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): April 27, 2021

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

Delaware	**001-36332**	**20-1968197**
(State or other jurisdiction of incorporation)	**(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))

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 April 27, 2021, Aldeyra Therapeutics, Inc. (the "Company") issued a press release (the "Press Release") regarding the top-line results from the Phase 3 INVIGORATE Clinical Trial of 0.25% reproxalap ophthalmic solution ("reproxalap") in patients with allergic conjunctivitis. The Company is holding a conference call on April 27, 2021. A copy of the supplemental presentation which will be referenced during the conference call and posted on the Company's website 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 April 27, 2021, the Company issued a press release regarding the top-line results from the Phase 3 INVIGORATE Clinical Trial of reproxalap 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.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Aldeyra Therapeutics, Inc. Presentation dated April 27, 2021.
99.2	Aldeyra Therapeutics, Inc. Press Release dated April 27, 2021.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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: April 27, 2021

ALDEYRA THERAPEUTICS, INC.

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

Exhibit 99.1

aldeyra

April 27, 2021

DATA RELEASE

Top-Line Results from the Phase 3 INVIGORATE Trial in Allergic Conjunctivitis

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, political, economic, legal, social and health risks, including the recent COVID-19 outbreak and subsequent public health measures and other responses to it, that may affect Aldeyra's business or the global economy, 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 preclinical or clinical trials may not be predictive of future results. As a result of the COVID-19 pandemic, clinical site availability, staffing, and patient recruitment have been negatively affected and the timelines to complete Aldeyra's clinical trials may be delayed. 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 systems-based approaches, later developments with the FDA that may be inconsistent with Aldeyra's expectations and beliefs, including the risk that the results from earlier clinical trials or portions of clinical trials may not accurately predict results of subsequent trials or the remainder of a clinical trial for the same or different indications, inconsistent expectations regarding FDA acceptance and review of the company's filings and submitted data sets, 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 plans and timelines may be subject to adjustment depending on funding, recruitment rate, regulatory review, preclinical and clinical results, and other factors any of which could result in changes to Aldeyra's development plans and programs or 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 April 27, 2021, 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.

Top-Line Results from Phase 3 INVIGORATE Clinical Trial of Reproxalap in Allergic Conjunctivitis

Statistical Significance Achieved for:

- Primary Endpoint of Ocular Itching at All Prespecified Timepoints (p<0.0001)
- Key Secondary Endpoint of Reduction in Ocular Redness (p<0.0001)
- Secondary Endpoints of Ocular Tearing (p<0.0001) and Total Ocular Severity Score (p<0.0001)

Results Consistent with Phase 3 ALLEVIATE Allergic Conjunctivitis Clinical Trial and Previous Chamber Results in Phase 2 Allergic Conjunctivitis Trial and Run-In Cohort of Phase 3 TRANQUILITY Dry Eye Disease Trial

Reproxalap Potentially Represents the First **New Allergic Conjunctivitis Therapeutic Mechanism** in Decades

The Prevalence 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 CO_2 levels are **rising.**

Pollen is spreading to new areas.

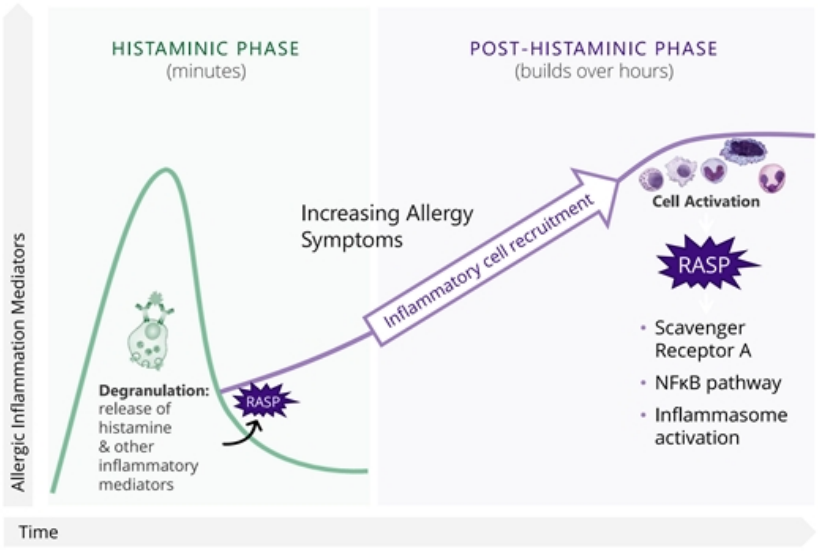
Allergy **seasons** are getting **longer and more severe.**

Millions of patients continue to suffer, and new treatments are needed.

aldeyra

Slide sources: 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.

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



REPROXALAP

Irreversibly inhibits RASP, limiting allergic inflammation

Potential to provide **differentiated activity** in post-histaminic allergy, which affects all allergic conjunctivitis patients

Potential to represent an important **alternative to topical corticosteroids**, which can lead to ocular toxicity

Potential to represent **one of the first new therapeutic mechanisms for allergic conjunctivitis in decades**

Topical ocular reproxalap is an investigational drug that has been studied in over 1,200 patients with no safety concerns reported; mild instillation site discomfort is the most commonly reported adverse event in clinical trials. RASP = reactive aldehyde species

aldeyra

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.
- allows for detailed assessment of prophylaxis and treatment with unparalleled standardization.

Subjects are exposed to naturalistic **moderate to high levels of ragweed pollen** continuously for approximately 3.5 hours.

- Drug or vehicle is administered prior to allergen exposure and at 90 minutes, when peak symptoms typically occur.
- Subject-reported ocular itching and tearing scores, and investigator-assessed ocular redness scores, are obtained approximately every 10 minutes.

aldeyra

Slide source: Clantha Research

The Phase 3 INVIGORATE Allergic Conjunctivitis Trial Design

Design

Randomized, two-way crossover, vehicle-controlled, double-masked allergen chamber challenge

Chamber Exposure & Dosing Schedule

- 3.5 hours continuous allergen exposure
- First dose just before chamber entry
- Second dose 90 minutes after entry (peak allergy symptoms)

Inclusion/Exclusion Criteria

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

Primary Endpoint

Statistical significance in patient-reported ocular itching (0-4 scale) at a majority of 11 timepoints between 110 and 210 minutes

Key Secondary Endpoint

Change from baseline in investigator-assessed ocular redness (0-4 scale) over the duration of the allergen chamber

Secondary Endpoints

- Patient-reported ocular tearing score (0-4 scale)
- Total ocular severity score (11-point composite of itching, tearing, and redness)

The INVIGORATE Trial Achieved All Primary and Secondary Endpoints

Primary Endpoint Achieved

Statistically significant improvement vs. vehicle ($p<0.0001$) over all 11 prespecified timepoints of patient-reported ocular itching score from 110-210 minutes in the allergen chamber

Key Secondary Endpoint Achieved

Statistically significant improvement vs. vehicle ($p<0.0001$) on key secondary endpoint of investigator-assessed ocular redness over the duration of the allergen chamber

Both Secondary Endpoints Achieved

Statistically significant improvement vs. vehicle on secondary endpoints of patient-reported ocular tearing and total ocular severity score achieved ($p<0.0001$ for both endpoints) over the duration of the allergen chamber

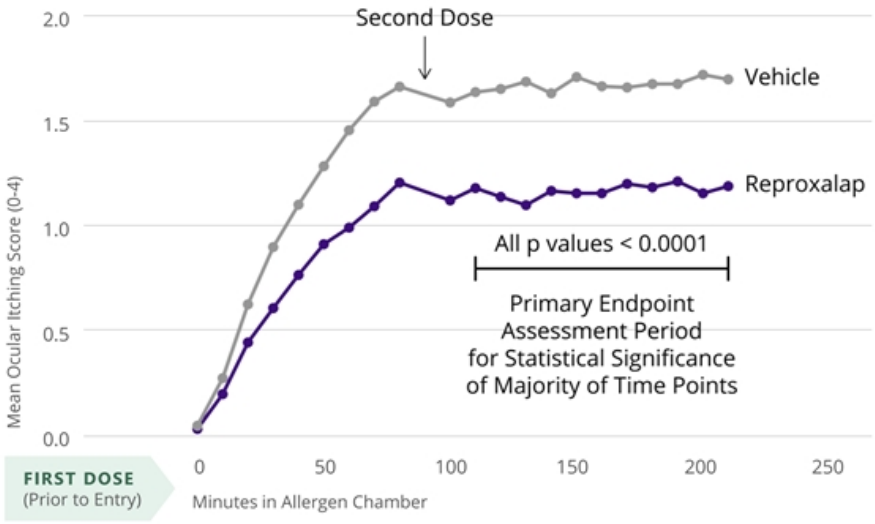
No Observed Safety or Tolerability Concerns

95 subjects enrolled, 89 of whom completed both treatments; no discontinuations due to adverse events

aldeyra

p values derived from mixed effect model of repeated measures (MMRM). Topical ocular reproxalap is an investigational drug that has been studied in over 1,200 patients with no safety concerns reported; mild instillation site discomfort is the most commonly reported adverse event in clinical trials. Slide source: INVIGORATE Phase 3 results

Reproxalap Achieved Primary Endpoint of Reduction in Ocular Itching in the INVIGORATE Trial



KEY RESULTS

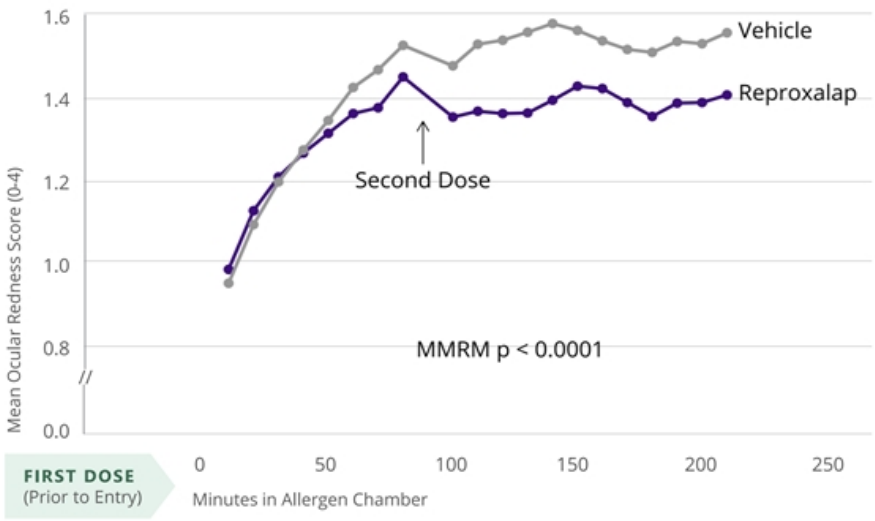
Primary endpoint of statistical significance for majority of timepoints **achieved** over prespecified time frame of 110-210 minutes after allergen chamber entry

All timepoints within 110-210 minutes **statistically significant** in favor of reproxalap (p<0.0001 for each timepoint)

Prophylactic and treatment effects of reproxalap demonstrated

Topical ocular reproxalap is an investigational drug that has been studied in over 1,200 patients with no safety concerns reported; mild instillation site discomfort is the most commonly reported adverse event in clinical trials. Slide source: INVIGORATE Phase 3 results.

Reproxalap Achieved Key Secondary Endpoint of Reduction in Ocular Redness in the INVIGORATE Trial



KEY RESULTS

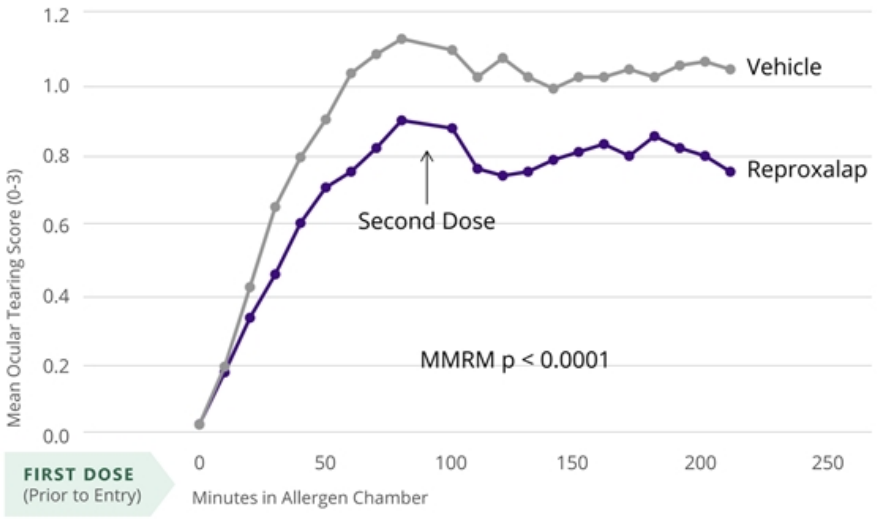
Key secondary endpoint of statistical significance over the entire chamber **achieved** (p<0.0001)

Prophylactic and treatment effects of reproxalap demonstrated

Topical ocular reproxalap is an investigational drug that has been studied in over 1,200 patients with no safety concerns reported; mild instillation site discomfort is the most commonly reported adverse event in clinical trials. Slide source: Reproxalap INVIGORATE Phase 3 results. MMRM = mixed effect model of repeated measures

aldeyra

Reproxalap Achieved Secondary Endpoint of Reduction in Ocular Tearing in the INVIGORATE Trial



KEY RESULTS

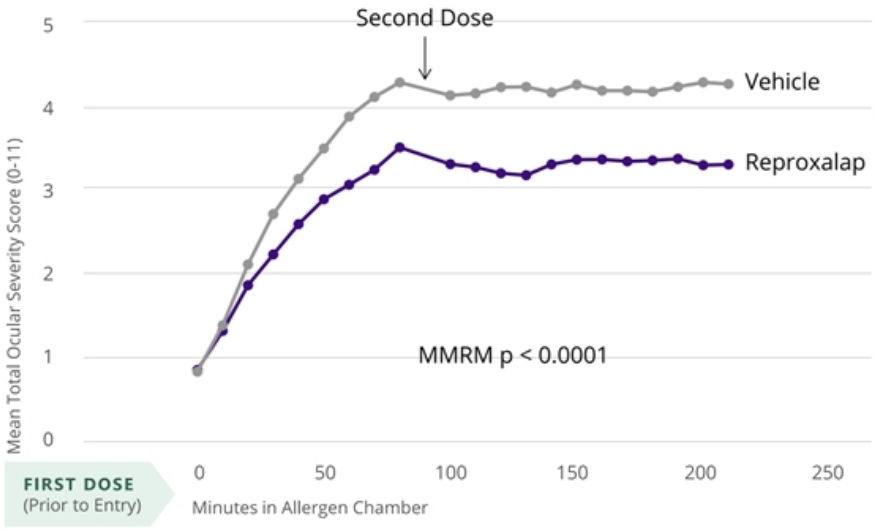
Secondary endpoint of statistical significance over the entire allergen chamber **achieved** (p<0.0001)

Prophylactic and treatment effects of reproxalap demonstrated

Topical ocular reproxalap is an investigational drug that has been studied in over 1,200 patients with no safety concerns reported; mild instillation site discomfort is the most commonly reported adverse event in clinical trials. Slide source: INVIGORATE Phase 3 results. MMRM = mixed effect model of repeated measures

aldeyra

Reproxalap Achieved Secondary Endpoint of Reduction in Total Ocular Severity Score in the INVIGORATE Trial



KEY RESULTS

Secondary endpoint of statistical significance over the entire allergen chamber **achieved** (p<0.0001)

Prophylactic and treatment effects of reproxalap demonstrated

Topical ocular reproxalap is an investigational drug that has been studied in over 1,200 patients with no safety concerns reported; mild instillation site discomfort is the most commonly reported adverse event in clinical trials. Slide source: INVIGORATE Phase 3 results. MMRM = mixed effect model of repeated measures

Reproxalap Was Generally Well Tolerated and No Safety Concerns Were Observed in the INVIGORATE Trial

NO observed safety or tolerability concerns

NO discontinuations due to adverse events

Consistent with other topically administered drugs, most common treatment-emergent events related to transient instillation site discomfort

NO observed clinically significant findings on safety assessments, including:

- visual acuity
- intraocular pressure
- slit lamp biomicroscopy
- dilated fundoscopy

Topical ocular reproxalap is an investigational drug that has been studied in over 1,200 patients with no safety concerns reported; mild instillation site discomfort is the most commonly reported adverse event in clinical trials. Source: INVIGORATE Phase 3 results. MMRM = mixed effect model of repeated measures

TOPICAL OCULAR REPROXALAP
administered to more than

1,200 patients

ACROSS

14 clinical trials

Reproxalap Has Demonstrated Consistent Success Across a Robust Clinical Development Program in Allergic Conjunctivitis

Conjunctival Allergen Challenge

PHASE 2a

100 patients	30 minutes post CAC	0.5% vs vehicle

PHASE 2b

154 patients	60 minutes post CAC	0.1% and 0.5% vs vehicle

Phase 3 ALLEVIATE Trial

318 patients	60 minutes post CAC	0.25% and 0.5% vs vehicle

Allergen Chamber

Phase 2 Allergen Chamber Trial

66 patients (crossover)	3.5 hours in chamber	0.25% and 0.5% vs vehicle

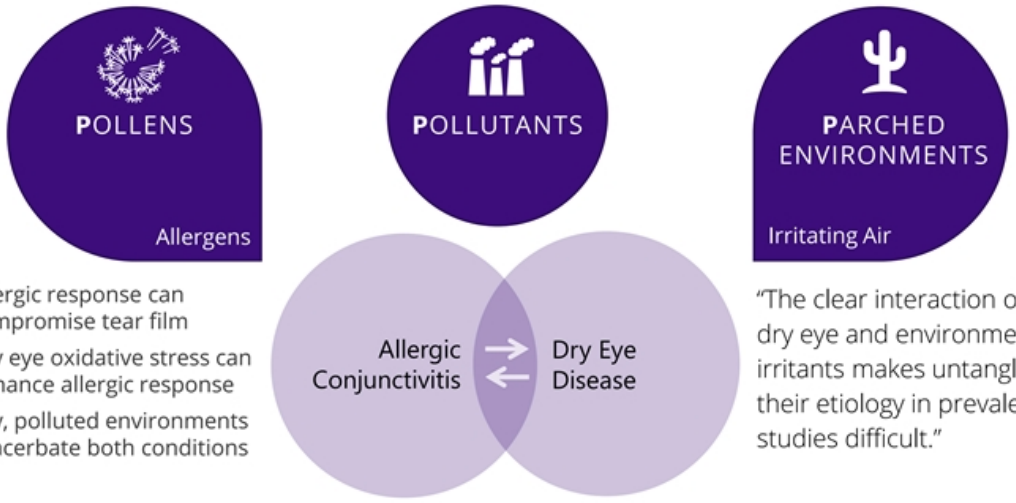
Phase 3 INVIGORATE Trial

95 patients (crossover)	3.5 hours in chamber	0.25% vs vehicle

Topical ocular reproxalap is an investigational drug that has been studied in over 1,200 patients with no safety concerns reported; mild instillation site discomfort s the most commonly reported adverse event in clinical trials. CAC = conjunctival allergen challenge

Allergic Conjunctivitis and Dry Eye Disease Are Interrelated Inflammatory Ocular Surface Diseases

The Three **P's** of Ocular Surface Inflammation



- Allergic response can compromise tear film
- Dry eye oxidative stress can enhance allergic response
- Dry, polluted environments exacerbate both conditions

"The clear interaction of allergy, dry eye and environmental irritants makes untangling their etiology in prevalence studies difficult."

aldeyra

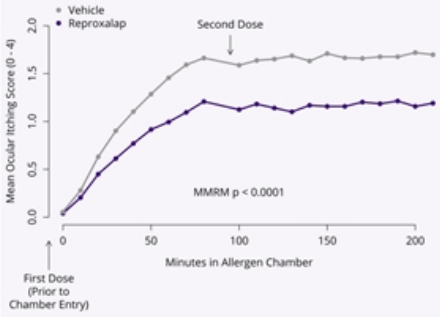
Slide sources: Concepts adapted from "The Whipsaw of Allergic Dry Eye" by Mark B. Abelson, MD and Lauren Lilyestrom in REVIEW of Ophthalmology; October 2008; and Hom MM, Nguyen AL, Bielory L. Allergic conjunctivitis and dry eye syndrome. Ann Allergy Asthma Immunol. 2012 Mar;108(3):163-6.

Reproxalap Has Demonstrated Consistent Improvement in Symptoms Across Two Distinct Chamber Challenge Models of Ocular Surface Disease

ITCHING

Allergen Chamber

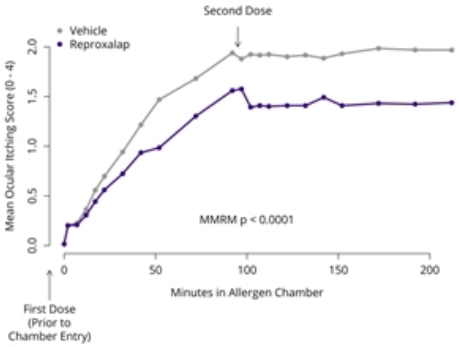
INVIGORATE Phase 3 Trial



ITCHING

Allergen Chamber

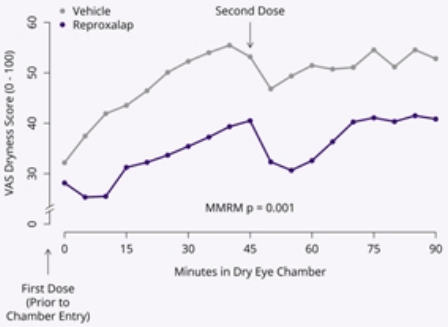
Phase 2 Trial



DRYNESS

Dry Eye Chamber

TRANQUILITY Run-In Cohort



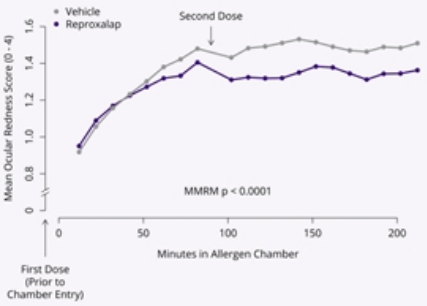
Topical ocular reproxalap is an investigational drug that has been studied in over 1,200 patients with no safety concerns reported; mild instillation site discomfort is the most commonly reported adverse event in clinical trials. Slide sources: TRANQUILITY run-in cohort results; Phase 2 Allergen Chamber clinical trial for 0.25% reproxalap (ClinicalTrials.gov #NCT03709121), INVIGORATE Phase 3 results. VAS = Visual Analog Scale, MMRM = mixed effect model of repeated measures

Reproxalap Has Demonstrated Consistent Reduction of Ocular Redness Across Two Distinct Chamber Challenge Models of Ocular Surface Disease

REDNESS

Allergen Chamber

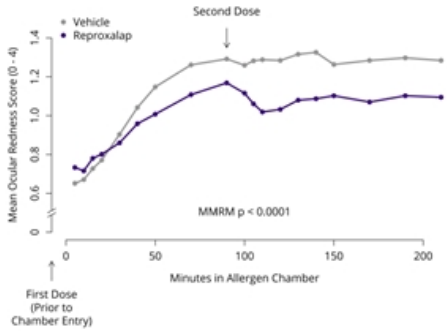
INVIGORATE Phase 3 Trial



REDNESS

Allergen Chamber

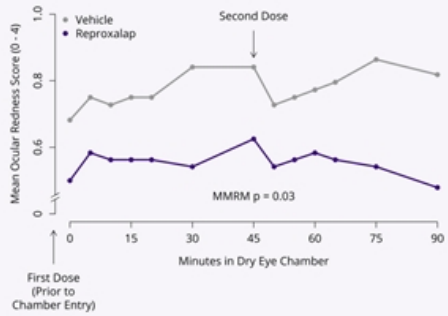
Phase 2 Trial



REDNESS

Dry Eye Chamber

TRANQUILITY Run-In Cohort



Topical ocular reproxalap is an investigational drug that has been studied in over 1,200 patients with no safety concerns reported; mild instillation site discomfort is the most commonly reported adverse event in clinical trials. Slide sources: TRANQUILITY run-in cohort results; Phase 2 Allergen Chamber clinical trial for 0.25% reproxalap (ClinicalTrials.gov #NCT03709121), INVIGORATE Phase 3 results. MMRM = mixed effect model of repeated measures

Upcoming Expected Reproxalap Development Milestones*

✓

Reproxalap
dry eye disease
Phase 3 TRANQUILITY main cohort initiation
H1 2021

✓

Reproxalap
allergic conjunctivitis
Phase 3 INVIGORATE top-line results
H1 2021

Reproxalap
dry eye disease
Phase 3 TRANQUILITY and TRANQUILITY-2 top-line results
H2 2021

Aldeyra plans to meet with the U.S. FDA in the second half of 2021 to discuss the INVIGORATE results and the potential submission of a New Drug Application.

aldeyra

*The timing of clinical trial initiation and completion depends, in part, on restrictions related to COVID-19, the availability of clinical research facilities and staffing, the ability to recruit patients, and regulatory feedback.

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

Dry Eye Disease

REPROXALAP 0.25%

- **Rapid symptom and redness improvement** within minutes
- **Broad and durable symptom control**

Allergic Conjunctivitis

REPROXALAP 0.25%

- **Clinically significant and durable symptom response** across two models of ocular allergy
- Potentially the first **new allergic conjunctivitis therapeutic mechanism** in decades

aldeyra

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

Exhibit 99.2

News Release

Aldeyra Therapeutics Achieves Statistical Significance for Primary Endpoint and All Secondary Endpoints in Phase 3 INVIGORATE Clinical Trial of Reproxalap in Allergic Conjunctivitis

- *Statistical Significance Achieved for Primary Endpoint of Ocular Itching at All Prespecified Timepoints ($p<0.0001$)*
- *Statistical Significance Achieved for Key Secondary Endpoint of Ocular Redness ($p<0.0001$)*
- *Statistical Significance Achieved for Secondary Endpoints of Ocular Tearing ($p<0.0001$) and Total Ocular Severity Score ($p<0.0001$)*
- *Results Consistent with Phase 3 ALLEVIATE Allergic Conjunctivitis Clinical Trial and Previous Chamber Results in Phase 2 Allergic Conjunctivitis Trial and Run-In Cohort of Phase 3 TRANQUILITY Dry Eye Disease Trial*
- *Reproxalap Potentially Represents the First New Allergic Conjunctivitis Therapeutic Mechanism in Decades*
- *Company to Discuss Results in Conference Call and Webcast at 8:00 a.m. ET Today*

LEXINGTON, Mass., April 27, 2021 – Aldeyra Therapeutics, Inc. (Nasdaq: ALDX) (Aldeyra), a clinical-stage biotechnology company focused on the development of novel therapies with the potential to improve the lives of patients with immune-mediated diseases, today announced positive top-line results from the Phase 3 INVIGORATE Clinical Trial of 0.25% reproxalap ophthalmic solution (reproxalap), an investigational new drug, in patients with allergic conjunctivitis. The clinical trial successfully achieved statistical significance for the primary endpoint and all secondary endpoints.

“The statistically significant superiority of reproxalap over vehicle across all allergic conjunctivitis symptoms and signs assessed in INVIGORATE is remarkable, and suggests utility in one of the world’s most common ocular surface diseases,” stated Todd C. Brady, M.D., Ph.D., President and CEO of Aldeyra. “We believe the consistent activity observed across chamber models in allergic conjunctivitis and dry eye disease bodes well for the commercial positioning of reproxalap as potentially the only broadly applicable topical anterior segment immune-modulating drug that may be used for chronic treatment, if approved for marketing.”

The randomized, double-masked, vehicle-controlled, two-way crossover design allergen chamber Phase 3 INVIGORATE Trial enrolled 95 allergic conjunctivitis patients. The primary efficacy endpoint was change from baseline in subject-reported ocular itching score on a 0-4 point scale over a majority of 11 timepoints from 110 to 210 minutes after allergen chamber entry. The key secondary endpoint was change from baseline in ocular redness on a 0-4 point scale over the duration of the allergen chamber (approximately 3.5 hours).

Relative to patients treated with vehicle, patients treated with reproxalap reported statistically significant ocular itching score reduction over all 11 prespecified primary endpoint comparisons ($p<0.0001$ for each comparison) from 110 to 210 minutes in the allergen chamber. The reproxalap-treated patients demonstrated statistically significant reduction from baseline compared to vehicle ($p<0.0001$) for the key secondary endpoint of investigator-assessed ocular redness over the duration of the allergen chamber. Statistical significance was also achieved for the two secondary endpoints of change from baseline in patient-reported ocular tearing score on a 0-3 point scale over the duration of the allergen chamber ($p<0.0001$) and change from baseline in total ocular severity score (11-point composite of the itching, redness, and tearing scores) over the duration of the allergen chamber ($p<0.0001$).

“Ocular allergy is a market that is ripe for innovation, and allergic conjunctivitis sufferers know it,” said Milton Hom, OD, of Canyon City Eyecare in Azusa, CA. “Exacerbated by the rise in global temperatures, seasonal pollen counts are exploding, leading to escalations in the prevalence of allergic conjunctivitis and dry eye disease that are growing unchecked. Even with the availability of treatments over the counter, many patients are using more than one prescription to manage ocular symptoms and redness. Based on my review of the INVIGORATE data, reproxalap, as one of the first new therapeutic mechanisms of action in years, would be a meaningful complement to the current treatment paradigm for moderate-to-severe allergic conjunctivitis patients.”

In the Phase 3 ALLEVIATE Trial, 0.25% reproxalap demonstrated statistically significant reductions from vehicle in patient-reported ocular itching over one hour following direct topical conjunctival allergen challenge. In Aldeyra’s Phase 2 allergen chamber trial, 0.25% reproxalap demonstrated statistically significant reductions from vehicle in patient-reported ocular itching and investigator-assessed ocular redness. In the run-in cohort of the Phase 3 TRANQUILITY Trial in dry eye disease patients, 0.25% reproxalap demonstrated statistically significant reductions from vehicle in patient-reported ocular dryness scores and investigator-assessed ocular redness in the dry eye chamber. The primary endpoint of the Phase 3 TRANQUILITY and TRANQUILITY-2 trials is ocular redness over the duration of the chamber. Results from the TRANQUILITY trials in dry eye disease are expected in the second half of 2021.

Reproxalap ophthalmic solution has now been administered to more than 1,200 patients across 14 clinical trials. Consistent with prior clinical experience with reproxalap, there were no observed safety or tolerability concerns in the INVIGORATE Trial and no observed adverse events other than mild and transient instillation site discomfort typical of many prescribed topical ophthalmic medications for anterior segment inflammation.

Aldeyra plans to meet with the U.S. Food and Drug Administration (FDA) in the second half of 2021 to discuss the INVIGORATE results and the potential submission of a New Drug Application.

Conference Call & Webcast Information

Aldeyra will host a conference call on at 8:00 a.m. ET today to discuss results of the INVIGORATE Trial. The dial-in numbers are (844) 940-4939 for domestic callers and (639) 380-0129 for international callers. The Conference ID is 7578367. Due to the expected high demand on our conference provider, please plan to dial in to the call at least 15 minutes prior to the start time.

A live webcast of the conference call will be available on the Investor Relations page of the company’s website at https://ir.aldeyra.com. After the live webcast, the event will remain archived on the Aldeyra Therapeutics website for 90 days.

About Reproxalap

Reproxalap, an investigational new drug, is a novel small-molecule immune-modulating covalent inhibitor of RASP (reactive aldehyde species), 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. Reproxalap is currently in Phase 3 clinical development as a 0.25% ophthalmic solution for the treatment of dry eye disease and allergic conjunctivitis, two ocular inflammatory diseases that often occur together.

About Allergic Conjunctivitis

Allergic conjunctivitis affects more than 1 billion people worldwide,[1] including more than 66 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-κB, 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] 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 utilizes corticosteroids or other adjunctive therapy in addition to antihistamines.

About Aldeyra Therapeutics

Aldeyra Therapeutics is a clinical-stage biotechnology company focused on the development of novel therapies with the potential to improve the lives of patients with immune-mediated diseases. Two of the company's lead investigational compounds, reproxalap and ADX-629, target RASP (reactive aldehyde species), which are elevated in ocular and systemic inflammatory disease and result in cytokine release via activation of a broad array of inflammatory factors, including NF-κB, inflammasomes, and Scavenger Receptor A. Reproxalap is being evaluated in Phase 3 clinical trials in patients with dry eye disease and allergic conjunctivitis. The company's clinical pipeline also includes ADX-2191, a dihydrofolate reductase inhibitor in Phase 3 testing for proliferative vitreoretinopathy. For more information, visit https://www.aldeyra.com and follow us on LinkedIn, Facebook, and Twitter.

Safe Harbor Statement

This release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including, but not limited to, statements regarding the planned NDA submission of reproxalap in allergic conjunctivitis and the commercial potential thereof. 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

---

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 ClinImmunol. 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/opep.11.1.17.26437

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,” “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; 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 clinical trials involving Aldeyra’s product candidates in clinical trials focused on the same or on different indications; the risk that the results from smaller clinical trials or portions of clinical trials may not accurately predict results of larger scale trials or the remainder of a clinical trial; 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; political, economic, legal, social and health risks, including the recent COVID-19 outbreak and subsequent public health measures, that may affect Aldeyra’s business or the global economy; 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, 2020, which is on file with the Securities and Exchange Commission (SEC) and available on the SEC's website at https://www.sec.gov/. Additional factors may be described in those sections of Aldeyra's Quarterly Report on Form 10-Q for the quarter ended March 31, 2021, expected to be filed with the SEC in the second quarter of 2021.

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:
Joshua Reed
Aldeyra Therapeutics, Inc.
Tel: 781-761-4904 ext. 218
jreed@aldeyra.com

Investor & Media Contact:
Scott Solomon
Sharon Merrill Associates, Inc.
Tel: 617-542-5300
ALDX@investorrelations.com