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): December 3, 2019

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).

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.001 par value per share	**ALDX**	**The Nasdaq Stock Market, LLC**

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.

On December 3, 2019, Aldeyra Therapeutics, Inc. (the "Company" or "Aldeyra") issued a press release and is holding a conference call regarding the top-line results from Part 1 of the adaptive Phase 3 RENEW Trial of topical ocular reproxalap in patients with dry eye disease. The press release is furnished herewith as Exhibit 99.1 and is incorporated by reference herein. A copy of the presentation which will be referenced during the conference call and posted on the Company's website is furnished herewith as Exhibit 99.2 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.

As reported under Item 7.01 of this Current Report on Form 8-K, on December 3, 2019, the Company issued a press release and is holding a conference call regarding the top-line results from Part 1 of the adaptive Phase 3 RENEW Trial of topical ocular reproxalap in patients with dry eye disease. The RENEW Trial is an ongoing adaptive, two-part, multi-center, randomized, vehicle-controlled, double-masked, parallel-group Phase 3 trial of 0.25% topical ocular reproxalap compared to vehicle in patients with moderate to severe dry eye disease. The primary objective of RENEW Part 1 was to confirm dosing regimen, endpoints, and sample size for RENEW Part 2. In Part 1 of RENEW, 422 patients were randomized equally to receive either four-times-daily reproxalap or vehicle for twelve weeks (the constant dosing group) or four-times-daily reproxalap or vehicle for four weeks, followed by twice-daily reproxalap or vehicle for eight weeks (the induction-maintenance dosing group).

The primary objective of RENEW Part 1 was achieved. Observed activity versus vehicle of the induction-maintenance dosing regimen of topical ocular reproxalap was greater than that of the constant dosing group, and the induction-maintenance dosing regimen will be advanced to RENEW Part 2. The expected primary endpoints for RENEW Part 2 are ocular dryness score and fluorescein nasal region ocular staining score. RENEW Part 2 is expected to initiate in the first half of 2020 and enroll approximately 400 patients per arm at approximately 90% power to achieve statistical significance.

In the induction-maintenance dosing group, the RENEW co-primary endpoint of patient-reported visual analog scale (VAS) ocular dryness from Weeks 2 to 12 was achieved ($p=0.0004$), and activity was observed as early as one week after initiation of therapy ($p=0.001$) and was maintained until the end of the trial. In the induction-maintenance dosing group from Weeks 2 to 12, reproxalap was statistically superior to vehicle in VAS ocular endpoints for itching ($p=0.03$), foreign body sensation ($p=0.004$), discomfort ($p=0.003$), photophobia ($p=0.004$), and pain ($p=0.03$). In the induction-maintenance dosing group from Weeks 2 to 12, reproxalap was statistically superior to vehicle in Ocular Discomfort & 4-Symptom Questionnaire ocular endpoints for dryness ($p=0.01$), discomfort ($p=0.03$), burning ($p=0.03$), grittiness ($p=0.003$), and stinging ($p=0.02$). Although the improvement effect size of the co-primary endpoint of fluorescein nasal region ocular staining did not reach statistical significance, reproxalap was statistically superior to vehicle in reduction from baseline in the induction-maintenance dosing group from Weeks 1 to 4 of treatment ($p=0.03$), and statistical separation from vehicle was observed at Week 2 ($p=0.04$).

In the trial, no adverse findings on safety assessments were observed, and reproxalap was well-tolerated. The most common reported adverse event in reproxalap-treated patients was transient and mild instillation site irritation. Less than 8% of reproxalap treated patients discontinued the trial due to adverse events, and moderate ocular adverse events were reported in fewer than 1% of subjects.

Various statements contained in this Current Report on Form 8-K are "forward-looking statements" under the securities laws, including, but not limited to, statements regarding 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," "on track," "scheduled," "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 risk that prior results, such as signals of safety, activity or durability of effect, observed from preclinical or clinical trials, will not be replicated or will not continue in ongoing or future studies or clinical trials involving Aldeyra's product candidates; the scope, progress, expansion, and costs of developing and commercializing 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 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, 2018 and Aldeyra's Quarterly Report on Form 10-Q for the quarter ended September 30, 2019, 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 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.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Aldeyra Therapeutics, Inc. Press Release dated December 3, 2019.
99.2	Aldeyra Therapeutics, Inc. Presentation dated December 3, 2019.

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.

Dated: December 3, 2019

ALDEYRA THERAPEUTICS, INC.

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

Aldeyra Therapeutics Announces Positive Top-Line Results from Part 1 of Adaptive Phase 3 RENEW Trial in Dry Eye Disease

- *Primary objective of RENEW Part 1 achieved: Induction-maintenance dosing regimen of topical ocular reproxalap advanced to RENEW Part 2*
- *Reproxalap statistically superior to vehicle in RENEW co-primary endpoint of ocular dryness score in induction-maintenance regimen - symptomatic improvement observed as early as one week after initiation of therapy and at all measured timepoints*
- *Relative to vehicle, induction-maintenance dosing regimen demonstrated broad and statistically significant activity across majority of assessed symptoms*
- *RENEW Part 2 expected to initiate in the first half of 2020*
- *Conference call to be held at 8:00 AM Eastern Standard Time today*

LEXINGTON, Mass., December 3, 2019 – 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, announced today positive top-line results from Part 1 of the adaptive Phase 3 RENEW Trial of topical ocular reproxalap in patients with dry eye disease.

“To our knowledge, reproxalap is the first topical dry eye disease drug to demonstrate statistically significant ocular dryness symptom improvement relative to vehicle as soon as one week after initiation of treatment, and thus has the potential to be first-line therapy,” commented Todd C. Brady, M.D., Ph.D., President and Chief Executive Officer of Aldeyra. “The breadth of symptomatic activity highlighted by the induction-maintenance dosing regimen results in RENEW Part 1 demonstrate the potential of reproxalap in treating dry eye disease, one of the largest - yet least-served - markets in ophthalmology.”

The RENEW Trial is an ongoing adaptive, two-part, multi-center, randomized, vehicle-controlled, double-masked, parallel-group Phase 3 trial of 0.25% topical ocular reproxalap compared to vehicle in patients with moderate to severe dry eye disease. The primary objective of RENEW Part 1 was to confirm dosing regimen, endpoints, and sample size for RENEW Part 2. In Part 1 of RENEW, 422 patients were randomized equally to receive either four-times-daily reproxalap or vehicle for twelve weeks (the constant dosing group) or four-times-daily reproxalap or vehicle for four weeks, followed by twice-daily reproxalap or vehicle for eight weeks (the induction-maintenance dosing group).

The primary objective of RENEW Part 1 was achieved. Observed activity versus vehicle of the induction-maintenance dosing regimen of topical ocular reproxalap was greater than that of the constant dosing group, and the induction-maintenance dosing regimen will be advanced to RENEW Part 2. The planned primary endpoints for RENEW Part 2 are ocular dryness score and fluorescein nasal region ocular staining score. RENEW Part 2 is expected to initiate in the first half of 2020 and enroll approximately 400 patients per arm at approximately 90% power to achieve statistical significance.

In the induction-maintenance dosing group, the RENEW co-primary endpoint of patient-reported visual analog scale (VAS) ocular dryness from Weeks 2 to 12 was achieved (p=0.0004), and activity was observed as early as one week after initiation of therapy (p=0.001) and was maintained until the end of the trial. In the induction-maintenance dosing group from Weeks 2 to 12, reproxalap was statistically superior to vehicle in VAS ocular endpoints for itching (p=0.03), foreign body sensation (p=0.004), discomfort (p=0.003), photophobia (p=0.004), and pain (p=0.03). In the induction-maintenance dosing group from Weeks 2 to 12, reproxalap was statistically superior to vehicle in Ocular Discomfort & 4-Symptom Questionnaire ocular endpoints for dryness (p=0.01), discomfort (p=0.03), burning (p=0.03), grittiness (p=0.003), and stinging (p=0.02). Although the improvement effect size of the co-primary endpoint of fluorescein nasal region ocular staining did not reach statistical significance, reproxalap was statistically superior to vehicle in reduction from baseline in the induction-maintenance dosing group from Weeks 1 to 4 of treatment (p=0.03), and statistical separation from vehicle was observed at Week 2 (p=0.04).

“The rapid amelioration of symptoms followed by symptomatic control in the induction-maintenance dosing regimen supports the potential of reproxalap to treat a wide range of dry eye disease states, from severe flares to persistent symptoms,” stated Dr. David Clark, Chief Medical Officer of Aldeyra. “In addition, consistent with our positive Phase 3 results in allergic conjunctivitis, reproxalap is one of the first dry eye disease drugs to demonstrate activity in reducing ocular itching, a prominent symptom associated with dry eye disease exacerbation, which is especially common during allergy seasons.”

Consistent with clinical experience in over 1,100 patients, no adverse findings on safety assessments were observed, and reproxalap was well-tolerated. The most common reported adverse event in reproxalap-treated patients was transient and mild instillation site irritation. Less than 8% of reproxalap-treated patients discontinued the trial due to adverse events, and moderate ocular adverse events were reported in fewer than 1% of subjects.

“Today’s dry eye disease population is underserved, and novel therapies are in demand. Currently available therapies often require weeks or months to demonstrate activity, and many patients exhibit limited or no response, leading to between 50% to 80% of patients dropping off therapy between their second and third refill,” stated David McMullin, Chief Commercial Officer of Aldeyra. “The early-onset and broad pattern of symptom improvement in the induction-maintenance dosing regimen of reproxalap demonstrated in RENEW Part 1 represents an attractive profile in the dry eye disease market.”

Conference Call

Aldeyra will host a conference call to discuss this announcement today, December 3, 2019, at 8:00 a.m. ET. The dial-in numbers are (866) 211-4098 for domestic callers and (647) 689-6613 for international callers. The Conference ID is 1592481. A live webcast of the conference call will also be available on the Investors Relations section of the Aldeyra Therapeutics website at https://ir.aldeyra.com. Presentation slides will be available on the investor relations page approximately 30 minutes prior to the start of the conference call and webcast.

After the live webcast, the event will remain archived on the Aldeyra Therapeutics website for thirty days.

About Reproxalap

Reproxalap is a novel, small-molecule immune-modulating covalent inhibitor of reactive aldehyde species (RASP), which are elevated in ocular and systemic inflammatory disease. Reproxalap's mechanism of action has been validated with the demonstration of statistically significant and clinically relevant activity in multiple physiologically distinct late-phase clinical indications.

About Dry Eye Disease

Dry eye disease is a common inflammatory disease estimated to affect approximately 34 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 and often requires weeks or months to demonstrate activity. In patients with dry eye disease, pro-inflammatory RASP may contribute to ocular inflammation and changes in tear lipid composition. 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.

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 investigational drug product candidates are potential first-in-class treatments in development for dry eye disease, allergic conjunctivitis, proliferative vitreoretinopathy, and Sjögren-Larsson Syndrome. The company is also developing other product candidates for retinal and systemic inflammatory diseases.

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 development plans and expectations for its product candidates, including plans relating to current or future clinical development of reproxalap in dry eye disease, the potential of reproxalap to treat a wide range of dry eye disease states and reduce ocular itching, and the potential to be first-line therapy and first-in-class. 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, 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; 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 risk that prior results, such as signals of safety, activity or durability of effect, observed from preclinical or clinical trials, will not be replicated or will not continue in ongoing or future studies or trials involving 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, 2018 and Aldeyra's Quarterly Report on Form 10-Q for the quarter ended September 30, 2019, 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.

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Exhibit 99.2

December 3, 2019

DATA RELEASE

The RENEW Trial in Dry Eye Disease: Part 1 Top-Line Results

Nasdaq: ALDX

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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 December 3, 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.

In Part 1 of RENEW, Reproxalap Demonstrated Early Onset and Broad Improvements in Symptoms

- **The RENEW Trial is an ongoing adaptive, two-part, Phase 3 clinical trial.**
  - The primary objective of Part 1 was to confirm dosing regimen, endpoints, and sample size for RENEW-Part 2.
- **The primary objective of RENEW-Part 1 was achieved.**
  - Reproxalap will advance to RENEW-Part 2.
  - Dosing regimen, endpoints, and sample size for RENEW-Part 2 were confirmed.
- **RENEW-Part 1 top-line results demonstrated early onset and broad symptomatic control following induction-maintenance dosing.**
  - Induction-maintenance dosing demonstrated greater activity vs. vehicle than constant dosing.
  - Statistical significance achieved for RENEW co-primary endpoint of ocular dryness score.
  - Rapid (as early as 1 week), broad, and statistically significant activity achieved across majority of assessed symptoms.
  - Improvement in fluorescein staining, although not statistically significant, enables powering of RENEW-Part 2.
- **RENEW-Part 2 to initiate in the first half of 2020.**
  - 0.25% topical ocular reproxalap to be administered via induction-maintenance dosing schedule.
  - Co-primary endpoints expected to be ocular dryness score and fluorescein nasal region ocular staining.
  - Approximately 400 patients per arm expected to be enrolled to achieve 90% statistical power.

Dry Eye Disease is a Persistently Disturbing Condition that is Inadequately Treated

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

Up to **75%**

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

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

Up to **80%**

Between 50% and 80% of Rx-treated **DED patients drop off of therapy** between their second and third refill.

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

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

DED = Dry eye disease

The RENEW Trial in Dry Eye Disease

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

Part 1 Top-Line Results

April 2019 — **December 2019**

RENEW-Part 1
Reproxalap 0.25%

- 422 patients
- 10 sites
- 2 dosing regimens
- Pre-specified analyses for protocol optimization

Primary Objective

- ☑ Confirm dosing regimen
- ☑ Confirm endpoints
- ☑ Confirm sample size

RENEW-Part 2
Reproxalap 0.25%

Advancing to Part 2

- ✓ Induction-maintenance dosing
- ✓ Ocular dryness and fluorescein staining co-primary endpoints
- ✓ Approximately 400 patients per arm for 90% statistical power

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

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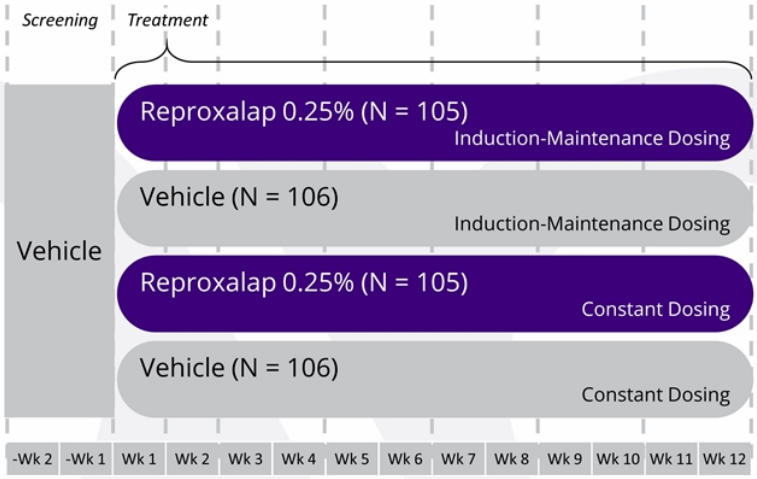
Induction-Maintenance Dosing = QID for Weeks 1-4 and BID for Weeks 5-12

RENEW-Part 1 Clinical Trial Design

- **RENEW-Part 1 primary objective:**
  - Evaluate efficacy of reproxalap ophthalmic solution (0.25%) vs. vehicle to confirm dosing regimen, endpoints, and sample size of RENEW-Part 2
- **RENEW-Part 1 inclusion/exclusion criteria:**
  - Moderate to severe dry eye disease
- **RENEW co-primary endpoints:**
  - Ocular dryness score (0-100mm VAS)
  - Fluorescein nasal region staining score
- **RENEW analysis strategy:**
  - Co-primary endpoints assessed using Mixed Model Repeated Measures (MMRM) from Week 2 to 12
  - Co-primary endpoints assessed in separate pre-specified patient populations
    - Ocular dryness score (OD4S): baseline score of ≥ 3
    - Fluorescein nasal region staining: baseline score ≥ 2

RENEW Phase 3 Dry Eye Disease Clinical Trial: Part 1



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

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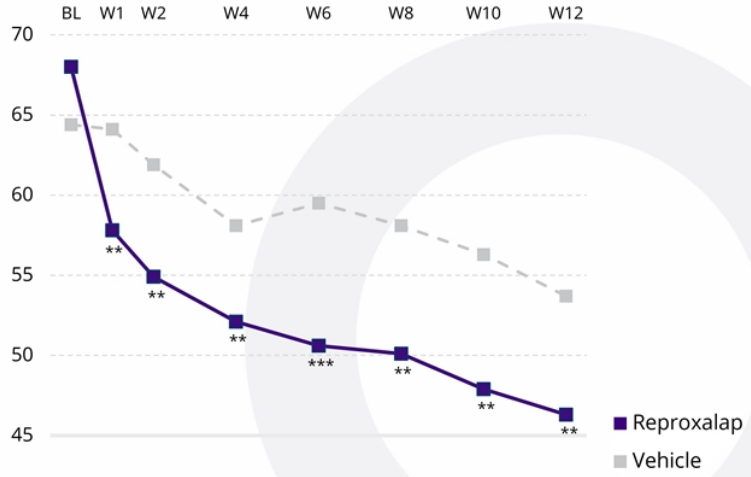
VAS = Visual Analog Scale
OD4S = Ocular Discomfort & 4-Symptom Questionnaire

Constant Dosing = QID for Weeks 1-12
Induction-Maintenance Dosing = QID for Weeks 1-4 and BID for Weeks 5-12

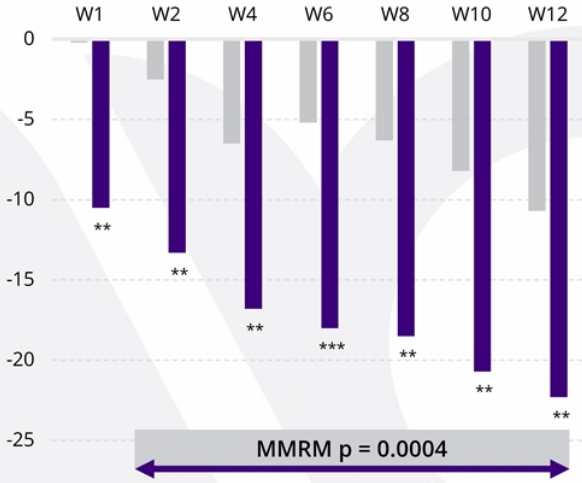
Reproxalap Demonstrated Rapid and Durable Improvement in Co-Primary Endpoint of Ocular Dryness Score in RENEW-Part 1

Co-Primary Symptom Endpoint for RENEW

Ocular Dryness Score (VAS)†
Baseline and Weeks 1 to 12



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

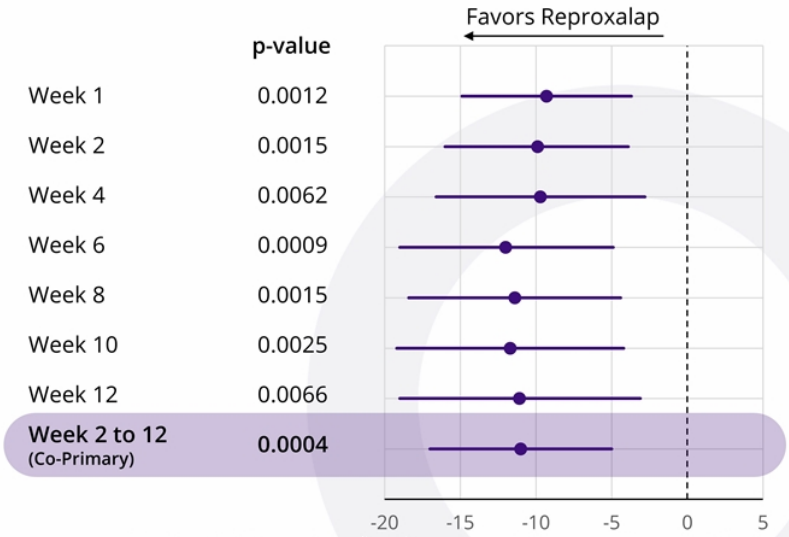


†Ocular Dryness Score co-primary endpoint assessed in pre-specified patient population having an ocular dryness (Ocular Dryness 4-Symptom) baseline score of ≥ 3 (N=170).
Source: RENEW-Part 1 induction-maintenance top-line results

**p<0.01 ***p<0.001
VAS = Visual Analog Scale
BL = Baseline; W = Week
MMRM = Mixed Effect Model Repeated Measures

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

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



Potential Competitive Advantages†

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

†Pending clinical data, regulatory discussions, payor negotiations, competition, potential legislative changes, and other factors, which may not be in Aldeyra's control.
*Treatment Difference defined as the difference between the changes from baseline for the evaluated drug vs. vehicle (LS Mean Difference ± 95% CI). Ocular Dryness Score co-primary endpoint assessed in pre-specified patient population having an OD4S dryness baseline score of ≥ 3 (N=170).
Source: RENEW-Part 1 induction-maintenance top-line results

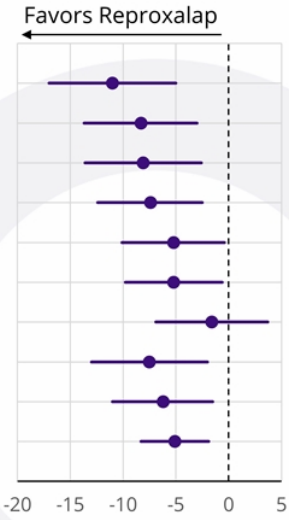
VAS = Visual Analog Scale

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

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

0-100 Ocular Symptom Scales

	p-value
VAS: Ocular Dryness (Co-Primary)	0.0004
VAS: Eye Discomfort	0.0025
VAS: Photophobia	0.0041
VAS: Foreign Body Sensation	0.0035
VAS: Itching	0.0346
VAS: Pain	0.0268
VAS: Burning/Stinging	NS
SANDE: Frequency	0.0080
SANDE: Severity	0.0102
OSDI (Total)	0.0020



0-4 & 0-5 Ocular Symptom Scales

	p-value
OD4S: Grittiness	0.0025
OD4S: Dryness	0.0134
OD4S: Ocular Discomfort	0.0268
OD4S: Burning	0.0306
OD4S: Stinging	0.0239
CAC Ocular Itching Scale	0.0034
Ocular Discomfort Scale	NS

*Treatment Difference defined as the difference between the changes from baseline for the evaluated drug vs. vehicle (LS Mean Difference ± 95% CI). Ocular Dryness Score co-primary endpoint assessed in pre-specified patient population having an OD4S dryness baseline score of ≥ 3 (N=170).
Source: RENEW-Part 1 induction-maintenance top-line results

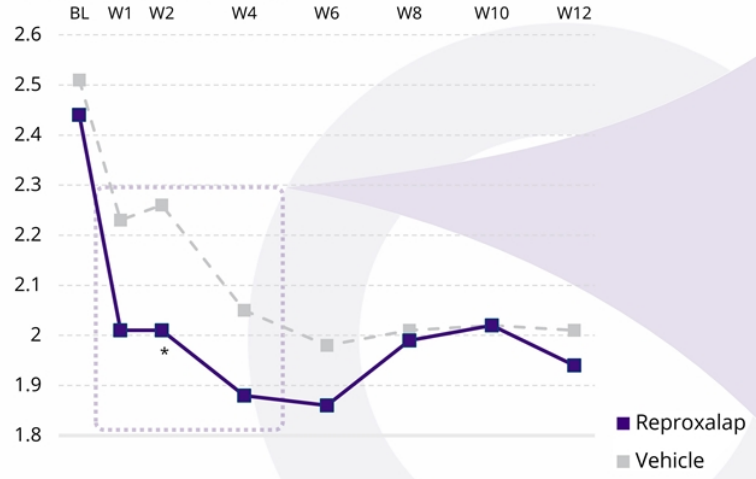
VAS = Visual Analog Scale
SANDE = Symptom Assessment in Dry Eye
OSDI = Ocular Surface Disease Index

NS = Not Significant
OD4S = Ocular Discomfort & 4-Symptom
CAC = Conjunctival Allergen Challenge

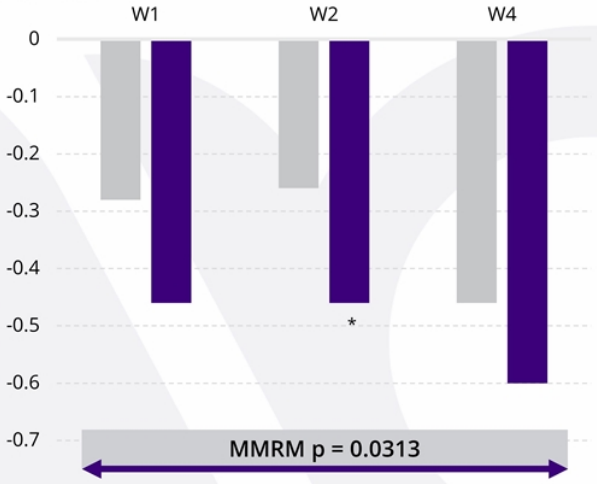
Reproxalap Demonstrated Rapid Improvement in Co-Primary Endpoint of Fluorescein Staining Score in RENEW-Part 1

Co-Primary Sign Endpoint for RENEW

Fluorescein Staining: Nasal Region† (0-4)
Baseline and Weeks 1 to 12



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



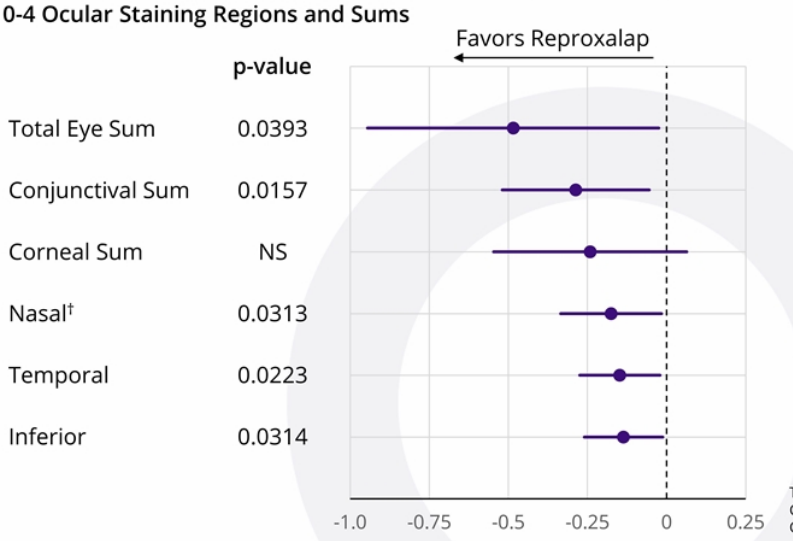
†Fluorescein Staining co-primary endpoint assessed in pre-specified patient population having a nasal region baseline score of ≥ 2 (N=179).
Source: RENEW-Part 1 induction-maintenance top-line results

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

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

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

0-4 Ocular Staining Regions and Sums



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

Potential Competitive Advantages†

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

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†Pending clinical data, regulatory discussions, payor negotiations, competition, potential legislative changes, and other factors, which may not be in Aldeyra's control.
*Treatment Difference defined as the difference between the changes from baseline for the evaluated drug vs. vehicle (LS Mean Difference ± 95% CI).
†Fluorescein Staining co-primary endpoint assessed in pre-specified patient population having a nasal region baseline score of ≥ 2 (N=179).
Source: RENEW-Part 1 induction-maintenance top-line results

Reproxalap Was Generally Well Tolerated and No Adverse Findings on Safety Assessments Were Observed in RENEW-Part 1

- No treatment-related serious adverse events were reported.
- The most common treatment-emergent event was mild transient instillation site irritation.
  - The majority of reported adverse events were mild; less than 1% of adverse events were moderate.
  - No taste disturbance or throat irritation was reported.
- No adverse findings on detailed safety assessments were observed.
- Discontinuation rates were consistent with clinical trials of currently approved* dry eye products.
  - In the induction-maintenance regimen, 7.6% of patients discontinued due to adverse events in the reproxalap group, and 0.9% of patients discontinued due to adverse events in the vehicle group.
- Topical ocular reproxalap has now been administered to over 1,100 patients across 12 clinical trials.

*Restasis® and Xiidra® clinical trial publications and FDA summary basis of approval filings
Source: RENEW-Part 1 induction-maintenance top-line results

In Part 1 of RENEW, Reproxalap Demonstrated Early Onset and Broad Improvements in Symptoms

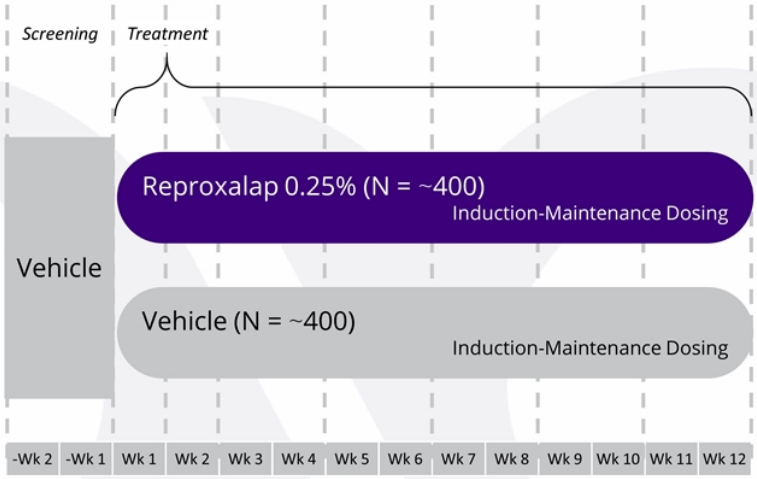
- **The RENEW Trial is an ongoing adaptive, two-part, Phase 3 clinical trial.**
  - The primary objective of Part 1 was to confirm dosing regimen, endpoints, and sample size for RENEW-Part 2.
- **The primary objective of RENEW-Part 1 was achieved.**
  - Reproxalap will advance to RENEW-Part 2.
  - Dosing regimen, endpoints, and sample size for RENEW-Part 2 were confirmed.
- **RENEW-Part 1 top-line results demonstrated early onset and broad symptomatic control following induction-maintenance dosing.**
  - Induction-maintenance dosing demonstrated greater activity vs. vehicle than constant dosing.
  - Statistical significance achieved for RENEW co-primary endpoint of ocular dryness score.
  - Rapid (as early as 1 week), broad, and statistically significant activity achieved across majority of assessed symptoms.
  - Improvement in fluorescein staining, although not statistically significant, enables powering of RENEW-Part 2.
- **RENEW-Part 2 to initiate in the first half of 2020.**
  - 0.25% topical ocular reproxalap to be administered via induction-maintenance dosing schedule.
  - Co-primary endpoints expected to be ocular dryness score and fluorescein nasal region ocular staining.
  - Approximately 400 patients per arm expected to be enrolled to achieve 90% statistical power.

RENEW-Part 2 Clinical Trial Design*

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

Expected to initiate H1 2020

RENEW Phase 3 Dry Eye Disease Clinical Trial: Part 2



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

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VAS = Visual Analog Scale
OD4S = Ocular Discomfort & 4-Symptom Questionnaire
*Contingent on funding, regulatory review, and other factors.

Induction-Maintenance Dosing = QID for Weeks 1-4 and BID for Weeks 5-12

A New Paradigm for the Treatment of Ocular Diseases: A Potential Single Treatment for Dry Eye Disease and Allergic Conjunctivitis*

Dry Eye Disease

Reproxalap 0.25%

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

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

DED trials in >950 patients

RENEW-Part 2 Phase 3
Initiation H1 2020

Allergic Conjunctivitis

Reproxalap 0.25%

Clinically significant and durable symptom response in allergen chamber trial

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

AC trials in >650 patients

INVIGORATE Phase 3
Initiation H1 2020

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

Upcoming and Recently Achieved Reproxalap Topical Ocular Development Milestones:*

- **Positive** reproxalap allergic conjunctivitis **allergen chamber trial top-line results**
- **Positive** reproxalap allergic conjunctivitis **ALLEVIATE Phase 3 trial results**
- **Primary objective met** in reproxalap dry eye disease **RENEW Phase 3-Part 1 top-line results**
- Reproxalap allergic conjunctivitis **INVIGORATE Phase 3 initiation H1 2020**
- NEW Reproxalap dry eye disease **RENEW Phase 3-Part 2 initiation H1 2020**

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