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): June 15, 2023

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 June 15, 2023, Aldeyra Therapeutics, Inc. (the "Company") issued a press release (the "Press Release") announcing top-line results from the Phase 3 INVIGORATE-2 Clinical Trial of 0.25% reproxalap ophthalmic solution ("reproxalap") in patients with allergic conjunctivitis. The Company is holding a conference call regarding the announcement on June 15, 2023. 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.

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 June 15, 2023
99.2	Aldeyra Therapeutics, Inc. Press Release dated June 15, 2023
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

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

ALDEYRA THERAPEUTICS, INC.

By: /s/ Todd C. Brady
Name: Todd C. Brady, M.D., Ph.D.
Title: Chief Executive Officer

Dated June 15, 2023


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DATA RELEASE
Top-Line Results from the Phase 3 INVIGORATE-2 Trial in Allergic Conjunctivitis
June 15, 2023
Nasdaq: ALDX
© Aldeyra Therapeutics, Inc. 2023

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, statements regarding Aldeyra's future expectations, plans and prospects, including, without limitation, statements regarding: Aldeyra's belief in the adequacy of the data it has submitted or plans to submit in the NDAs for reproxalap and ADX-2191; the potential timing for FDA review of such NDAs or the potential for FDA acceptance of such NDAs; the potential for regulatory approval and commencement of commercialization of reproxalap and ADX-2191 and Aldeyra's goals as to timing; the potential profile and benefit of reproxalap in dry eye disease and allergic conjunctivitis and its other product candidates in the indications for which they are developed; and other statements regarding the goals, opportunity and potential for reproxalap, anticipated clinical or regulatory milestones for ADX-2191, ADX-246, ADX-248, and ADX-629 including expectations regarding the results of scheduled FDA meetings, clinical trial initiations and completions and submissions to the FDA; and other statements regarding the goals, opportunity and potential for reproxalap, ADX-2191, ADX-246, ADX-248, ADX-629 and Aldeyra's other product candidates, and for Aldeyra's business, research, development and regulatory plans or expectations, political, economic, legal, social and health risks, including the COVID-19 pandemic and related 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. 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," "on track," "scheduled," "target," "design," "estimate," "predict," "contemplates," "likely," "potential," "continue," "ongoing," "aim," "plan," or the negative of these terms, and similar expressions intended to identify forward-looking statements.

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 of, and clinical and regulatory plans or expectations for Aldeyra's investigational new drugs (including reproxalap and ADX-2191), 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, portions of clinical trials, or pooled clinical data 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 or post-hoc 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, which regulatory review timeline may be flexible and subject to change based on the regulator's workload and other potential review issues, 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, enrolment, 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 June 15, 2023, 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.

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The Phase 3 INVIGORATE-2 Trial of Reproxalap in Allergic Conjunctivitis Achieved All Primary and Secondary Endpoints

Statistical significance was achieved for:

- The primary endpoint of reduction in ocular itching at all prespecified timepoints (P<0.0001)
- The key secondary endpoint of reduction in ocular redness (P=0.004)
- All secondary endpoints (ocular tearing [P<0.0001] and total ocular severity score [P<0.0001])

The results are consistent with other allergic conjunctivitis clinical trials of reproxalap: the Phase 3 INVIGORATE Trial, the Phase 3 ALLEVIATE Trial, and a Phase 2 allergen chamber trial.

The observed activity of reproxalap in allergic conjunctivitis **may also benefit patients with dry eye disease**, approximately half of whom suffer from ocular allergy.[†]

[†]Ann Allergy Asthma Immunol, 108(3): 163-6, 2012. Topical ocular reproxalap is an investigational drug candidate that has been studied in more than 2,400 patients with no observed safety concerns; mild and transient instillation site irritation is the most commonly reported adverse event in clinical trials.

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

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

Patients are exposed to moderate to high levels of ragweed pollen continuously for approximately 3.5 hrs

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

Slide source: Clantha Research

To our knowledge, no other late-stage investigational allergic conjunctivitis drug has been rigorously tested in an allergen chamber.

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The Phase 3 INVIGORATE-2 Allergic Conjunctivitis Trial Design

Design

Randomized, two-way crossover, vehicle-controlled, double-masked allergen chamber challenge design with 0.25% topical ocular reproxalap

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 (0-3 scale)
- Total ocular severity score (11-point composite of itching, redness & tearing)

ClinicalTrials.gov Identifier: NCT05234554

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The INVIGORATE-2 Trial Achieved All Primary and Secondary Endpoints

Primary Endpoint: ACHIEVED	Key Secondary Endpoint: ACHIEVED	Both Secondary Endpoints: ACHIEVED	NO Observed Safety or Tolerability Concerns
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	Statistically significant improvement vs. vehicle (P=0.004) on key secondary endpoint of investigator-assessed ocular redness over the duration of the allergen chamber	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	131 subjects enrolled, 130 of whom completed both treatments; no discontinuations due to adverse events

P values derived from mixed effect model of repeated measures analysis. Topical ocular reproxalap is an investigational drug candidate that has been studied in more than 2,400 patients with no observed safety concerns; mild and transient instillation site irritation is the most commonly reported adverse event in clinical trials.

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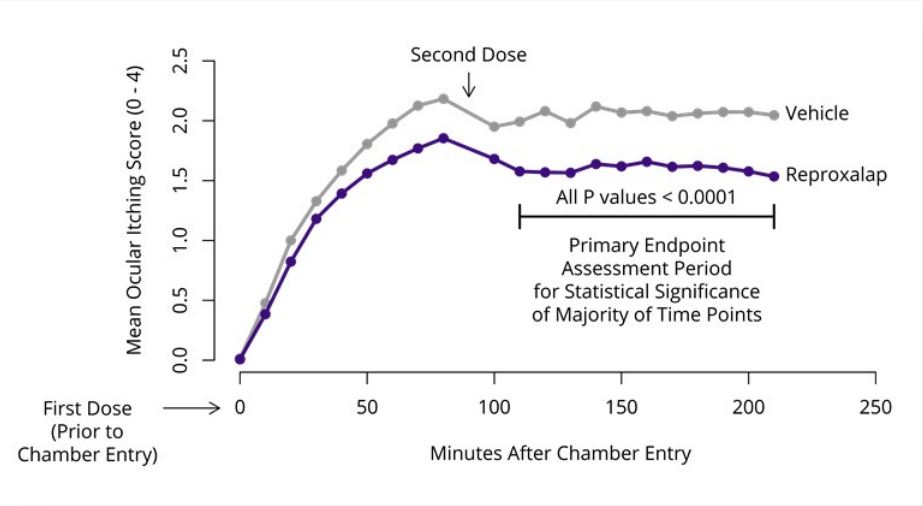
Reproxalap Achieved Primary Endpoint of Reduction in Ocular Itching in the INVIGORATE-2 Trial



KEY RESULTS

Primary endpoint of statistical significance for majority of timepoints **achieved** over prespecified time frame of 110-210 minutes after allergen chamber entry in change from baseline in patient-reported **ocular itching**

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

P values derived from mixed effect model of repeated measures analysis. Topical ocular reproxalap is an investigational drug candidate that has been studied in more than 2,400 patients with no observed safety concerns; mild and transient instillation site irritation is the most commonly reported adverse event in clinical trials.

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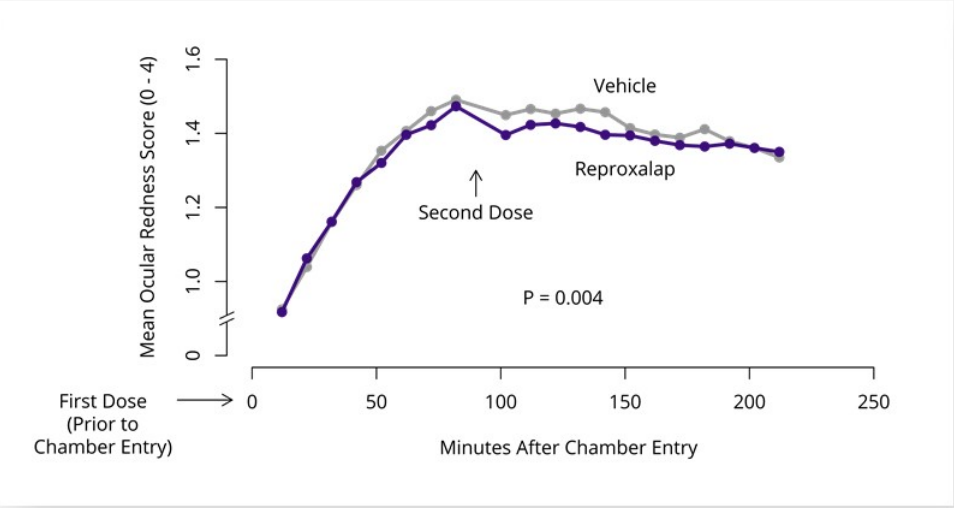
Reproxalap Achieved Key Secondary Endpoint of Reduction in Ocular Redness in the INVIGORATE-2 Trial



KEY RESULTS

Key secondary endpoint of statistical significance in change from baseline in investigator-assessed **ocular redness** over the entire chamber **achieved** (P=0.004)

Prophylactic and treatment effects of reproxalap demonstrated

P values derived from mixed effect model of repeated measures analysis. Topical ocular reproxalap is an investigational drug candidate that has been studied in more than 2,400 patients with no observed safety concerns; mild and transient instillation site irritation is the most commonly reported adverse event in clinical trials.

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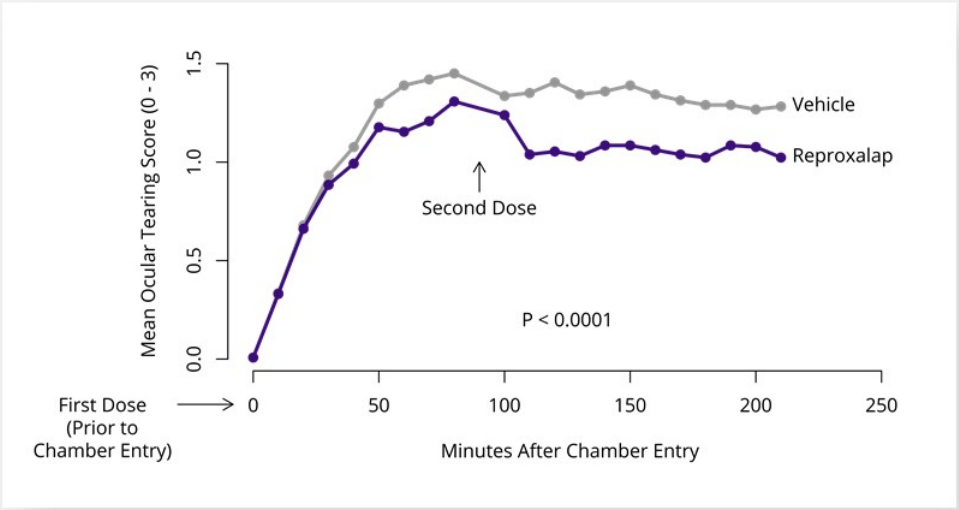
Reproxalap Achieved Secondary Endpoint of Reduction in Ocular Tearing in the INVIGORATE-2 Trial



KEY RESULTS

Secondary endpoint of statistical significance in change from baseline in patient-reported **ocular tearing score** over the entire allergen chamber **achieved** (P<0.0001)

Prophylactic and treatment effects of reproxalap demonstrated

P values derived from mixed effect model of repeated measures analysis. Topical ocular reproxalap is an investigational drug candidate that has been studied in more than 2,400 patients with no observed safety concerns; mild and transient instillation site irritation is the most commonly reported adverse event in clinical trials.

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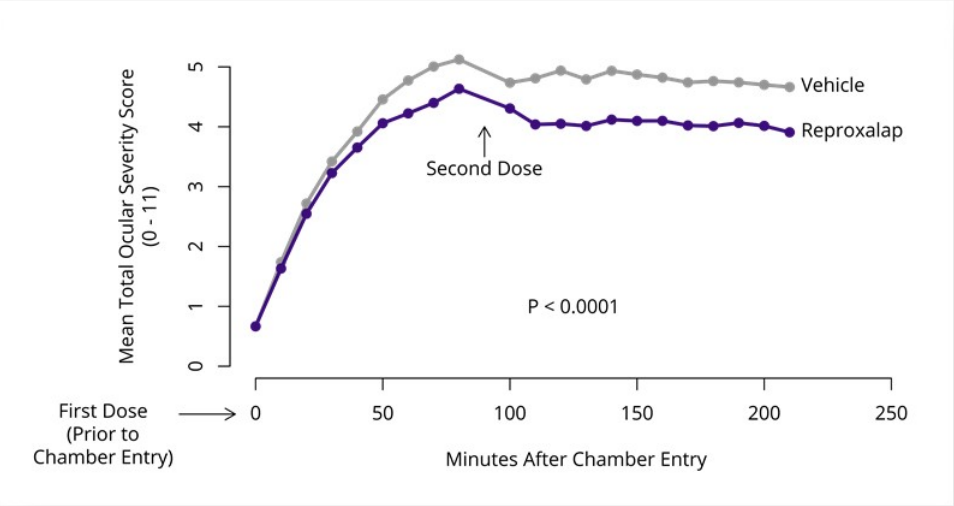
Reproxalap Achieved Secondary Endpoint of Reduction in Total Ocular Severity Score in the INVIGORATE-2 Trial



KEY RESULTS

Secondary endpoint of statistical significance in **total ocular severity score**, a composite of patient-reported ocular itching and tearing scores and investigator-assessed ocular redness score over the entire allergen chamber, **achieved** (P<0.0001)

Prophylactic and treatment effects of reproxalap demonstrated

P values derived from mixed effect model of repeated measures analysis. Topical ocular reproxalap is an investigational drug candidate that has been studied in more than 2,400 patients with no observed safety concerns; mild and transient instillation site irritation is the most commonly reported adverse event in clinical trials.

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Reproxalap Was Generally Well Tolerated and No Safety Concerns Were Observed in the INVIGORATE-2 Trial

- ☑ No observed safety or tolerability concerns
- ☑ No discontinuations due to adverse events
- ☑ Consistent with other topically administered drugs, most common treatment-emergent adverse events related to transient instillation site irritation
- ☑ No observed clinically significant findings on safety assessments, including:
  - visual acuity
  - intraocular pressure
  - slit lamp biomicroscopy
  - dilated fundoscopy

TOPICAL OCULAR REPROXALAP
administered to more than

2,400 patients

across **21** clinical trials

Topical ocular reproxalap is an investigational drug candidate that has been studied in more than 2,400 patients with no observed safety concerns; mild and transient instillation site irritation is the most commonly reported adverse event in clinical trials.

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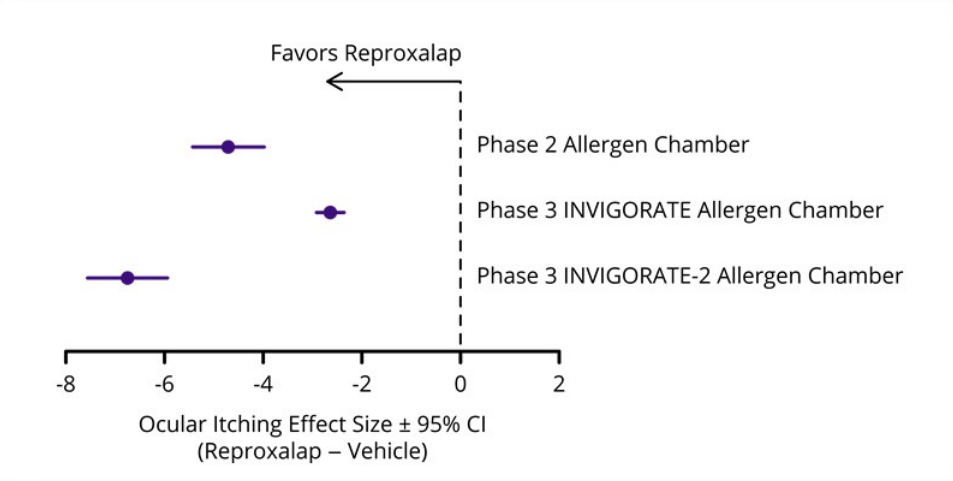
Reproxalap Demonstrated Consistent Improvement in Ocular Itching Symptoms Across Late-Stage Allergic Conjunctivitis Clinical Trials



KEY RESULTS

Consistent statistically significant symptomatic activity of reproxalap over vehicle in patients with allergic conjunctivitis demonstrated across Phase 2 and Phase 3 allergen chamber trials

Large effect sizes suggest **clinically meaningful difference** between reproxalap and vehicle in reduction of patient-reported ocular itching

Topical ocular reproxalap is an investigational drug that has been studied in over 2,400 patients with no safety concerns reported; mild instillation site discomfort is the most commonly reported adverse event in clinical trials. Effect size is change from baseline divided by baseline standard deviation. **CI** = confidence interval.

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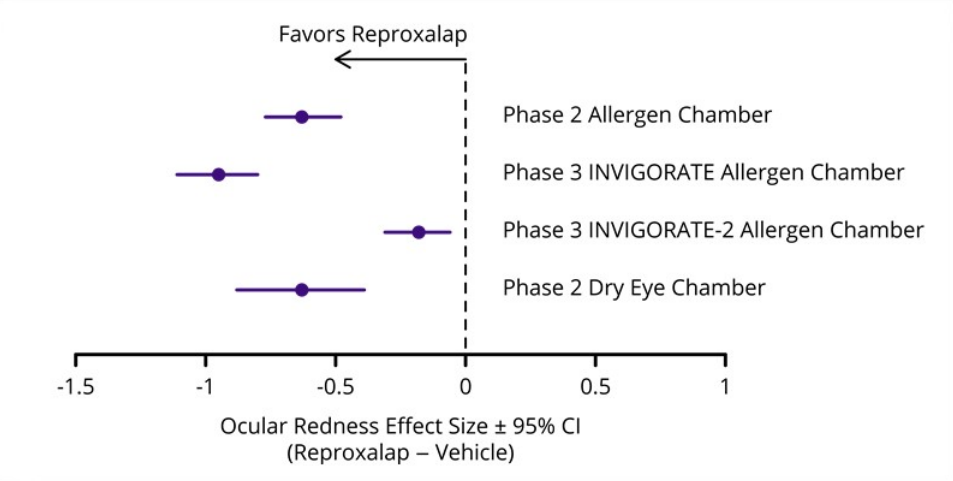
Reproxalap Demonstrated Consistent Reduction of Ocular Redness Across Two Distinct Crossover Chamber Challenge Models of Ocular Surface Disease



KEY RESULTS

Consistent statistically significant activity of reproxalap over vehicle in **reduction of ocular redness** demonstrated across Phase 2 and Phase 3 chamber trials in allergic conjunctivitis and dry eye disease

Overall effect size exceeds clinically relevant threshold of 0.5 for ocular redness between reproxalap and vehicle

Topical ocular reproxalap is an investigational drug that has been studied in over 2,400 patients with no safety concerns reported; mild instillation site discomfort is the most commonly reported adverse event in clinical trials. Effect size is change from baseline divided by baseline standard deviation. **CI** = confidence interval.

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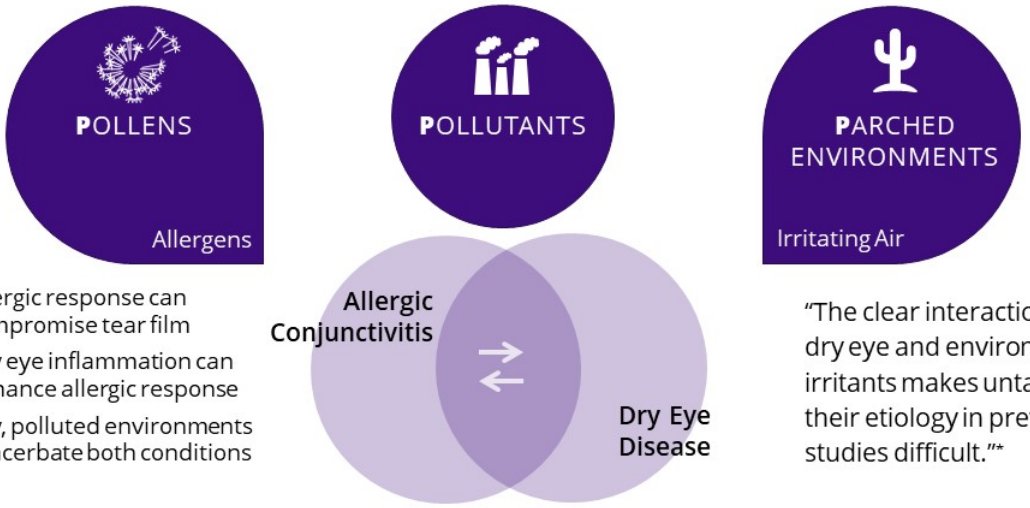
Allergic Conjunctivitis and Dry Eye Disease Are Interrelated Inflammatory Ocular Surface Diseases



- Allergic response can compromise tear film
- Dry eye inflammation 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."*

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 Ann Allergy Asthma Immunol, 108(3): 163-6, 2012.

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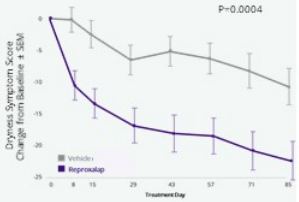
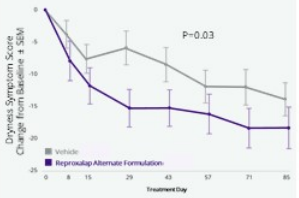
Aldeyra Has Submitted What is Believed to be the Most Comprehensive Dry Eye Disease NDA, which Includes Symptoms and Multiple Signs†

Ocular Dryness Symptom Score

Phase 3 RENEW–Part 1

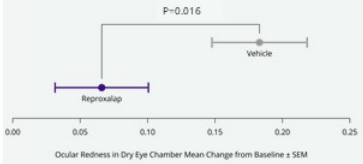


Formulation Phase 2‡

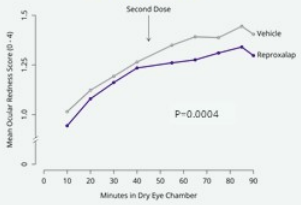


Ocular Redness

Phase 2 Dry Eye Chamber Trial‡

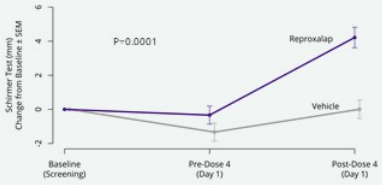


Crossover Trial

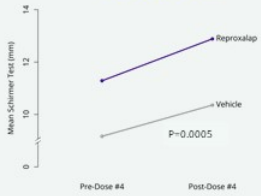


Schirmer Test

Phase 3 TRANQUILITY-2 Trial



Crossover Trial



≥10 mm Schirmer Test Responder Analysis

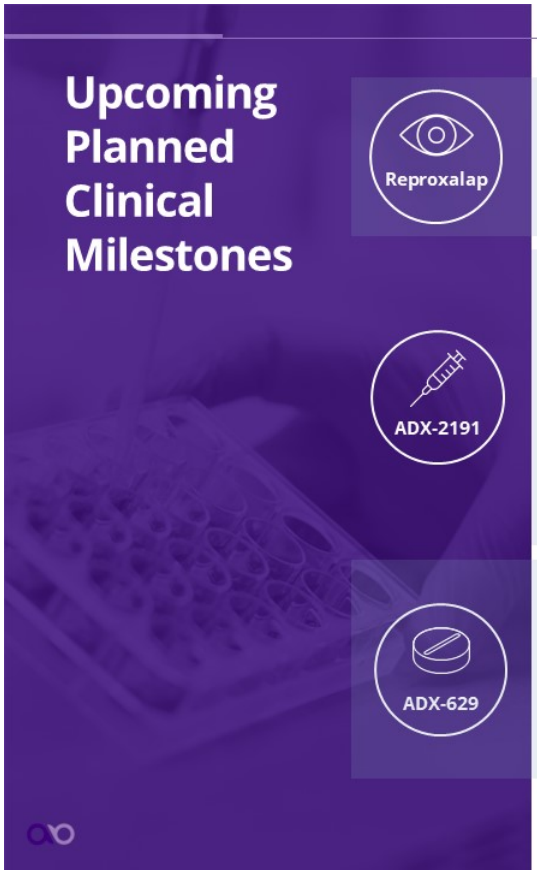
Phase 3 TRANQUILITY-2 Trial

Change from Baseline	
Odds ratio	2.625
P value versus vehicle	<0.0001

Raw Score	
Odds ratio	1.551
P value versus vehicle	0.0361

†The NDA submission includes a combination of primary, secondary, multiplicity-adjusted, and nominal P-value endpoints. ‡Adequate and well-controlled Phase 2 or Phase 3 clinical trials can be submitted as pivotal. **NDA** = New Drug Application, **SEM** = standard error of the mean. Topical ocular reproxalap is an investigational drug candidate that has been studied in more than 2,300 patients with no observed safety concerns; mild and transient instillation site irritation is the most commonly reported adverse event in clinical trials.

Upcoming Planned Clinical Milestones



Reproxalap

Dry Eye Disease
PDUFA date of November 23, 2023†

ADX-2191

Primary Vitreoretinal Lymphoma
PDUFA date of June 21, 2023†

Proliferative Vitreoretinopathy
Type C meeting with FDA to discuss completion of clinical development planned for H2 2023

Retinitis Pigmentosa
Phase 2 clinical trial top-line results expected in Q2 2023‡

ADX-629

Atopic Dermatitis (Part 1), Chronic Cough, Idiopathic Nephrotic Syndrome (Part 1), and Sjögren-Larsson Syndrome*
Phase 2 clinical trial top-line results expected in 2023‡

Moderate Alcohol-Associated Hepatitis
Initiation of Phase 2 clinical trial expected in H2 2023‡

†Regulatory review timelines are flexible and subject to change based on the regulator's workload and other potential review issues. ‡The timing of ongoing clinical trials depends, in part, on the availability of clinical research facilities and staffing, and the ability to recruit patients. *Investigator sponsored.

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Exhibit 99.2

Aldeyra Therapeutics Announces Achievement of Statistical Significance for Primary Endpoint and All Secondary Endpoints in Phase 3 INVIGORATE-2 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=0.004)**
- **Statistical Significance Achieved for Secondary Endpoints of Ocular Tearing (P<0.0001) and Total Ocular Severity Score (P<0.0001)**
- **Results Consistent with Previous Phase 2 and Phase 3 Clinical Trials in Allergic Conjunctivitis**
- **Activity in Allergic Conjunctivitis Complements Commercial Potential in Dry Eye Disease**
- **Company to Discuss Results in Conference Call and Webcast at 8:00 a.m. ET Today**

LEXINGTON, Mass.--(BUSINESS WIRE)--June 15, 2023--Aldeyra Therapeutics, Inc. (Nasdaq: ALDX) (Aldeyra), a biotechnology company devoted to discovering and developing innovative therapies designed to treat immune-mediated diseases, today announced positive top-line results from the Phase 3 INVIGORATE-2 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.

“Consistent with the results of the Phase 3 INVIGORATE Trial and in conjunction with a number of successful Phase 2 and Phase 3 clinical trials in dry eye disease, achievement of the primary endpoint and all secondary endpoints in INVIGORATE-2 supports the potential of reproxalap as a treatment for inflammatory diseases of the ocular surface,” stated Todd C. Brady, M.D., Ph.D., President and CEO of Aldeyra. “We believe that the rapid-onset activity of reproxalap evidenced in the INVIGORATE clinical trials may offer hope to allergic conjunctivitis patients who are today not adequately treated, and also to dry eye disease patients, up to 50% of whom suffer from ocular allergy.”

The randomized, double-masked, vehicle-controlled, two-way crossover design allergen chamber Phase 3 INVIGORATE-2 Trial enrolled 131 allergic conjunctivitis patients. The primary efficacy endpoint was change from baseline in patient-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 across 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=0.004) 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).

“The co-morbidity of allergic conjunctivitis and dry eye disease poses diagnostic and treatment challenges to patients and healthcare providers,” stated William B. Trattler, MD., Vice Chair of Research and Associate Professor of Ophthalmology at Herbert Wertheim College of Medicine. “For patients who have had a poor response to over-the-counter ocular allergy medications, the data announced today may suggest that reproxalap could satisfy a substantial unmet need in patients who suffer from allergic conjunctivitis and dry eye disease.”

Reproxalap ophthalmic solution has now been administered to more than 2,400 patients across 21 clinical trials. Consistent with prior clinical experience with reproxalap, there were no observed safety or tolerability concerns in the INVIGORATE-2 Trial; the most common adverse event was mild and transient instillation site irritation. No patients discontinued due to adverse events, and 130 of 131 randomized patients completed the clinical trial. A New Drug Application (NDA) of reproxalap for the treatment of dry eye disease is under review at the U.S. Food and Drug Administration. The NDA Prescription Drug User Fee Act (PDUFA) date for reproxalap for the treatment of dry eye disease is November 23, 2023.

Conference Call & Webcast Information

Aldeyra will host a conference call at 8:00 a.m. ET today to discuss results of the INVIGORATE-2 Trial. The dial-in numbers are (833) 470-1428 for domestic callers and (404) 975-4839 for international callers. The access code is 349573. A live audio webcast of the conference call also will be accessible from the “Investors & Media” section of Aldeyra's website at ir.aldeyra.com. 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 candidate, is a first-in-class small-molecule modulator of RASP (reactive aldehyde species), which are elevated in ocular and systemic inflammatory disease. The mechanism of action of reproxalap has been supported by the demonstration of statistically significant and clinically relevant activity in multiple physiologically distinct late-phase clinical indications. Reproxalap has been studied in more than 2,400 patients with no observed safety concerns; mild and transient instillation site irritation is the most commonly reported adverse event in clinical trials.

About Aldeyra

Aldeyra Therapeutics is a biotechnology company devoted to discovering innovative therapies designed to treat immune-mediated diseases. Our approach is to develop pharmaceuticals that modulate immunological systems, instead of directly inhibiting or activating single protein targets, with the goal of optimizing multiple pathways at once while minimizing toxicity. Our product candidates include RASP (reactive aldehyde species) modulators ADX-629, ADX-246, ADX-248, and chemically related molecules for the potential treatment of systemic and retinal immune-mediated diseases. Our pre-commercial product candidates are reproxalap, a RASP modulator for the potential treatment of dry eye disease (under U.S. Food and Drug Administration New Drug Application Review) and allergic conjunctivitis, and ADX-2191, a novel formulation of intravitreal methotrexate for the potential treatment of primary vitreoretinal lymphoma (under U.S. Food and Drug Administration New Drug Application Priority Review), proliferative vitreoretinopathy, and other rare sight-threatening retinal diseases. 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 likelihood and timing of the FDA’s potential approval of the NDA for reproxalap by the PDUFA date, or at any other time, and the adequacy of the data included in the NDA submission, and the commercial potential of reproxalap. 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,” “on track,” “scheduled,” “target,” “design,” “estimate,” “predict,” “contemplates,” “likely,” “potential,” “continue,” “ongoing,” “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, funding, and other factors that could delay the initiation, enrollment, 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; delay in or failure to obtain regulatory approval of Aldeyra's product candidates, including as a result of the FDA not accepting Aldeyra’s regulatory filings, requiring additional clinical trials or data prior to review or approval of such filings; 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 different indications; the scope, progress, expansion, and costs of developing and commercializing Aldeyra's product candidates; the current and potential future impact of the COVID-19 pandemic on Aldeyra’s business, results of operations, and financial position; uncertainty as to Aldeyra’s ability to commercialize (alone or with others) and obtain reimbursement for 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 future revenue, the timing of future 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 commercialization, marketing and manufacturing capabilities and strategy; 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; political, economic, legal, social, and health risks, including the COVID-19 pandemic and subsequent public health measures, and war or other military actions, that may affect Aldeyra’s business or the global economy; 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, 2022, and Aldeyra’s Quarterly Report on Form 10-Q for the quarter ended March 31, 2023, which are 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 June 30, 2023, expected to be filed with the SEC in the third quarter of 2023.

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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