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

FORM 8-K

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

Date of Report (Date of earliest event reported): September 26, 2018

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

Delaware		
(State or other jurisdiction of incorporation)		
001-36332		**20-1968197**
(Commission File No.)		(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)

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. ☒

Item 7.01. Regulation FD Disclosure.

As reported under Item 8.01 of this Current Report on Form 8-K, on September 26, 2018, Aldeyra Therapeutics, Inc. (the "Company") issued a press release (the "Press Release") announcing positive results from a randomized, vehicle-controlled, parallel-group, multi-center, double-masked Phase 2b clinical trial of topical ocular reproxalap in patients with dry eye disease. The Company is holding a conference call regarding the Phase 2b clinical trial results on September 26, 2018. A copy of the presentation being used in connection with this conference call is furnished herewith as Exhibit 99.1 and is incorporated by reference herein.

This information in this Item 7.01 of this Current Report on Form 8-K shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that Section, or incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in any such filing.

Item 8.01. Other Events.

On September 26, 2018, the Company announced in the Press Release positive results for its Phase 2b clinical trial of topical ocular reproxalap in patients with dry eye disease. The Press Release is filed as Exhibit 99.2 to this Current Report on Form 8-K and is incorporated by reference herein.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Aldeyra Therapeutics, Inc. Presentation dated September 26, 2018.
99.2	Aldeyra Therapeutics, Inc. Press Release dated September 26, 2018.

SIGNATURES

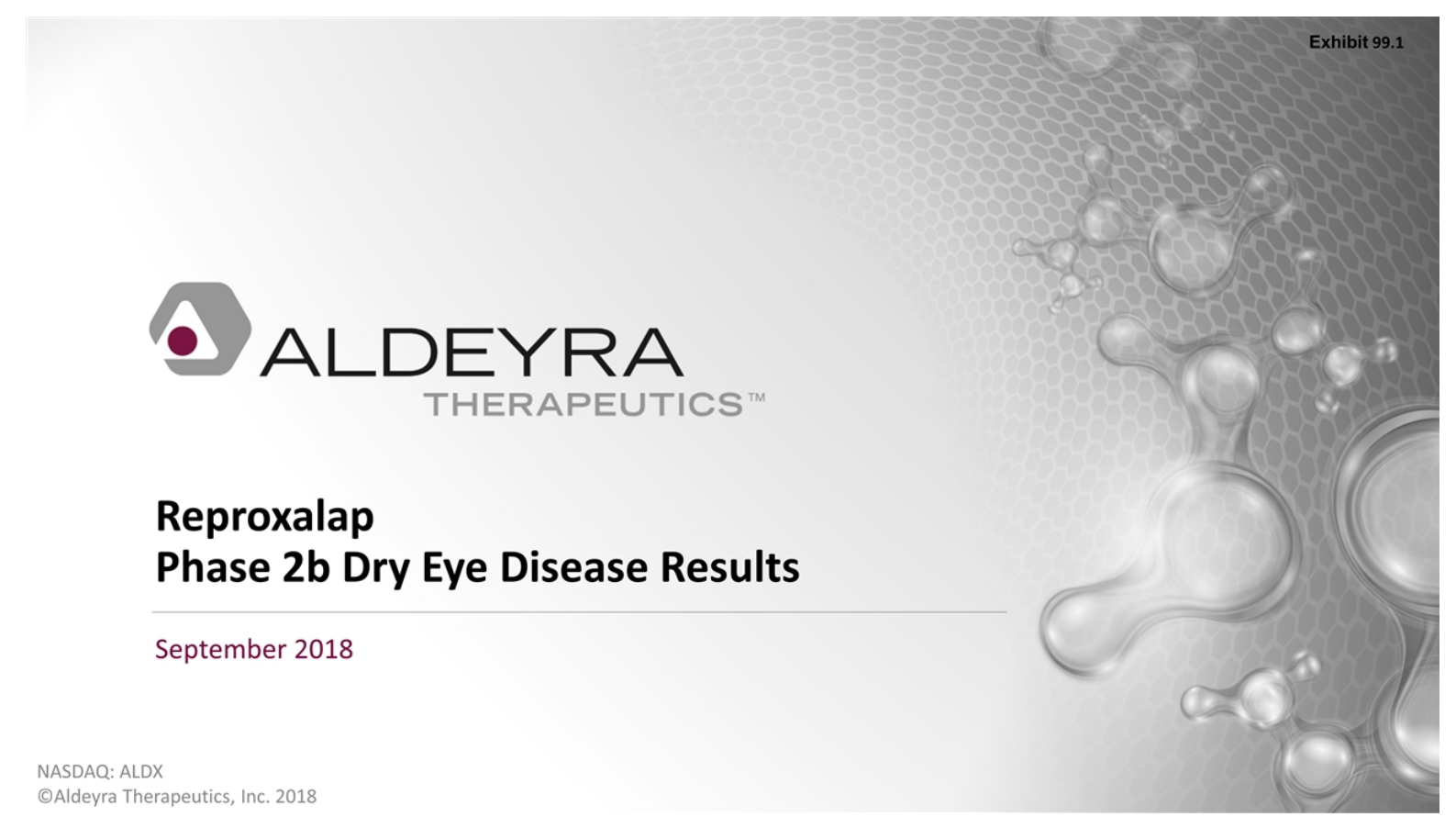
Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

ALDEYRA THERAPEUTICS, INC.

By: /s/ Joshua Reed
Name: Joshua Reed
Title: Chief Financial Officer

Dated: September 26, 2018

Exhibit 99.1



Reproxalap
Phase 2b Dry Eye Disease Results

September 2018

NASDAQ: ALDX

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 September 26, 2018**, 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.

Dry Eye Disease:
A Chronic Disease with Inadequate Therapy

Large Disease Burden

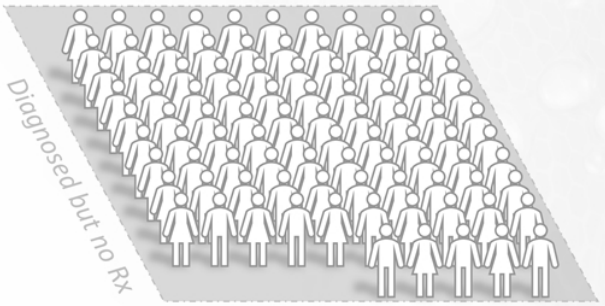
20 million # of **adults in the U.S.** estimated to suffer from Dry Eye Disease (DED)

Women are twice as likely to suffer from DED than men

Age 50+ >3x DED **increases with age**, with those over age 50 three times more likely to suffer from DED

DED can significantly effect vision-related **quality of life**

Under-served Patient Population



Rx Treated Patients

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

Sources: "Dry Eyes" by R. M. Shtein, MD; www.uptodate.com, May 2018; Farrand et al; American Journal of Ophthalmology 90:98, 2017; Aldeyra primary and secondary research and estimates; Clin Ophthalmol. 2009; 3: 405–412; Symphony Rx Data.

Reproxalap:
A Novel Drug Candidate For the Treatment of Dry Eye Disease

Positive Phase 2b Clinical Trial Results

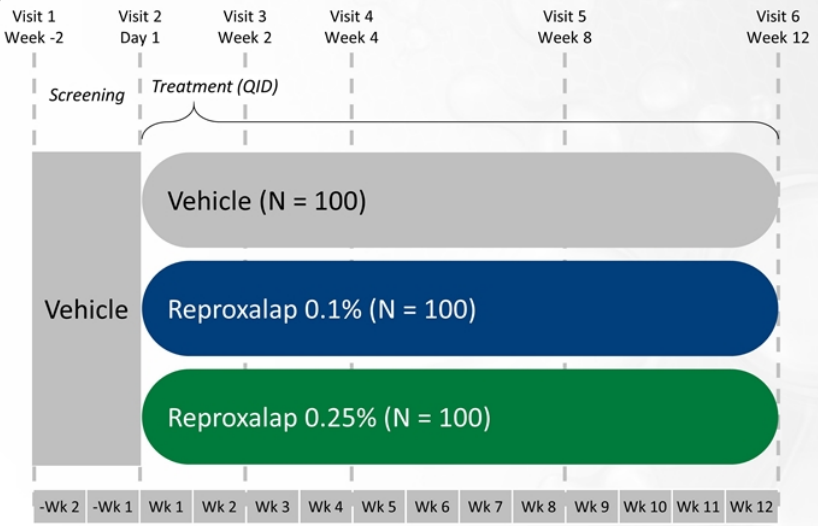
- **Primary objective achieved:**
  Endpoint selection and sample size powering confirmed for Phase 3 clinical trials
- Reproxalap demonstrated **statistically significant improvements** versus vehicle across multiple symptom and sign measures, consistent with novel and broad mechanism of action
- **Pathway to registration trials confirmed** with ocular dryness symptom score, ocular staining score, and 0.25% reproxalap dose
- **Improvements in symptoms and signs observed as early as two weeks**, consistent with prior reproxalap clinical trial results and supportive of differentiated product profile
- Aldeyra plans to discuss results with regulatory authorities, and expects to **initiate Phase 3 clinical trials in 2019**
- Rigorous clinical data demonstrate the efficacy and safety of reproxalap in **dry eye disease and allergic conjunctivitis**, two medical conditions with considerable overlap

Phase 2b Dry Eye Disease Clinical Trial Design
January – July 2018

- **Primary objective:**
  - Evaluate efficacy of reproxalap ophthalmic solutions vs. baseline and vehicle to **confirm endpoint selection and sample size for Phase 3 clinical trials**

- **Inclusion/exclusion highlights:**
  - History of dry eye disease for at least 6 months
  - Moderate to severe dry eye disease
    - ≥ 2 on OD & 4-Symptom Questionnaire (in at least one symptom score)
    - Schirmer's Test ≤ 10 mm and ≥ 1 mm
    - Tear Film Break-Up Time ≤ 5 sec
    - ≥ 2 staining score in at least one corneal region, and ≥ 4 in sum corneal
    - ≥ 2 staining score in sum conjunctival
    - Demonstrate Controlled Adverse Environment (CAE) response

Phase 2b Dry Eye Disease Clinical Trial



OD = Ocular Discomfort
QID = four times daily
Source: Reproxalap DED Phase 2b clinical trial protocol

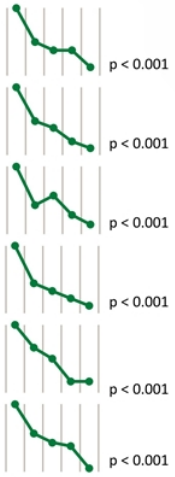
Reproxalap's Broad Activity Across Dry Eye Symptoms and Signs Consistent with Previous Clinical Trials

0.25% Reproxalap Change From Baseline (N=100)

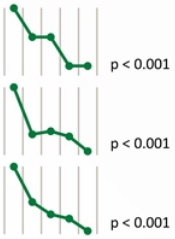
Baseline | Wk 2 | Wk 4 | Wk 8 | Wk 12

ITT Population with Observed Data Only

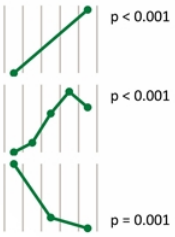
Symptom Severity Measures



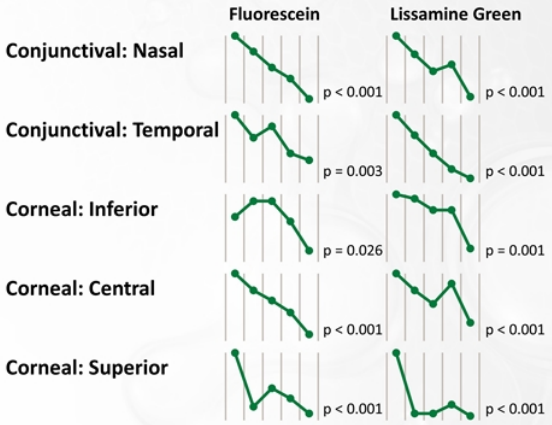
Symptom Frequency Measures



Tear Quantity and Quality Signs



Ocular Surface Damage Signs (Stains)



p values subject to change based on quality control analysis

Source: Reproxalap DED Phase 2b clinical trial results

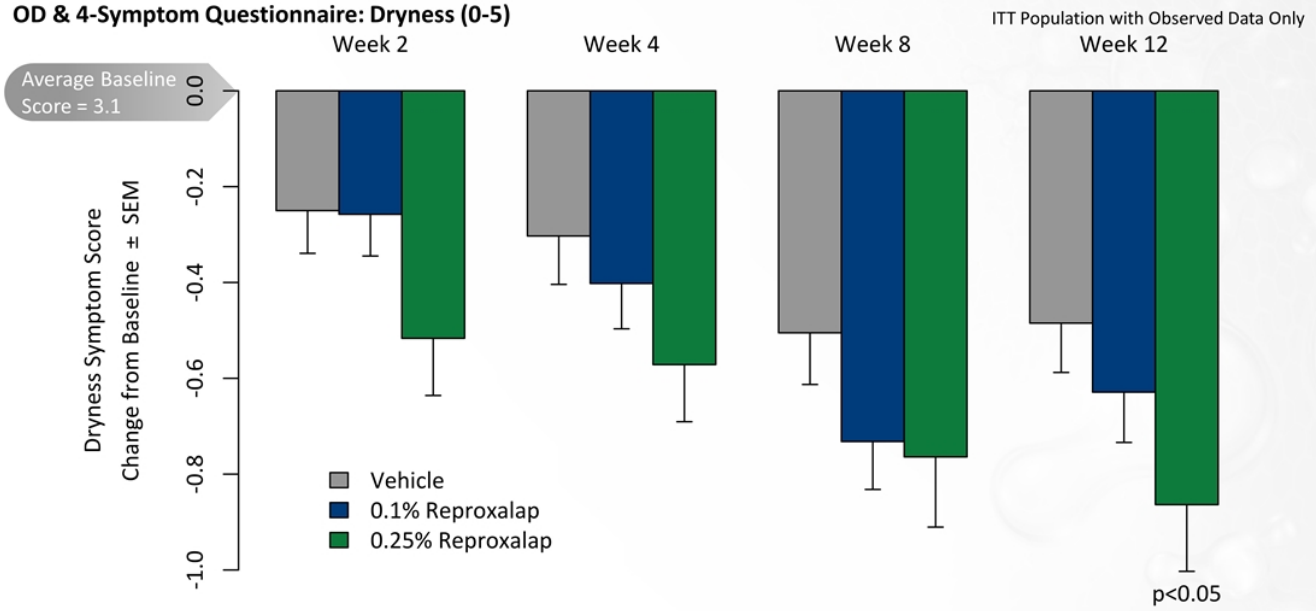
OD&4S = Ocular Discomfort & 4 Symptom
ODS = Ocular Discomfort Scale
OSDI = Ocular Surface Disease Index
SANDE = Symptom Assessment in Dry Eye
TFBUT = Tear Film Break-Up Time

ALDEYRA THERAPEUTICS™

Proposed Co-Primary Endpoint: Reproxalap Improved Ocular Dryness vs. Vehicle

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

ITT Population with Observed Data Only



p values subject to change based on quality control analysis

Source: Reproxalap DED Phase 2b clinical trial results

OD = Ocular Discomfort

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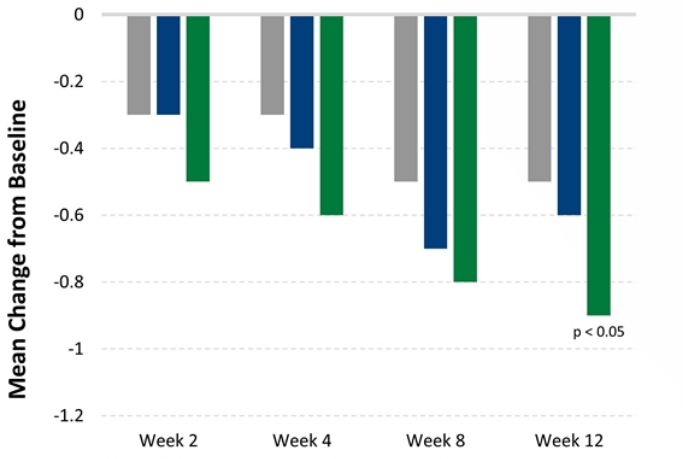
Drug Potency Supported by Ocular Dryness Improvement vs. Vehicle in Higher Baseline Patients

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

Total Population (N=100|100|100)
ITT Population with Observed Data Only

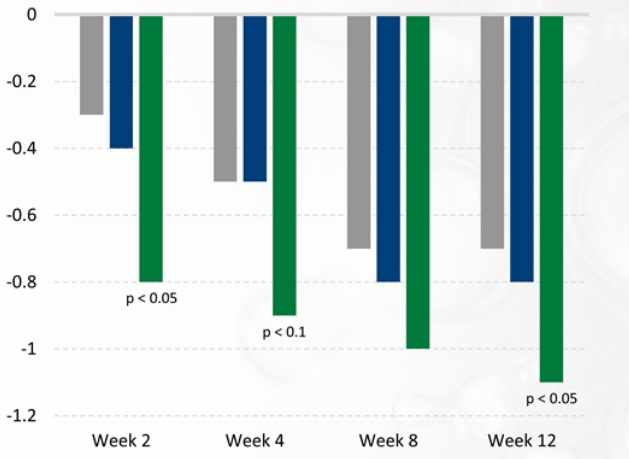
Total Population Average Baseline Score = 3.1



vs.

Above Median Baseline Population (N=79|69|69)
ITT Population with Observed Data Only

Above Median Population Average Baseline Score = 3.6



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

Vehicle ■ Reproxalap (0.1%) ■ Reproxalap (0.25%)

OD = Ocular Discomfort

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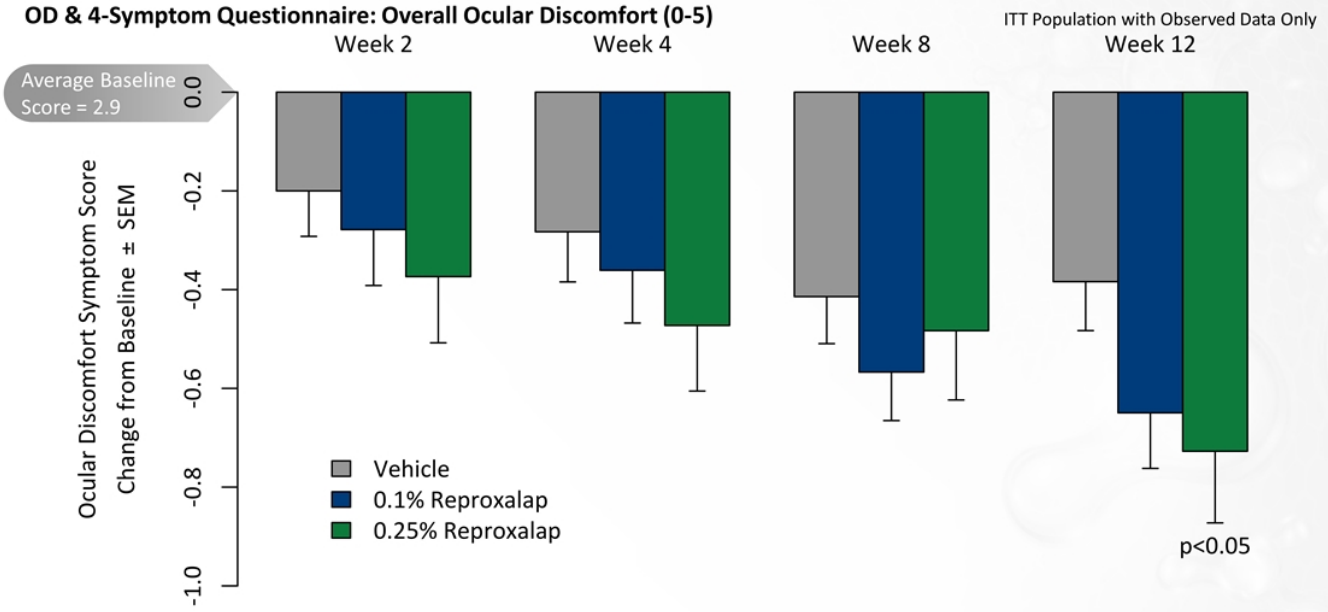
Ocular Discomfort Symptom Results Support Observed Improvement in Ocular Dryness Score



p values subject to change based on quality control analysis

Source: Reproxalap DED Phase 2b clinical trial results

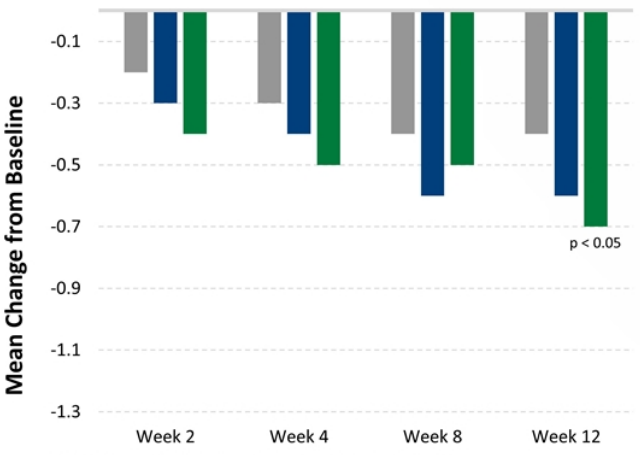
OD = Ocular Discomfort

Drug Potency Supported by Ocular Discomfort Improvement vs. Vehicle in Higher Baseline Patients

OD & 4-Symptom Questionnaire: Overall Ocular Discomfort (0-5)

Total Population (N=100|100|100)
ITT Population with Observed Data Only

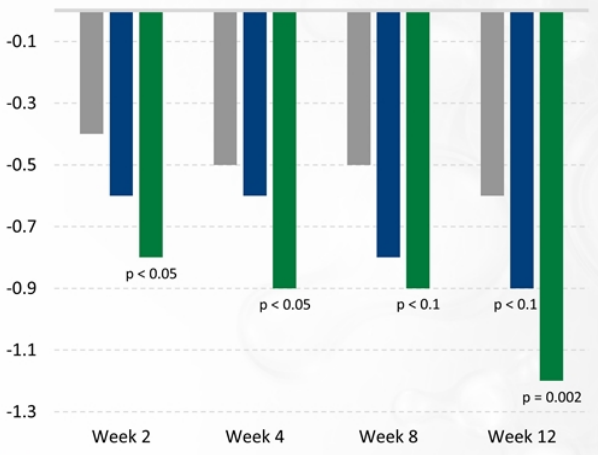
Total Population Average Baseline Score = 2.9



VS.

Above Median Baseline Population (N=69|65|64)
ITT Population with Observed Data Only

Above Median Population Average Baseline Score = 3.4



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

Vehicle ■ Reproxalap (0.1%) ■ Reproxalap (0.25%)

OD = Ocular Discomfort

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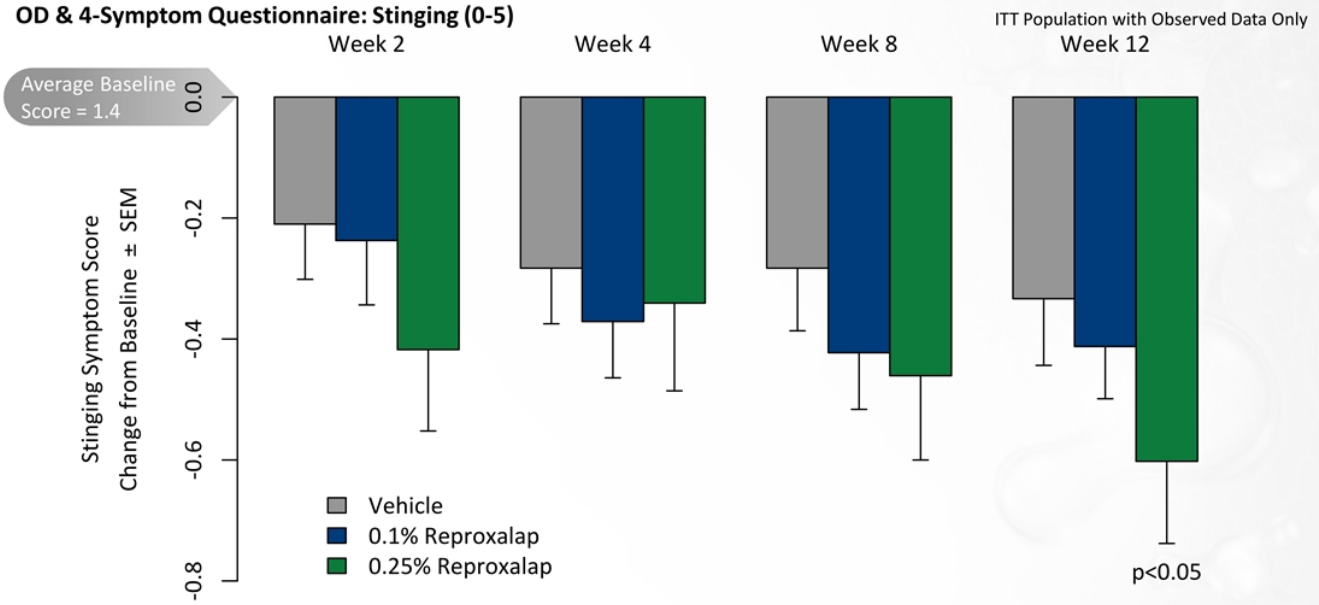
Ocular Stinging Symptom Results Support Observed Improvement in Ocular Dryness Score



p values subject to change based on quality control analysis

Source: Reproxalap DED Phase 2b clinical trial results

OD = Ocular Discomfort

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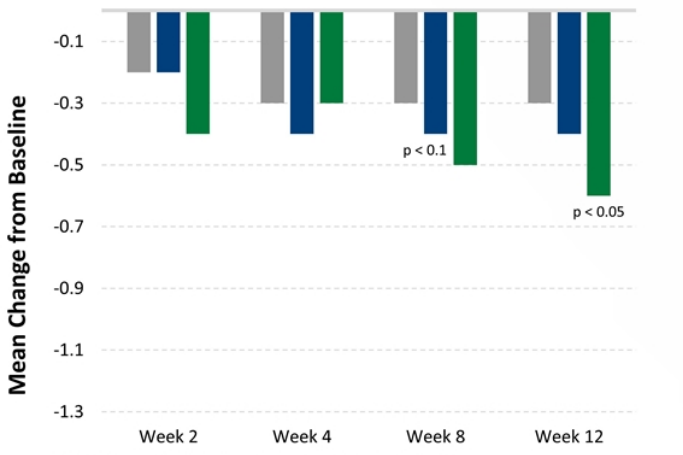
Drug Potency Supported by Ocular Stinging Improvement vs. Vehicle in Higher Baseline Patients

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

Total Population (N=100|100|100)
ITT Population with Observed Data Only

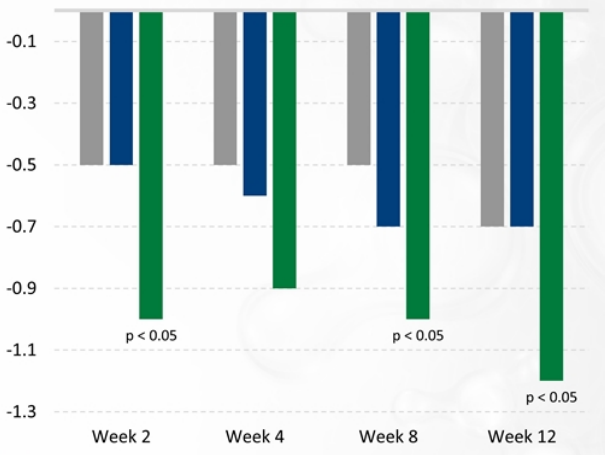
Total Population Average Baseline Score = 1.4



VS.

Above Median Baseline Population (N=66|56|67)
ITT Population with Observed Data Only

Above Median Population Average Baseline Score = 2.2



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

Vehicle ■ Reproxalap (0.1%) ■ Reproxalap (0.25%)

OD = Ocular Discomfort

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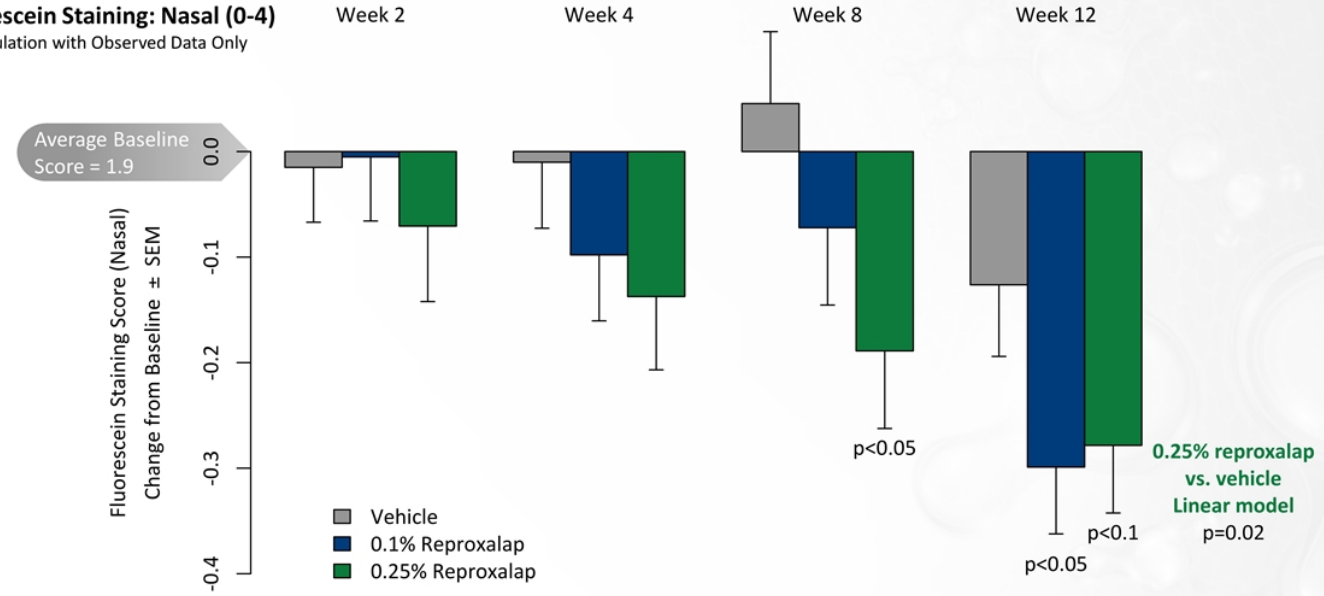
Proposed Co-Primary Endpoint: Reproxalap Improved Ocular Staining vs. Vehicle

Fluorescein Staining: Nasal (0-4)
ITT Population with Observed Data Only



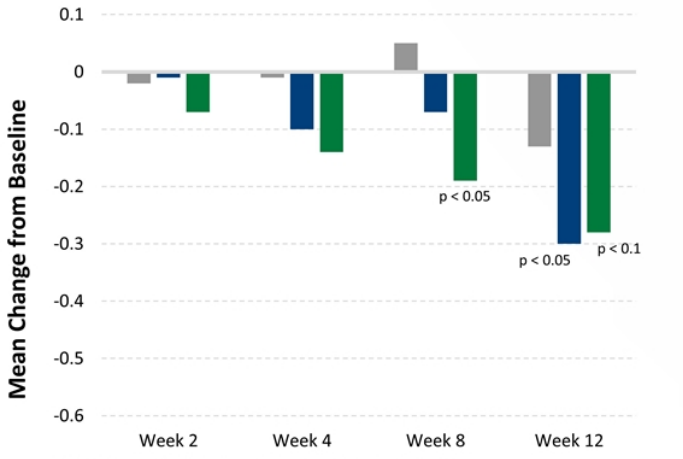
p values subject to change based on quality control analysis
Source: Reproxalap DED Phase 2b clinical trial results

Drug Potency Supported by Ocular Staining Improvement vs. Vehicle in Higher Baseline Patients

Fluorescein Staining: Nasal (0-4)

Total Population (N=100|100|100)
ITT Population with Observed Data Only

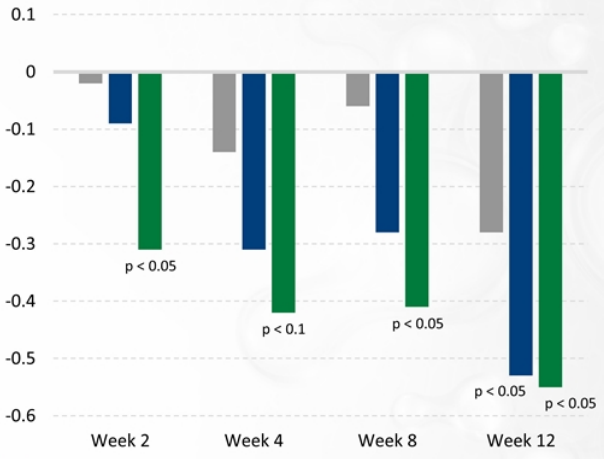
Total Population Average Baseline Score = 1.9



VS.

Above Median Baseline Population (N=59|56|62)
ITT Population with Observed Data Only

Above Median Population Average Baseline Score = 2.3



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

Vehicle ■ Reproxalap (0.1%) ■ Reproxalap (0.25%)

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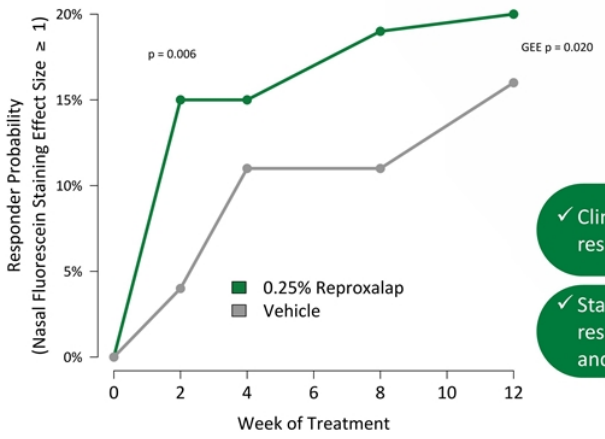
Ocular Staining Responder Analyses Demonstrate Statistical Superiority of Reproxalap over Vehicle

Fluorescein Staining (Nasal)

ITT Population with Observed Data Only

Probability of Response for Staining



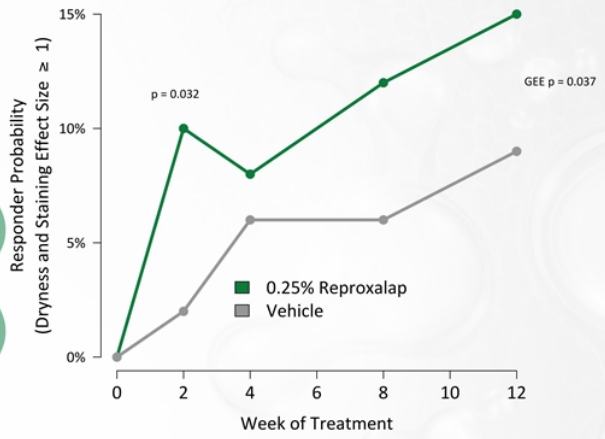
✓ Clinically significant response in 2 weeks

✓ Statistically significant response in symptom and sign vs. vehicle

OD&4S: Ocular Dryness and Fluorescein Staining (Nasal)

ITT Population with Observed Data Only

Probability of Response for both Ocular Dryness and Staining



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

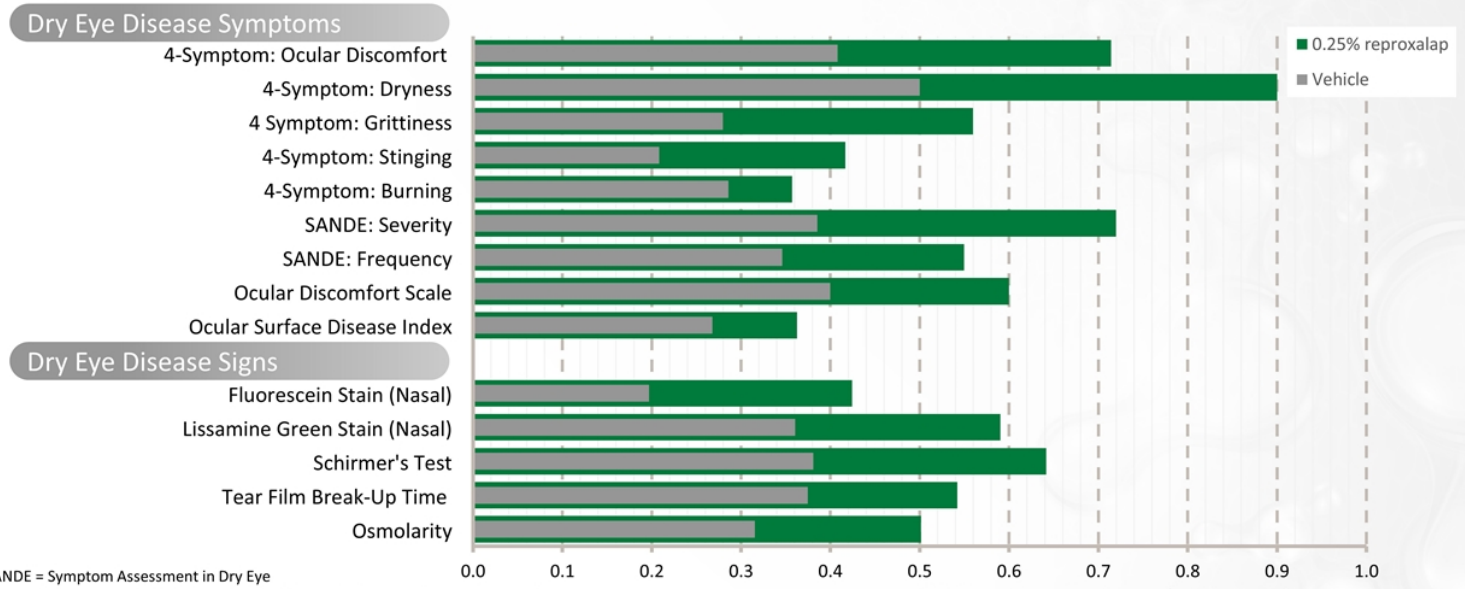
OD&4S = Ocular Discomfort & 4 Symptom
Effect Size = Change from Baseline / Standard Deviation at Baseline

GEE = Generalized Estimating Equations

Broad Pattern of Drug Activity Across Dry Eye Disease Symptoms and Signs Supports Differentiated Product Profile

Improvement Effect Size at Week 12

ITT Population with Observed Data Only



SANDE = Symptom Assessment in Dry Eye

Average improvement effect size across both eyes for tear quality and tear quantity measures (Schirmer's Test, Tear Film Break-Up Time, and Osmolarity)

Improvement Effect size = Change from Baseline / Standard Deviation at Baseline

Source: Reproxalap DED Phase 2b clinical trial results

ALDEYRA THERAPEUTICS™

Reproxalap: No Observed Safety Concerns and Generally Well Tolerated

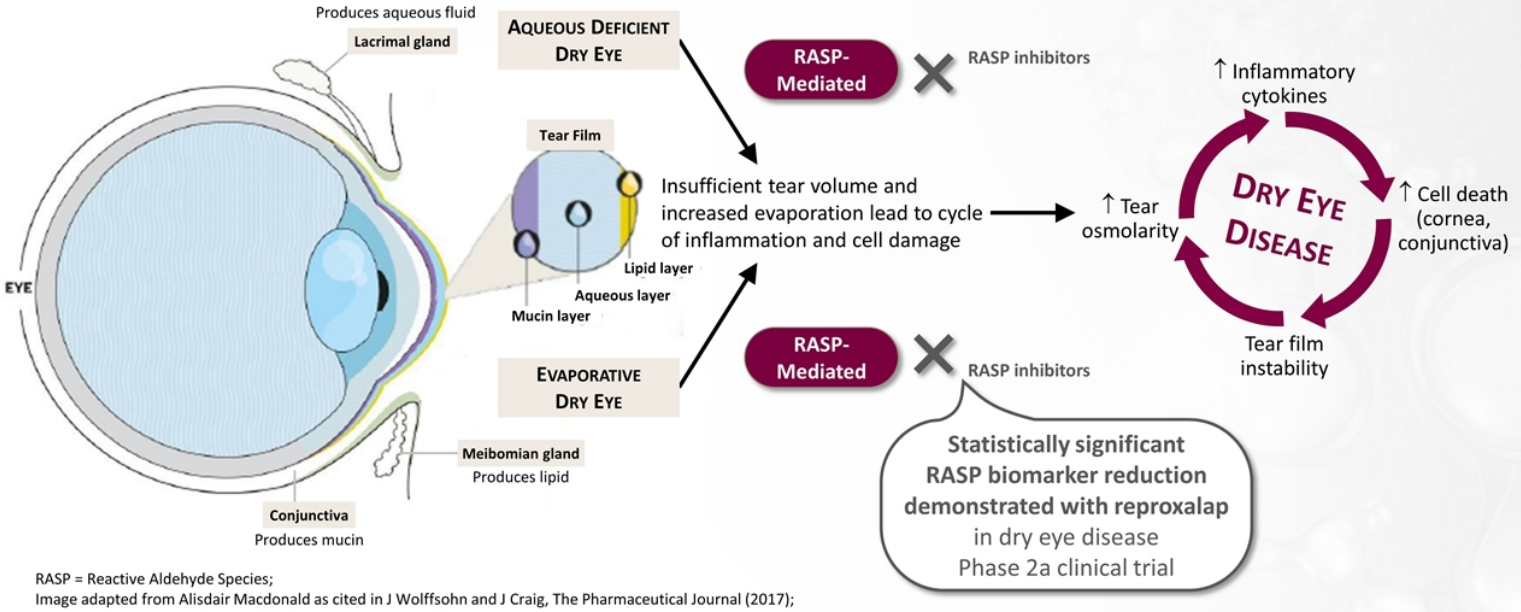
- Consistent with prior topical reproxalap clinical experience in over 500 patients, no observed safety concerns, and predominantly mild instillation site irritation reported

	0.1% reproxalap	0.25% reproxalap	Vehicle
Discontinuations	3/100 (3%)	12/100 (12%)	1/100 (1%)

- Rates consistent with recent Phase 2 dry eye disease clinical trials

Source: Reproxalap DED Phase 2b clinical trial results

Reproxalap's Novel Mechanism of Action has the Potential to Address the Two Major Forms of Dry Eye Disease



RASP = Reactive Aldehyde Species;
Image adapted from Alisdair Macdonald as cited in J Wolffsohn and J Craig, The Pharmaceutical Journal (2017);
RASP activity as shown based on published literature and Aldeyra data on file.

Reproxalap:
A Novel Drug Candidate For the Treatment of Dry Eye Disease

Positive Phase 2b Clinical Trial Results

- **Primary objective achieved:**
  Endpoint selection and sample size powering confirmed for Phase 3 clinical trials
- Reproxalap demonstrated **statistically significant improvements** versus vehicle across multiple symptom and sign measures, consistent with novel and broad mechanism of action
- **Pathway to registration trials confirmed** with ocular dryness symptom score, ocular staining score, and 0.25% reproxalap dose
- **Improvements in symptoms and signs observed as early as two weeks**, consistent with prior reproxalap clinical trial results and supportive of differentiated product profile
- Aldeyra plans to discuss results with regulatory authorities, and expects to **initiate Phase 3 clinical trials in 2019**
- Rigorous clinical data demonstrate the efficacy and safety of reproxalap in **dry eye disease and allergic conjunctivitis**, two medical conditions with considerable overlap

Reproxalap Planned Phase 3 Dry Eye Disease Program

- Two Phase 3 clinical trials expected to be initiated in 2019, following discussion with regulatory authorities
- First Phase 3 clinical trial is an adaptive two-stage design; expected initiation in 2019
  - Stage 1: Protocol optimization and sample size confirmation (12 weeks)
  - Stage 2: Randomized, double masked, two-arm, parallel-group design, reproxalap vs vehicle (12 weeks)
- Primary endpoints: Ocular dryness score and ocular staining
- Secondary endpoints include ocular itch, based on positive reproxalap allergic conjunctivitis program results and high comorbidity of allergic conjunctivitis in dry eye disease patients
- Estimated sample size of 400-500 per arm with approximately 90% statistical power
- Second Phase 3 clinical trial expected to initiate in 2019

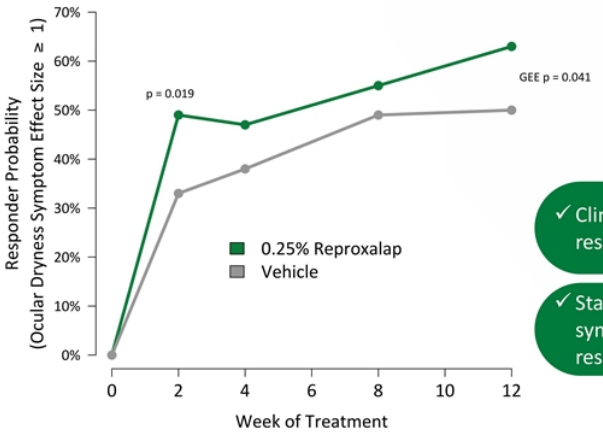
Contingent on funding, regulatory review, and other factors.

Reproxalap's Differentiated Product Profile Evidenced by Responder Analyses – Rapid and Symptom-Free (Ocular Dryness)

OD & 4-Symptom Questionnaire: Dryness

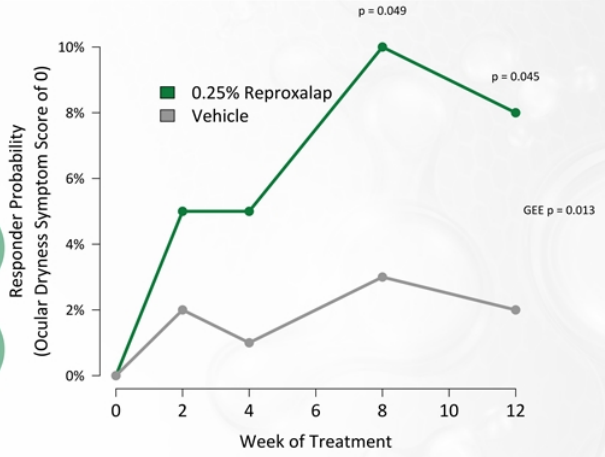
ITT Population with Observed Data Only

Probability of Response (Improvement Effect Size ≥1)



- ✓ Clinically significant response in 2 weeks
- ✓ Statistically significant symptom-free response vs. vehicle

Probability of Symptom-Free (Ocular Dryness Score = 0)



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

OD = Ocular Discomfort
Effect Size = Change from Baseline / Standard Deviation at Baseline

GEE = Generalized Estimating Equations

Reproxalap: A Unique and Novel Product Candidate For Dry Eye Disease

Patients & Physicians Not Satisfied

Current prescription options **may take up to six weeks or longer** to have an effect

Up to **75%**

of patients with DED **are not satisfied with current prescription options**

Up to **50%**

of patients **treated for DED** with current therapies **fail and discontinue** according to prescribing physicians

A Unique Opportunity

Reproxalap

Early and consistent symptom improvements in Phase 2b clinical trial

Broad symptom and sign improvements in Phase 2b clinical trial

Novel mechanism of action and differentiated approach to treat DED

Sources: Aldeyra primary patient market research, primary physician market research, secondary market research, and estimates; Clin Ophthalmol. 2009; 3: 405–412.

Reproxalap: Late-Stage Development For Dry Eye Disease and Allergic Conjunctivitis – Two Medical Conditions with Significant Overlap

Dry Eye Disease

- Initiated reproxalap **Phase 2b clinical trial in dry eye disease January 2018**
- **Positive** reproxalap dry eye disease **Phase 2b clinical trial results September 2018**

Anticipated Milestones*

- New: Reproxalap dry eye disease **Phase 3 clinical trial program initiation 2019**
  - *Ocular itch endpoint to be included (as secondary)*

Allergic Conjunctivitis

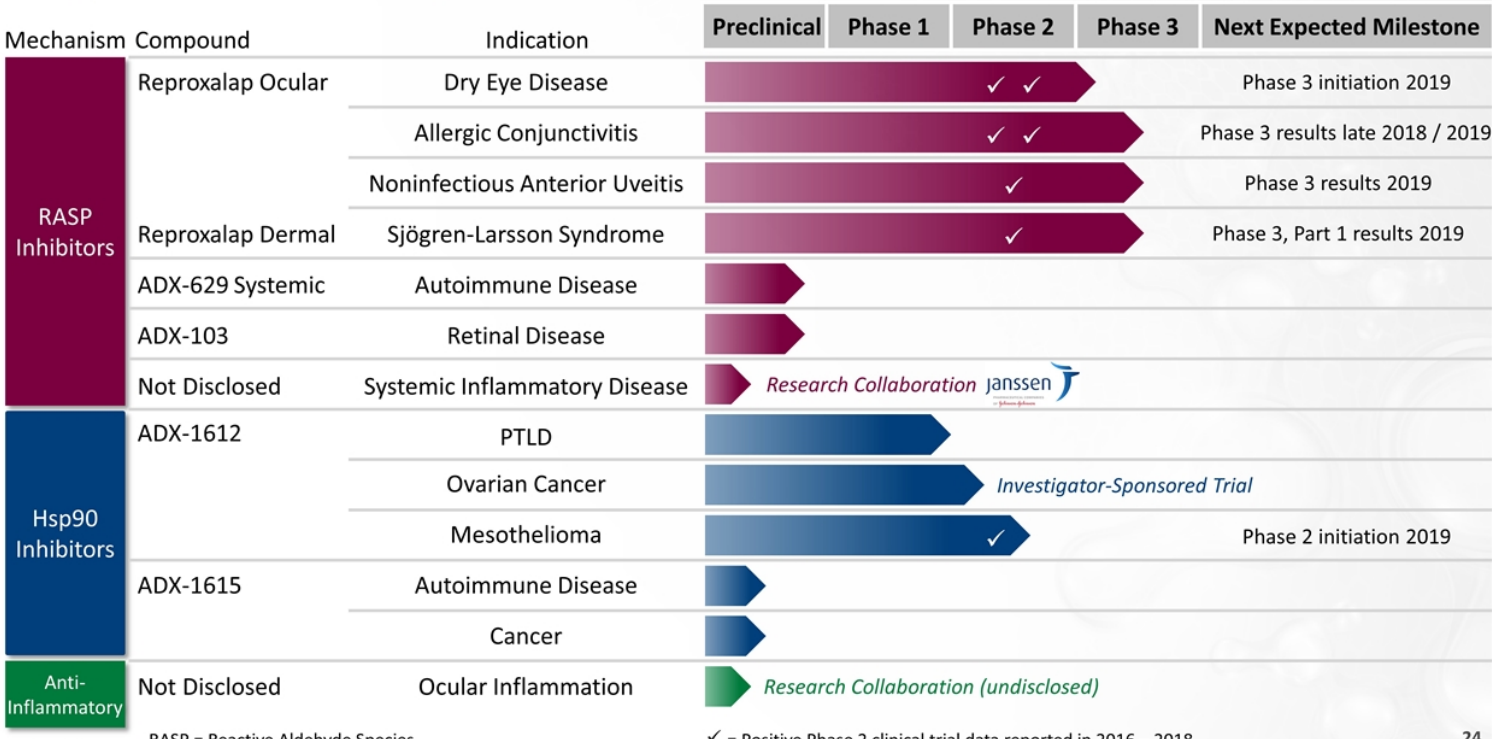
- Initiated reproxalap **ALLEVIATE Phase 3 clinical trial in allergic conjunctivitis April 2018**

Anticipated Milestones*

- Reproxalap allergic conjunctivitis ALLEVIATE Phase 3 trial **results late 2018/early 2019**

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

Deep and Innovative Pipeline



RASP = Reactive Aldehyde Species
PTLD = Post-Transplant Lymphoproliferative Disorder

✓ = Positive Phase 2 clinical trial data reported in 2016 – 2018

Phase 2 count includes mesothelioma investigator-sponsored trial; Phase 3 trials contingent on funding, regulatory review, and other factors.

Aldeyra Therapeutics Announces Positive Results from Phase 2b Dry Eye Disease Clinical Trial

Statistically Significant Improvement Across Multiple Symptom and Sign Measures

Early Onset and Broad Range of Activity Supports Differentiated Product Profile

Pivotal Clinical Testing Expected to Begin in 2019 Following Discussion with Regulatory Authorities

LEXINGTON, Mass., September 26, 2018 (PRNewswire) — Aldeyra Therapeutics, Inc. (NASDAQ: ALDX) (Aldeyra), a biotechnology company devoted to development of next-generation medicines to improve the lives of patients with immune-mediated diseases, today announced positive results from its Phase 2b clinical trial of topical ocular reproxalap in patients with dry eye disease.

“The early onset and broad activity observed in the Phase 2b clinical trial suggests that reproxalap could be an important treatment option relative to existing therapies,” commented John Sheppard, M.D., Professor of Ophthalmology, Eastern Virginia Medical School. “The results announced today confirm the potential of reproxalap, a drug with a novel mechanism of action, as a promising and differentiated therapeutic agent for dry eye disease, which remains a persistently challenging condition for large numbers of patients worldwide.”

The randomized, vehicle-controlled, parallel-group, multi-center, double-masked Phase 2b clinical trial investigated 0.1% and 0.25% concentrations of reproxalap topical ophthalmic solution versus vehicle. Relative to patients treated with vehicle, patients treated with the 0.25% concentration of reproxalap had statistically significant and clinically relevant reductions in the Four-Symptom Ocular Dryness Score ($p<0.05$) and the Overall Ocular Discomfort Symptom Score ($p<0.05$). Symptom improvement greater than that of vehicle was consistently observed across all measures, and activity versus vehicle was demonstrated as early as two weeks (the first assessment following initiation of therapy). The early onset of symptomatic improvement is consistent with the Phase 2a clinical trial of topical ocular reproxalap in dry eye disease, and is supportive of a differentiated product profile relative to current standard of care. Patients treated with the 0.25% concentration of reproxalap also demonstrated reductions in ocular fluorescein staining score that were statistically superior to those of patients treated with vehicle ($p<0.05$).

Both 0.1% and 0.25% reproxalap concentrations demonstrated activity relative to vehicle, and a clear dose response was observed. Consistent with previous clinical trials, topical ocular reproxalap was well tolerated, and reported adverse events were generally mild.

Three hundred patients with dry eye disease were randomized equally to receive 0.1%, 0.25%, or vehicle for 12 weeks. The primary objective of the trial was to evaluate the safety and efficacy of reproxalap for the treatment of the symptoms and signs of dry eye disease in order to select a drug concentration, confirm endpoint selection, and determine sample size for a pivotal Phase 3 clinical program.

“Based on the successful Phase 2b results, we look forward to initiating a Phase 3 program in dry eye disease in 2019 following our discussion with regulatory authorities,” commented Todd C. Brady, M.D., Ph.D., Chief Executive Officer of Aldeyra. “The addition of dry eye disease to our late-stage clinical portfolio, which includes Phase 3 clinical trials in allergic conjunctivitis and noninfectious anterior uveitis, highlights the potential of reproxalap as a highly differentiated and novel ophthalmic therapy.”

Conference Call

Aldeyra will hold a conference call on September 26, 2018 at 8:00 a.m. ET to discuss results of the clinical trial. The dial-in numbers are 1-877-266-8979 for domestic callers and 1-412-317-5231 for international callers. A live webcast of the conference call will also be available on the investor relations page of Aldeyra’s corporate website at ir.aldeyra.com. After the live webcast, the event will remain archived on Aldeyra’s website for one year.

About Aldeyra Therapeutics

Aldeyra Therapeutics is developing 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 and other forms of ocular inflammation. Aldeyra is also developing other product candidates for autoimmune disease, post-transplant lymphoproliferative disease, retinal inflammation, metabolic disease, and cancer. None of Aldeyra’s product candidates have been approved for sale in the U.S. or elsewhere.

About Dry Eye Disease

Dry eye disease is a common inflammatory disease estimated to affect approximately 20 million people in the United States. The disease is characterized by insufficient moisture and lubrication in the anterior surface of the eye, leading to dryness, inflammation, pain, discomfort, irritation, diminished quality of life, and in severe cases, permanent vision impairment. Among physicians and patients, existing therapy for dry eye disease is generally regarded as inadequate. In patients with dry eye disease, pro-inflammatory RASP (Reactive Aldehyde Species) may contribute to ocular inflammation. By diminishing RASP levels, Aldeyra’s RASP inhibitor platform represents a novel and differentiated approach for the treatment of the symptoms and signs of dry eye disease.

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

reproxalap, including the timing of initiating a Phase 3 program, and its other product candidates. 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 June 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.

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.

Corporate Contact:
David McMullin
Aldeyra Therapeutics, Inc.
Tel: 781-761-4904 ext. 218
dmcmullin@aldeyra.com

Investor Contact:
Chris Brinzey
Westwicke Partners
Tel: 339-970-2843
Chris.brinzey@westwicke.com

Media Contact:
Cammy Duong
MacDougall Biomedical Communications
781-591-3443
cduong@macbiocom.com