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 29, 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 29, 2023, Aldeyra Therapeutics, Inc. (the "Company") issued a press release (the "Press Release") announcing positive top-line results from the Phase 2 clinical trial of ADX-2191 in patients with retinitis pigmentosa. The Company is holding a conference call regarding the announcement on June 29, 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 29, 2023
99.2	Aldeyra Therapeutics, Inc. Press Release dated June 29, 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 29, 2023

Exhibit 99.1


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DATA RELEASE
Top-Line Results from the Phase 2 Clinical Trial of ADX-2191 in Retinitis Pigmentosa
June 29, 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, ADX-629, 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.

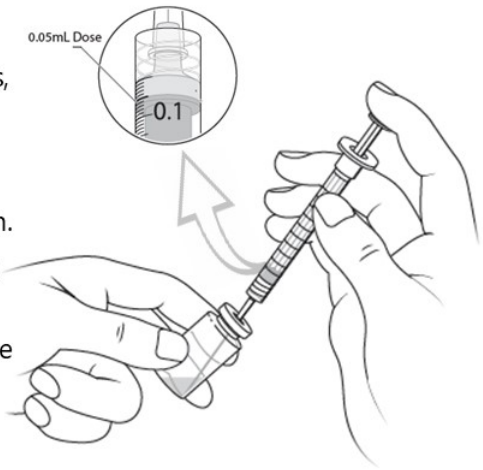
In addition to the risks described above and in Aldeyra's other filings with the SEC, other unknown or unpredictable factors also could affect Aldeyra's results. No forward-looking statements can be guaranteed, and actual results may differ materially from such statements. The information in this presentation is provided only as of June 29, 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.

ADX-2191 Demonstrated Activity and Was Well Tolerated in Retinitis Pigmentosa Phase 2 Clinical Trial

- Best-corrected and low-light visual acuity statistically significantly improved.
- As assessed by electroretinography, retinal response to light numerically improved, and time to retinal response statistically significantly improved.
- As assessed by macular integrity assessment and dark-adapted chromatic perimetry, retinal sensitivity to light statistically significantly improved.
- Consistent with the Phase 3 GUARD results in proliferative vitreoretinopathy, ADX-2191 was well tolerated and no safety concerns were identified.
- Planned Phase 2/3 clinical trial to be discussed with regulatory authorities.

ADX-2191, an Investigational Vitreous-Compatible Formulation of Methotrexate, Represents a Platform Approach for Rare Retinal Diseases

- ADX-2191 (methotrexate injection, USP) is the first sterile, non-compounded formulation of methotrexate designed to meet the unique requirements of intravitreal administration for specific rare retinal diseases, including retinitis pigmentosa and proliferative vitreoretinopathy.
- The ADX-2191 intravitreal formulation is designed to be vitreous-compatible and optimized for excipient composition, viscosity, density, tonicity, pH, active ingredient concentration, and volume of administration.
- ADX-2191, if approved, will be the first cGMP manufactured methotrexate drug product for intravitreal administration.
- ADX-2191 has received U.S. FDA Orphan Drug Designation for proliferative vitreoretinopathy and retinitis pigmentosa.



ADX-2191 (methotrexate injection, USP) for intravitreal administration is an investigational drug candidate. **USP** = United States Pharmacopeia; **cGMP** = current good manufacturing practice.

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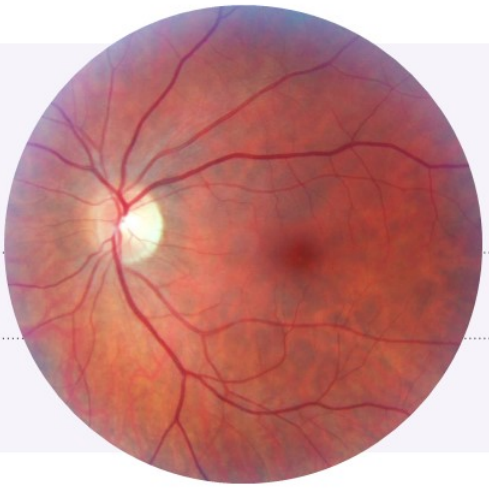
In the Phase 3 GUARD Trial of ADX-2191 in Proliferative Vitreoretinopathy, the Primary Endpoint Was Achieved

	ADX-2191 (n=68)	Historical Control† (n=292)
Patients with retinal detachment within 6 months of surgery	16	113
Odds ratio (95% CI) vs. historical control	0.49 (0.26, 0.89)	
P value vs. historical control*	0.024	



*Ophthalmology 124(6):757-767, 2017; Archives of Ophthalmology 25(9):1161-7, 2007. †Fisher exact test. ADX-2191 (methotrexate injection, USP) for intravitreal administration is an investigational drug candidate.
CI = confidence interval.

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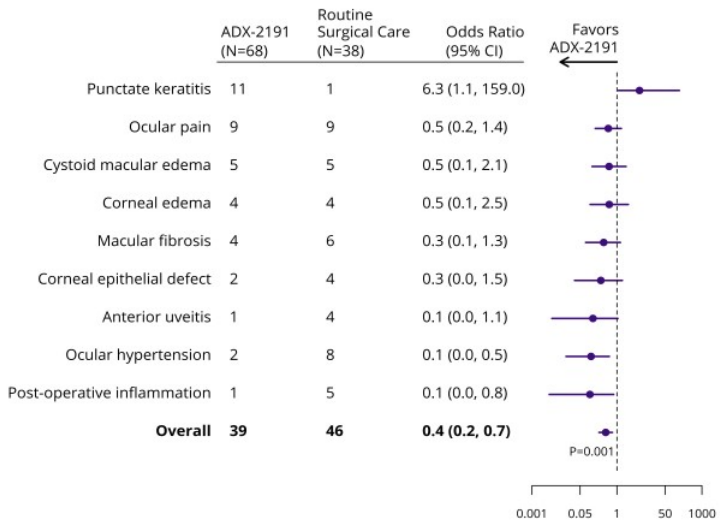
ADX-2191 Was Numerically Favored Over Routine Surgical Care for Key Safety Endpoints in the GUARD Trial

All treatment-emergent adverse events affecting at least 10% of patients in either treatment group



ADX-2191 (methotrexate injection, USP) for intravitreal administration is an investigational drug candidate. The most common adverse event associated with ADX-2191 administration was punctate keratitis, a well-known side effect of intravitreal methotrexate. CI = confidence interval.

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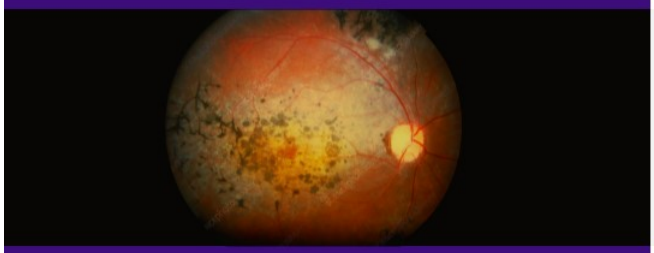
ADX-2191 Has the Potential to be the First Approved Drug for Retinitis Pigmentosa, a Clinical Group of Rare Genetic Eye Diseases

Retinitis pigmentosa refers to a group of inherited retinal diseases characterized by cell death and loss of vision.



- Retinitis pigmentosa **affects more than 1 million people** worldwide. Mutations leading to rhodopsin misfolding account for approximately one-third of cases.
- There is **no approved therapy** for retinitis pigmentosa.
- **U.S. FDA Orphan Drug Designation** for ADX-2191 for the treatment of retinitis pigmentosa was granted in August 2021.

Preclinical electroretinographic evidence in a P23H rhodopsin mutation mouse model of retinitis pigmentosa **suggests that methotrexate improves retinal function.**

ADX-2191 (methotrexate injection, USP) for intravitreal administration is an investigational drug candidate.
Sources: Aldeyra internal estimates; FASEBJ. 34(8): 10146-10167, 2020.
PBS = phosphate-buffered saline; **MTX** = methotrexate.

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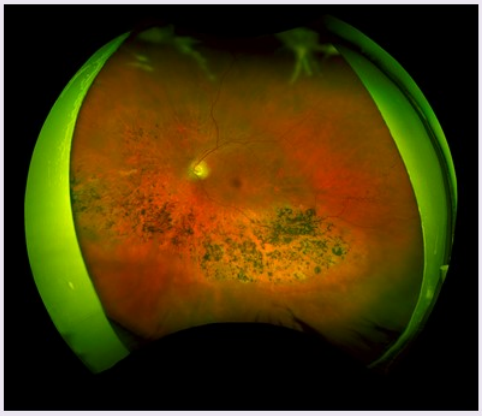
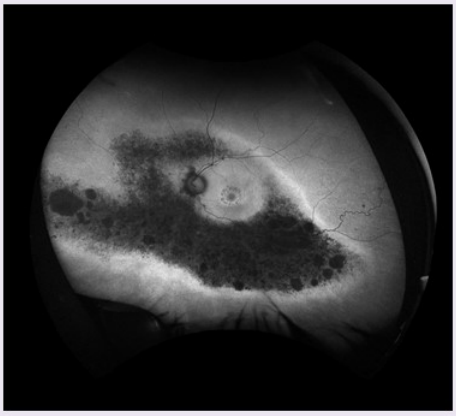
Illustrative Retinal Images from an Enrolled Patient in the Phase 2 Retinitis Pigmentosa Trial

Color Fundus Photograph



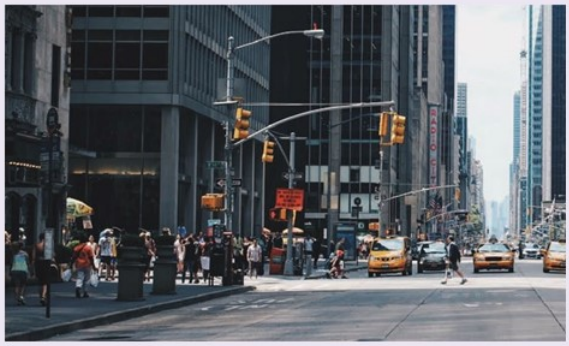
Autofluorescence Photograph



ADX-2191 (methotrexate injection, USP) for intravitreal administration is an investigational drug candidate.

Simulated Vision of Patients with Advanced Retinitis Pigmentosa

Unaffected Individual



Advanced Retinitis Pigmentosa

Angelopoulos, A. (2019). Enhanced Depth Navigation Through Augmented Reality Depth Mapping in Patients with Low Vision. Scientific Reports.

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ADX-2191: Phase 2 Clinical Trial Design in Retinitis Pigmentosa

Design

Single-center, dose-ranging, open-label clinical trial of ADX-2191 (400µg methotrexate in 0.05mL) in patients with retinitis pigmentosa

Inclusion Highlights

Diagnosis of retinitis pigmentosa due to rhodopsin gene mutations, including P23H

Dosing Regimen

Cohort A (n = 4):
Monthly injections of ADX-2191 for three months

Cohort B (n = 4):
Twice-monthly injections of ADX-2191 for three months

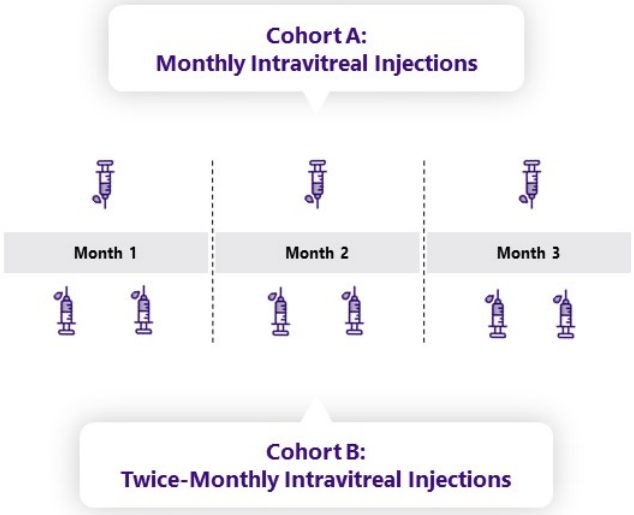
Primary Endpoint

Safety and tolerability

Secondary Endpoints

1. Best corrected and low-light visual acuity
2. Macular retinal sensitivity as assessed by MAIA perimetry
3. Dark-adapted flash analyzed by ERG
4. Peripheral retinal sensitivity as assessed by DAC perimetry
5. Retinal morphology as assessed by OCT

Acuity, perimetry, and OCT assessments were performed monthly for four months from initiation of therapy. ERG was performed at baseline and at 90 days from initiation of therapy.



ADX-2191 (methotrexate injection, USP) for intravitreal administration is an investigational drug candidate. **MAIA** = Macular Integrity Assessment; **ERG** = full field electroretinography; **DAC** = dark-adapted chromatic; **OCT** = optical coherence tomography.

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Baseline Characteristics Were Similar Across Groups

	MONTHLY COHORT Mean (SD) or %	TWICE-MONTHLY COHORT Mean (SD) or %
Mean Age (Years)	62.3 (12.8)	56.5 (13.7)
Gender	Male (50%), Female (50%)	Male (25%), Female (75%)
Visual Acuity (Letters)	77.6 (10.5)	84.3 (6.8)
Macular Sensitivity (Decibels)	11.9 (11.1)	17.9 (7.4)

ADX-2191 (methotrexate injection, USP) for intravitreal administration is an investigational drug candidate. Visual acuity is best corrected visual acuity. 78 letters represents approximately 20/30 vision, and 84 letters represents approximately 20/20 vision. **SD** = standard deviation.

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ADX-2191 Was Well Tolerated and No Safety Signals Were Observed

8 patients were enrolled, and all patients completed the trial per protocol.

	MONTHLY COHORT	TWICE-MONTHLY COHORT
Serious Adverse Events	0	0
Severe Adverse Events	0	0
Moderate Adverse Events	4 (injection site pain)	0
Mild Adverse Events	6 (injection site pain, lacrimation, dry eye and foreign body sensation)	1 (injection air bubble)
Adverse Events that Led to Discontinuation	0	0

ADX-2191 (methotrexate injection, USP) for intravitreal administration is an investigational drug candidate. Events reflect treatment-related adverse events deemed at least possibly related to drug.

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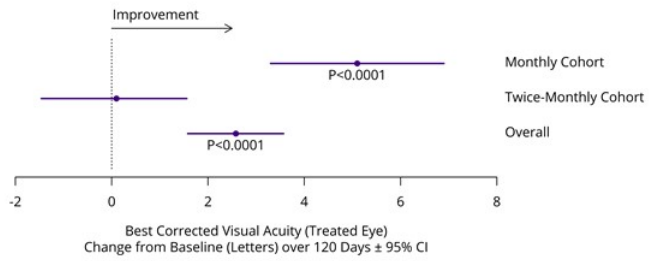
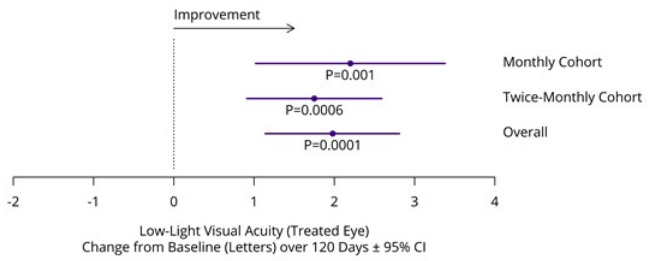
Statistically Significant Improvement in Visual Acuity Observed in the Retinitis Pigmentosa Phase 2 Clinical Trial

Normal Lighting



Dim Lighting



ADX-2191 (methotrexate injection, USP) for intravitreal administration is an investigational drug candidate. Baseline best corrected visual acuity for the twice-monthly dosing cohort was on average approximately 20/20. Data derived from mixed model for repeated measures with baseline, day, and dose (if applicable) as factors. **CI** = confidence interval.

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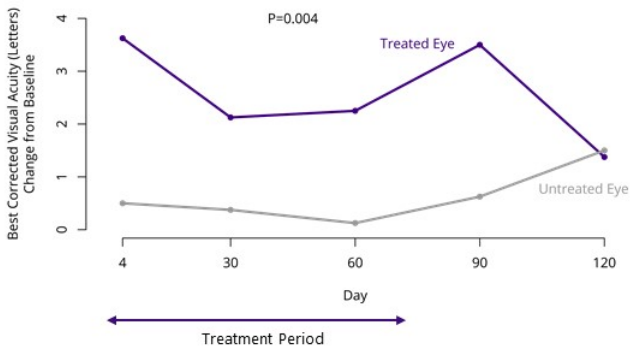
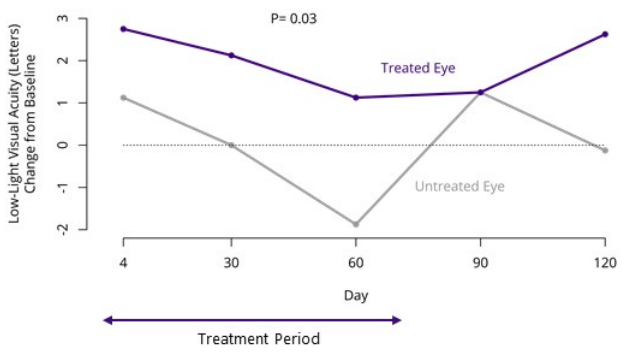
In the Retinitis Pigmentosa Phase 2 Clinical Trial, Visual Acuity in ADX-2191-Treated Eyes Was Superior to that of Untreated Eyes

Normal Lighting



Dim Lighting



ADX-2191 (methotrexate injection, USP) for intravitreal administration is an investigational drug candidate. Data derived from mixed model for repeated measures of both dosing cohorts with baseline, day, dose, and treatment eye as factors.

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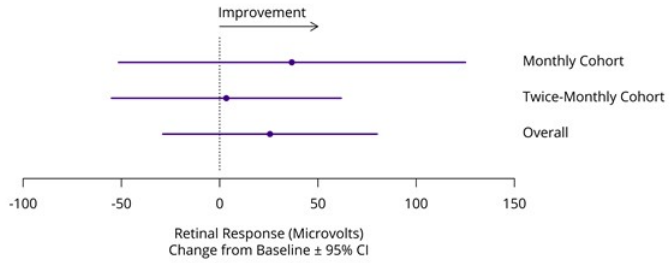
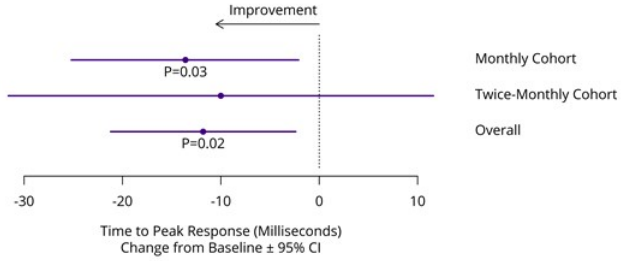
As Assessed by ERG, Retinal Function Improved in the Retinitis Pigmentosa Phase 2 Clinical Trial

Peak Response



Time to Response



ADX-2191 (methotrexate injection, USP) for intravitreal administration is an investigational drug candidate. B-wave response and implicit time following dim flash under scotopic conditions were assessed.
Data derived from mixed model for repeated measures with baseline and dose (if applicable) as factors. **CI** = confidence interval; **ERG** = full field electroretinography.

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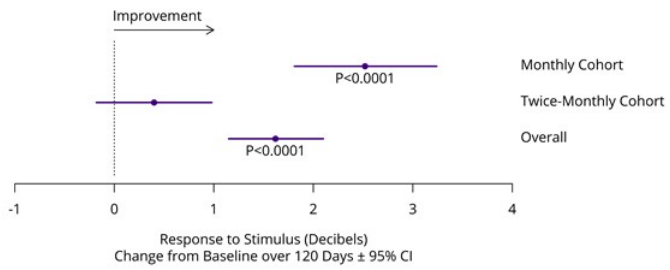
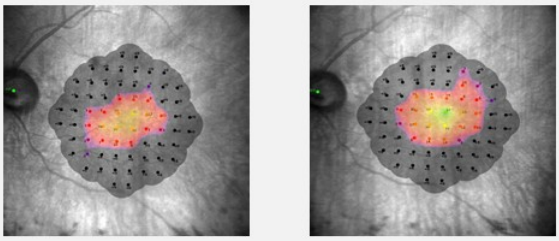
As Assessed by MAIA Microperimetry, Statistically Significant Improvement in Retinal Sensitivity Observed in the Retinitis Pigmentosa Phase 2 Clinical Trial

Retinal Sensitivity



Illustrative results from an enrolled patient indicate central and peripheral improvement in macular retinal sensitivity.

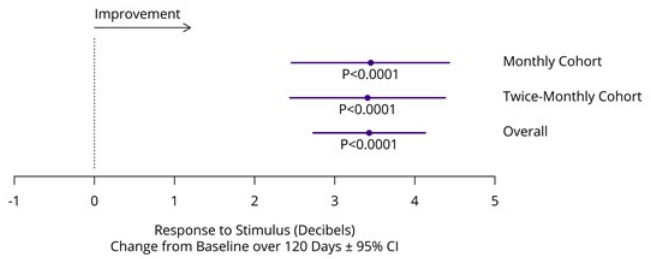
Baseline **Day 90**



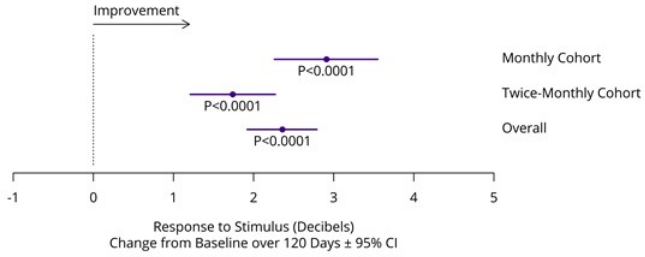
ADX-2191 (methotrexate injection, USP) for intravitreal administration is an investigational drug candidate. Baseline retinal sensitivity was approximately 50% higher in the twice-monthly dosing cohort than in the monthly dosing cohort. Data derived from mixed model for repeated measures with baseline, day, and dose (if applicable) as factors. Retinal sensitivity assessed where non-zero sensitivity losses were ≥ 7 decibels from nearest concentric assessment. **MAIA** = Macular Integrity Assessment; **CI** = confidence interval.

As Assessed by DAC Perimetry, Statistically Significant Improvement in Retinal Sensitivty Observed in the Retinitis Pigmentosa Phase 2 Clinical Trial

Green Stimulus



Red Stimulus



ADX-2191 (methotrexate injection, USP) for intravitreal administration is an investigational drug candidate. Data derived from mixed model for repeated measures with baseline, day, and dose (if applicable) as factors. Retinal sensitivity assessed where non-zero sensitivity losses were ≥7 decibels from nearest concentric assessment. **DAC** = dark-adapted chromatic; **CI** = confidence interval.

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Upcoming Planned Clinical Milestones

Dry Eye Disease
PDUFA date of November 23, 2023†

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

Atopic Dermatitis (Part 1), 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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Aldeyra Therapeutics Announces Improvement from Baseline in Retinal Function in Phase 2 Clinical Trial of ADX-2191 in Patients with Retinitis Pigmentosa

- **Best Corrected and Low-Light Visual Acuity Statistically Significantly Improved**
- **As Assessed by Electroretinography, Time to Retinal Response Statistically Significantly Improved**
- **As Assessed by Macular and Dark-Adapted Perimetry, Retinal Sensitivity Statistically Significantly Improved**
- **ADX-2191 Was Well Tolerated and No Safety Concerns Were Identified**
- **Planned Phase 2/3 Clinical Trial to be Discussed with Regulatory Authorities**
- **Company to Discuss Results in Conference Call and Webcast at 8:00 a.m. ET Today**

LEXINGTON, Mass.--(BUSINESS WIRE)--June 29, 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 2 clinical trial of intravitreal ADX-2191 (methotrexate injection, USP), an investigational drug candidate, in patients with retinitis pigmentosa. Relative to baseline, the clinical trial demonstrated statistically significant improvement in retinal function across a number of different physiological and psychophysical assessments.

“The improvement in retinal function relative to baseline observed in this retinitis pigmentosa clinical trial of ADX-2191 may offer hope to patients that today have no therapeutic options,” stated Todd C. Brady, M.D., Ph.D., President and CEO of Aldeyra. “Based on compelling proof-of-concept clinical activity that is consistent with a well-defined mechanism of action supported by preclinical evidence, we are excited to meet with regulatory authorities to discuss initiation of a potentially pivotal Phase 2/3 clinical trial, as we enthusiastically advance ADX-2191 to the next stage of development.”

Based on preclinical evidence suggesting that methotrexate may facilitate the clearance of mutated rhodopsin[1], a protein critical for visual cycle function, an open-label, single-center Phase 2 clinical trial of ADX-2191 was performed in eight retinitis pigmentosa patients with rhodopsin misfolding mutations. Over three months of treatment with ADX-2191, four patients received monthly injections and four patients received twice-monthly injections. The primary endpoint of the clinical trial was safety. Secondary endpoints included change from baseline in visual acuity; retinal function, as assessed by macular and dark-adapted chromatic perimetry and electroretinography; and retinal morphology, as assessed by optical coherence tomography. Visual acuity, perimetry, and morphology assessments were performed monthly for four months from initiation of therapy. Electroretinography was performed at baseline and at 90 days from initiation of therapy.

All enrolled patients completed the trial per protocol. Relative to baseline, across all patients, statistical significance was achieved for improvement in best corrected visual acuity ($P<0.0001$), low-light visual acuity ($P=0.0001$), time to electroretinographic response to light ($P=0.02$), macular sensitivity to light ($P<0.0001$), and dark-adapted peripheral sensitivity to light ($P<0.0001$). ADX-2191 was well tolerated, and no safety concerns were identified. No treatment-related adverse events associated with retinal morphology were observed. No serious adverse events were reported, and no patients discontinued due to adverse events.

“Retinitis pigmentosa is a relentlessly progressive disease that inevitably leads to loss of vision,” stated Ramiro S. Maldonado, MD., the Principal Investigator of the clinical trial and Assistant Professor of Ophthalmology at Duke University Medical Center. “The promising results presented today are supportive of a potential novel approach for the treatment of retinitis pigmentosa patients with rhodopsin mutations.”

ADX-2191 is a novel intravitreal formulation of methotrexate in clinical development for proliferative vitreoretinopathy and retinitis pigmentosa, both of which are rare, sight-threatening retinal diseases with no approved therapies. The prevalence of retinitis pigmentosa is more than one million people worldwide, and genetic mutations leading to rhodopsin misfolding account for approximately one-third of cases. ADX-2191 has been granted orphan drug designation by the U.S. Food and Drug Administration for the treatment of proliferative vitreoretinopathy and retinitis pigmentosa.

Conference Call & Webcast Information

Aldeyra will host a conference call at 8:00 a.m. ET today to discuss top-line results of the Phase 2 clinical trial of ADX-2191 in retinitis pigmentosa. The dial-in numbers are (888) 415-4305 for domestic callers and (646) 960-0336 for international callers. The access code is 5858366. 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 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 proliferative vitreoretinopathy and retinitis pigmentosa.

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 Aldeyra's future expectations, plans, and prospects, including without limitation statements regarding: the goals, opportunity, including market size, and potential for ADX-2191 and anticipated clinical developments or regulatory milestones for ADX-2191. 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," "on schedule," "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 may 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.

[1]FASEB J. 34(8): 10146-10167, 2020.

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