

**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): October 31, 2019

ALDEYRA THERAPEUTICS, INC.

(Exact name of Registrant as specified in its charter)

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)

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.

As reported under Item 8.01 of this Current Report on Form 8-K, on October 31, 2019, Aldeyra Therapeutics, Inc. (the “Company” or “Aldeyra”) issued a press release (the “Press Release”) announcing expanded results from the Company’s allergen chamber clinical methods trial and plans for the Phase 3 INVIGORATE clinical trial in patients with allergic conjunctivitis. The Company is holding a conference call regarding the matters disclosed in the Press Release. A copy of the presentation which will be referenced during this conference call and posted on the Company’s website is furnished herewith as Exhibit 99.1 and is incorporated by reference herein.

Channels for Disclosure of Information

Investors and others should note that the Company may announce material information to the public through filings with the Securities and Exchange Commission, its website (www.aldeyra.com), press releases, public conference calls, and public webcasts. The Company uses these channels, as well as social media, to communicate with the public about the Company, its product candidates and other matters. It is possible that the information the Company posts on social media could be deemed to be material information. As such, investors, the media, and others are encouraged to follow the channels listed above and to review the information disclosed through such channels. Please note that this list may be updated from time to time

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 October 31, 2019, the Company announced in the Press Release the expanded results from the Company’s allergen chamber clinical methods trial and plans for the Phase 3 INVIGORATE clinical trial in patients with allergic conjunctivitis. The Press Release is filed as Exhibit 99.2 to this Current Report on Form 8-K and is incorporated by reference herein.

In addition, on October 31, 2019, the Company announced that in September 2019 it borrowed \$15.0 million under its previously disclosed credit facility.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

| <u>Exhibit No.</u> | <u>Description</u> |
|------------------------|--|
| 99.1 | Aldeyra Therapeutics, Inc. Presentation dated October 31, 2019. |
| 99.2 | Aldeyra Therapeutics, Inc. Press Release dated October 31, 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: October 31, 2019

ALDEYRA THERAPEUTICS, INC.

By: /s/ Joshua Reed

Name: Joshua Reed

Title: Chief Financial Officer



October 31, 2019

DATA RELEASE

Allergic Conjunctivitis Allergen
Chamber Clinical Methods Trial
Expanded Data Release

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. The results of earlier clinical trials may not be predictive of future results. 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 October 31, 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.

The Prevalence and Economic Burden of Allergic Conjunctivitis is Rising



Allergic diseases are **hyperendemic and prevalence is increasing**



Allergic conjunctivitis affects **more than 1 billion people worldwide**, including 100 million in the U.S.



Temperatures and CO₂ levels are rising



Allergy seasons are getting **longer and more severe**



Pollen is spreading to **new areas**

Millions of patients continue to suffer and new treatments are needed

Source: Ziska LH, Makra L, Harry, SK, et al. Lancet Planetary Health. 2019; Trends in prevalence and treatment of ocular allergy - Curr. Opin. Allergy Clin. Immunol. 2014 Oct; White Book on Allergy (2013 Update) ; Singh K, Axelrod S, Bielory L, J Allergy Clin Immunol. 2010; Pitt AD, Smith AF, Lindsell L, et al. Ophthal. Epidemiol. 2004.

Physicians and Patients Say That Currently Available Treatments Are Inadequate



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



Antihistamines are not effective in an estimated 24% of treated allergic conjunctivitis patients



Many allergic conjunctivitis **patients make significant sacrifices** due to lack of drug activity



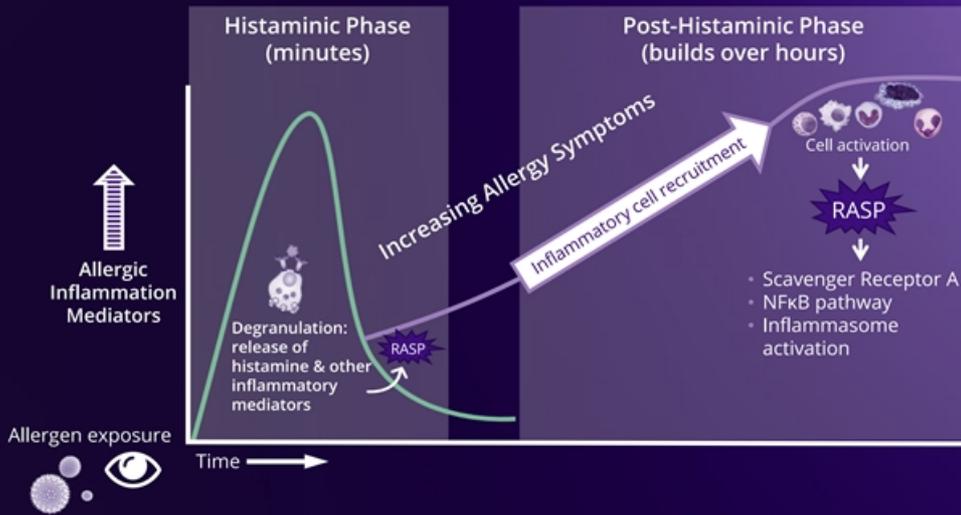
1 in 5

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

The allergic conjunctivitis patient population is underserved, and novel therapies are in demand.

*IQVIA analysis of diagnosed AC patients utilizing topical ocular Rx treatments.
Source: Aldeyra internal estimates based on primary and secondary market research; published literature

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



Reproxalap

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

The Allergen Chamber is Designed to Mimic Real-World Exposure to Airborne Allergens With Control and Consistency

Clinical Model Comparison
For Allergic Conjunctivitis Clinical Trial Design



Patients administer drug at home during allergy season and maintain a journal.

- ✓ Real-world exposure to allergen
- ✓ Repeated exposure to allergen throughout study
- ✗ Uncontrolled allergen content and concentration
- ✗ Variable participant behavior



Investigator administers one drop of allergen mixture on to conjunctiva and records results.

- ✓ Specified allergen content and concentration
- ✓ Participants observed and assisted by investigator
- ✗ Artificial allergen exposure
- ✗ Single exposure limitation



Investigator monitors and assists patients in a controlled allergen chamber.

- ✓ Real-world exposure to allergen
- ✓ Specified allergen content and concentration
- ✓ Repeated exposure to allergen throughout study
- ✓ Participants observed and assisted by investigator
- ✓ Assessment of prophylaxis and treatment

The Allergen Chamber: A Demanding Real-World Drug Assessment in Allergic Conjunctivitis

- To our knowledge, no late-stage investigational allergic conjunctivitis drug has been rigorously tested in an allergen chamber.
- The allergen chamber enables a controlled, environmental allergen exposure that mimics real-world exposure to airborne allergens.
- Subjects are exposed to allergen continuously for approximately 3.5 hours.
- Subject-reported ocular itch and tearing scores, and investigator-assessed redness scores, are obtained approximately every 10 minutes.
- Drug or vehicle is administered prior to allergen exposure and at 90 minutes, when peak symptoms typically occur.
- The chamber allows for detailed assessment of prophylaxis and treatment with unparalleled standardization.



Reproxalap Allergen Chamber Clinical Trial Design*

- **Primary objective:**

- Evaluate efficacy of reproxalap ophthalmic solution vs. vehicle to confirm dosing regimen and sample size for Phase 3 clinical testing

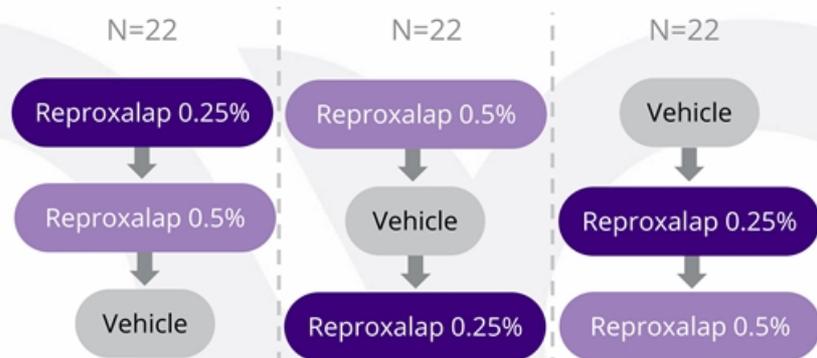
- **Inclusion/exclusion criteria:**

- History of moderate to severe allergic conjunctivitis to ragweed pollen
- Itching score of ≥ 2.5 or redness score ≥ 2 in baseline chamber test

- **Endpoints:**

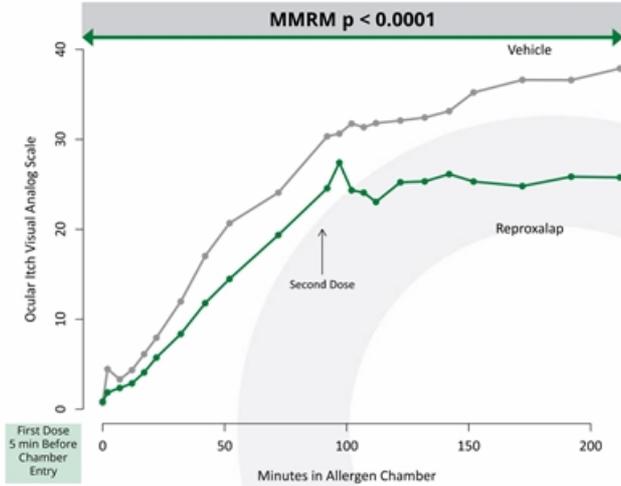
- Patient-reported ocular itch score and tearing score
- Investigator-assessed ocular redness score
- Total ocular symptom score

Three-Way Randomized Crossover



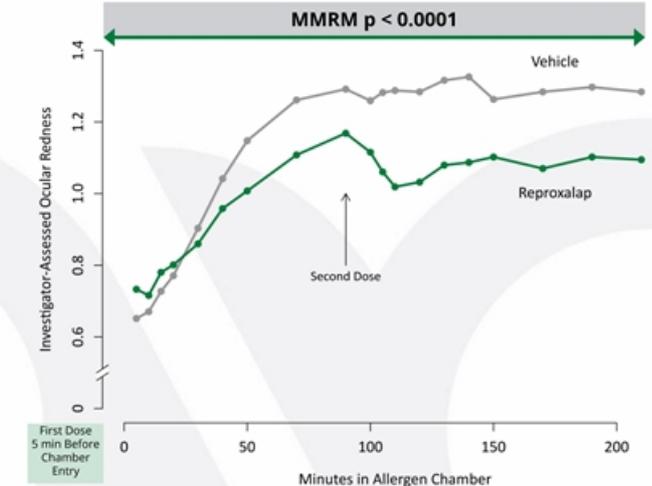
Reproxalap Showed Greater and More Durable Clinical Responses Than Vehicle in Allergen Chamber Clinical Trial

Ocular Itch Score (0-100) During 3.5 Hours of Allergen Exposure



Statistically significant reduction in ocular itch vs. vehicle for more than three hours of exposure to allergen

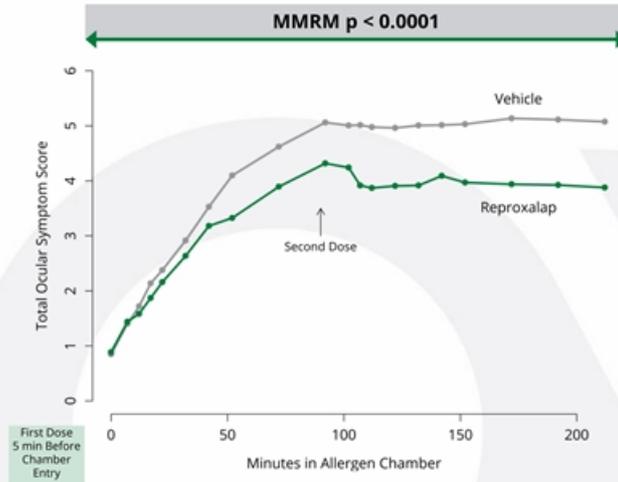
Ocular Redness Score (0-4) During 3.5 Hours of Allergen Exposure



Statistically significant reduction in ocular redness vs. vehicle for more than three hours of exposure to allergen

Reproxalap Demonstrated Prophylactic and Treatment Activity in Allergen Chamber Clinical Trial

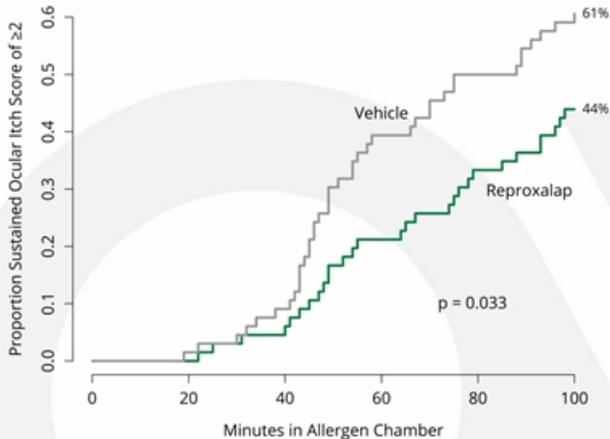
Total Ocular Symptom Score (0-11 scale) During 3.5 Hours of Allergen Exposure



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

Relative to Vehicle Treatment, Fewer Reproxalap-Treated Subjects Reached Sustained Ocular Itch Scores ≥ 2 in Allergen Chamber Clinical Trial

Proportion of Subjects with Sustained Ocular Itch Scores ≥ 2 (0-4 Scale)



Development of sustained ocular itch scores of greater than or equal to 2 (scale 0 - 4) was slower and less frequent in reproxalap-treated subjects than in vehicle-treated subjects, supporting the clinical relevance of the itch score results.



*Time to response analysis baseline adjusted, p-value of log-rank analysis.
Source: Aldeyra Therapeutics allergen chamber clinical trial - reproxalap 0.25% (ClinicalTrials.gov #NCT03709121); n=66

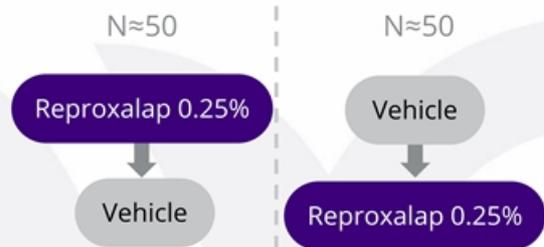
Reproxalap Was Generally Well Tolerated and No Safety Concerns Were Observed in Allergen Chamber Clinical Trial

- No observed safety or tolerability concerns
- Most common treatment-emergent event was transient instillation site irritation
- No observed findings on safety assessments:
 - Visual Acuity (ETDRS chart)
 - Intraocular pressure (contact tonometry)
 - Slit lamp biomicroscopy
 - Dilated fundoscopy
- Topical ocular reproxalap has now been administered to over 1,000 patients across twelve clinical trials.

The INVIGORATE Phase 3 Clinical Trial Design

- **Primary endpoint:**
 - Statistical significance in ocular itch (0-4 scale) at a majority of eleven time points between 110 and 210 minutes
- **Secondary endpoints:**
 - Investigator-assessed ocular redness score
 - Patient-reported ocular tearing score
 - Total ocular symptom score
- **Inclusion/exclusion criteria:**
 - Same as prior allergen chamber trial
- **Dosing schedule and chamber exposure:**
 - Same as prior allergen chamber trial

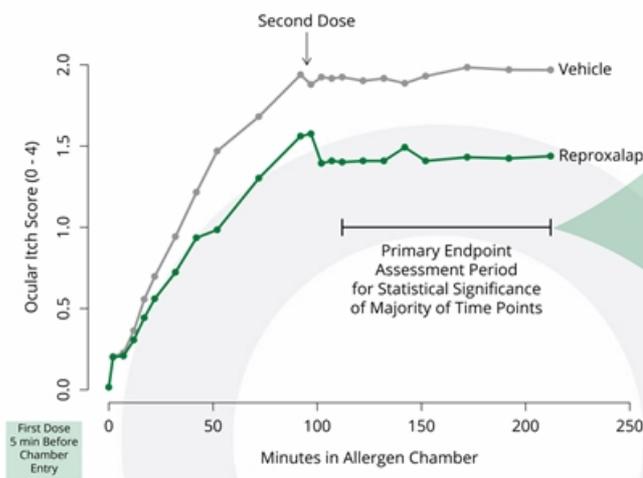
Two-Way Randomized Crossover



Agreement on trial design and primary endpoint reached with FDA on October 1, 2019.

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

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



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

All time points from 110 to 210 minutes were statistically significant in allergen chamber trial.



*The safety and efficacy results of later phase or subsequent clinical trials may not confirm the results of earlier trials; p-value derived from Mixed effect Model Repeat Measurement (MMRM) time point analyses.
Source: Aldeyra Therapeutics allergen chamber clinical trial – reproxalap 0.25% (ClinicalTrials.gov #NCT03709121); n=66

INVIGORATE Phase 3 Trial Design And Primary Endpoint Confirmed

Positive Allergen Chamber Clinical Trial Results

- Reproxalap showed greater and durable clinical responses vs. vehicle
 - Statistically significant reduction in ocular itch ($p < 0.0001$), ocular redness ($p < 0.0001$), and total ocular symptoms score ($p < 0.0001$)
- Reproxalap demonstrated prophylaxis and treatment activity for more than three hours of continuous allergen exposure
- Clinical relevance of itch score results supported by responder analysis
 - Less frequent development of sustained ocular itch score ≥ 2 in reproxalap-treated subjects vs. vehicle (0-4 scale)

INVIGORATE Phase 3 Clinical Trial

- Design and primary endpoint agreement with FDA on October 1, 2019
 - Dosing schedule and chamber exposure same as prior allergen chamber trial
 - Phase 3 primary endpoint defined as statistical significance in ocular itching at a majority of time points over a pre-specified range
- Confirmed primary endpoint achieved in prior allergen chamber clinical trial*

Expected to initiate H1 2020

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

○ = Ocular Diseases
○ = Systemic Diseases

- ✓ Reproxalap allergic conjunctivitis design for **INVIGORATE Phase 3 confirmed October 2019**
- ADX-2191 proliferative vitreoretinopathy **GUARD Phase 3 - Part 1 clinical trial initiation Q4 2019**
- ADX-1612 post-transplant lymphoproliferative disorder **Phase 2 clinical trial initiation H2 2019**
- Reproxalap dry eye disease **RENEW Phase 3 - Part 1 completion Q4 2019**
- **New** Reproxalap allergic conjunctivitis **INVIGORATE Phase 3 initiation H1 2020**
- ✓ ADX-629 systemic **Phase 1 clinical trial initiation H2 2019**
- ✓ Reproxalap Sjögren-Larsson Syndrome **RESET Phase 3 - Part 1 completion Q2 2019**
- ✓ **Positive** reproxalap allergic conjunctivitis **allergen chamber trial top-line results**
- ✓ Reproxalap dry eye disease **RENEW Phase 3 - Part 1 clinical trial initiation April 2019**
- ✓ **Positive** reproxalap allergic conjunctivitis **ALLEVIATE Phase 3 trial results March 2019**



Aldeyra Therapeutics Releases Expanded Results from Allergen Chamber Trial and Announces Plans to Initiate the Phase 3 INVIGORATE Trial in Patients with Allergic Conjunctivitis

- *Highly statistically significant activity relative to vehicle across every assessed symptom and sign observed in allergen chamber clinical trial*
- *Agreement reached with U.S. FDA on design of Phase 3 INVIGORATE trial, expected to initiate in the first half of 2020*
- *Company to host conference call and webcast at 8:00 a.m. ET today*

LEXINGTON, Mass., October 31, 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, today announced expanded results from the company's allergen chamber clinical methods trial ([#NCT03709121](#)) of topical ocular reproxalap in patients with allergic conjunctivitis, and Phase 3 clinical trial plans based on recent feedback from the U.S. Food & Drug Administration (FDA).

“The expanded results from our allergen chamber trial demonstrate highly statistically significant activity of reproxalap relative to vehicle across all assessed symptoms and signs,” commented Todd C. Brady, M.D., Ph.D., President and CEO of Aldeyra. “Based on the positive outcome of the trial, we have reached agreement with the FDA on the design and the primary endpoint for our Phase 3 INVIGORATE trial – statistical significance in ocular itching at a majority of time points over a pre-specified range. Importantly, in the completed allergen chamber trial, all time points to be pre-specified in the INVIGORATE trial were statistically significant.”

The double-masked, randomized, vehicle-controlled, crossover allergen chamber clinical methods trial assessed the efficacy and safety of 0.25% and 0.5% concentrations of reproxalap topical ophthalmic solution compared with vehicle in 70 patients with ocular allergy to ragweed. Patient-reported ocular itching and tearing, and investigator-assessed ocular redness, were recorded at various intervals over approximately 3.5 hours during exposure to a standardized amount of ragweed pollen. Test article was administered before chamber entry and at 90 minutes post-entry, near the peak of allergy symptoms and signs.

Relative to patients treated with vehicle, patients treated with 0.25% or 0.5% reproxalap demonstrated statistically significant reduction in ocular itching ($p < 0.0001$), redness ($p < 0.0001$), and tearing ($p < 0.0001$). The total ocular symptom score, a combination of itching, redness, and

tearing, was also significantly lower in reproxalap-treated subjects than in vehicle-treated subjects ($p < 0.0001$ for both concentrations). Consistent with the positive results from the ALLEVIATE Phase 3 clinical trial in allergic conjunctivitis released earlier this year, there was no statistical difference between the activity of 0.25% and 0.5% reproxalap. Consistent with all prior clinical experience with topical ocular reproxalap in over 1,000 patients across 12 clinical trials, there were no observed safety or tolerability concerns, and the most common treatment-emergent adverse event was transient instillation site irritation.

“We believe that the allergic conjunctivitis results released today, in aggregate, represent the first rigorous demonstration of activity of a late-stage, novel immune-modulating agent in an allergen chamber,” stated David J. Clark, M.D., M.R.C.P., Chief Medical Officer of Aldeyra. “The allergen chamber is an innovative and demanding assessment that combines real-world applicability with controlled allergen exposure. The results from the trial indicated distinct prophylactic and treatment activity of reproxalap in reducing all of the primary signs and symptoms of allergic conjunctivitis: ocular itching, redness, and tearing.”

The Phase 3 INVIGORATE trial, which is expected to initiate in the first half of 2020, will evaluate 0.25% reproxalap versus vehicle in an allergen chamber. The primary endpoint will be achieved if statistically significant reduction in ocular itching between drug and vehicle is demonstrated at the majority of eleven time points in a pre-specified range from 110 to 210 minutes following chamber entry. In the completed allergen chamber trial, reproxalap was statistically superior to vehicle at every time point to be pre-specified in INVIGORATE.

Conference Call

Aldeyra will host a conference call to discuss this announcement today, October 31, 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 4695959. A live, listen-only audio webcast of the conference call can be accessed on the investor relations page of Aldeyra’s corporate website at 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 Allergic Conjunctivitis

Allergic conjunctivitis affects more than 1 billion people worldwide,¹ including more than 100 million in the U.S.² The disease is thought to be mediated in part by reactive aldehyde species (RASP), leading to activation of intracellular inflammatory factors, including NF- κ B, inflammasomes, and Scavenger Receptor A. The symptoms of allergic conjunctivitis – ocular itching and tearing – are chronic, painful, and persistent, affecting quality of life and leading to loss of work that can create a substantial economic burden for patients and their families.³ Allergic conjunctivitis is hyperendemic and prevalence is increasing. Although allergic conjunctivitis is one of the most common diseases treated by ophthalmologists and optometrists, in many cases physicians and patients report that currently available therapy is inadequate. Today nearly one in five allergic conjunctivitis patients utilize corticosteroids or other adjunctive therapy in addition to antihistamines.

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 first-in-class potential 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.

¹ White Book on Allergy (2013 Update)

² Singh K, Axelrod S, Bielory L. The epidemiology of ocular and nasal allergy in the United States, 1988-1994. *J Allergy Clin Immunol*. 2010;126(4):778-783. e6

³ Andrew D. Pitt, Andrew F. Smith, Lynda Lindsell, Li Wern Voon, Peter W. Rose & Anthony J. Bron (2004) Economic and quality-of-life impact of seasonal allergic conjunctivitis in Oxfordshire, *Ophthalmic Epidemiology*, 11:1, 17-33, DOI: 10.1076/oep.11.1.17.26437

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 reproxalap and strategy, future operations, future financial position, projected costs and expenses, prospects, plans, and objectives and Aldeyra's plans and expectations for its product candidates, including plans relating to current or future clinical development. 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 safety and efficacy results of later phase or larger clinical trials confirming the results of Aldeyra's earlier trials; delay in or failure to obtain regulatory approval of Aldeyra's product candidates; the ability to maintain regulatory approval of Aldeyra's product candidates, and the labeling for any approved products; 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; the scope, progress, expansion, and costs of developing and commercializing Aldeyra's product candidates; uncertainty as to Aldeyra's ability to commercialize (alone or with others) Aldeyra's product candidates following regulatory approval, if any; 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 limited sales and marketing infrastructure; Aldeyra's ability to establish and

maintain development partnerships; Aldeyra's ability to successfully integrate acquisitions into its business; 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 June 30, 2019, which are on file with the Securities and Exchange Commission (SEC) and available on the SEC's website at www.sec.gov. Additional factors may be set forth in those sections of Aldeyra's Quarterly Report on Form 10-Q for the quarter ended September 30, 2019, expected to be filed with the SEC in the fourth 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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