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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549**

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**FORM 8-K**

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**CURRENT REPORT  
Pursuant to Section 13 or 15(d)  
of the Securities Exchange Act of 1934**

**Date of Report (Date of earliest event reported): February 28, 2019**

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**ALDEYRA THERAPEUTICS, INC.**  
(Exact name of Registrant as specified in its charter)

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**Delaware**  
(State or other jurisdiction of incorporation)

**001-36332**  
(Commission File No.)

**20-1968197**  
(IRS Employer Identification No.)

**131 Hartwell Avenue, Suite 320  
Lexington, MA 02421**  
(Address of principal executive offices and zip code)

**Registrant's telephone number, including area code: (781) 761-4904**

**Not Applicable**  
(Former Name or Former Address, if Changed Since Last Report)

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Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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**Item 7.01. Regulation FD.**

On February 28, 2019, Aldeyra Therapeutics, Inc. ("Aldeyra") intends to make a slide presentation at its 2019 Research & Development Day in person in New York City and by webcast on Aldeyra's website. A copy of Aldeyra's slide presentation is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference herein.

The furnishing of the attached slide presentation is not an admission as to the materiality of any information contained therein. The information contained in the slide presentation is summary information that is intended to be considered in the context of more complete information included in Aldeyra's filings with the Securities and Exchange Commission ("SEC") and other public announcements that Aldeyra has made and may make from time to time by press release or otherwise. Aldeyra undertakes no duty or obligation to update or revise the information contained in this report, although it may do so from time to time as its management believes is appropriate.

Various statements to be made during the conference call are "forward-looking statements" under the securities laws, including, but not limited to, statements regarding Aldeyra's strategy, future operations, future prospects, plans, and objectives and Aldeyra's plans and expectations for its product candidates. In some cases, you can identify forward looking statements by terms such as, but not limited to, "may," "might," "will," "objective," "intend," "should," "could," "can," "would," "expect," "believe," "anticipate," "project," "target," "design," "estimate," "predict," "potential," "aim," "plan" or the negative of these terms, and similar expressions intended to identify forward-looking statements. Such forward-looking statements are based upon current expectations that involve risks, changes in circumstances, assumptions and uncertainties.

Aldeyra is at an early stage of development and may not ever have any products that generate significant revenue. All of Aldeyra's development timelines may be subject to adjustment depending on recruitment rate, regulatory review, preclinical and clinical results, and other factors that could delay the initiation or completion of clinical trials. Important factors that could cause actual results to differ materially from those reflected in Aldeyra's forward-looking statements include, among others, the timing of enrollment, commencement and completion of Aldeyra's clinical trials, the timing and success of preclinical studies and clinical trials conducted by Aldeyra and its development partners; the ability to obtain and maintain regulatory approval of Aldeyra's product candidates, and the labeling for any approved products; the scope, progress, expansion, and costs of developing and commercializing Aldeyra's product candidates; the size and growth of the potential markets and pricing for Aldeyra's product candidates and the ability to serve those markets; Aldeyra's expectations regarding Aldeyra's expenses and revenue, the sufficiency or use of Aldeyra's cash resources and needs for additional financing; the rate and degree of market acceptance of any of Aldeyra's product candidates; Aldeyra's expectations regarding competition; Aldeyra's anticipated growth strategies; Aldeyra's ability to attract or retain key personnel; Aldeyra's ability to successfully integrate its new senior management team members; Aldeyra's ability to establish and maintain development partnerships; Aldeyra's expectations regarding federal, state and foreign regulatory requirements; regulatory developments in the United States and foreign countries; Aldeyra's ability to obtain and maintain intellectual property protection for Aldeyra's product candidates; the anticipated trends and challenges in Aldeyra's business and the market in which it operates; and other factors that are described in the "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of Aldeyra's Annual Report on Form 10-K for the year ended December 31, 2017 and Aldeyra's Quarterly Report on Form 10-Q for the

quarter ended September 30, 2018, both of which are on file with the SEC and available on the SEC's website at [www.sec.gov](http://www.sec.gov). Additional factors may be described in those sections of Aldeyra's Annual Report on Form 10-K for the year ended December 31, 2018, expected to be filed with the SEC in the first quarter of 2019.

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 conveyed on the conference call is provided only as of the date of the call, and Aldeyra undertakes no obligation to update any forward-looking statements presented on the call on account of new information, future events, or otherwise, except as required by law.

The information in Item 7.01 of this Form 8-K shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference under the Securities Act of 1933, as amended, except as expressly set forth by specific reference in such a filing, regardless of any general incorporation language in any such filing, unless Aldeyra expressly sets forth in such filing that such information is to be considered "filed" or incorporated by reference therein.

**Item 8.01 Other Events.**

On February 28, 2019, Aldeyra issued a press release that provided an update on Aldeyra's clinical development plans and pipeline. A copy of the press release is attached as Exhibit 99.2 to this Current Report on Form 8-K and is incorporated herein by reference.

**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	<a href="#">Slide presentation of Aldeyra Therapeutics, Inc. dated February 28, 2019.</a>
99.2	<a href="#">Press Release of Aldeyra Therapeutics, Inc. dated February 28, 2019.</a>

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

ALDEYRA THERAPEUTICS, INC.

By: /s/ Joshua Reed

Name: Joshua Reed

Title: Chief Financial Officer

Dated: February 28, 2019



## R&D Day 2019

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Update on Research Programs

February 28, 2019

Nasdaq: ALDX  
©Aldeyra Therapeutics, Inc. 2019

## 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, research and development plans or expectations, trends, 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. 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," "target," "design," "estimate," "predict," "potential," "plan" or similar expressions and the negatives of those terms.

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, clinical and regulatory plans or expectations for Aldeyra's product candidates and Aldeyra's continuing 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 timelines may be subject to adjustment depending on recruitment rate, regulatory review, preclinical and clinical results, and other factors that could delay the initiation, 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 28, 2019**, 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.

## Agenda

- Opening Welcome  
Todd Brady, CEO
- Corporate Strategy & Pipeline Growth  
David McMullin, CCO
- Proliferative Vitreoretinopathy – A Rare Retinal Disease  
Dean Elliott, M.D.  
Harvard Medical School  
Mass. Eye and Ear Infirmary
- Ocular Disease Area Program Updates  
David Clark, CMO
- Ocular Disease Area Market Opportunities  
Chris Pearson, VP Commercial
- Conclusion  
Todd Brady, CEO
- Q&A

## Our Mission

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



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



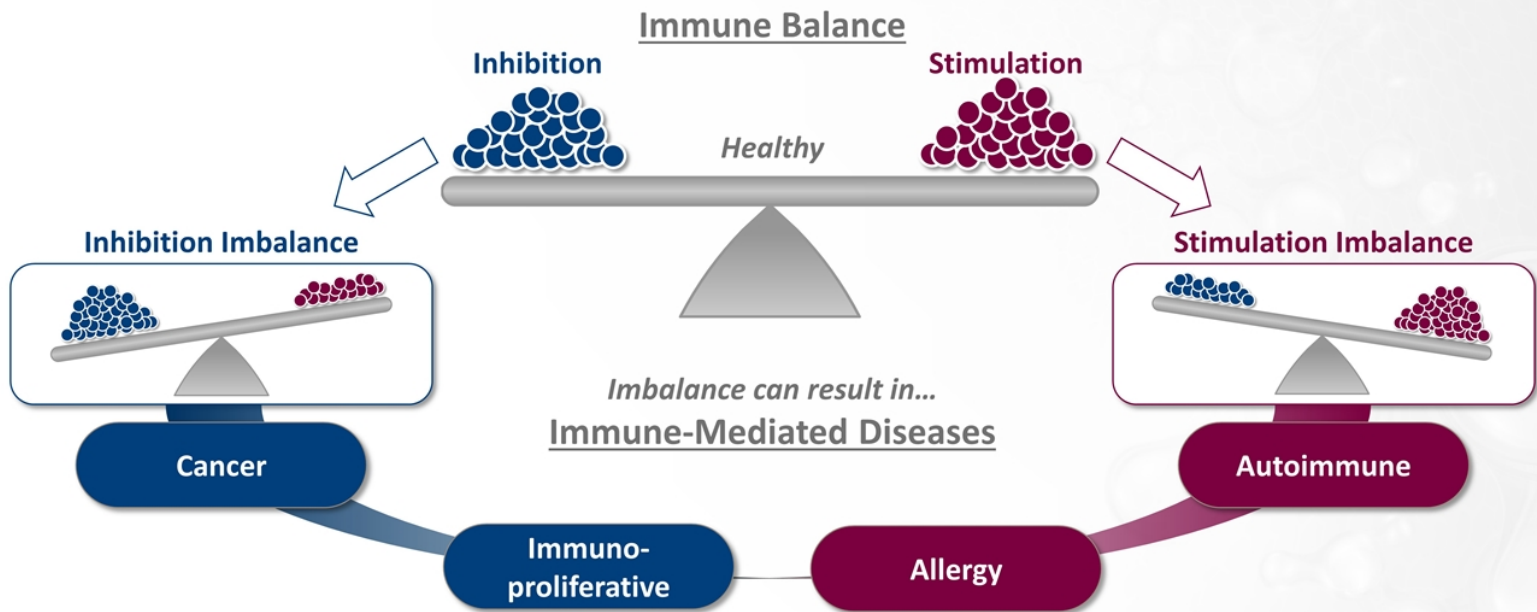
Disease control elusive despite existing therapies, and thus **novel approaches are needed**

Source: Lerner, Jeremias, and Matthias, International Journal of Celiac Disease, vol. 3, no. 4 (2015): 151-155;

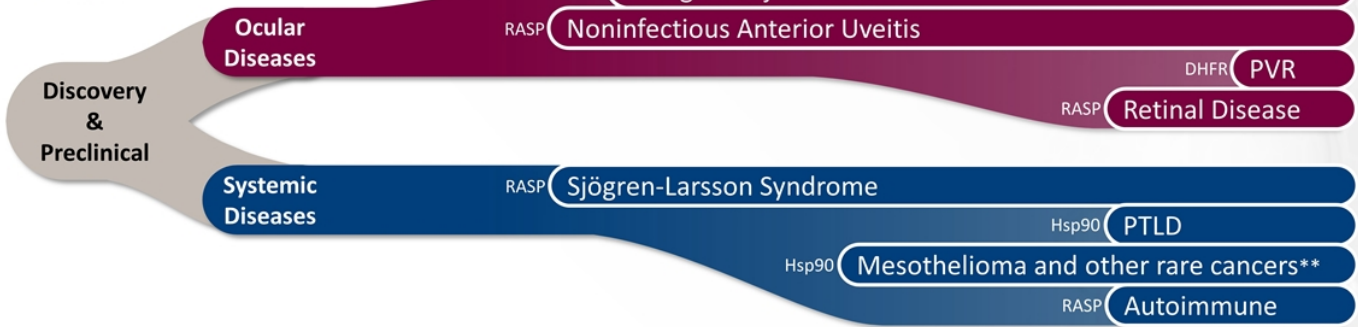
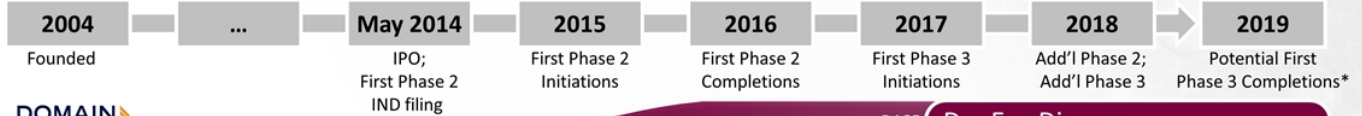
Shurin and Smolkin, Advances in Experimental Medicines and Biology 601:3-12, 2007; Kuek et al, Postgraduate Medical Journal 83(978): 251-260, 2007.



# Immune System Imbalance Leads to Immune-Mediated Disease



# Deliberate Focus on Ocular Diseases and Select Systemic Diseases

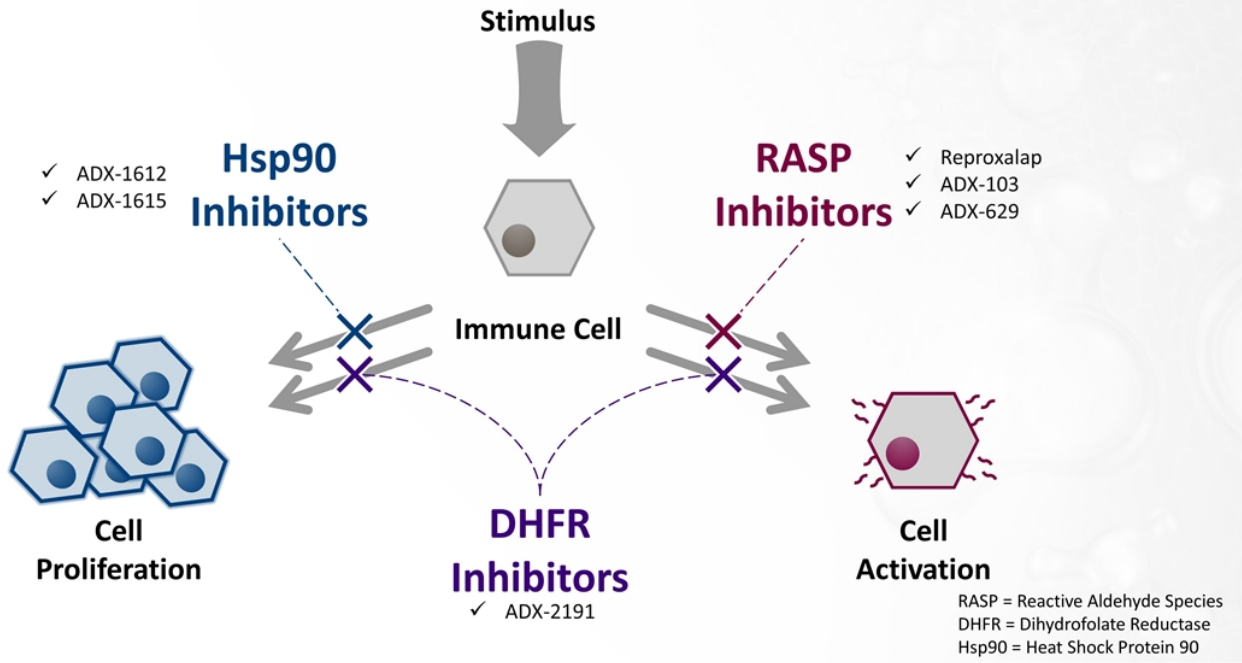


RASP = Reactive Aldehyde Species Inhibitor  
 DHFR = Dihydrofolate Reductase Inhibitor  
 Hsp90 = Heat Shock Protein 90 Inhibitor  
 PTLD = Post-Transplant Lymphoproliferative Disorder  
 PVR = Proliferative Vitreoretinopathy


\*Contingent on funding, regulatory review, and other factors.  
 \*\*Initially supporting Investigator Sponsored Trials upon Hsp90 licensure.



# Our Novel Approaches to Address Immune-Mediated Disease



# 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-Part 1 initiation H1 2019
			Allergic Conjunctivitis	✓ ✓				Phase 3 results early 2019
			Noninfectious Anterior Uveitis	✓				Phase 3 results H2 2019
	ADX-2191	[DHFR]	Proliferative Vitreoretinopathy					Phase 3-Part 1 initiation H2 2019
	ADX-103	[RASP]	Retinal Disease					Phase 1/2 initiation 2020
Undisclosed		Ocular Inflammation	Research Collaboration (undisclosed)					
Systemic Diseases	Reproxalap	[RASP]	Sjögren-Larsson Syndrome	✓				Phase 3-Part 1 results H2 2019
	ADX-1612	[Hsp90]	PTLD					Phase 2 initiation H2 2019
			Mesothelioma	✓				Phase 2 initiation H1 2019
			Ovarian Cancer	Investigator-Sponsored Trial				
	ADX-629	[RASP]	Autoimmune Disease					Phase 1 initiation H2 2019
	ADX-1615	[Hsp90]	Autoimmune Disease / Cancer					
Undisclosed	[RASP]	Systemic Inflammatory Disease	Research Collaboration 					

RASP = Reactive Aldehyde Species Inhibitor  
 DHFR = Dihydrofolate Reductase Inhibitor  
 Hsp90 = Heat Shock Protein 90 Inhibitor  
 PTLD = Post-Transplant Lymphoproliferative Disorder

✓ = Positive Phase 2 clinical trial data reported in 2016 – 2018  
 Trial initiations contingent on funding, regulatory review, and other factors

## Helio Vision Acquisition Expands Pipeline in Support of Our Strategic Growth Plans

- ✓ **Retinal disease a strategic priority** for pipeline growth
- ✓ **Novel therapeutic approach** leveraging an immunological mechanism that diminishes inflammation and cell proliferation
- ✓ Addition of **Phase 3-ready clinical program**
- ✓ **Orphan drug designation** for proliferative vitreoretinopathy, a potentially blinding disease with **no approved treatment**
- ✓ Potential **applicability to a variety of other diseases**



## Ocular Disease Area Program Updates

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- Proliferative Vitreoretinopathy
- Allergic Conjunctivitis
- Dry Eye Disease
- Upcoming Milestones



## Ocular Disease Area Program Updates

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- Proliferative Vitreoretinopathy
- Dry Eye Disease
- Allergic Conjunctivitis
- Upcoming Milestones

# ADX-2191: Adaptive Phase 3 Proliferative Vitreoretinopathy Clinical Program Expected to Initiate H2 2019

## Adaptive Phase 3 Program

- ✓ Part 1 controlled, randomized trial design
- ✓ Confirm endpoints, safety and tolerability
- ✓ Confirm sample size for subsequent trial

## Phase 3 Program Design Elements

Expected initiation H2 2019

Adaptive Phase 3 (Part 1) PVR Trial

Adaptive Phase 3 (Part 2) PVR Trial

Confirmatory Phase 3 PVR Trial

NDA

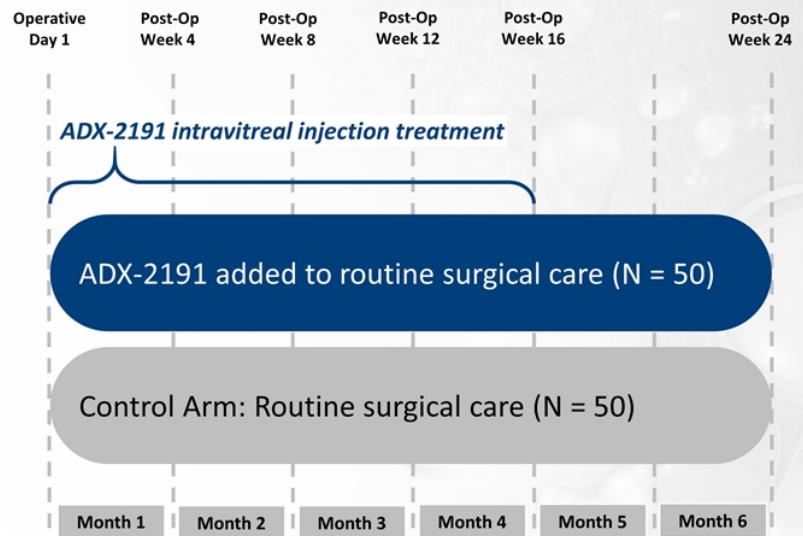
*Illustrative only*



# ADX-2191: Adaptive Phase 3 (Part 1) Proliferative Vitreoretinopathy 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, non-masked, randomized, controlled, two-part, adaptive Phase 3 clinical trial
- **Inclusion highlights:**
  - Recurrent retinal detachment due to PVR, or
  - Retinal detachment associated with open-globe trauma
- **Dosing regimen:**
  - Weekly (x10) then every other week (x3) 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





## Ocular Disease Area Program Updates

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- Proliferative Vitreoretinopathy
- Allergic Conjunctivitis
- **Dry Eye Disease**
- Upcoming Milestones

# Reproxalap: Adaptive Phase 3 Dry Eye Disease Clinical Program Expected to Initiate H1 2019

## 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

## Phase 3 Program Design Elements

Expected initiation H1 2019

Adaptive DED  
Phase 3 (Part 1)

Adaptive DED Phase 3  
(Part 2)

Confirmatory DED  
Phase 3

NDA

Phase 3 DED Safety Study

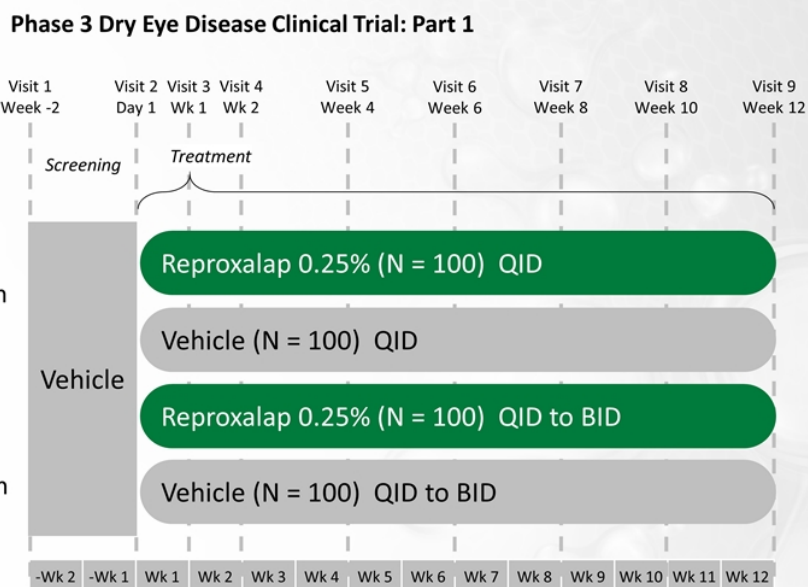
*Illustrative only*

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

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

# Reproxalap: Adaptive Phase 3 (Part 1) Dry Eye Disease Clinical Trial Design

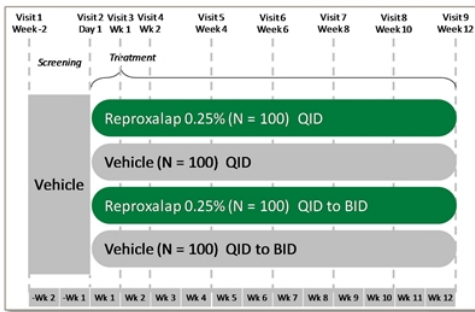
- Primary objective:**
  - Evaluate efficacy of reproxalap ophthalmic solution (0.25%) vs. vehicle to confirm dosing regimen and sample size for Part 2
- Inclusion/exclusion criteria:**
  - Same as used for Phase 2b
  - Moderate to severe dry eye disease
- Co-primary endpoints:**
  - Ocular dryness score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



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

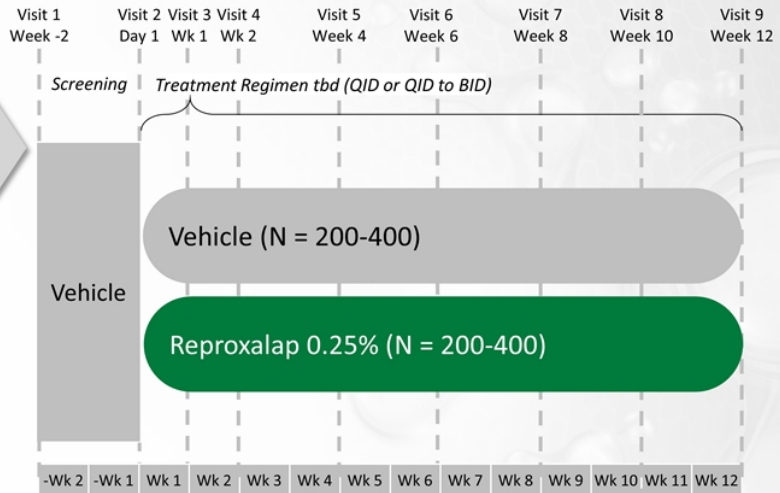
# Reproxalap: Adaptive Phase 3 (Part 2) Dry Eye Disease Clinical Trial Design

## Phase 3 Dry Eye Disease Clinical Trial: Part 1



✓ Confirmed sample size  
✓ Confirmed dosing regimen

## Phase 3 Dry Eye Disease Clinical Trial: Part 2



## Phase 3 Dry Eye Disease Clinical Trial: Part 2

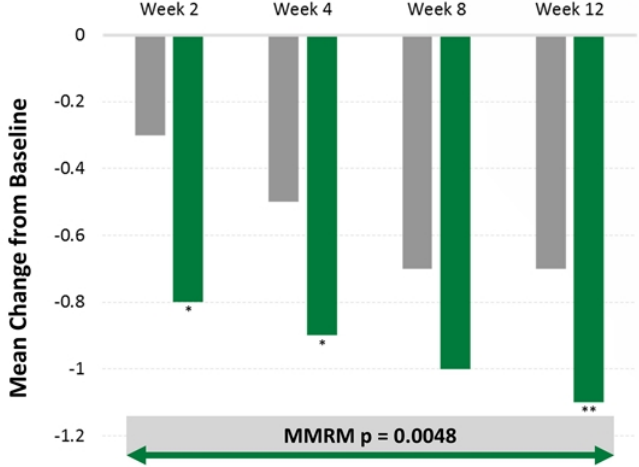
- **Primary objective:**  
Evaluate efficacy of reproxalap ophthalmic solution (0.25%) vs. vehicle on co-primary symptom and sign endpoints
- **Population selection and design:**  
Same as Part 1

# Reproxalap: Dry Eye Disease Symptom and Sign Endpoints Achieved in Phase 2b Clinical Trial

## Primary Symptom Endpoint for Phase 3 DED

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

Baseline Score  $\geq 3$  (N=69|69)



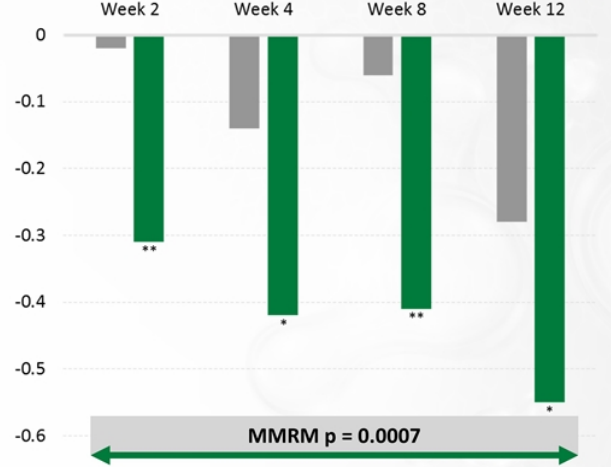
p values subject to change based on quality control analysis  
Source: Reproxalap DED Phase 2b clinical trial results

■ Vehicle ■ Reproxalap (0.25%)

## Primary Sign Endpoint for Phase 3 DED

### Fluorescein Staining: Nasal (0-4)

Baseline Score  $\geq 2$  (N=62|56)



\*p<0.05 \*\*p<0.01  
OD = Ocular Discomfort  
MMRM = Mixed effect Model Repeated Measures



## Ocular Disease Area Program Updates

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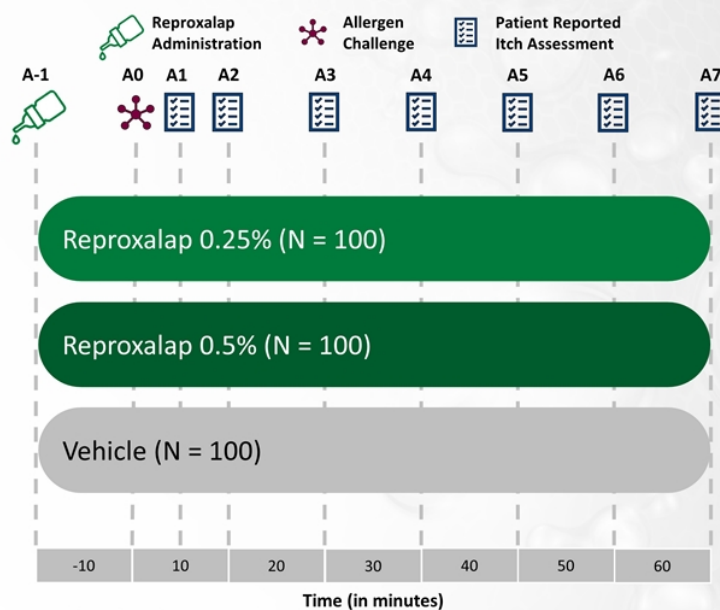
- Proliferative Vitreoretinopathy
- Dry Eye Disease
- Allergic Conjunctivitis
- Upcoming Milestones

# Reproxalap: ALLEVIATE Phase 3 Trial Design in Allergic Conjunctivitis

- Primary objective:**
  - Evaluate efficacy of reproxalap ophthalmic solutions (0.25% & 0.5%) compared to vehicle for the treatment of ocular itching associated with acute allergic conjunctivitis
- Inclusion/exclusion highlights:**
  - Positive history of ocular allergies and positive skin test reaction to a seasonal allergen
  - Positive bilateral conjunctival allergen challenge (CAC) reaction of  $\geq 2.5$  for itching and  $\geq 2$  for redness within 10 min of allergen instillation at first baseline visit
  - Positive bilateral CAC reaction for at least two out of first three time points following challenge at second baseline visit
- Endpoints:**
  - Ocular itch score area under the curve (primary)
  - Two-point responder comparison (key secondary)
- Results expected to be announced early 2019**

ALLEVIATE is the first of two required Phase 3 clinical trials, pending regulatory review. In preparation for a subsequent Phase 3 clinical trial, Aldeyra is conducting clinical method development studies to assess the feasibility of measuring ocular itching following environmental exposure to allergen.

## Phase 3 Conjunctival Allergen Challenge Trial

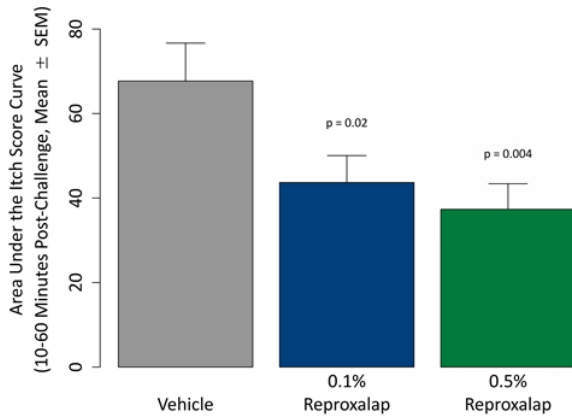


Further information can be found on [www.clinicaltrials.gov](http://www.clinicaltrials.gov): Trial #NCT03494504.



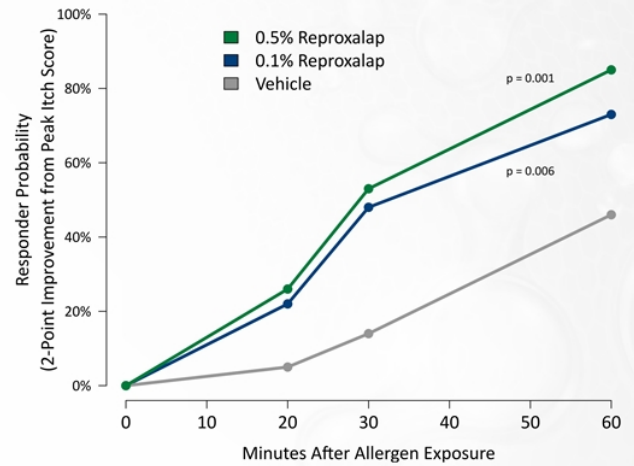
# Reproxalap: AC Ocular Itch Area Under The Curve and Responder Endpoints Achieved in Phase 2b Clinical Trial

Area Under the Curve: Ocular Itch Score (0-4)



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

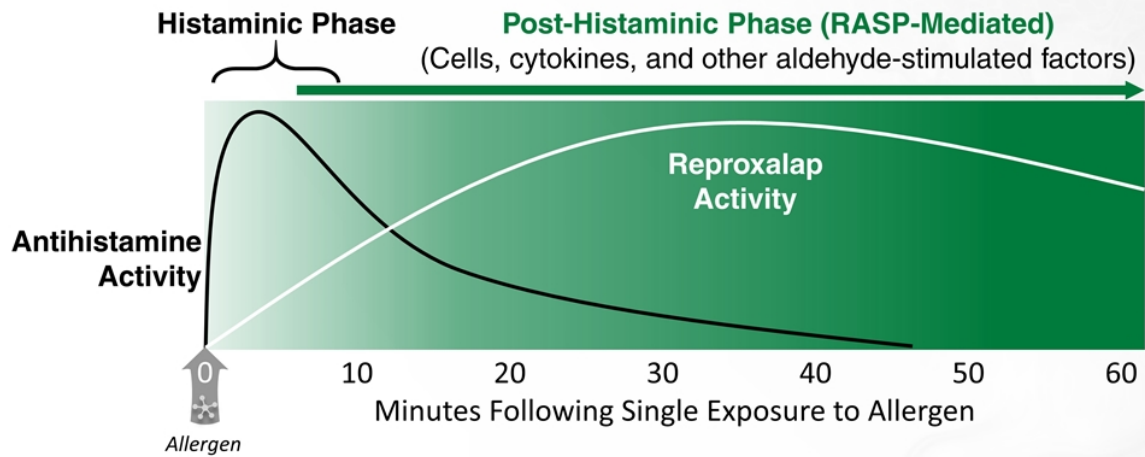
Probability of Response: Ocular Itch Score (0-4)



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

Source: Reproxalap AC Phase 2b clinical trial results (~30 patients per arm, seasonal allergy)

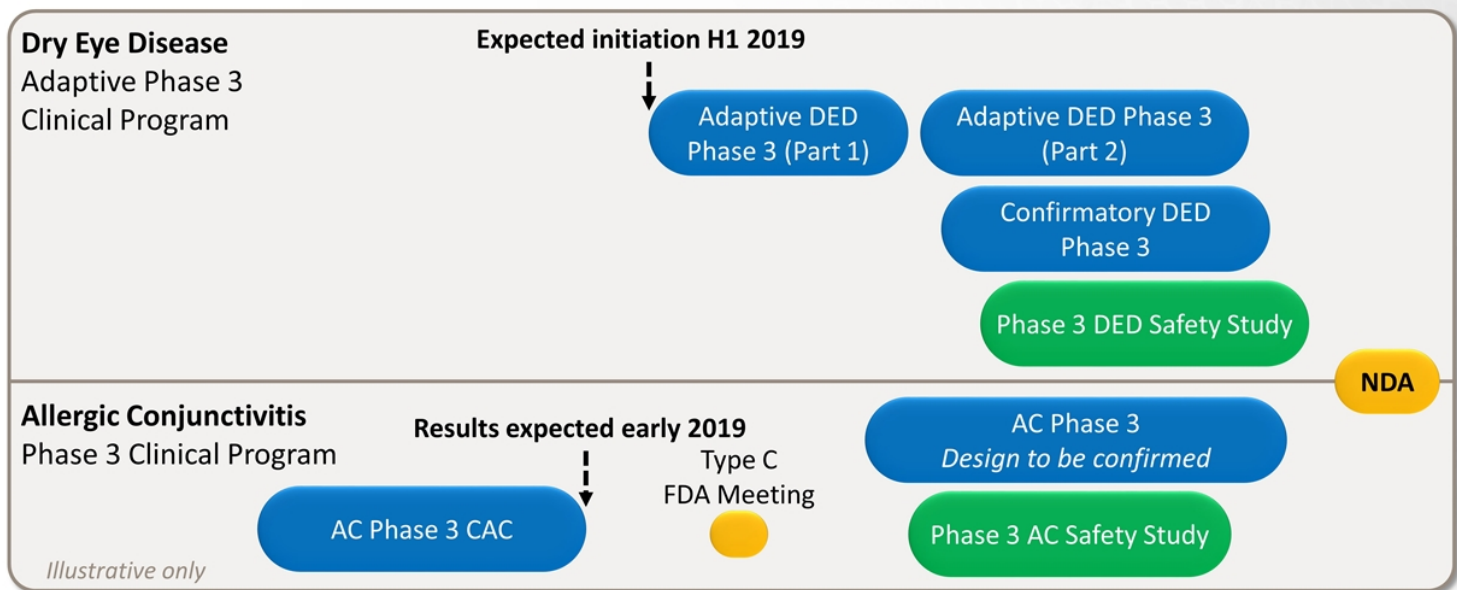
## Reproxalap's Novel Mechanism of Action has the Potential to Provide More Durable Activity Than Antihistamines



Reproxalap has the potential to be uniquely effective in post-histaminic allergy, for which no drug is approved, and which affects all allergic conjunctivitis patients.

RASP = Reactive Aldehyde Species

# Reproxalap: Parallel Dry Eye Disease and Allergic Conjunctivitis Phase 3 Clinical Programs Support Concurrent NDA Filings



DED = Dry eye disease  
AC = Allergic conjunctivitis



## Ocular Disease Area Program Updates

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- Proliferative Vitreoretinopathy
- Dry Eye Disease
- Allergic Conjunctivitis
- **Upcoming Milestones**

# Multiple Upcoming Ocular Disease Area Clinical Program Milestones

## Ocular Disease Area Anticipated Milestones\*

2019



**Early 2019:** Reproxalap ALLEVIATE Phase 3 allergic conjunctivitis trial



**H1 2019:** Reproxalap Phase 3 dry eye disease clinical trial program



**H2 2019:** Reproxalap SOLACE Phase 3 noninfectious anterior uveitis trial



**H2 2019:** ADX-2191 Phase 3 proliferative vitreoretinopathy clinical trial program



**2020:** ADX-103 Phase 1/2 retinal disease clinical trial

2020

\*Contingent on funding, regulatory review, and other factors.

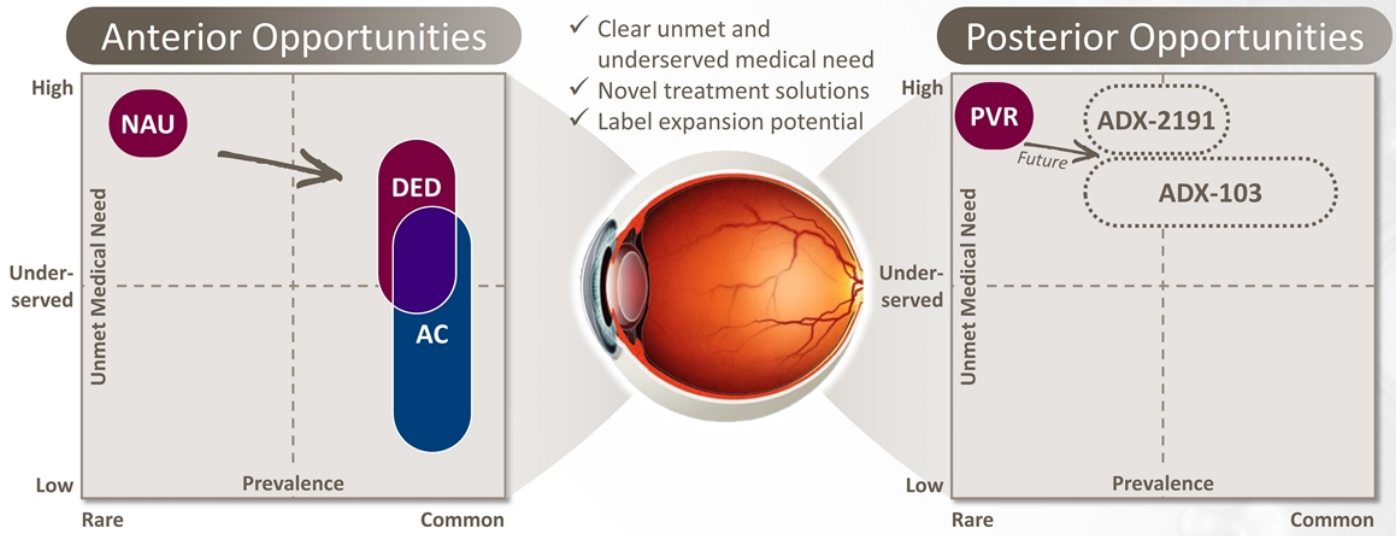


## Ocular Disease Area Market Opportunities

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- Proliferative Vitreoretinopathy
- Dry Eye Disease and Allergic Conjunctivitis
- Noninfectious Anterior Uveitis
- Pathway to Commercialization

# We Intend to Target Unmet Medical Needs in Anterior and Posterior Ocular Diseases





## Ocular Disease Area Market Opportunities

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- Proliferative Vitreoretinopathy
- Dry Eye Disease and Allergic Conjunctivitis
- Noninfectious Anterior Uveitis
- Pathway to Commercialization



## PVR: A Rare Sight-Threatening Retinal Disease

PVR is the **leading complication** of retinal detachment surgery and **prevents successful reattachment**



With no therapies available, PVR **necessitates repeat surgery** with a repeat surgery **failure rate of ~50%**

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

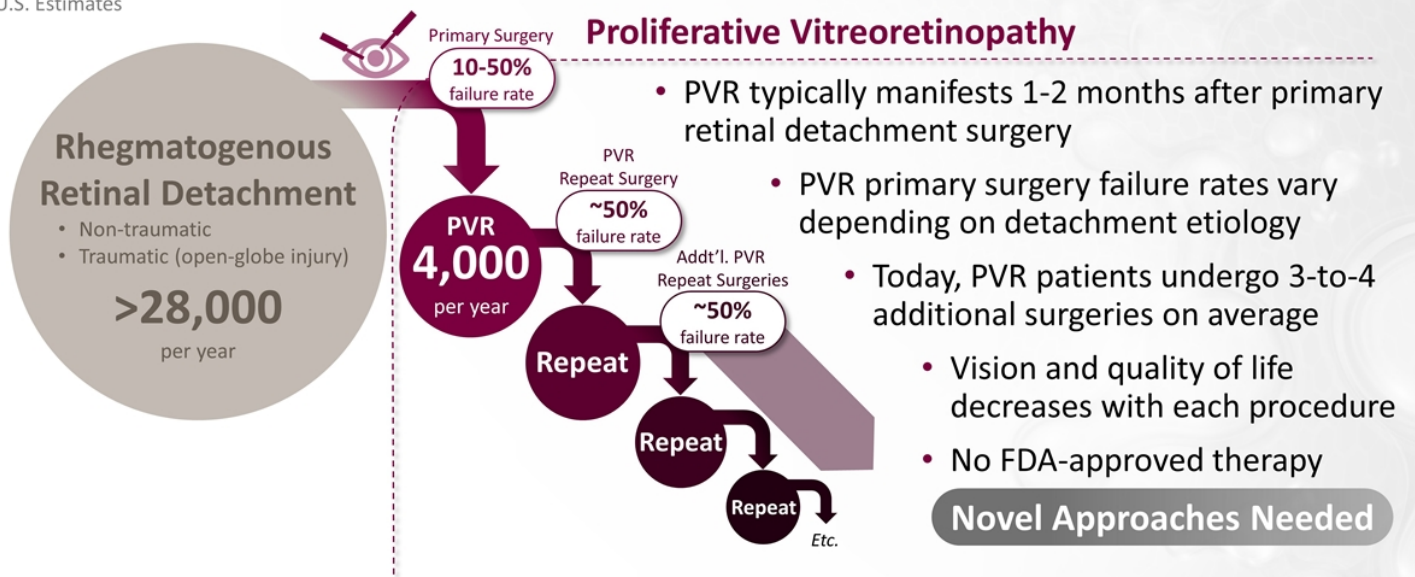
**4,000**  
U.S.



PVR is an **serious condition leading to permanent vision loss** in up to 75% of cases

# PVR: High Unmet Medical Need With No Approved Therapies

U.S. Estimates



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

# ADX-2191: A Unique Approach and Novel Product Candidate for PVR

## PVR: A Sight-Threatening Disease



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



No FDA- or EMA-approved therapy



**Repeat surgery and subsequent vision loss** currently the only possible course of action

## A Unique Opportunity

### ADX-2191

- A **novel approach and potential therapeutic breakthrough** in PVR treatment
- **Granted U.S. orphan designation**
- **Tolerability and reattachment success** during study period **demonstrated in Phase 1b** clinical trial
- Adaptive Phase 3 clinical trial **expected to initiate H2 2019**



## Ocular Disease Area Market Opportunities

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- Proliferative Vitreoretinopathy
- Noninfectious Anterior Uveitis
- Dry Eye Disease and Allergic Conjunctivitis
- Pathway to Commercialization

# DED and AC: Persistently Disturbing and Overlapping Disease Burdens

## Dry Eye Disease


**20**  
million  
20 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


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


 Significant **negative quality of life** impact

## DED+AC Comorbidity

 Studies have shown that **DED and AC can be interrelated** and often overlap


**50-60%**  
~50-60% of **DED and AC patients experience** clinically significant **itch and dryness**


 **Allergen exposure** can contribute to **DED seasonality**

 Significant **negative quality of life** impact x2

## Allergic Conjunctivitis

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

 AC patients experience symptoms throughout **all decades of adult life**

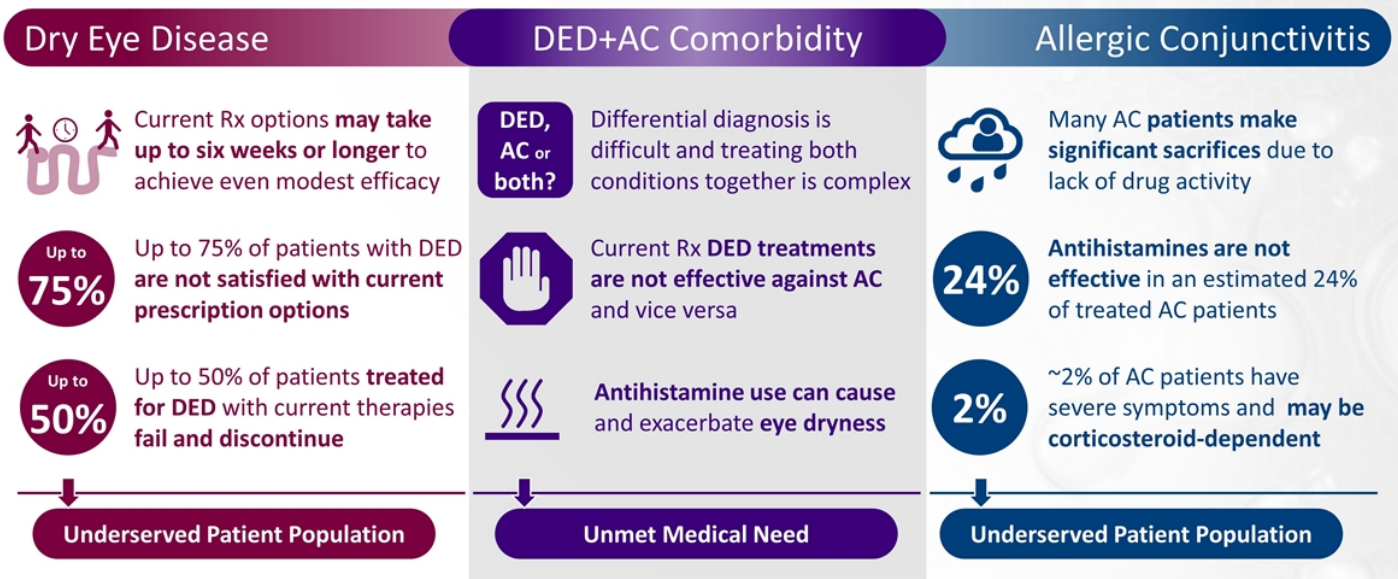
 AC can result in **acute, intermittent, and chronic** symptoms

 Significant **negative quality of life** impact

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

DED = Dry eye disease  
AC = Allergic conjunctivitis

# DED and AC: Chronic Diseases With Inadequate Therapies

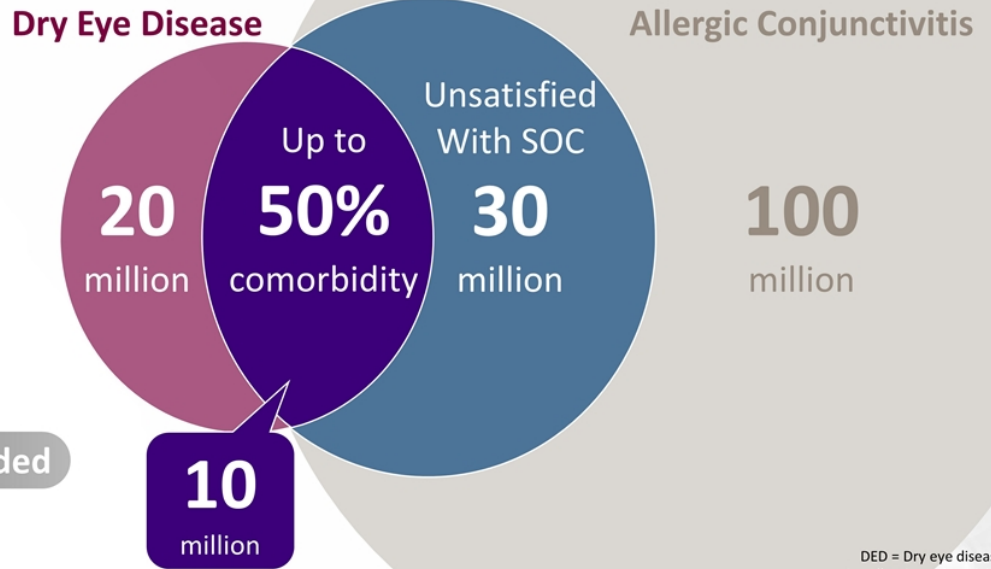


## DED and AC: Large Market Opportunities With Unmet Medical Needs

U.S. Patient Estimates

- Significant negative quality of life
- Complex, overlapping, and difficult to treat chronic conditions
- Substantial unmet medical need with current treatments

**Novel Approaches Needed**



DED = Dry eye disease  
AC = Allergic conjunctivitis  
SOC = Standard of Care

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

# Reproxalap: A Unique and Novel Product Candidate for DED and AC

## Dry Eye Disease

### 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

## DED+AC Overlap

### Reproxalap



Observed improvements in both DED and AC Phase 2b clinical trials



Both patients and physicians have a strong desire for better DED and AC treatments

## Allergic Conjunctivitis

### Reproxalap in AC



Clinically significant and durable symptom response in Phase 2b clinical trial



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



Novel mechanism of action and differentiated approach to treat DED and AC





## Ocular Disease Area Market Opportunities

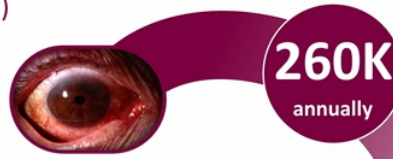
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- Proliferative Vitreoretinopathy
- Dry Eye Disease and Allergic Conjunctivitis
- Noninfectious Anterior Uveitis
- Pathway to Commercialization

# NAU: A Severe Ocular Inflammatory Disease

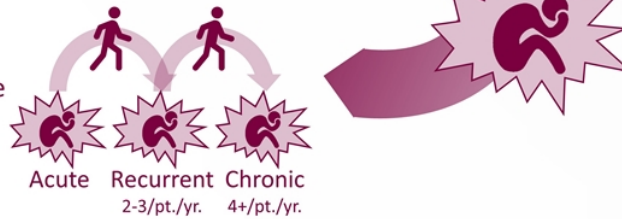
## Disease Burden Overview

Noninfectious anterior uveitis (NAU) is a **severe ocular inflammation** causing **pain, photophobia, and vision loss**



NAU is the **most common form of uveitis** with an estimated 260,000 U.S. patients per year

~50% of NAU patients have **recurrent or chronic conditions** requiring multiple interventions per year



NAU **dramatically impacts quality of life**, leading to loss of work and significant economic burden

# NAU: Significant Repeat Episodes and Steroid Toxicity Creates the Need for Novel Approaches

U.S. Estimates

## Prevalence:

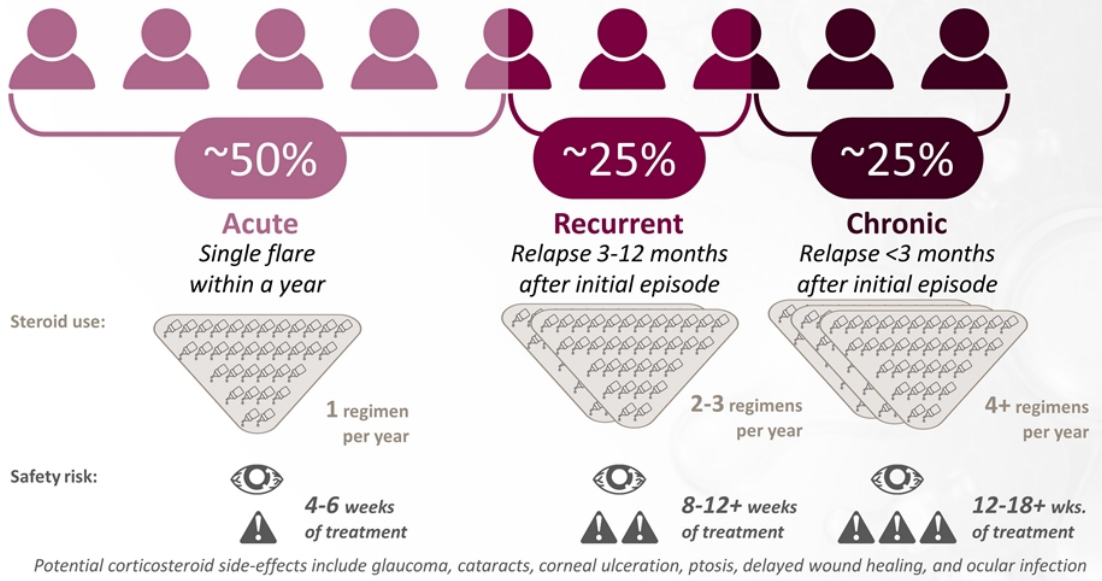
Approximately 260,000 noninfectious anterior uveitis (NAU) patients in the U.S.

## Corticosteroid treatment:

8-12 times/day tapered over 4-6 weeks

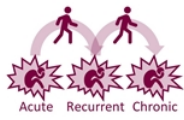
Prolonged corticosteroid usage increases risks of serious side effects

NAU episode frequency:



# Reproxalap: A Unique and Novel Product Candidate for NAU

## NAU: A Serious Inflammatory Disease With Inadequate Current Therapy



~50% of noninfectious anterior uveitis (NAU) patients have **recurrent or chronic conditions** requiring multiple interventions per year



**Corticosteroids** currently SOC and **require monitoring due to serious toxicities**



Prolonged usage may lead to **glaucoma, cataracts, corneal ulceration**, and other serious side effects

## A Unique Opportunity

### Reproxalap

- A **novel and differentiated** approach to treat NAU
- **Reduced anterior chamber cell count** observed in a Phase 2 clinical trial, **statistically non-inferior to corticosteroid treatment**
- **Safety and tolerability without IOP increase** in a Phase 2 clinical trial
- SOLACE Phase 3 clinical trial **results expected H2 2019**

NAU = Noninfectious anterior uveitis  
SOC = Standard of Care  
IOP = Intraocular pressure

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



## Ocular Disease Area Market Opportunities

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- Proliferative Vitreoretinopathy
- Dry Eye Disease and Allergic Conjunctivitis
- Noninfectious Anterior Uveitis
- **Pathway to Commercialization**

Nasdaq: ALDX  
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# We Intend to Commercialize Directly and Through Partnerships

<b>Late Stage Programs</b>	<b>Estimated U.S. Population*</b>	<b>U.S. Healthcare Providers</b>	<b>Competitive Value Proposition</b>	<b>Infrastructure Requirement</b>	<b>Commercial Planning</b>
<i>Ocular Diseases</i>					<b>Commercial Planning</b> ✓ Launch readiness ✓ Maximize value ↓ Characterize the business model Prepare for commercialization Develop partnership options
<b>Dry Eye Disease</b>	20 million DED Up to 10 million with DED & AC 30 million 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	
<b>Allergic Conjunctivitis</b>					
<b>Noninfectious Anterior Uveitis</b>	260,000	~200 U.S. uveitis sub-specialists	Effective non-steroid alternative	Small targeted sales force	
<b>Proliferative Vitreoretinopathy</b>	4,000	Retina specialists at targeted centers	Orphan: First and only Rx treatment	Small specialized operation	
<i>Systemic Diseases</i>					
<b>Sjögren-Larsson Syndrome</b>	1,000	Geneticists and ped. neurologists	Orphan: First and only Rx treatment	Small specialized operation	

\*Aldeyra estimates of the addressable market  
 Source: Aldeyra internal estimates based on primary and secondary market research; published literature








## Conclusion





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## Expected Development Milestones: Novel Approaches to Address Immune-Mediated Disease

### Ocular Diseases: Anticipated Milestones\*

-  Reproxalap allergic conjunctivitis ALLEVIATE Phase 3 trial **results early 2019**
-  Reproxalap dry eye disease **Phase 3 clinical trial program initiation H1 2019**
-  Reproxalap noninfectious anterior uveitis SOLACE Phase 3 clinical trial **results H2 2019**
-  ADX-2191 Proliferative Vitreoretinopathy **Phase 3 clinical program initiation H2 2019**
-  ADX-103 retinal disease **Phase 1/2 clinical trial initiation 2020**

### Systemic Diseases: Anticipated Milestones\*

-  Reproxalap Sjögren-Larsson Syndrome RESET Phase 3 - Part 1 clinical trial **results H2 2019**
-  ADX-629 **Phase 1 clinical trial initiation H2 2019** followed by NASH and/or IBD Phase 2a
-  ADX-1612 post-transplant lymphoproliferative disorder **Phase 2 clinical trial initiation 2019**
-  ADX-1612 mesothelioma **Phase 2 clinical trial initiation 2019**

\*Contingent on funding, regulatory review, and other factors.





**Aldeyra Therapeutics Provides Update on Ophthalmic Programs at 2019 Research & Development Day**

**Phase 3 Results from ALLEVIATE Trial in Allergic Conjunctivitis Expected in Early 2019**

**Co-Primary Endpoints Confirmed for Phase 3 Clinical Trial in Dry Eye Disease, Expected to Begin in First Half of 2019**

**Phase 3 Clinical Trial of ADX-2191 in Proliferative Vitreoretinopathy Expected to Begin in Second Half of 2019**

**Phase 3 Results from SOLACE Clinical Trial in Noninfectious Anterior Uveitis Expected in Second Half of 2019**

LEXINGTON, Mass., February 28, 2019 (PRNewswire) — Aldeyra Therapeutics, Inc. (Nasdaq: ALDX) (Aldeyra), a biotechnology company devoted to developing and commercializing next-generation medicines to improve the lives of patients with immune-mediated diseases, today updated progress on ophthalmic programs at a 2019 Research & Development Day in New York City. Presentations were given by members of the Aldeyra executive team along with Dean Elliott, M.D., the Stelios Evangelos Gragoudas Professor of Ophthalmology at Harvard Medical School, Director of the Retina Service at Massachusetts Eye and Ear Infirmary, and Director of the Retina Fellowship at Harvard and Massachusetts Eye and Ear Infirmary. Presentations covered the development and commercialization plans for novel product candidates in proliferative vitreoretinopathy, dry eye disease, allergic conjunctivitis, and noninfectious anterior uveitis.

A webcast of the presentation and slide deck will be available via Aldeyra's investor relations website at <http://ir.aldeyra.com> until February 28, 2020.

"Over the past few years, we have deliberately expanded our pipeline in support of our corporate strategic initiatives. Today, we have six different compounds in development, representing three unique mechanisms of action, targeting ten potential clinical indications," commented Todd C. Brady, M.D., Ph.D., President and CEO of Aldeyra. "With a deliberate focus on ocular disease and select systemic conditions, we now have five Phase 3 programs in progress or expected to be initiated this year. We look forward to updating investors on the first of the Phase 3 programs, the ALLEVIATE trial in allergic conjunctivitis, early this year."

## R&D Day Highlights

- **ADX-2191 for Proliferative Vitreoretinopathy (PVR):** The first Phase 3 clinical trial of ADX-2191, acquired this year for the prevention of PVR, is expected to begin in 2019. PVR is a rare inflammatory fibroproliferative disorder that leads to severe retinal scarring and blindness and is the leading cause of failure of retinal reattachment surgery. Over 50% of PVR cases result in severe uncorrectable vision loss, and 75% of PVR patients suffer from at least moderate uncorrectable vision loss. With no currently approved therapy available, PVR is a serious and sight-threatening disease that affects approximately 4,000 patients in the United States and nearly twice as many in Europe and Japan. Aldeyra plans to begin a two-part, multi-center, non-masked, randomized, controlled, adaptive Phase 3 clinical program in the second half of 2019, following discussions with regulatory authorities. ADX-2191 has received Orphan Drug Designation for the prevention of PVR.
- **Reproxalap for Dry Eye Disease (DED):** In September 2018, Aldeyra reported Phase 2b results in DED that demonstrated statistical superiority of reproxalap versus vehicle across multiple DED symptoms and signs. Based on these results, Aldeyra plans to initiate Part 1 of a two-part adaptive Phase 3 clinical trial in the first half of 2019. Part 1 of the clinical trial will evaluate the efficacy of reproxalap ophthalmic solution (0.25%) vs. vehicle in 400 patients with moderate-to-severe DED. Results from Part 1 will confirm dosing and size for Part 2 of the Phase 3 clinical trial. The co-primary endpoints of this trial will be ocular dryness, and fluorescein nasal region staining in pre-specified moderate to severe patient subsets analyzed over twelve weeks of therapy using Mixed effects Model Repeated Measures (MMRM). In the Phase 2b clinical trial, the MMRM p values for the Phase 3 co-primary endpoints of dryness and staining were 0.0048 and 0.0007, respectively. DED impacts approximately 20 million adults in the United States and represents a highly underserved patient population with up to 50% of patients discontinuing treatment due to limited efficacy or slow onset with current treatment options.
- **Reproxalap for Allergic Conjunctivitis (AC):** Aldeyra expects to report results of the Phase 3 ALLEVIATE trial in early 2019. ALLEVIATE is a multi-center, double-masked, parallel-group, vehicle-controlled Phase 3 clinical trial that will measure ocular itch score area under the curve and patient responder rate. In preparation for a subsequent Phase 3 clinical trial, Aldeyra is also conducting clinical method development studies to assess the feasibility of measuring ocular itch following environmental exposure to allergen. Allergic conjunctivitis represents a large and underserved market with an estimated 30 million patients in the United States who are inadequately treated with the current standard of care. In two Phase 2 clinical trials, reproxalap was observed to be well tolerated and demonstrated the potential to be effective in post-histaminic allergy, for which no drug is approved, and which affects all patients suffering from allergic conjunctivitis.
- **Reproxalap for Overlapping Treatment of Dry Eye Disease and Allergic Conjunctivitis:** Studies have shown that DED and AC are interrelated, with up to 50% of the patient population suffering from DED/AC comorbidity. Reproxalap has demonstrated efficacy against both DED and AC in separate Phase 2b clinical trials. Aldeyra plans to advance parallel Phase 3 programs in DED and AC that could support concurrent New Drug Application filings with the U.S. Food and Drug Administration for both conditions.

- **Reproxalap – Noninfectious Anterior Uveitis (NAU):** NAU is a rare ocular disease caused by an inflammatory response that leads to surface irritation, pain, photophobia, and in some cases vision loss, and affects approximately 260,000 patients in the United States per year. An estimated 50% of patients suffer from repeat or chronic NAU episodes, increasing the risk of serious ocular toxicity as a result of prolonged exposure to corticosteroids, the current standard of care. The anti-inflammatory product profile of reproxalap has the potential to treat patients without the toxicities commonly associated with corticosteroids. The Phase 3 SOLACE clinical trial of reproxalap in NAU is currently ongoing, and results are expected to be announced in the second half of 2019.

#### ***About Aldeyra Therapeutics***

Aldeyra Therapeutics is a biotechnology company devoted to developing and commercializing next-generation medicines to improve the lives of patients with immune-mediated diseases. Aldeyra's lead product candidate, reproxalap, is a first-in-class treatment in late-stage development for dry eye disease, allergic conjunctivitis, noninfectious anterior uveitis, and Sjögren-Larsson Syndrome. The company is also developing other product candidates for proliferative vitreoretinopathy and other retinal diseases, post-transplant lymphoproliferative disease, autoimmune disease, metabolic disease, and cancer. None of Aldeyra's product candidates have been approved for sale in the U.S. or elsewhere.

#### ***Safe Harbor Statement***

This release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including statements regarding Aldeyra's strategy, future operations, future prospects, plans, and objectives and Aldeyra's plans and expectations for its product candidates, including plans to initiate further clinical testing, the timing of results from clinical programs, and its regulatory plans. Aldeyra intends such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 21E of the Securities Exchange Act of 1934 and the Private Securities Litigation Reform Act of 1995. In some cases, you can identify forward-looking statements by terms such as "may," "might," "will," "objective," "intend," "should," "could," "can," "would," "expect," "believe," "anticipate," "project," "target," "design," "estimate," "predict," "potential," "aim," "plan" or the negative of these terms, and similar expressions intended to identify forward-looking statements. Such forward-looking statements are based upon current expectations that involve risks, changes in circumstances, assumptions and uncertainties. Aldeyra is at an early stage of development and may not ever have any products that generate significant revenue. All of Aldeyra's development timelines may be subject to adjustment depending on recruitment rate, regulatory review, preclinical and clinical results, and other factors that could delay the initiation or completion of clinical trials. Important factors that could cause actual results to differ materially from those reflected in Aldeyra's forward-looking statements include, among others, the timing of

enrollment, commencement and completion of Aldeyra's clinical trials, the timing and success of preclinical studies and clinical trials conducted by Aldeyra and its development partners; updated or refined data based on Aldeyra's continuing review and quality control analysis of clinical data, Aldeyra's ability to design clinical trials with protocols and endpoints acceptable to applicable regulatory authorities, the ability to obtain and maintain regulatory approval of Aldeyra's product candidates, and the labeling for any approved products; the scope, progress, expansion, and costs of developing and commercializing Aldeyra's product candidates; the size and growth of the potential markets and pricing for Aldeyra's product candidates and the ability to serve those markets; Aldeyra's expectations regarding Aldeyra's expenses and revenue, the sufficiency or use of Aldeyra's cash resources and needs for additional financing; the rate and degree of market acceptance of any of Aldeyra's product candidates; Aldeyra's expectations regarding competition; Aldeyra's anticipated growth strategies; Aldeyra's ability to attract or retain key personnel; Aldeyra's ability to establish and maintain development partnerships; Aldeyra's expectations regarding federal, state and foreign regulatory requirements; regulatory developments in the United States and foreign countries; Aldeyra's ability to obtain and maintain intellectual property protection for its product candidates; the anticipated trends and challenges in Aldeyra's business and the market in which it operates; and other factors that are described in the "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of Aldeyra's Annual Report on Form 10-K for the year ended December 31, 2017 and Aldeyra's Quarterly Report on Form 10-Q for the quarter ended September 30, 2018, both of which are on file with the Securities and Exchange Commission (SEC) and available on the SEC's website at [www.sec.gov](http://www.sec.gov). Additional factors may be set forth in those sections of Aldeyra's Annual Report on Form 10-K for the year ended December 31, 2018, to be filed with the SEC in the first quarter of 2019.

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 release is provided only as of the date of this release, and Aldeyra undertakes no obligation to update any forward-looking statements contained in this release on account of new information, future events, or otherwise, except as required by law.

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