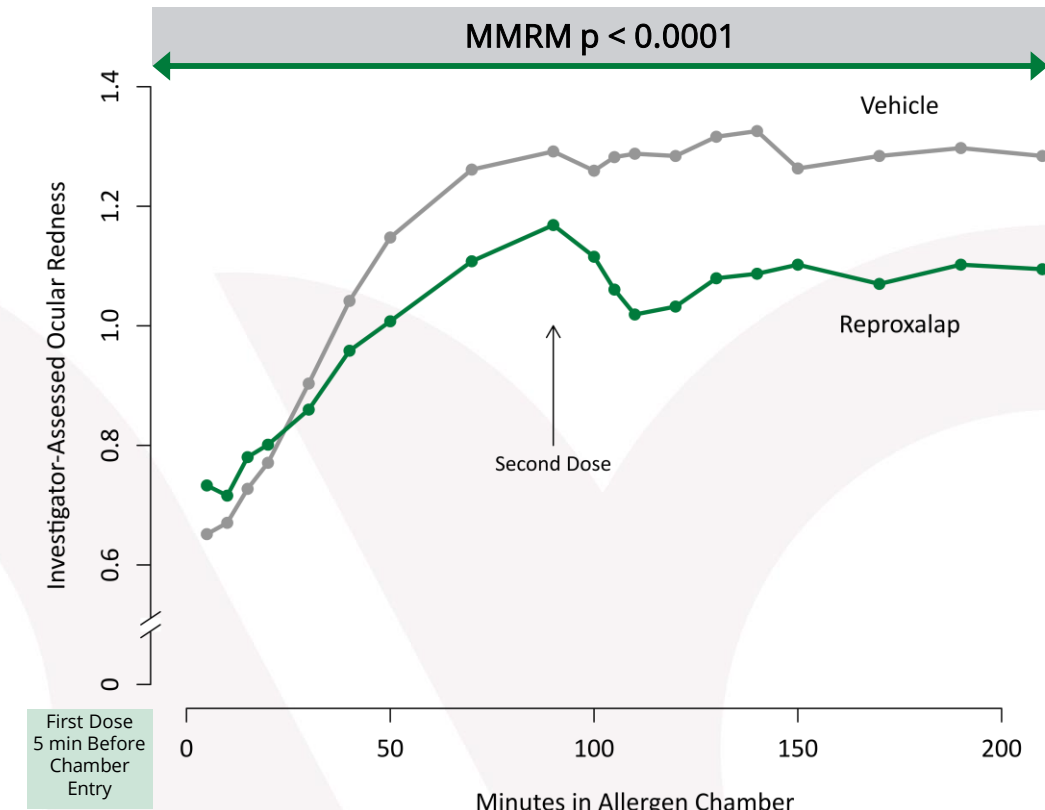
Reproxalap Demonstrated Greater and More Durable Clinical Responses than Vehicle in Allergen Chamber Clinical Trial

Total Ocular Symptom Score (0-11 scale) During 3.5 Hours of Exposure



Statistically significant reduction in all assessed ocular symptoms and signs (itch, redness, and tearing) for 3.5 hours of continuous exposure to allergen

Ocular Redness Score (0-4) During 3.5 Hours of Exposure

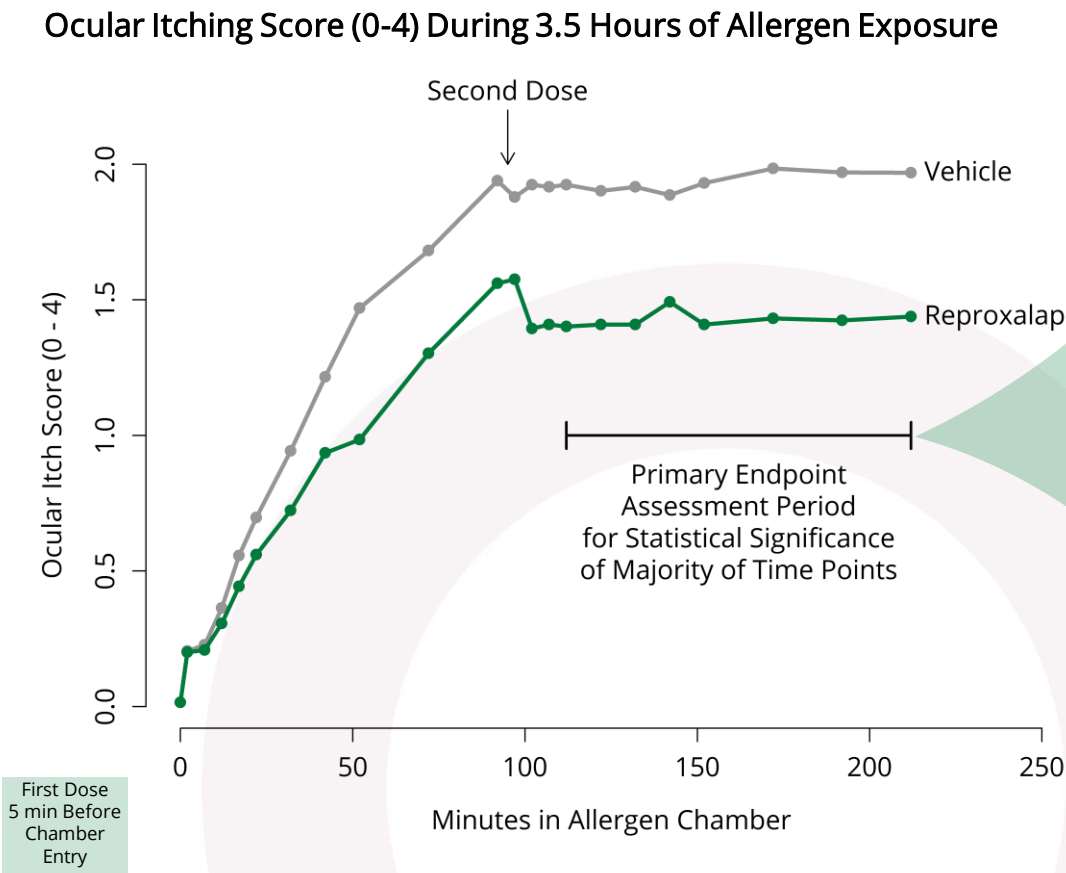


Statistically significant reduction in ocular redness vs. vehicle for 3.5 hours of continuous exposure to allergen



Topical ocular reproxalap has been studied in over 1,100 patients thus far with no observed safety concerns; mild instillation site irritation is the most commonly reported adverse event in clinical trials.
Source: Aldeyra Therapeutics methodology development clinical trial (reproxalap 0.25%; ClinicalTrials.gov #NCT03709121); n=66

Confirmed INVIGORATE Phase 3 Primary Endpoint Achieved in Allergen Chamber Clinical Trial*



Allergen chamber time point	p value
112	0.0002
122	0.0004
132	0.0002
142	0.0044
152	0.0001
172	<0.0001
192	<0.0001
212	0.0002

All time points from 110 to 210 minutes were statistically significant in Allergen Chamber trial



*The safety and efficacy results of later phase or subsequent clinical trials may not confirm the results of earlier trials; p-value derived from Mixed effect Model Repeat Measurement (MMRM) time point analyses. Topical ocular reproxalap has been studied in over 1,100 patients thus far with no observed safety concerns; mild instillation site irritation is the most commonly reported adverse event in clinical trials.

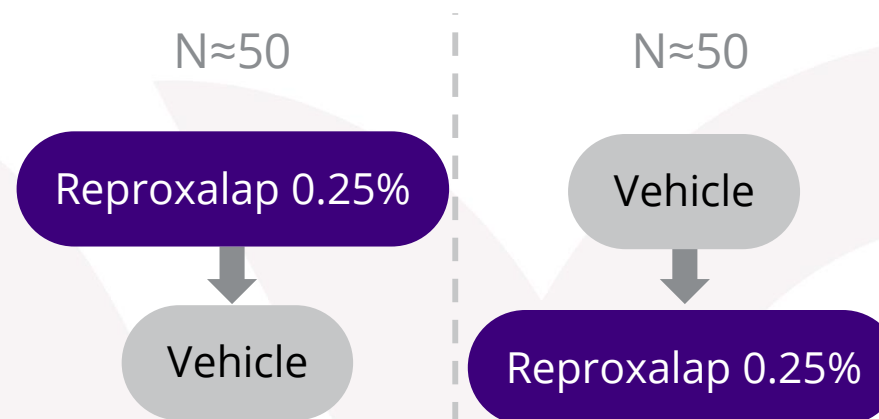
Source: Aldeyra Therapeutics allergen chamber clinical trial – reproxalap 0.25% (ClinicalTrials.gov #NCT03709121); n=66

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:**
 - Same as prior allergen chamber trial
- **Dosing schedule and chamber exposure:**
 - Same as prior allergen chamber trial

Initiated January 2020

Two-Way Randomized Crossover





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CORPORATE REVIEW

Ocular Disease Area

- DRY EYE DISEASE
- ALLERGIC CONJUNCTIVITIS
- **PROLIFERATIVE VITREORETINOPATHY**

ADX-2191 Represents a New Approach for PVR

– A Rare Sight-Threatening Retinal Disease With No Approved Therapy

Proliferative vitreoretinopathy

ADX-2191

4,000
U.S.

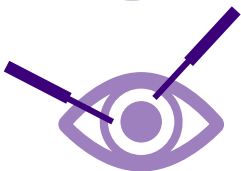
PVR is a **rare disease**, with ~4,000 patients per year in the U.S. and nearly twice as many in Europe and Japan combined.



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



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



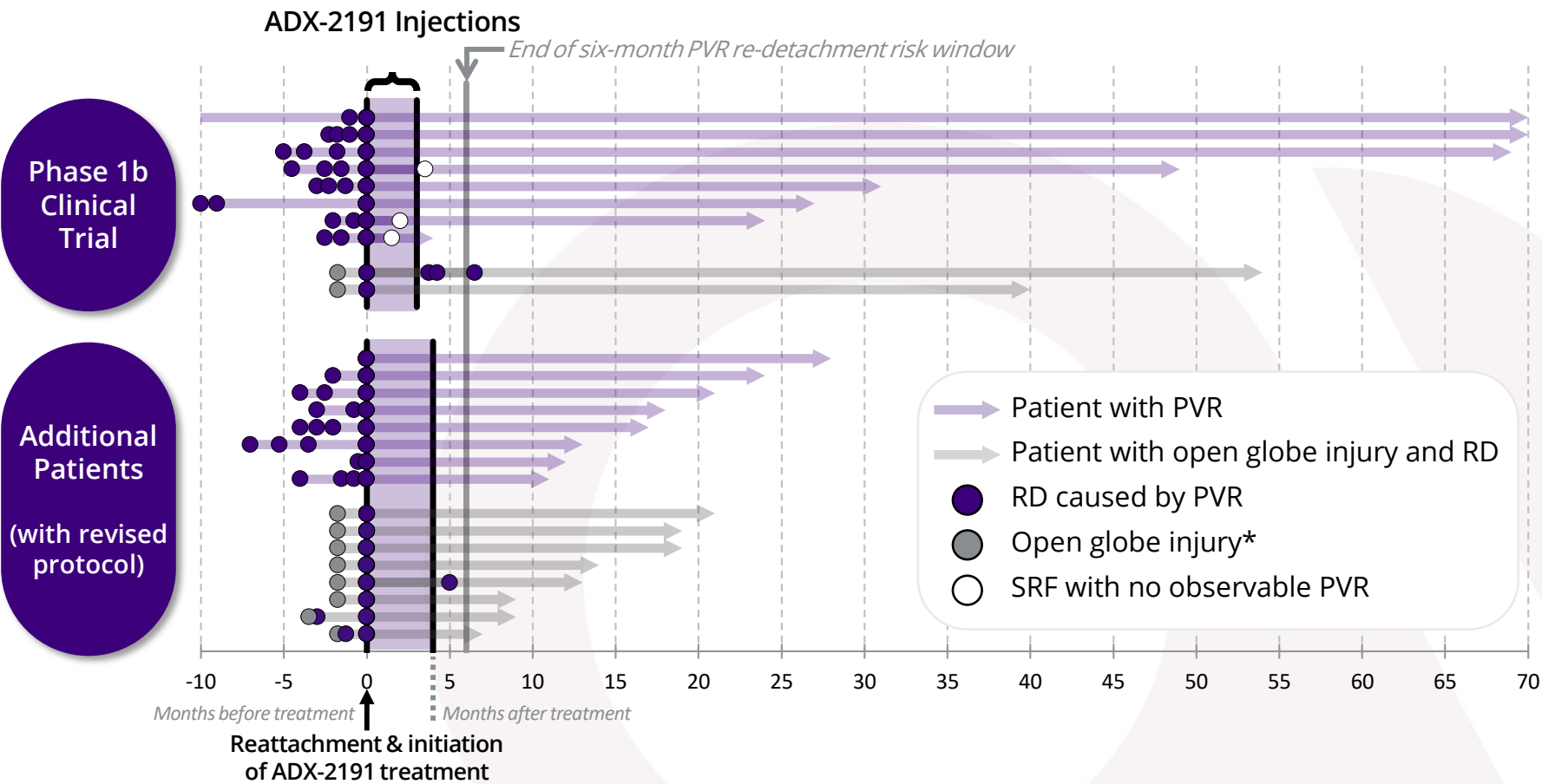
Repeat surgery, which can lead to **vision loss**, is currently the only possible course of action.

ADX-2191

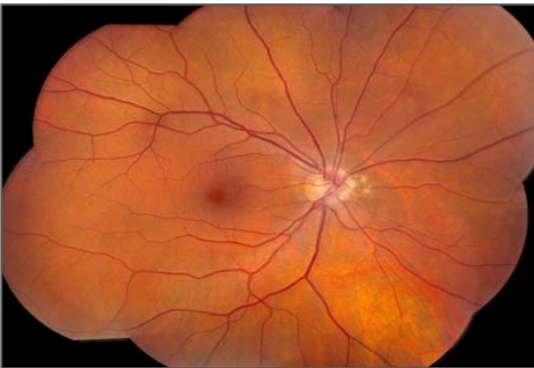
- A **novel approach and potential therapeutic breakthrough** in PVR treatment
- **Granted U.S. orphan designation** for the prevention of PVR
- **Granted FDA fast track designation** for the prevention of PVR
- **Tolerability and reattachment success** during study period **demonstrated in Phase 1b** 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



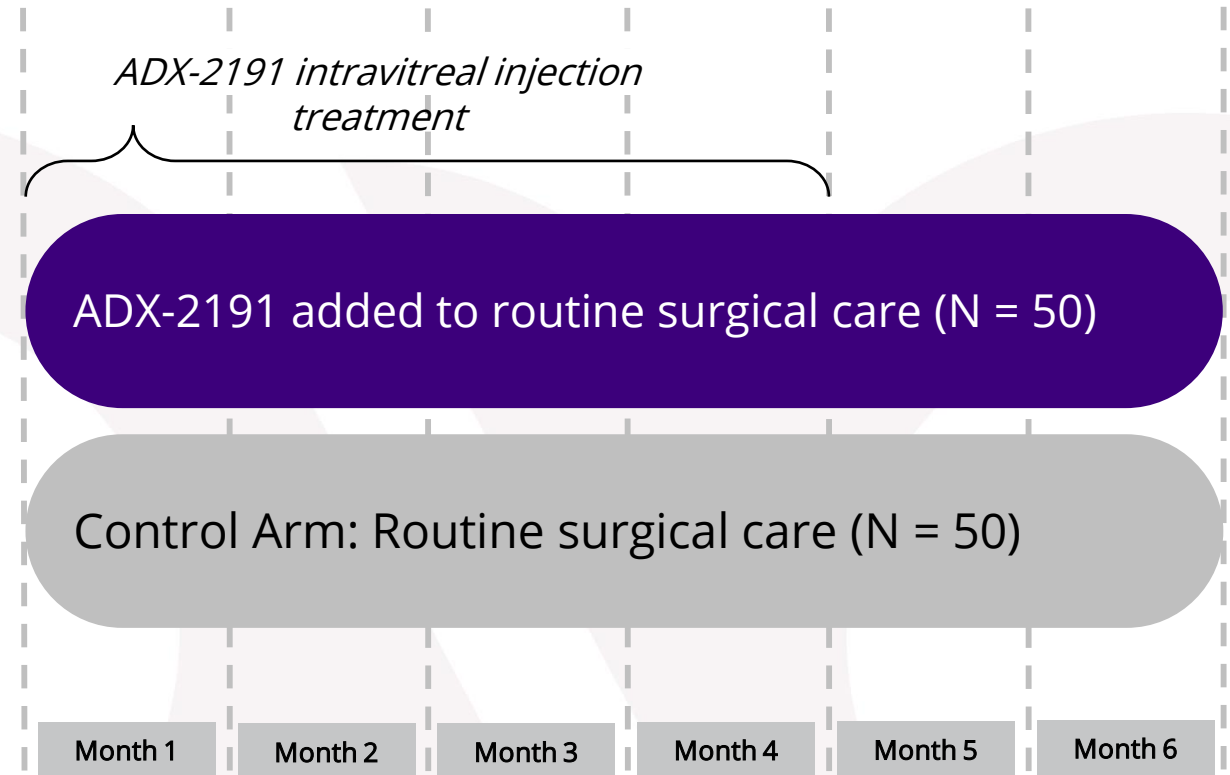
*Timing of open globe injury as shown is estimated. Typically 6-8 weeks prior to reattachment & initiation of ADX-2191.
There is no assurance that prior results, such as signals of safety, activity or durability of effect, observed from this open label investigator sponsored trial will be replicated 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



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CORPORATE REVIEW

Systemic Disease Area

- SJÖGREN-LARSSON SYNDROME

Reproxalap Represents a New Approach For SLS

– A Rare RASP-Mediated Disease with No Approved Therapy

Sjögren-Larsson Syndrome

1,000
U.S.

SLS is a rare inborn error of metabolism caused by a mutation in the gene encoding fatty aldehyde dehydrogenase; there are ~1,000 SLS patients in the U.S. and a greater number in Europe.



Severe symptoms significantly impact SLS patient and caregiver quality of life.



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



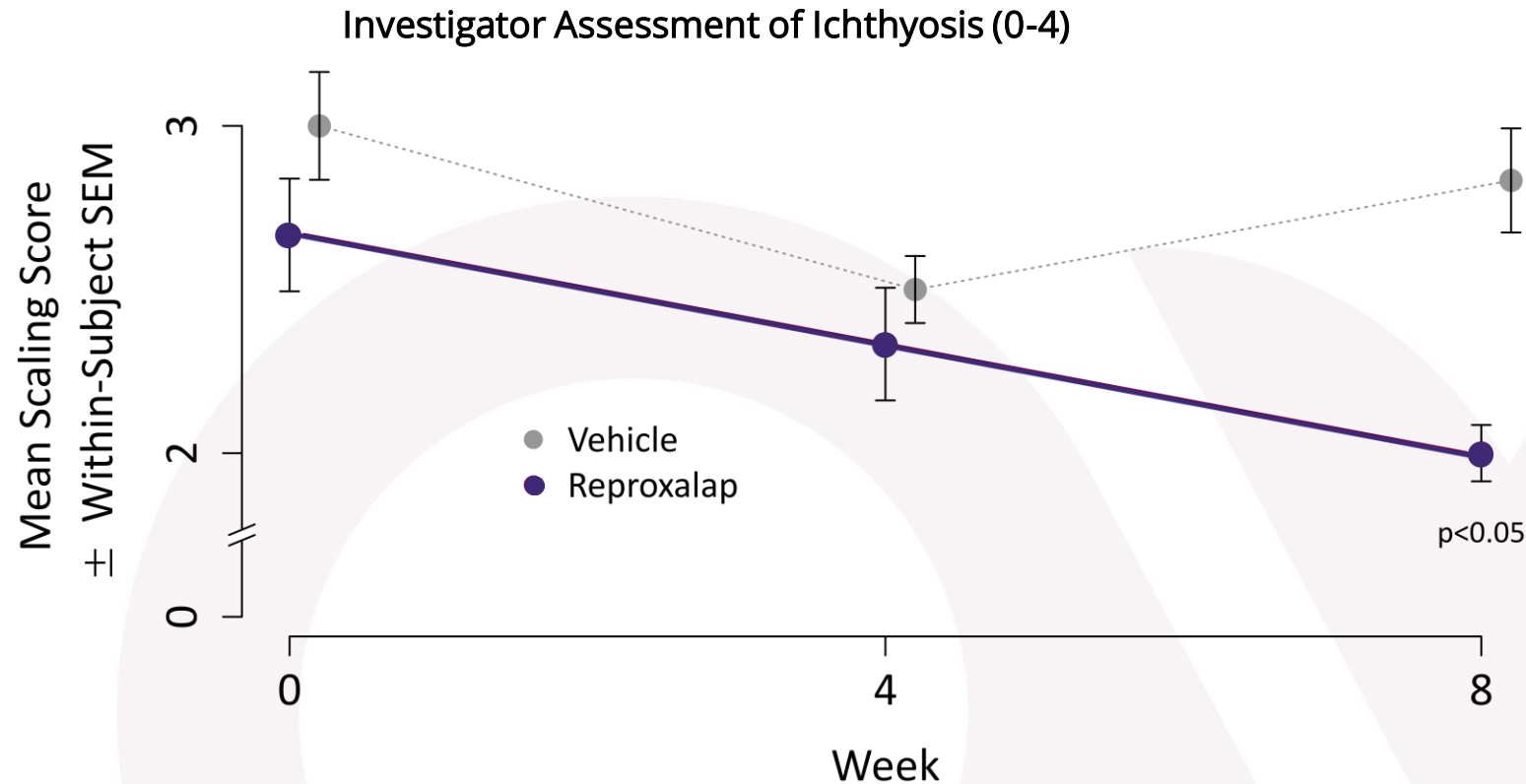
Nonstop disease burden diminishes quality of patient/caregiver life, with hours devoted to managing painful scaling, monitoring, & care.

Reproxalap

Reproxalap

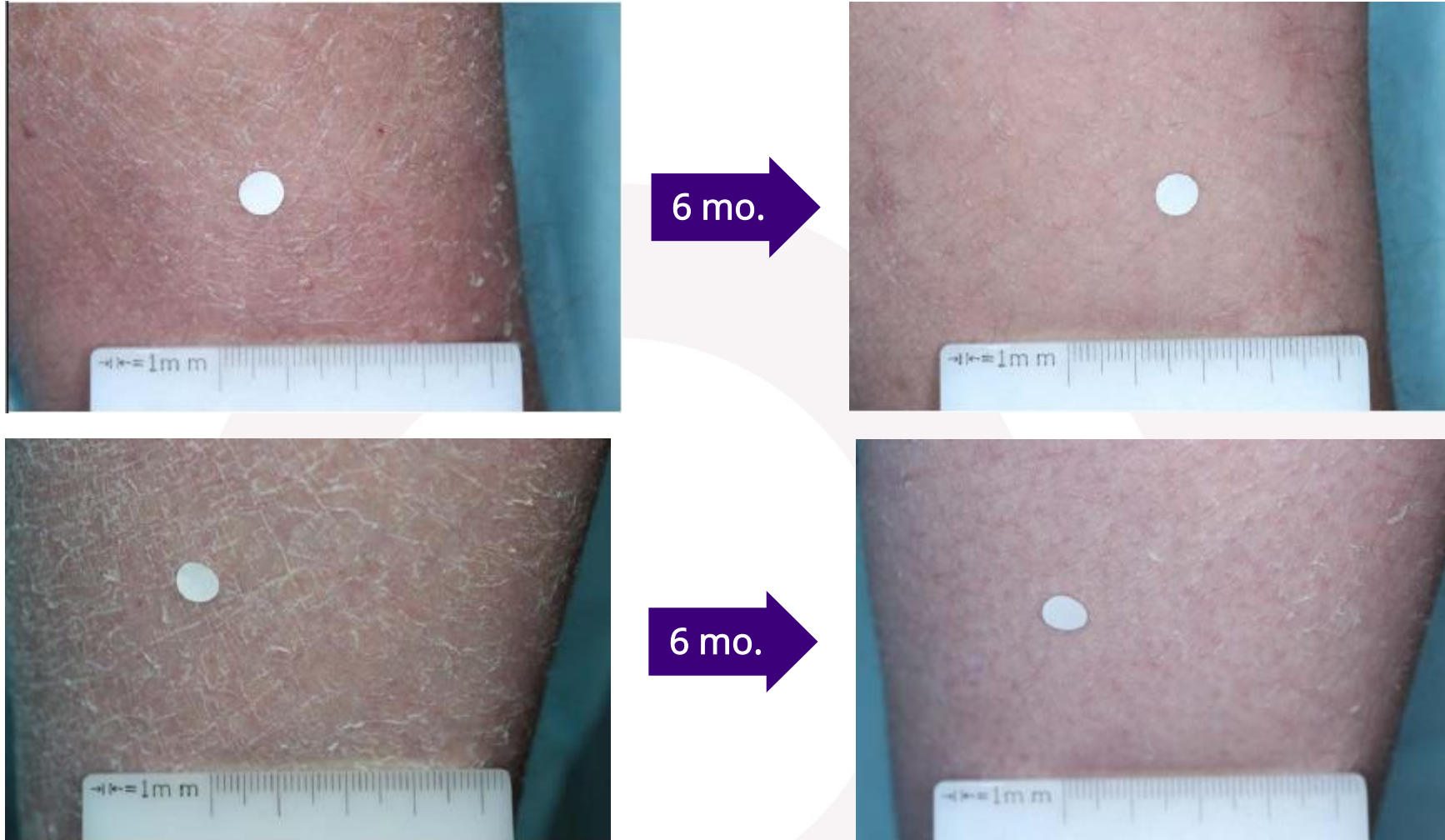
- A novel approach and potential lifelong therapy to replace missing enzymatic activity in SLS
- Granted U.S. orphan designation for the treatment of congenital ichthyosis (primary symptom of SLS)
- Significantly reduced SLS ichthyosis in a randomized, vehicle-controlled Phase 2 clinical trial
- RESET Phase 3-Part 1 completed Q2 2019; results to be discussed with regulatory authorities prior to initiating subsequent clinical testing

Reproxalap Demonstrated Clinically Relevant and Consistent Activity in Phase 2 Clinical Trial



Over two months of treatment, ichthyosis improved consistently from moderate to mild disease

Scaling Scores Statistically Lower Than Baseline Observed in Reproxalap-Treated Patients in RESET Part 1





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CORPORATE REVIEW

An Innovative Platform for Ocular and Systemic Immune- Mediated Diseases

Nasdaq: ALDX
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Deep and Innovative Pipeline Focused on 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				
	ADX-103/10X	RASP	Retinal Disease				
	Undisclosed		Ocular Inflammation	Research Collaboration (undisclosed)			
Systemic Diseases	Reproxalap	RASP	Sjögren-Larsson Syndrome				
	ADX-1612	CHP	PTLD				
			Mesothelioma	Investigator-Sponsored Trial			
			Ovarian Cancer	Investigator-Sponsored Trial			
	ADX-629	RASP	Autoimmune / Metabolic Disease				
	ADX-1615	CHP	Autoimmune Disease / Cancer				
	Undisclosed	RASP	Systemic Inflammatory Disease	Research Collaboration			

Upcoming and Recently Achieved Development Milestones: Novel Approaches to Address Immune-Mediated Disease

○ = Ocular Diseases
○ = Systemic Diseases



Primary objective met reproxalap dry eye disease
RENEW-Part 1 top-line results December 2019



ADX-2191 proliferative vitreoretinopathy **GUARD**
Phase 3 - Part 1 clinical trial initiation Dec. 2019



Reproxalap allergic conjunctivitis **INVIGORATE**
Phase 3 initiation January 2020



Reproxalap dry eye disease **RENEW** Phase 3-Part 2
initiation H1 2020



ADX-629 SAD/MAD **Phase 1 clinical trial results H1**
2020



Reproxalap allergic conjunctivitis design for
INVIGORATE Phase 3 confirmed October 2019



ADX-629 systemic **Phase 1 clinical trial initiation**
H2 2019



Reproxalap Sjögren-Larsson Syndrome
RESET Phase 3 - Part 1 completion Q2 2019



Positive reproxalap allergic conjunctivitis **allergen**
chamber trial top-line results



Reproxalap dry eye disease **RENEW** Phase 3 - Part
1 clinical trial initiation April 2019



Positive reproxalap allergic conjunctivitis
ALLEVIATE Phase 3 trial results March 2019

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 Clark, M.D.
Chief Medical Officer

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

Stephen Machatha, Ph.D.
SVP Technical Operations



Board of Directors

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

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



A New Paradigm for the Treatment of Immune- Mediated Diseases