November 2019

CORPORATE REVIEW

Innovating Transformative Therapies

Nasdaq: ALDX

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Our Mission

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

~7%

Of Western Society

Suffer from some form of **immune-mediated disease,** and **incidence is increasing**

Disease control elusive despite existing therapies, and thus **novel approaches are needed**

Source: Lerner, Jeremias, and Matthias, International Journal of Celiac Disease, vol. 3, no. 4 (2015): 151-155;
Shurin and Smolkin, Advances in Experimental Medicines and Biology 601:3-12, 2007; Kuek et al, Postgraduate Medical Journal 83(978): 251-260, 2007.

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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	Next Anticipated Milestone
Ocular Diseases	Reproxalap	[RASP]	Dry Eye Disease	Phase 3	Phase 3-Part 1 completion Q4 2019
			Allergic Conjunctivitis	Phase 3	Phase 3 initiation H1 2020
	ADX-2191	[DHFR]	Proliferative Vitreoretinopathy	Phase 3	Phase 3-Part 1 initiation Q4 2019
	ADX-103/10X	[RASP]	Retinal Disease	Phase 1	Phase 1/2 initiation 2020
	Undisclosed		Ocular Inflammation	Preclinical	*Research Collaboration (undisclosed)*
Systemic Diseases	Reproxalap	[RASP]	Sjögren-Larsson Syndrome	Phase 3	Parallel Regulatory Advice
	ADX-1612	[CHP]	PTLD	Phase 2	Phase 2 initiation H2 2019
			Mesothelioma	Phase 2	*Investigator-Sponsored Trial*
			Ovarian Cancer	Phase 2	*Investigator-Sponsored Trial*
	ADX-629	[RASP]	Autoimmune / Metabolic Disease	Phase 2	
	ADX-1615	[CHP]	Autoimmune Disease / Cancer	Preclinical	
	Undisclosed	[RASP]	Systemic Inflammatory Disease	Preclinical	*Research Collaboration* janssen

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RASP Mechanism = Reactive Aldehyde Species Inhibitor
DHFR Mechanism = Dihydrofolate Reductase Inhibitor
CHP Mechanism = Chaperome Inhibitor
PTLD = Post-Transplant Lymphoproliferative Disorder

Trial initiations contingent on funding, regulatory review, and other factors

Our Lead Programs May Offer Potential Benefits Over Standard of Care

Late Stage Programs	Current Standard of Care	Pricing Benchmarks†	Drug Candidate and Dev. Stage	Potential Competitive Advantages †
Ocular Diseases				
Dry Eye Disease	Xiidra®, Restasis®	$500-550 per month (dry eye disease pricing)	Reproxalap: Phase 3	Rapid onset, broad activity, reduction in itch
Allergic Conjunctivitis	Antihistamines		Reproxalap: Phase 3	Non-drying, durable activity; Responder superiority vs. vehicle
Proliferative Vitreoretinopathy	None (repeat surgeries)	$30,000 per course (avg. cost of surgeries)	ADX-2191: Phase 3	Clinically demonstrated activity; Currently no FDA- or EMA-approved therapy
Systemic Diseases				
Sjögren-Larsson Syndrome	None (manage symptoms)	$200,000 - $400,000 per year	Reproxalap: Phase 3	Clinically demonstrated activity; Currently no FDA- or EMA-approved therapy

†Pending clinical data, regulatory discussions, payor negotiations, competition, potential legislative changes, and other factors, which may not be in Aldeyra's control. Preliminary assumptions are subject to change.
Source: Aldeyra internal estimates based on primary and secondary market research; published literature

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Our Lead Programs Represent Compelling Commercial Opportunities

Late Stage Programs	Estimated U.S. Population†	U.S. Healthcare Providers	Competitive Value Proposition	Infrastructure Requirement‡
Ocular Diseases				
Dry Eye Disease	34 million DED Up to 10 million with DED & AC	~18,000 ophthalmologists and ~40,000 optometrists	Potential benefits over current therapies, which do not work well for many patients	Medium sized sales force for national reach
Allergic Conjunctivitis	30 million AC (addressable market)			
Proliferative Vitreoretinopathy	4,000	Retina specialists at targeted centers	Potential first and only Rx treatment	Small specialized operation
Systemic Diseases				
Sjögren-Larsson Syndrome	1,000	Geneticists and ped. neurologists	Potential first and only Rx treatment	Small specialized operation

†Pending clinical data, regulatory discussions, payor negotiations, competition, potential legislative changes, and other factors, which may not be in Aldeyra's control. Preliminary assumptions are subject to change.
Source: Aldeyra internal estimates based on primary and secondary market research; published literature

DED = Dry eye disease
AC = Allergic conjunctivitis

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CORPORATE REVIEW

Ocular Disease Area

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

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Reproxalap Represents a New Approach For Dry Eye Disease – A Persistently Disturbing And Inadequately Treated Condition

Dry Eye Disease

34 million

34 million or more **adults in the U.S.** suffer from DED.

Age 50+ >3x

DED **increases with age**, with those over age 50 three times more likely to suffer from DED.

vs

Women are twice as likely to suffer from DED than men.

Significant **negative quality of life** impact

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

Up to 75%

Up to 75% of patients with DED **are not satisfied with current prescription options**.

Up to 50%

Up to 50% of patients **treated for DED** with current therapies **fail and discontinue**.

Underserved Patient Population

Reproxalap

Reproxalap in DED

Early and consistent symptom and sign improvements in Phase 2b clinical trial

Broad symptom and sign improvements in Phase 2b clinical trial

Source: Aldeyra internal estimates based on primary and secondary market research; published literature

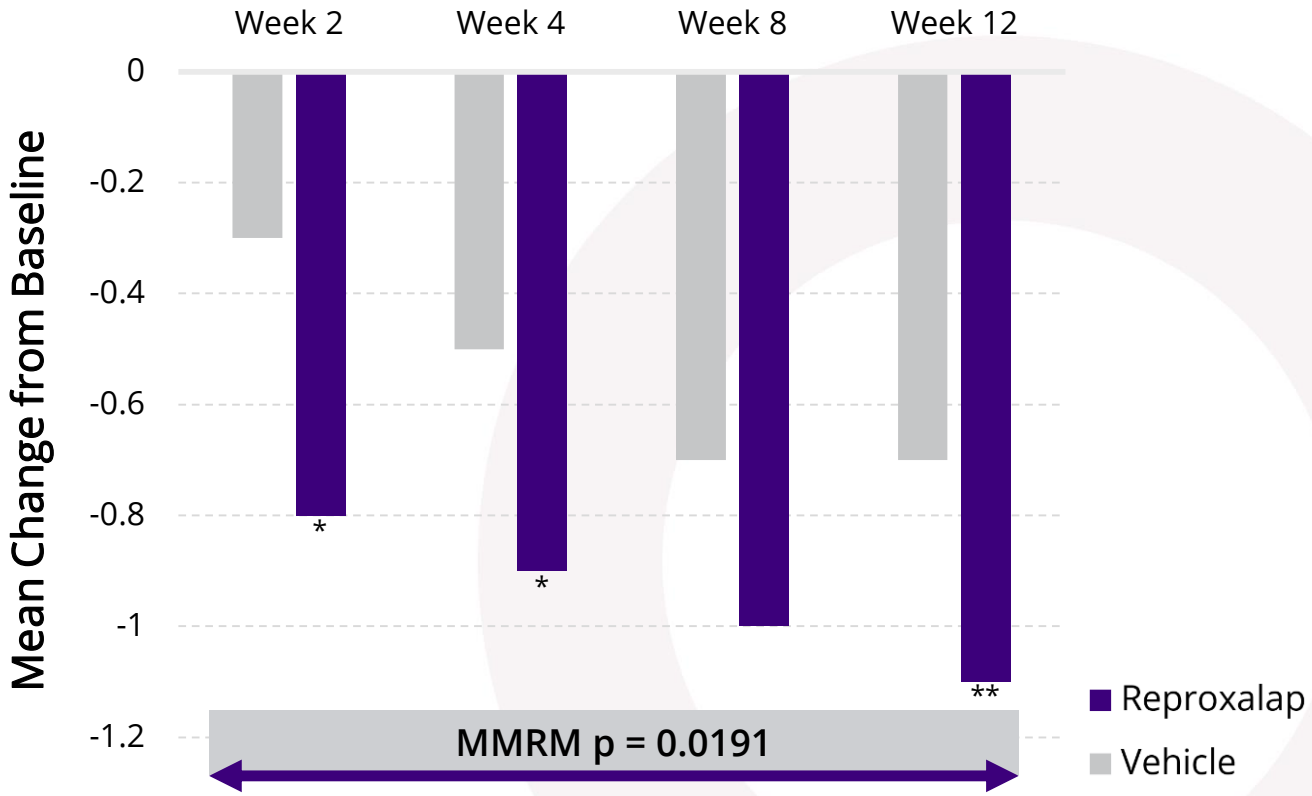
DED = Dry eye disease

Phase 3 Dry Eye Disease Symptom and Sign Endpoints Achieved in Phase 2b Clinical Trial†

Primary Symptom Endpoint for Phase 3‡

OD & 4-Symptom Questionnaire: Dryness (0-5)

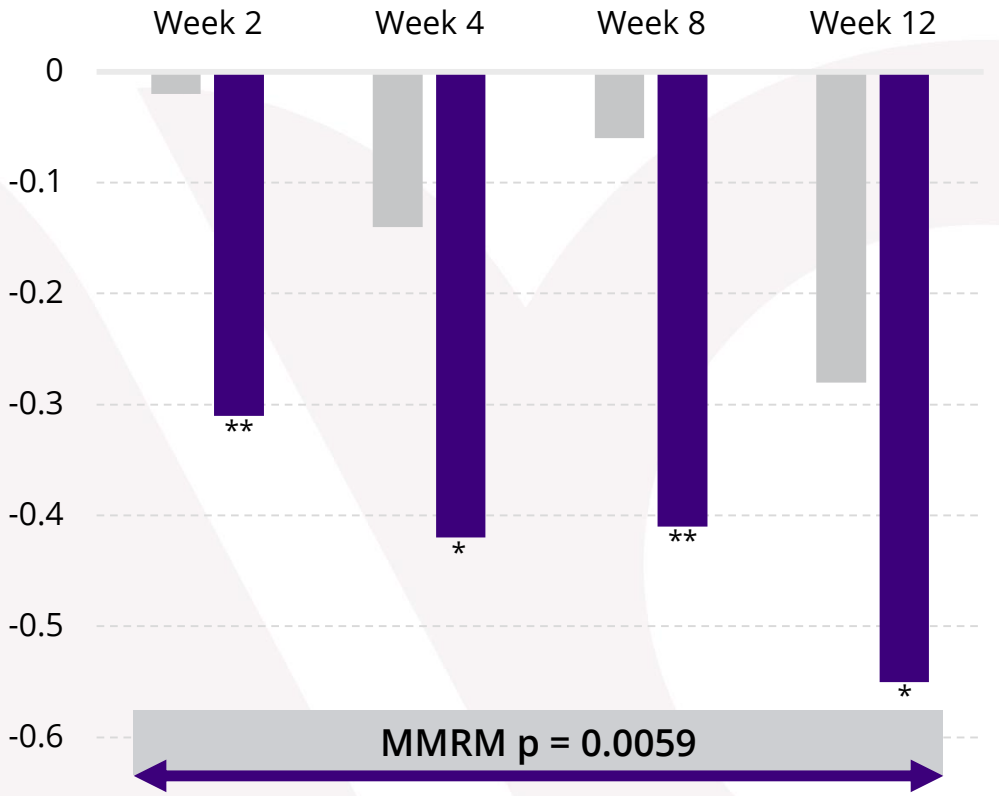
Baseline Score ≥ 3 (N=69|69)



Primary Sign Endpoint for Phase 3‡

Fluorescein Staining: Nasal (0-4)

Baseline Score ≥ 2 (N=62|56)



Topical ocular reproxalap has been studied in over 1,000 patients thus far with no observed safety concerns; mild instillation site irritation is the most commonly reported adverse event in clinical trials.

† The safety and efficacy results of later phase or subsequent clinical trials may not confirm the results of earlier trials.

‡ RENEW Phase 3 symptom co-endpoints are ocular dryness score VAS (0-100mm) and fluorescein nasal region staining.

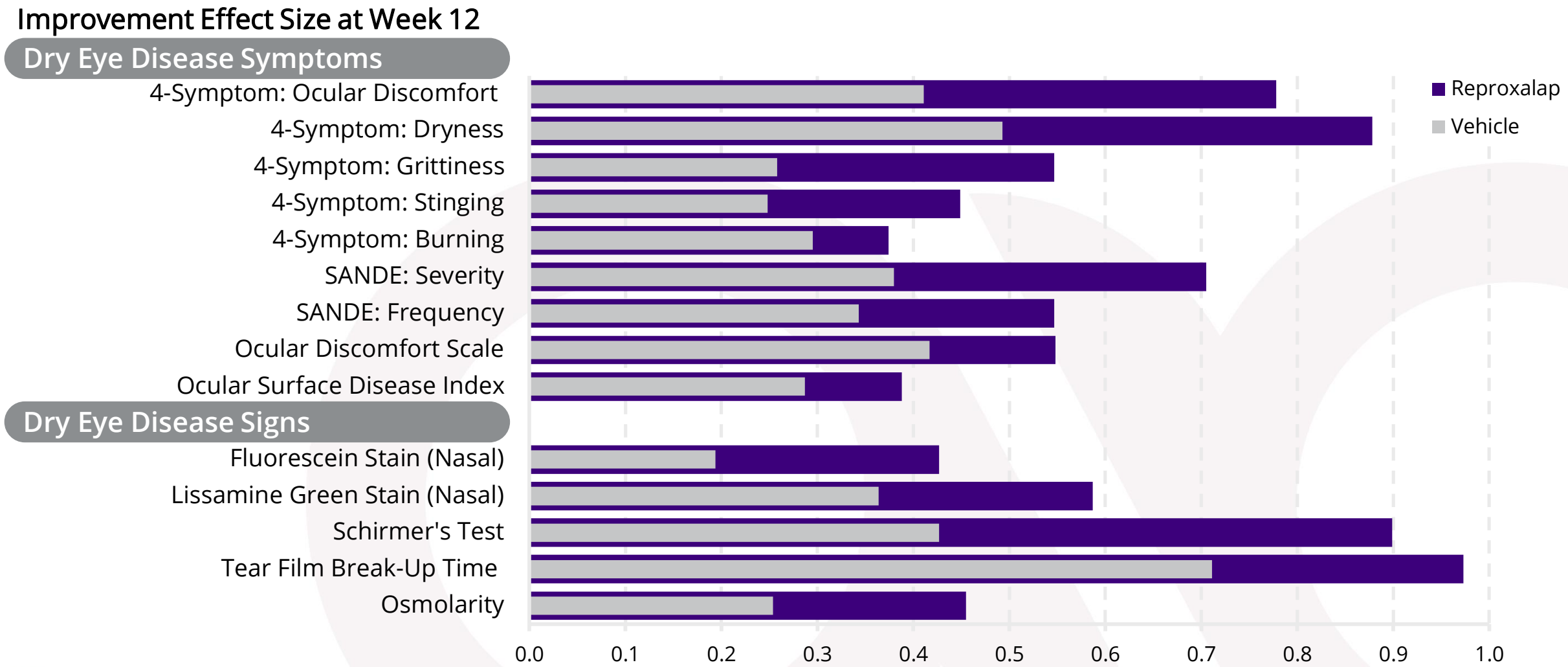
Source: Reproxalap 0.25% DED Phase 2b clinical trial results; p values shown represent reproxalap effect vs vehicle.

*p<0.05 **p<0.01

OD = Ocular Discomfort

MMRM = Mixed Effect Model Repeated Measures (across 12 weeks)

Broad Drug Activity Across All Measured Dry Eye Disease Symptoms and Signs in Phase 2b Clinical Trial Supports Differentiated Product Profile



Average improvement effect size across both eyes for Schirmer's Test, Tear Film Break-Up Time, and Osmolarity
Topical ocular reproxalap has been studied in over 1,000 patients thus far with no observed safety concerns; mild instillation site irritation is the most commonly reported adverse event in clinical trials.

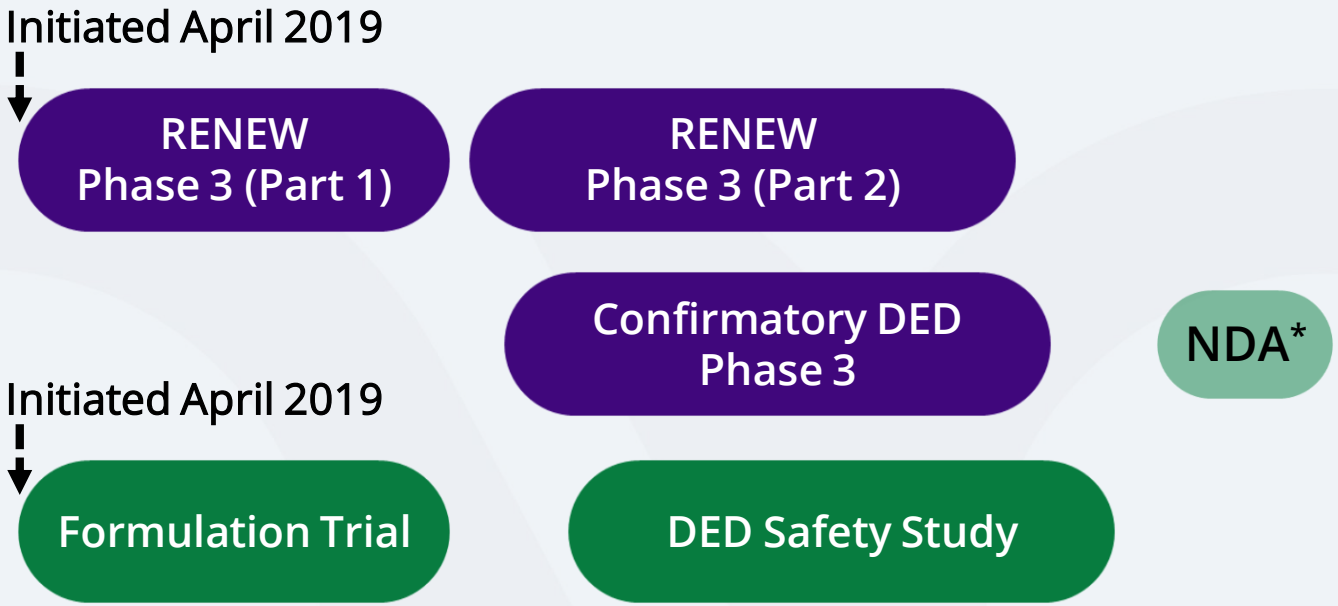
SANDE = Symptom Assessment in Dry Eye
Improvement Effect size = Change from Baseline / Standard Deviation at Baseline
Source: Reproxalap 0.25% DED Phase 2b clinical trial results

Adaptive Phase 3 Dry Eye Disease Clinical Program

Adaptive Phase 3 Program

- Confirm symptom and sign endpoints from Phase 2b trial
- Confirm dosing regimen (QID vs. QID to BID taper)
- Confirm sample size for subsequent trial

Dry Eye Disease
Clinical Program to NDA Submission



Adaptive design, co-primary endpoints, and innovative analysis strategy confirmed with FDA at EOP2 Meeting

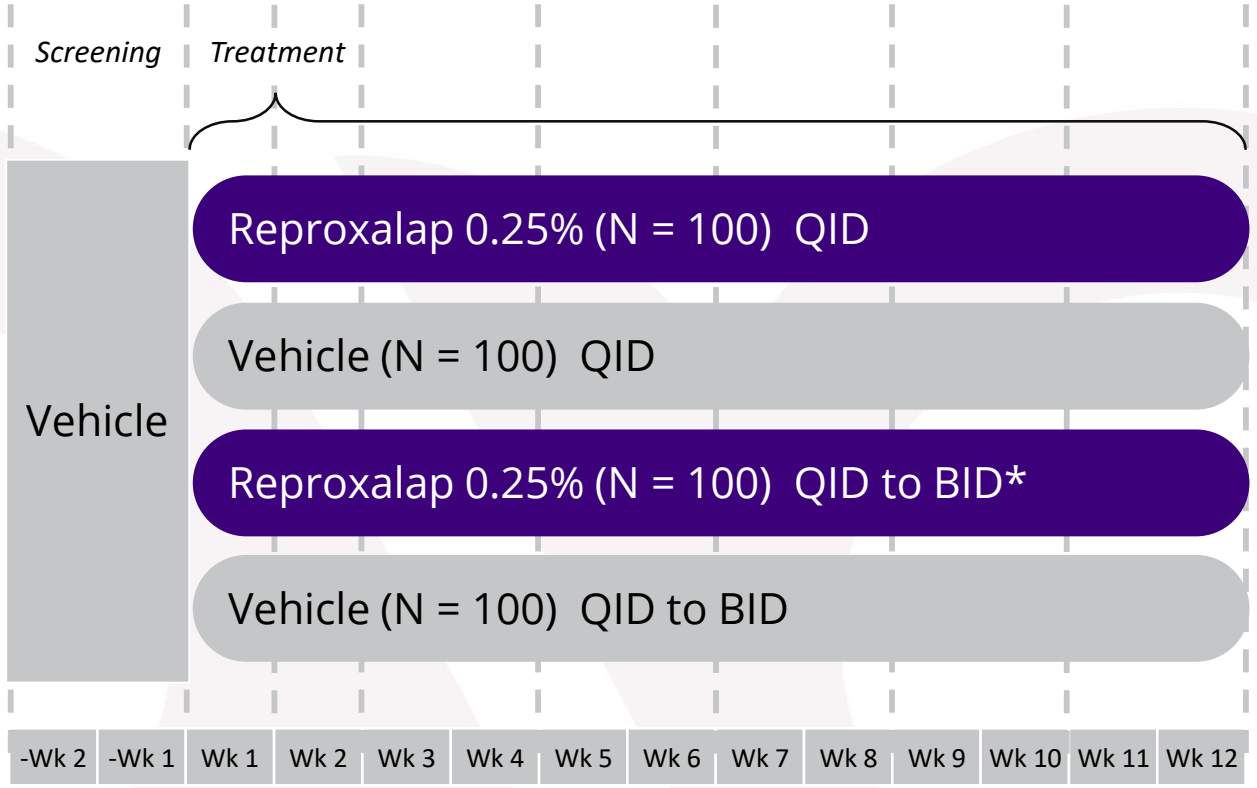
*Subject to regulatory discussions following Phase 3 trial completion.
Contingent on funding, clinical results, regulatory review, and other factors.

DED = Dry eye disease
BID = Two times daily
QID = Four times daily
EOP2 = End of Phase 2

The RENEW Phase 3 Clinical Trial in Dry Eye Disease Part 1 Initiated April 2019

- **RENEW-Part 1 primary objective:**
  - Evaluate efficacy of reproxalap ophthalmic solution (0.25%) vs. vehicle to confirm dosing regimen and sample size for RENEW-Part 2
- **RENEW-Part 1 inclusion/exclusion criteria:**
  - Same as used for Phase 2b
  - Moderate to severe dry eye disease
- **RENEW co-primary endpoints:**
  - Ocular dryness score (0-100mm VAS) and fluorescein nasal region staining
- **RENEW analysis strategy:**
  - Both co-primary endpoints will be assessed using Mixed Model Repeated Measures (MMRM) from week 2 to 12
  - Both co-primary endpoints will be assessed in separate pre-specified patient populations
    - Ocular dryness score (OD4SS): baseline score of $\geq$ 3
    - Fluorescein nasal staining: baseline score $\geq$ 2

Phase 3 Dry Eye Disease Clinical Trial: Part 1



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

*QID for weeks 1-4 and BID for weeks 5-12

VAS = Visual analog scale
OD4SS = Ocular Discomfort 4-Symptom Score

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Ocular Disease Area

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

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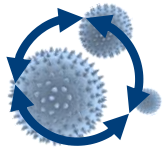
Reproxalap Represents a New Approach of Allergic Conjunctivitis – A Burdensome and Growing Disease with Unmet Medical Need

Allergic Conjunctivitis



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

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

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.

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

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

Growing and burdensome unmet medical need

Underserved Patient Population

Reproxalap

Reproxalap in AC

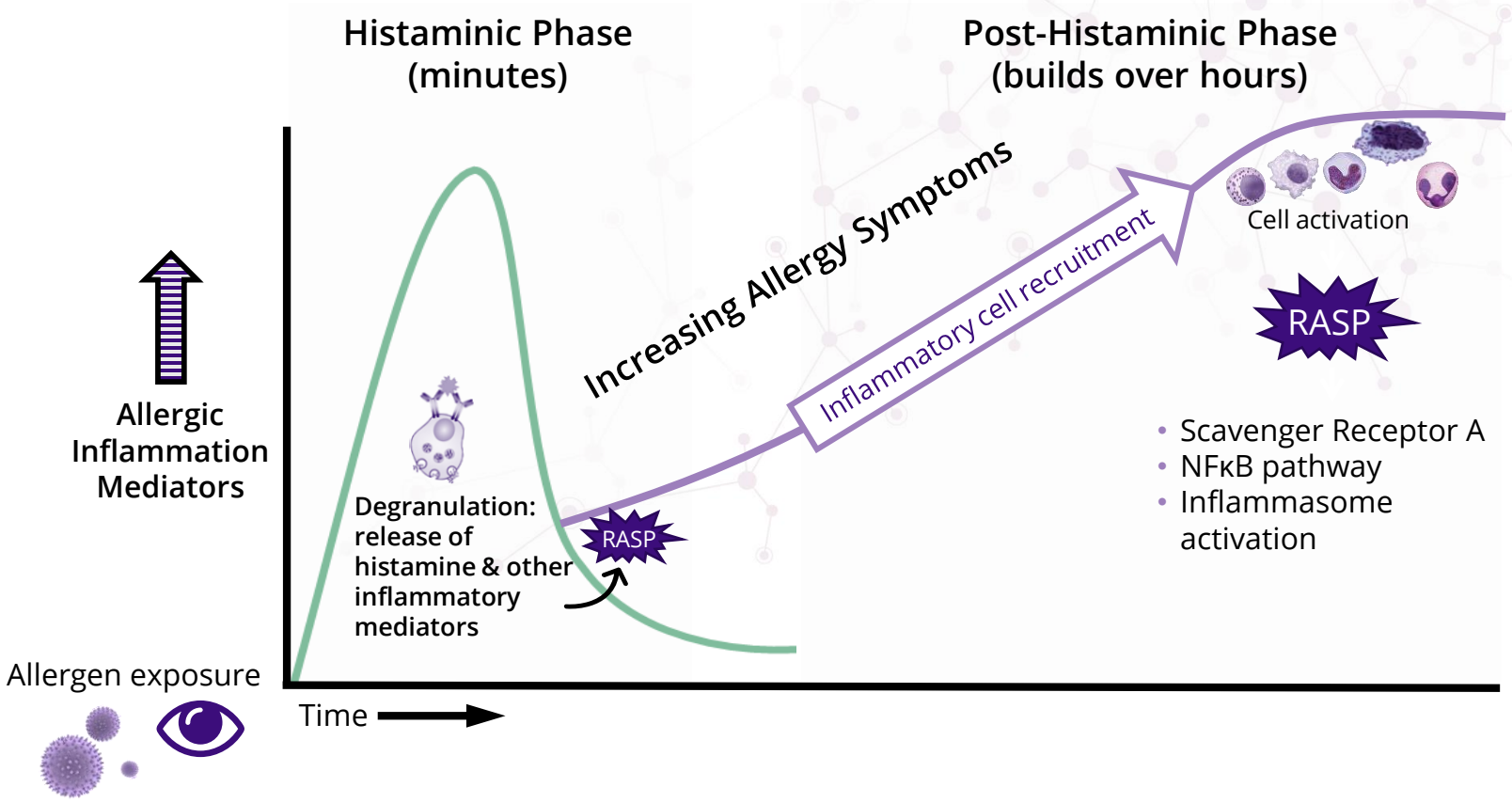
Clinically significant and durable symptom response in ALLEVIATE Phase 3 and allergen chamber clinical trials

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

*Analysis of Symphony Health Integrated Dataverse from 2010-2019 and publicly reported U.S. population growth estimates .
**IQVIA analysis of diagnosed AC patients utilizing topical ocular Rx treatments.
Source: Aldeyra internal estimates based on primary and secondary market research; published literature

AC = Allergic conjunctivitis

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



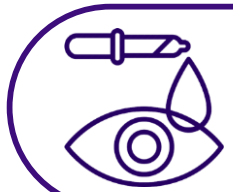
Reproxalap

- Reproxalap irreversibly inhibits RASP, limiting allergic inflammation.
- Reproxalap has the potential to be uniquely effective in post-histaminic allergy, which affects all allergic conjunctivitis patients.

RASP = Reactive Aldehyde Species

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

Expected to initiate H1 2020

- ✓ Supported by positive allergen chamber trial results

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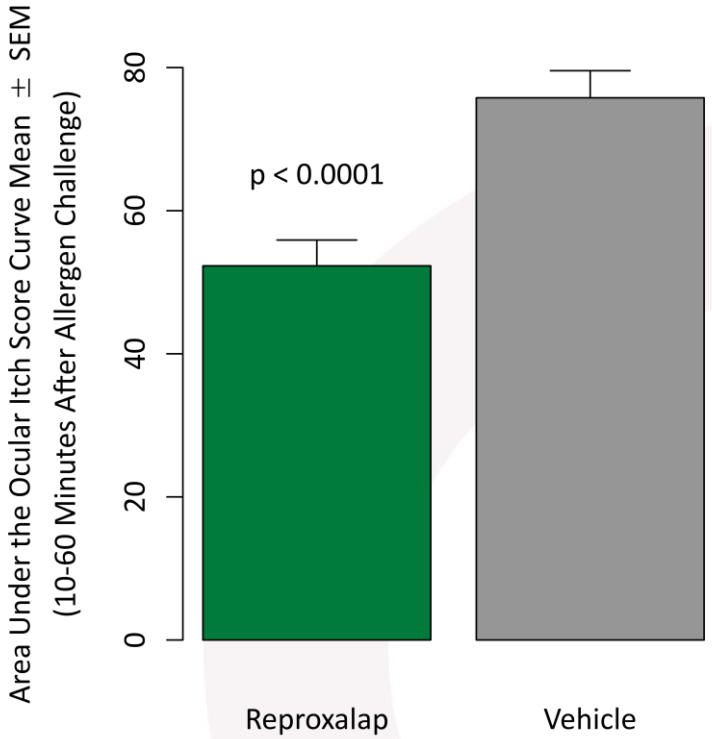
Reproxalap Demonstrated Greater and More Durable Clinical Responses than Vehicle Group in ALLEVIATE Phase 3 Clinical Trial

Primary Endpoint

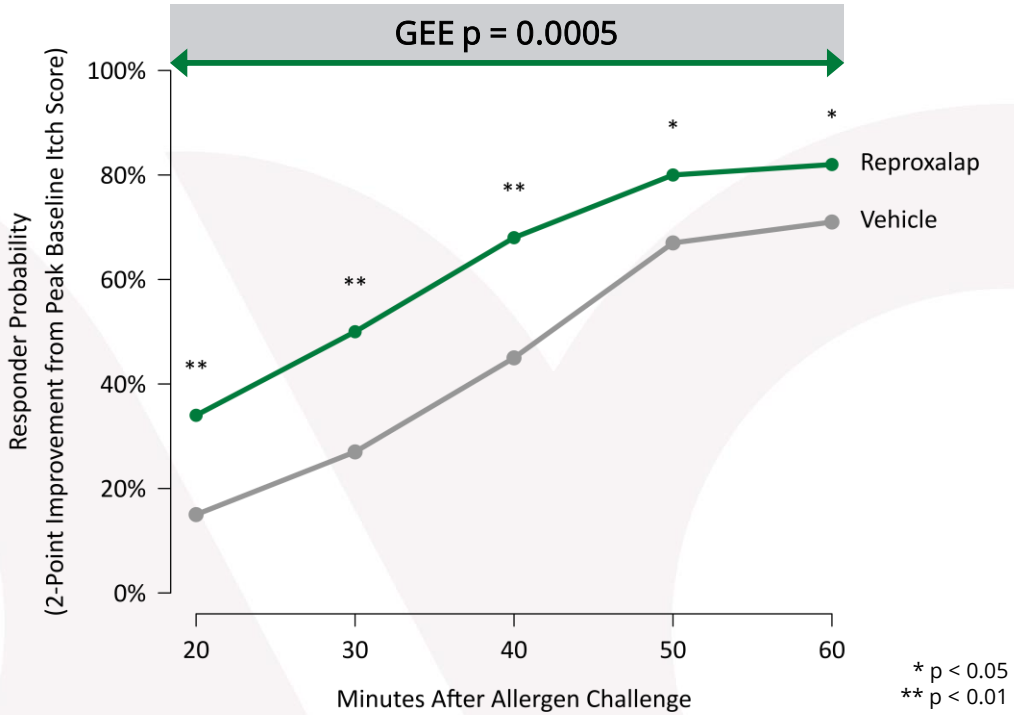
Area Under the Curve: Ocular Itch Score (0-4) 10 to 60 Minutes After Conjunctival Allergen Challenge



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



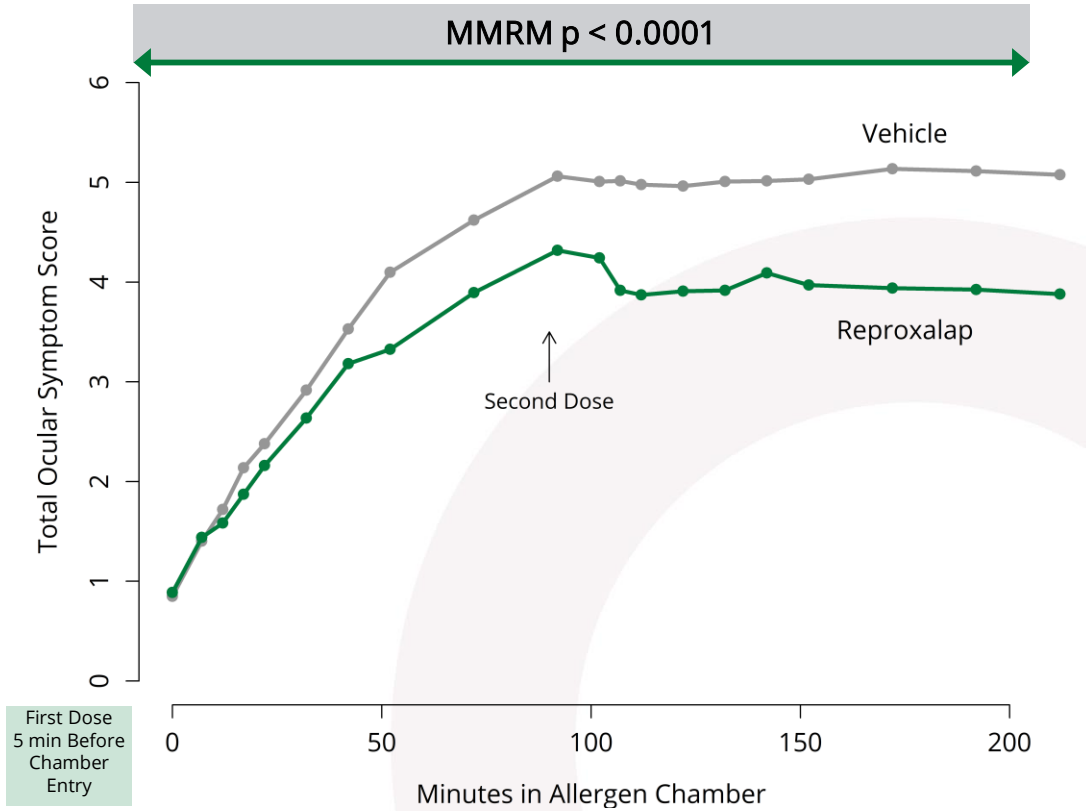
Clinically significant response rate of reproxalap statistically higher than that of vehicle

Topical ocular reproxalap has been studied in over 1,000 patients thus far with no observed safety concerns reported; mild instillation site irritation is the most commonly reported adverse event in clinical trials.
Source: ALLEVIATE allergic conjunctivitis Phase 3 clinical trial results (reproxalap 0.25%); Ocular itch scale 0 (no itch) to 4 (incapacitating itch)

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

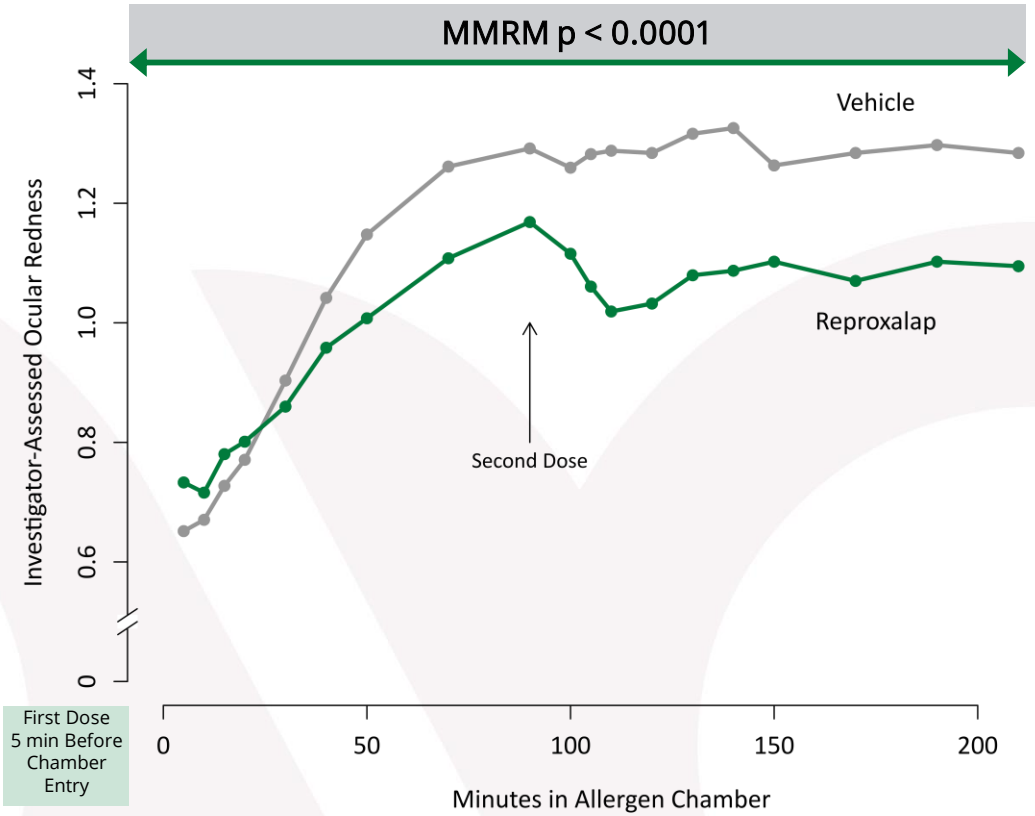
Reproxalap Demonstrated Greater and More Durable Clinical Responses than Vehicle in Allergen Chamber Clinical Trial

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



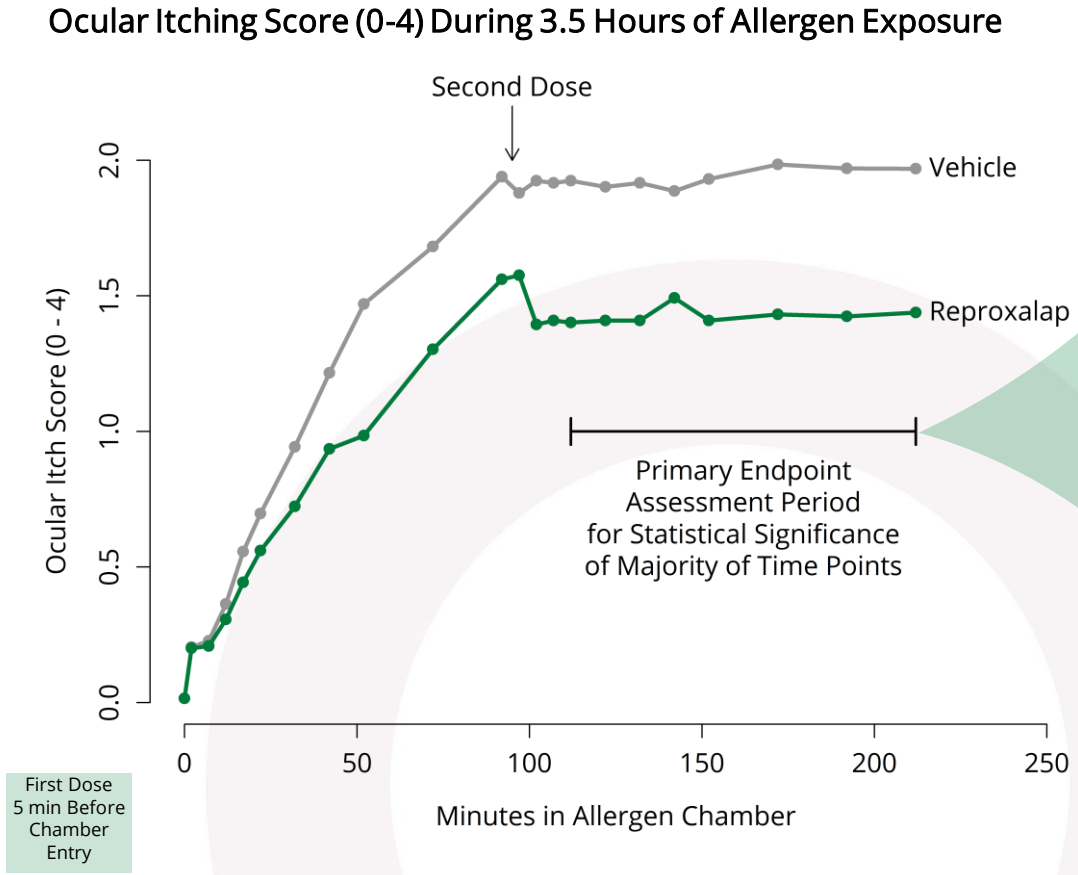
Statistically significant reduction in ocular redness vs. vehicle for 3.5 hours of continuous exposure to allergen

Topical ocular reproxalap has been studied in over 1,000 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

MMRM = Mixed Effect Model Repeated Measures

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

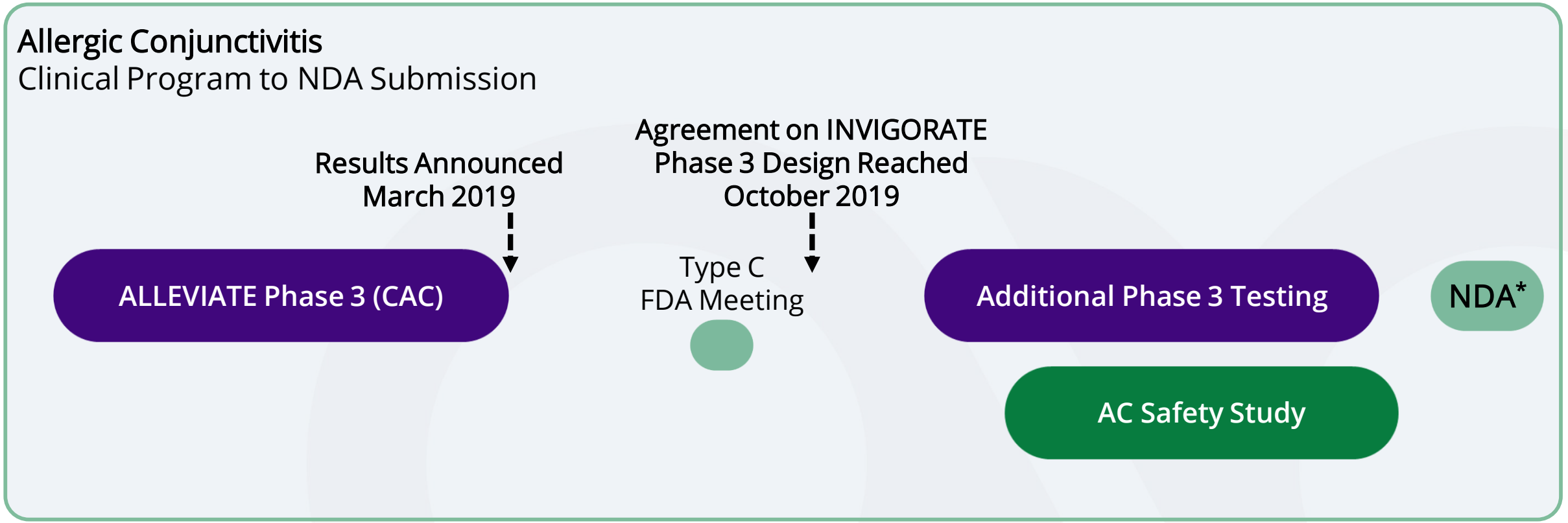


Allergen chamber time point	p value
112	0.0002
122	0.0004
132	0.0002
142	0.0044
152	0.0001
172	<0.0001
192	<0.0001
212	0.0002

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

Allergic Conjunctivitis Phase 3 Clinical Program



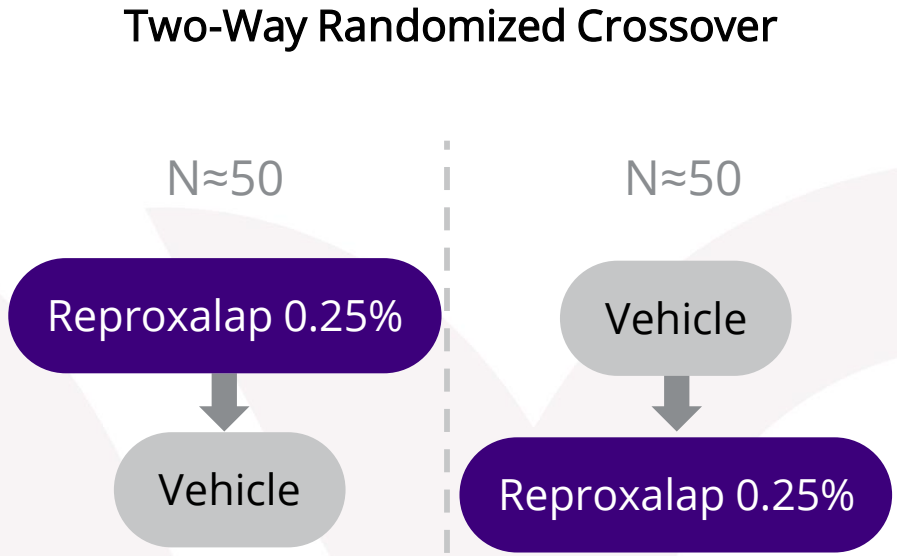
*Subject to regulatory discussions following Phase 3 trial completion.
Contingent on funding, clinical results, regulatory review, and other factors.

AC = Allergic conjunctivitis
CAC = Conjunctival Allergen Challenge

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

Expected to initiate H1 2020



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

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November 2019

CORPORATE REVIEW

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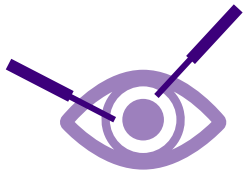
ADX-2191 Represents a New Approach For PVR – A Rare Sight-Threatening Retinal Disease With No Approved Therapy

Proliferative vitreoretinopathy

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

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

ADX-2191

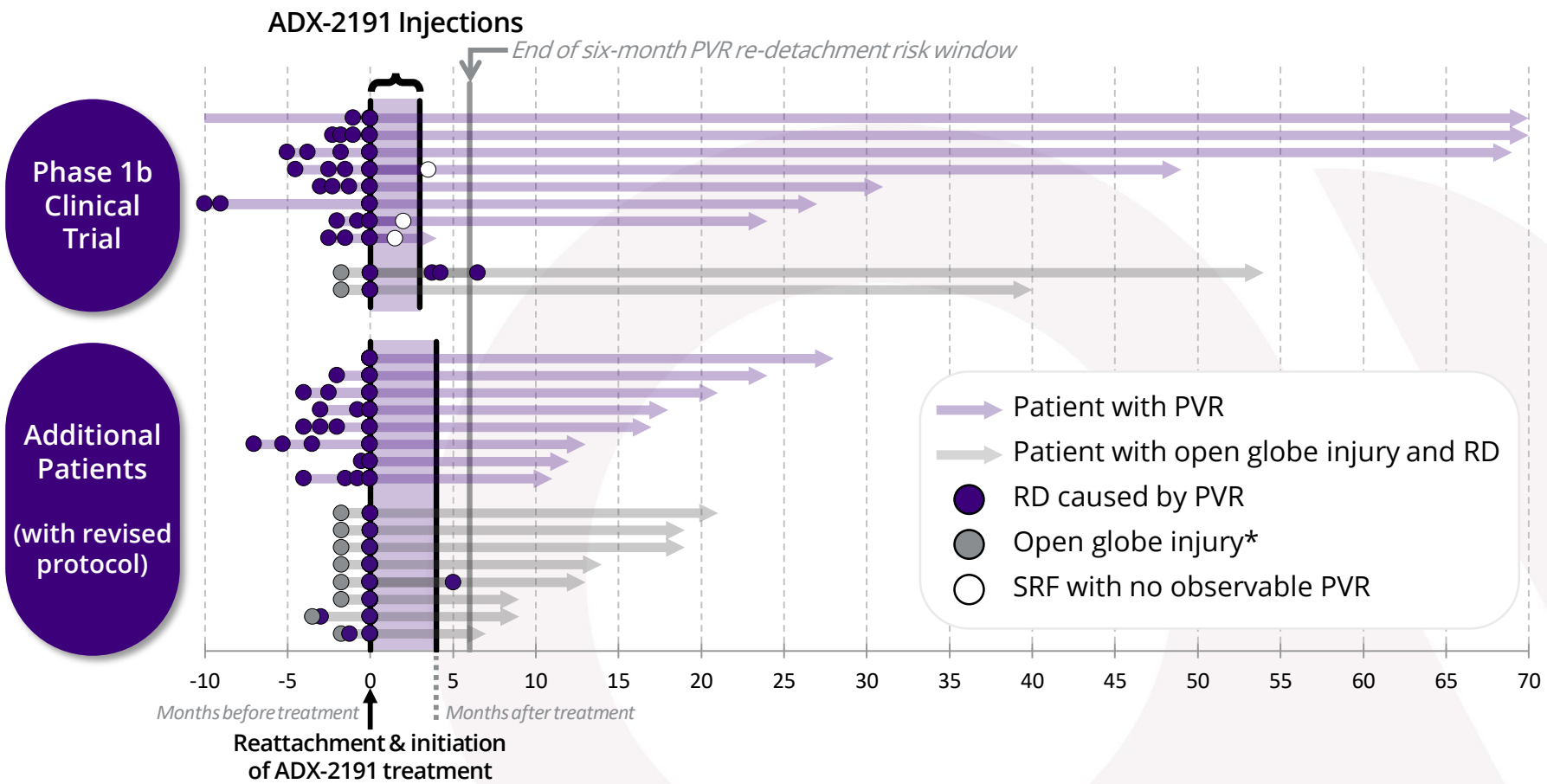
- A **novel approach and potential therapeutic breakthrough** in PVR treatment
- **Granted U.S. orphan designation** for the prevention of PVR
- **Granted FDA fast track designation** for the prevention of PVR
- **Tolerability and reattachment success** during study period **demonstrated in Phase 1b** open-label investigator sponsored clinical trial
- GUARD adaptive Phase 3 clinical trial **expected to initiate Q4 2019**

Source: Aldeyra internal estimates based on primary and secondary market research; published literature

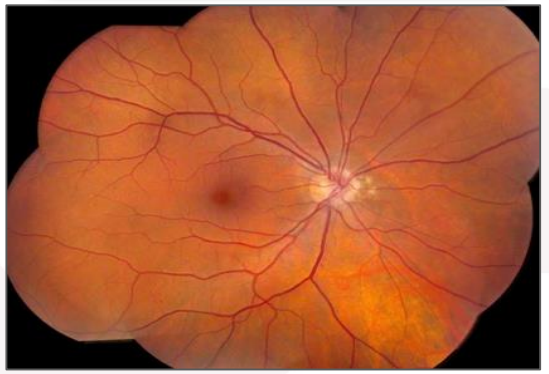
PVR = Proliferative vitreoretinopathy

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)

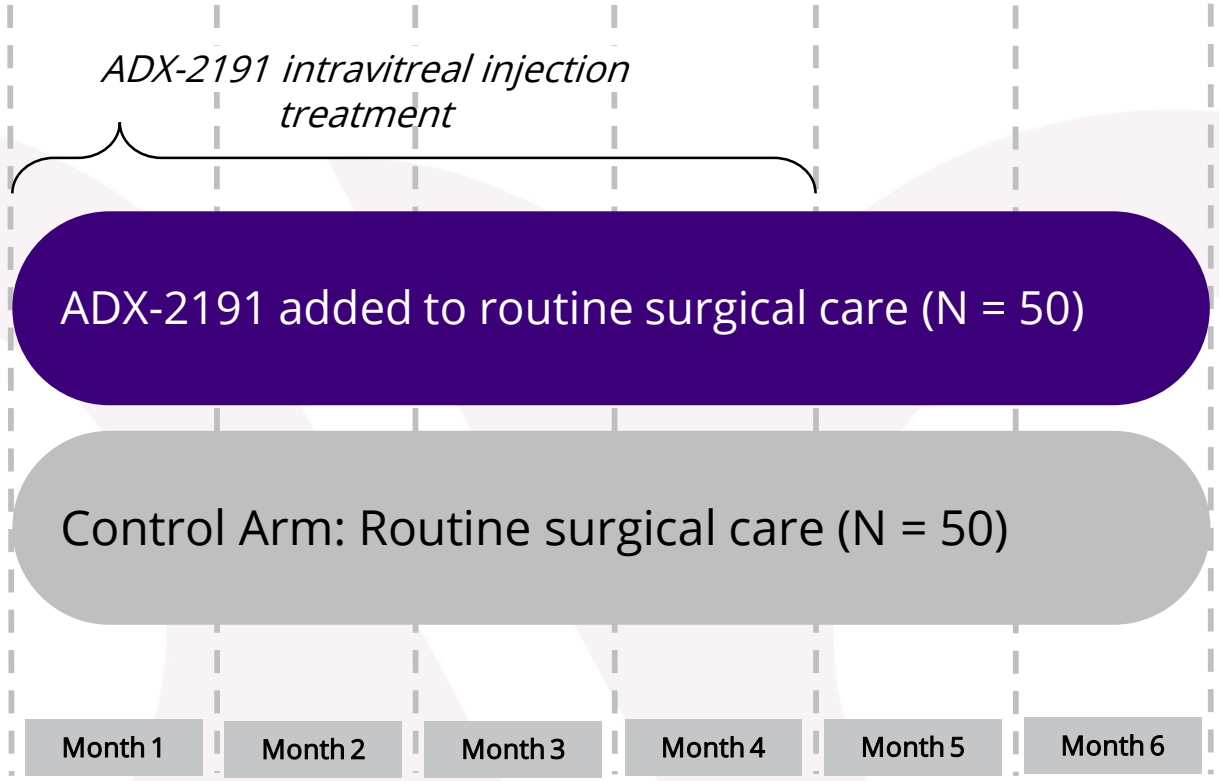
RD = Retinal detachment
PVR = Proliferative vitreoretinopathy
SRF = Subretinal fluid

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

Expected to initiate Q4 2019

Adaptive Phase 3 PVR Clinical Trial Design: Part 1



OCT = Optical Coherence Tomography
Contingent on funding, regulatory review, and other factors.

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Systemic Disease Area

- SJÖGREN-LARSSON SYNDROME

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Reproxalap Represents a New Approach For SLS – A Rare RASP-Mediated Disease with No Approved Therapy

Sjögren-Larsson Syndrome

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

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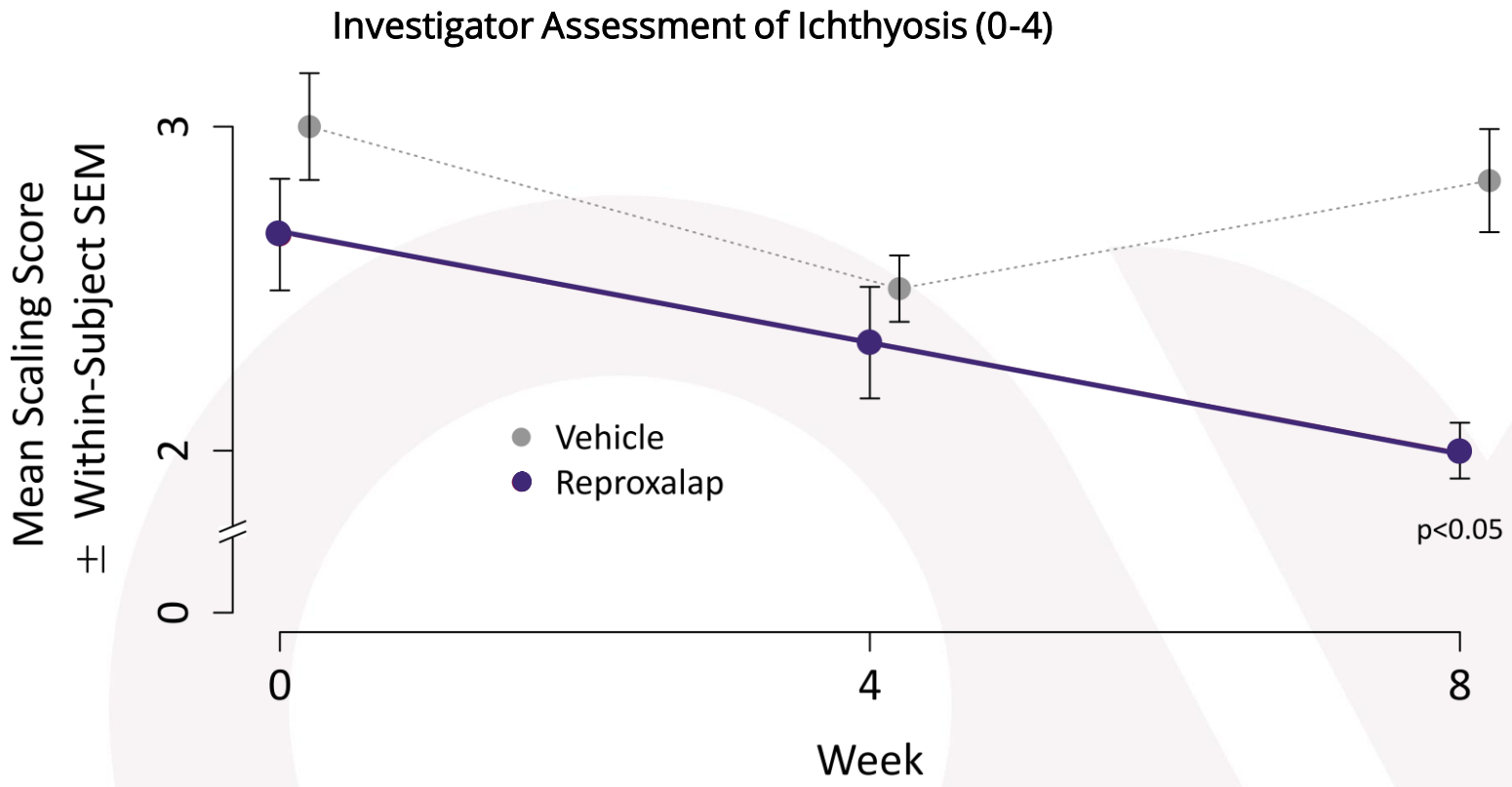
Source: Aldeyra internal estimates based on primary and secondary market research; published literature

RASP = Reactive Aldehyde Species
SLS = Sjögren-Larsson Syndrome

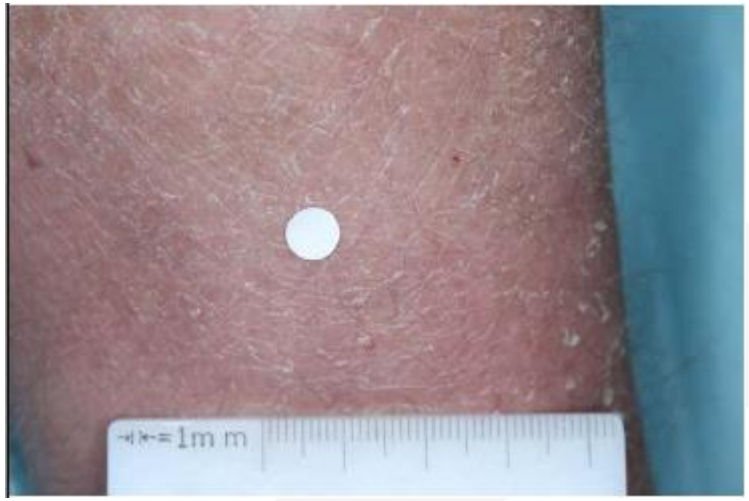
Reproxalap Demonstrated Clinically Relevant and Consistent Activity in Phase 2 Clinical Trial



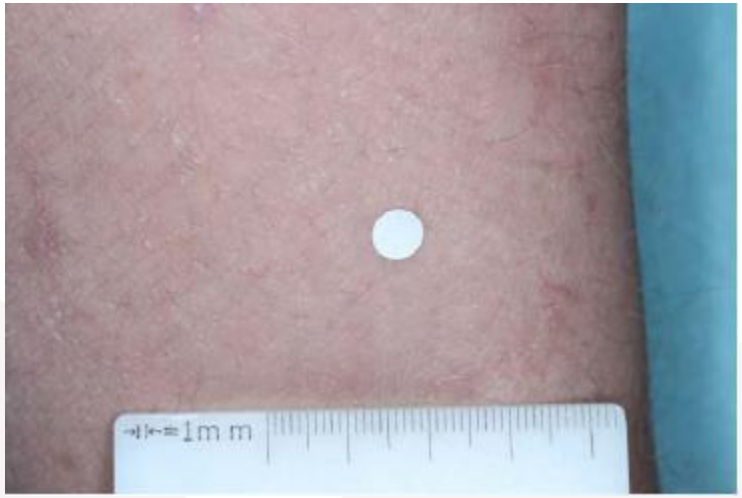
Over two months of treatment, ichthyosis improved consistently from moderate to mild disease

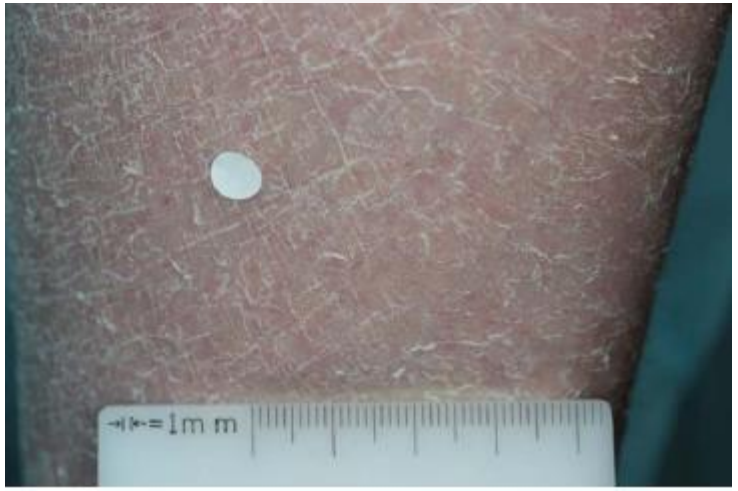
Source: Reproxalap SLS Phase 2 clinical trial results (6 patients per arm; reproxalap 1%)

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

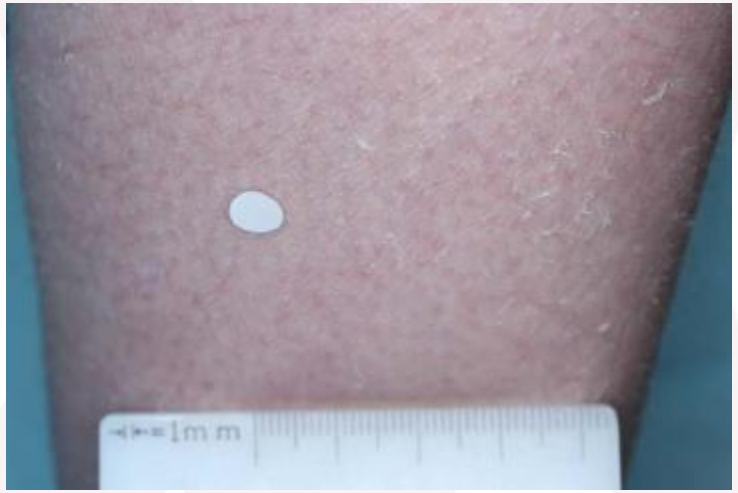


6 mo.





6 mo.



Source: Reproxalap RESET Phase 3 – Part 1 in SLS

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November 2019

CORPORATE REVIEW

Building The Future

Nasdaq: ALDX

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Our Value Proposition

Deep and Innovative Pipeline focused on immune-mediated diseases

Near-Term Development Catalysts support path to commercialization

Solid Track Record of development success

Large Market Potential of late-stage pipeline

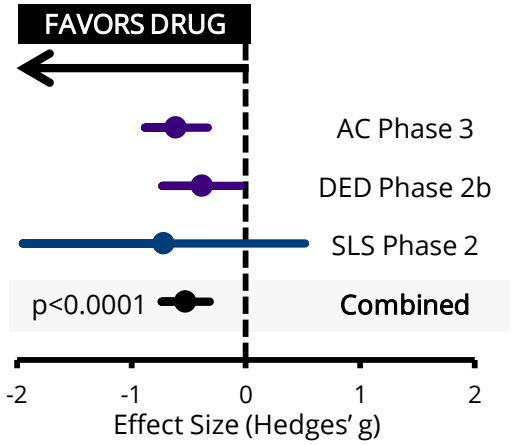
Solid Cash Position

Cash, cash equivalents and marketable securities were $76.2 million as of September 30, 2019

Our Phase 3 Drug Candidates Are Protected and Well Positioned

Reproxalap

- **Worldwide rights**, royalty free
- **Composition of matter IP through 2033** (with Hatch-Waxman extension) and extensive additional patent protection
- **FDA Orphan Drug Designation** for the treatment of congenital ichthyosis (primary symptom of SLS)
- **Meta analysis strongly supports drug activity**



Bars represent 95% confidence intervals. Between-group comparisons used for vehicle controlled trials (DED, AC, SLS). Results based on dryness (OD & 4 Symptom Score) in DED, area under the curve ocular itch in AC, and scaling in SLS.

ADX-2191

- **Worldwide rights**
- FDA **505(b)(2) approval pathway**
- **Methods of use (therapeutic and delivery) IP** and additional patent work ongoing
- **FDA Orphan Drug Designation** for the prevention of PVR
- If approved, ADX-2191 has the potential to be the only approved form of the drug for use in the eye
- U.S. **Drug Quality and Security Act** prohibits the compounding of approved drugs

Source: Aldeyra analysis of Phase 2 and Phase 3 clinical trial data on file.

DED = Dry eye disease
AC = Allergic conjunctivitis
PVR = Proliferative vitreoretinopathy
SLS = Sjögren-Larsson Syndrome
IP = Intellectual property

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

Richard Douglas, Ph.D. CHAIRMAN	Former SVP Corporate Development at Genzyme
Ben Bronstein, M.D.	Former CEO Peptimmune[8]
Marty Joyce, M.B.A.	Former CFO of Serono USA
Gary Phillips, M.D.	CEO OrphoMed
Jesse Treu, Ph.D.	Domain Associates
Neal Walker, D.O.	CEO Aclaris Therapeutics
Todd Brady, M.D., Ph.D.	CEO Aldeyra Therapeutics

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

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

= Ocular Diseases
= Systemic Diseases

- Reproxalap allergic conjunctivitis design for **INVIGORATE Phase 3 confirmed October 2019**
- ADX-2191 proliferative vitreoretinopathy **GUARD Phase 3 - Part 1 clinical trial initiation Q4 2019**
- ADX-1612 post-transplant lymphoproliferative disorder **Phase 2 clinical trial initiation H2 2019**
- Reproxalap dry eye disease **RENEW Phase 3 - Part 1 completion Q4 2019**
- NEW Reproxalap allergic conjunctivitis **INVIGORATE Phase 3 initiation H1 2020**
- 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**

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

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Innovating Transformative Therapies

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