UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): October 6, 2022

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 October 6, 2022, Aldeyra Therapeutics, Inc. ("Aldeyra" or the "Company") issued a press release (the "Press Release") announcing top-line results from Part 1 of the Phase 3 GUARD Trial of ADX-2191 (methotrexate injection, United States Pharmacopeia) for intravitreal administration, an investigational drug candidate, for the prevention of proliferative vitreoretinopathy, a rare sight-threatening retinal disease with no approved therapy. The Company is holding a conference call regarding this announcement on October 6, 2022. A copy of the supplemental presentation which will be referenced during the conference call 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 October 6, 2022.
99.2	Aldeyra Therapeutics, Inc. Press Release dated October 6, 2022.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

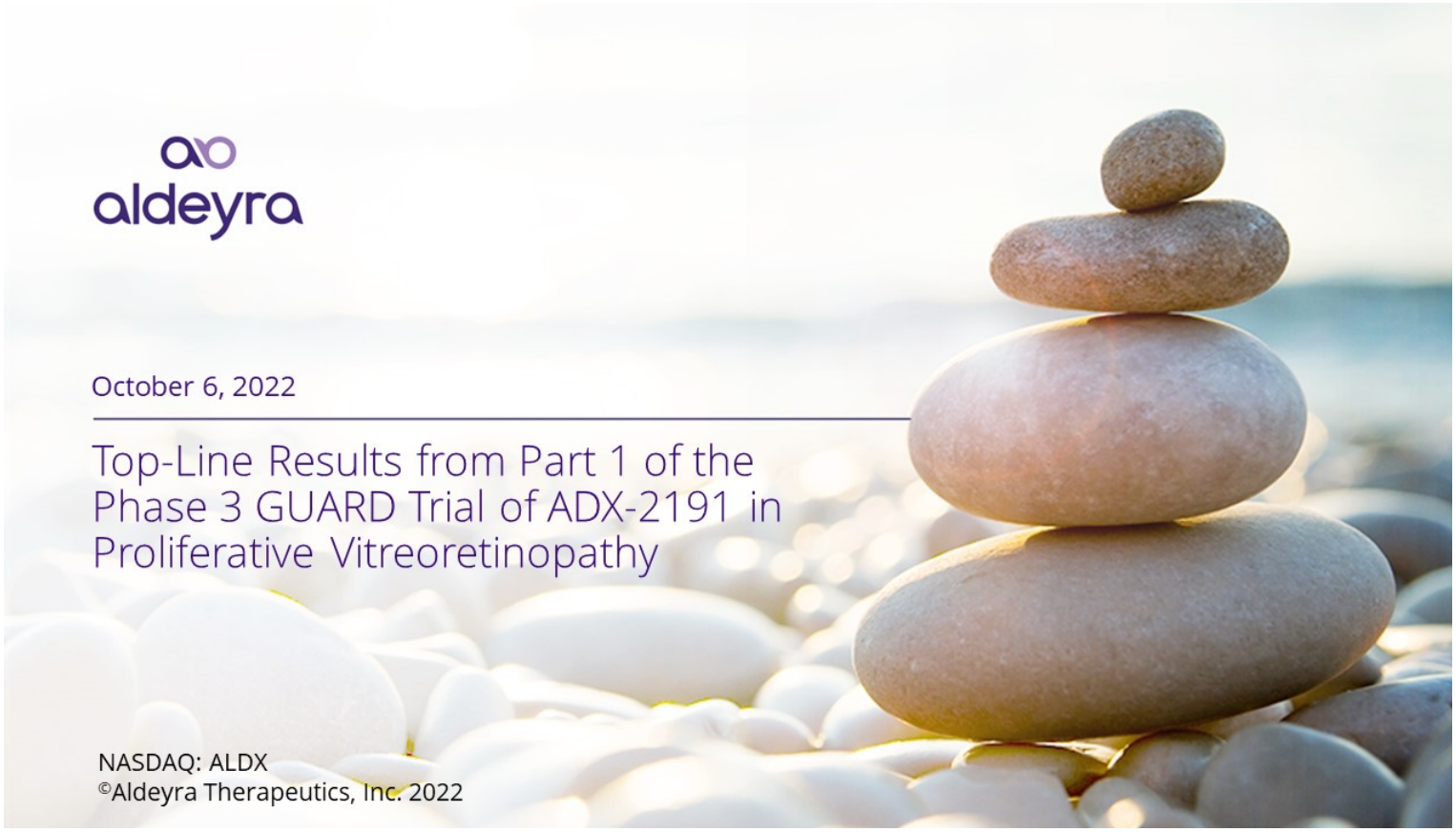
SIGNATURE

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: October 6, 2022



October 6, 2022

Top-Line Results from Part 1 of the Phase 3 GUARD Trial of ADX-2191 in Proliferative Vitreoretinopathy

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; statements regarding Aldeyra's future expectations, plans, prospects, including without limitation statements regarding: the potential regulatory approval of ADX-2191 and Aldeyra's goals as to timing; the potential profile and benefit of ADX-2191; and other statements regarding the goals, opportunity and potential for ADX-2191, anticipated clinical or regulatory milestones for ADX-2191, including expectations regarding timing and results of meetings with the FDA, including scheduled Type C and pre-NDA meetings, and submissions to the FDA; research, development, and regulatory plans or expectations; and 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," "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 of and clinical and regulatory plans or expectations for Aldeyra's investigational new drugs (including ADX-2191); 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 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; 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, 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, enrollment, completion, or reporting of clinical trials.

In addition to the risks described above and in Aldeyra's other filings with the SEC, other unknown or unpredictable factors also could affect Aldeyra's results. No forward-looking statements can be guaranteed, and actual results may differ materially from such statements. The information in this presentation is provided only **as of October 6, 2022**, and Aldeyra undertakes no obligation to update any forward-looking statements contained in this presentation on account of new information, future events, or otherwise, except as required by law.

The Phase 3 GUARD Trial of ADX-2191 in Proliferative Vitreoretinopathy Met the Primary Endpoint

- The primary endpoint of reduction of retinal detachment over 6 months in ADX-2191-treated patients vs. historical control* was achieved (P=0.024).
- Numerical superiority of ADX-2191 over routine surgical care was demonstrated for multiple secondary and exploratory endpoints, none of which were statistically powered, which in aggregate reached statistical significance (P=0.047).
- ADX-2191 was well tolerated with no observed safety concerns. Numerical superiority of ADX-2191 over routine surgical care was demonstrated for multiple safety endpoints, which in aggregate reached statistical significance (P=0.0002).

*Ophthalmology 124(6):757-767, 2017; Archives of Ophthalmology 25(9):1161-7, 2007.
ADX-2191 (methotrexate injection, USP) for intravitreal administration is an investigational drug candidate.
USP = United States Pharmacopeia

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 primary vitreoretinal lymphoma 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, primary vitreoretinal lymphoma, and retinitis pigmentosa.

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

ADX-2191 Represents a Novel Potential Therapeutic Option For the Prevention of Proliferative Vitreoretinopathy

PROLIFERATIVE VITREORETINOPATHY (PVR)

PVR is a rare disease, with ~4,000 patients per year in the U.S.

Left untreated, retinal detachment due to PVR **can progress to permanent blindness.**

There is currently **no FDA- or EMA-approved therapy**.

Repeat surgery, which can lead to vision loss, is currently one of the main courses of action.

ADX-2191

ADX-2191 was granted **U.S. FDA Orphan Drug Designation and U.S. FDA Fast Track Designation** for the prevention of PVR, and **EU Orphan Medicinal Product Designation** for the treatment of retinal detachment.

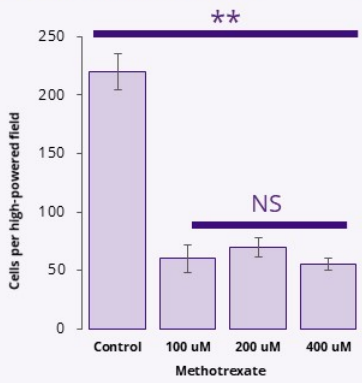
Tolerability and reattachment success demonstrated in Phase 1b open-label investigator sponsored clinical trial.

Published clinical data support the use of methotrexate for the prevention of recurrent retinal detachment due to PVR.

Source: Aldeyra internal estimates. Data on file. **PVR** = proliferative vitreoretinopathy.
ADX-2191 (methotrexate injection, USP) for intravitreal administration is an investigational drug candidate.

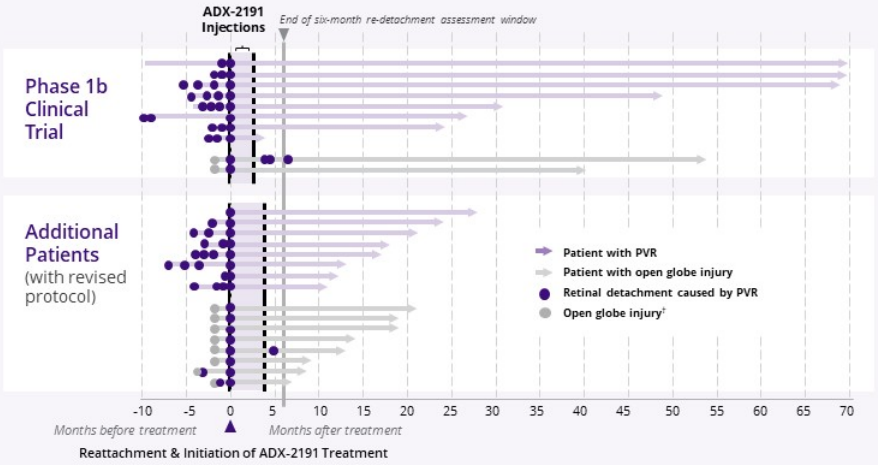
Preclinical and Clinical Results Support the Anti-Proliferative Activity of Methotrexate for the Prevention of Proliferative Vitreoretinopathy

Preclinical reduction in cellular proliferation



Clinical reduction in retinal detachment

Retinal Detachments Over Time by Patient



Sources: ADX-2191 PVR Phase 1b investigator sponsored clinical trial (n=10) results and additional in-practice use (n=16); Invest Ophthalmol Vis. Sci. 2017; 58:3940–3949. †Timing of open globe injury as shown is estimated. There is no assurance that prior results, such as signals of safety, activity or durability of effect, observed from this open label investigator sponsored trial will be replicated in more rigorous clinical trials involving ADX-2191. ****** = $p \leq 0.01$. **NS** = not significant, **PVR** = proliferative vitreoretinopathy.

The Activity of Methotrexate for the Prevention of Proliferative Vitreoretinopathy is Supported by Peer-Reviewed Publications

RETINAL CASES & BRIEF REPORTS – JANUARY 2022

Rescue Intravitreal Methotrexate Treatment Following Early Recognition of Proliferative Vitreoretinopathy

Alabi R, et al

AMERICAN SOCIETY OF RETINAL SPECIALISTS 2022 MEETING

Management of Proliferative Vitreoretinopathy with Intravitreal Methotrexate using a Treat-and-Extend Protocol

Walter S, et al

AMERICAN SOCIETY OF RETINAL SPECIALISTS 2022 MEETING

Intravitreal methotrexate reduces reoperation rate and improves vision after vitrectomy for retinal detachment, trauma, and proliferative diabetic retinopathy

Franklin A, et al

GRAEFE'S ARCHIVE FOR CLINICAL AND EXPERIMENTAL OPHTHALMOLOGY, OCTOBER 2021

Adjunctive serial post-operative intravitreal methotrexate injections in the management of advanced proliferative vitreoretinopathy

Roca J, et al

ARVO ANNUAL MEETING ABSTRACT – JUNE 2020

Post-operative Intravitreal Methotrexate Injections after Recurrent Retinal Detachment Repair Can Reduce the Risk and Progression of Proliferative Vitreoretinopathy

Wa C, et al

ADX-2191: Design of Part 1 of the Adaptive Phase 3 GUARD Trial in Proliferative Vitreoretinopathy

Primary Objective
Evaluate efficacy of intravitreal ADX-2191 injections for prevention of PVR-associated retinal detachment to estimate statistical power for Part 2 of GUARD

Design
Multi-center Phase 3 clinical trial of ADX-2191 vs. historical control* and routine surgical care

Inclusion Highlights
- Recurrent retinal detachment due to PVR, or
- Retinal detachment associated with open-globe injury

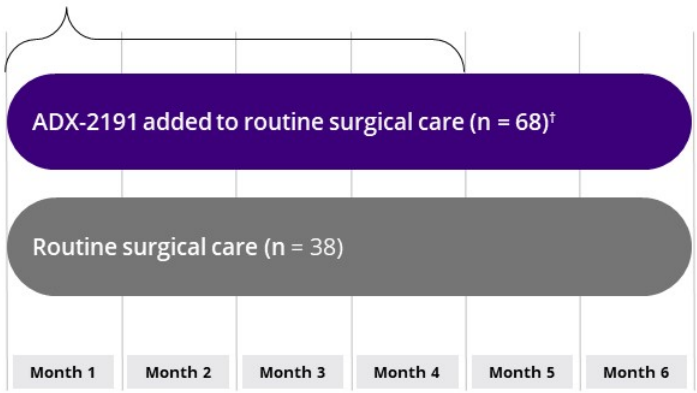
Dosing Regimen
At surgery, weekly (x8), and then every other week (x4) intravitreal injections

Primary Endpoint
Retinal re-detachments due to PVR requiring re-operation within 6 months vs. historical control

Secondary Endpoints
- Retinal re-detachments due to PVR vs. routine surgical care
- Visual acuity vs. routine surgical care

Exploratory Endpoints
Macular thickness, epiretinal membrane formation, hypotony vs. routine surgical care

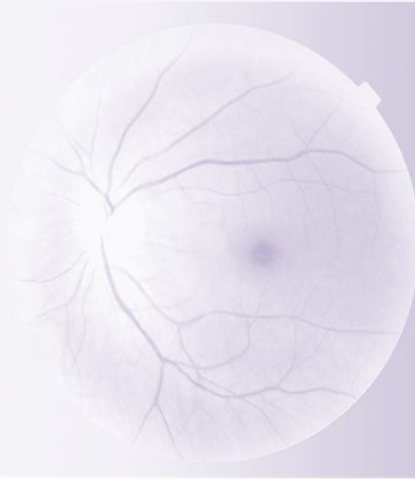
ADAPTIVE PHASE 3 PVR CLINICAL TRIAL DESIGN: PART 1



†Includes 41 subjects enrolled under the open-label portion of the protocol. *Ophthalmology 124(6):757-767, 2017; Archives of Ophthalmology 25(9):1161-7, 2007.
PVR = proliferative vitreoretinopathy. **Hypotony** = intraocular pressure less than 5 mm Hg.
ADX-2191 (methotrexate injection, USP) for intravitreal administration is an investigational drug candidate.

The Primary Endpoint of Reduction of Retinal Detachment vs. Historical Control 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	



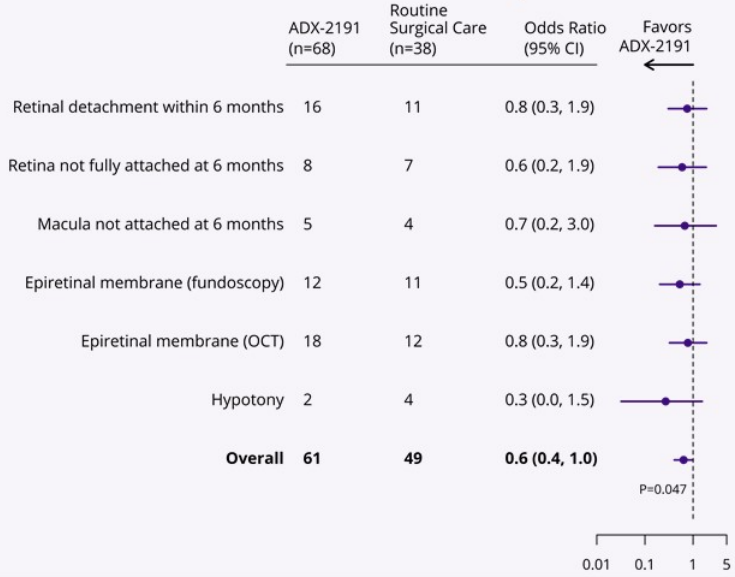
†Ophthalmology 124(6):757-767, 2017; Archives of Ophthalmology 25(9):1161-7, 2007. *Fisher exact test. **CI** = confidence interval.
ADX-2191 (methotrexate injection, USP) for intravitreal administration is an investigational drug candidate.

The Majority of Secondary and Exploratory Endpoints, While Not Statistically Powered, Were Numerically in Favor of ADX-2191

Continuous Endpoints

	ADX-2191 (n=68)	Routine Surgical Care (n=38)
Letters of visual acuity (SD)	32.9 (19.7)	36.5 (25.0)
Central macular subfield thickness (μM, SD)	382 (182)	484 (233)

Dichotomous Endpoints



SD = standard deviation. **CI** = confidence interval. **Hypotony** = intraocular pressure less than 5 mm Hg. **OCT** = optical coherence tomography. P value derived from random effect meta-analysis. ADX-2191 (methotrexate injection, USP) for intravitreal administration is an investigational drug candidate.

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

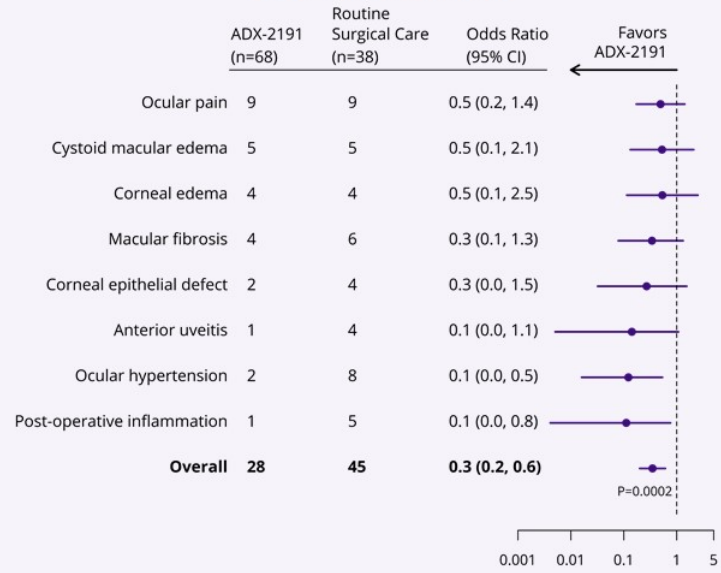
- The most common adverse event associated with ADX-2191 administration was punctate keratitis (n=11, 16%), a well-known side effect of intravitreal methotrexate. Nine events were mild; two were moderate.
- The incidence of punctate keratitis was substantially less than that previously reported (58%)[†] for intravitreal methotrexate.
- ADX-2191 treatment was discontinued in one (1%) patient, due to scheduling difficulty.

aldeyra

[†]Annals of Hematology, 95(4), 593–601, 2016.
ADX-2191 (methotrexate injection, USP) for intravitreal administration is an investigational drug candidate.

ADX-2191 Was Numerically Favorable to Routine Surgical Care for Additional Key Safety Endpoints

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



CI = confidence interval. P value derived from random effect meta-analysis.
ADX-2191 (methotrexate injection, USP) for intravitreal administration is an investigational drug candidate.

Upcoming Planned Clinical Milestones for ADX-2191*

Primary Vitreoretinal Lymphoma

Pre-NDA meeting scheduled for Q4 2022

Proliferative Vitreoretinopathy

Planned Type C meeting with FDA in H1 2023 to discuss completion of clinical development

Retinitis Pigmentosa

Phase 2 clinical trial results expected in H1 2023

*The timing of ongoing clinical trials depends, in part, on the availability of clinical research facilities and staffing, and the ability to recruit patients.

Aldeyra Therapeutics Achieves Primary Endpoint in Part 1 of Phase 3 GUARD Trial of ADX-2191 in Proliferative Vitreoretinopathy

- ***ADX-2191 Statistically Superior to Historical Control for Primary Endpoint of Prevention of Retinal Detachment (P=0.024)***
- ***Numerical Superiority of ADX-2191 over Routine Surgical Care Achieved for Majority of Secondary, Exploratory, and Safety Endpoints***
- ***ADX-2191 Observed to be Well Tolerated with No Safety Concerns Noted***
- ***Company Plans to Discuss Completion of Clinical Development in Proliferative Vitreoretinopathy with the U.S. Food and Drug Administration in the First Half of 2023***
- ***Company to Host Conference Call at 8:00 a.m. ET Today***

LEXINGTON, Mass.--(BUSINESS WIRE)--October 6, 2022--Aldeyra Therapeutics, Inc. (Nasdaq: ALDX) (Aldeyra or the Company) today announced the achievement of the primary endpoint in Part 1 of the Phase 3 GUARD Trial of ADX-2191 (methotrexate injection, USP[1]) for intravitreal administration, an investigational drug candidate, for the prevention of proliferative vitreoretinopathy (PVR), a rare sight-threatening retinal disease with no approved therapy. ADX-2191 was statistically superior to historical control[2] for the prevention of retinal detachment due to PVR over six months (P=0.024).

“Proliferative vitreoretinopathy represents a major unmet medical need and is particularly difficult to treat, highlighting the need for an effective therapy,” stated Marco Zarbin, M.D., Ph.D., Professor and Chair of the Institute of Ophthalmology and Visual Science, Rutgers New Jersey Medical School. “The recent reports describing the activity of methotrexate in preventing PVR, in conjunction with the results of the GUARD Trial, offer hope to many patients and physicians that today have few options for treatment.”

Part 1 of the GUARD Trial was designed to assess the preliminary activity of ADX-2191, a novel vitreous-compatible formulation of methotrexate, versus historical control and routine surgical care without therapy in patients with PVR. Sixty-eight patients received ADX-2191, and 38 patients received routine surgical care. Relative to historical control, statistically significant reduction (P=0.024) in retinal detachment over six months was observed following serial intravitreal injection of ADX-2191. Although not statistically powered for secondary or exploratory endpoints, the results of the GUARD Trial demonstrated numerical superiority of ADX-2191 over routine surgical care in reducing the dichotomous endpoints of retinal detachment rate over six months, hypotony (low intraocular pressure), complete retinal attachment by six months, macular attachment by six months, and epiretinal membrane formation (overall P=0.047). Visual acuity was similar between ADX-2191 treatment and routine surgical care groups. Central macular thickness was numerically lower in ADX-2191-treated patients.

No safety signals were observed in the trial, and ADX-2191 was well tolerated; there were no observed treatment-emergent serious adverse events. The most common adverse event associated with ADX-2191 treatment was punctate keratitis, a well-known side effect of intravitreal methotrexate, that was most commonly mild in severity. Across all other treatment-emergent adverse events occurring in at least 10% of patients in either treatment arm, relative to patients treated with routine surgical care, ADX-2191-treated patients had numerically fewer side effects, including pain, cystoid macular edema, corneal edema, macular fibrosis, corneal epithelial defects, anterior uveitis, ocular hypertension, and post-operative inflammation (overall P=0.0002). In the ADX-2191 group, there was one discontinuation, which was due to scheduling difficulties.

Aldeyra intends to discuss completion of clinical development of ADX-2191 for the prevention of PVR in a Type C meeting with the U.S. Food and Drug Administration (FDA) in the first half of 2023. ADX-2191 has received FDA Orphan Drug Designation and FDA Fast Track Designation for the prevention of PVR, and EU Orphan Medicinal Product Designation for the treatment of retinal detachment. ADX-2191 has also received FDA Orphan Drug Designation for the treatment of primary vitreoretinal lymphoma and retinitis pigmentosa.

“The ADX-2191 platform for the prevention and treatment of rare retinal disease continues to advance towards commercialization, and is a critical late-stage pipeline program with the potential to address a number of diseases with no FDA-approved therapies,” stated Todd C. Brady, M.D., Ph.D., President and Chief Executive Officer of Aldeyra.

Conference Call Information

Aldeyra will host a conference call to discuss this announcement at 8:00 a.m. ET today, October 6, 2022. The dial-in numbers are (844) 200-6205 for domestic callers and (646) 904-5544 for international callers. The access code is 005042. A live webcast of the conference call will also be available on the "Investors & Media" section of the Aldeyra website at https://ir.aldeyra.com. Presentation slides, which contain material information and should be reviewed in conjunction with this press release, will be available on the investor relations page prior to the start of the conference call and webcast.

After the live webcast, the event will remain archived on the Aldeyra website for 90 days.

About ADX-2191

ADX-2191 (methotrexate injection, USP) is a sterile, non-compounded intravitreal formulation of methotrexate for the potential prevention or treatment of specific rare retinal diseases, including primary vitreoretinal lymphoma, proliferative vitreoretinopathy, and retinitis pigmentosa. The ADX-2191 intravitreal formulation is preservative-free, designed to be vitreous-compatible, and optimized for excipient composition, viscosity, density, tonicity, pH, concentration, and volume of administration. ADX-2191 has received FDA Orphan Drug Designation for the prevention of proliferative vitreoretinopathy, and the treatment of primary vitreoretinal lymphoma and retinitis pigmentosa.

About Proliferative Vitreoretinopathy

Proliferative vitreoretinopathy (PVR) is a rare inflammatory fibroproliferative disorder that leads to severe retinal scarring and blindness, and is the leading cause of failure of retinal reattachment surgery. Left untreated, retinal detachment due to PVR can progress to permanent blindness. PVR affects approximately 4,000 patients per year in the U.S. There is currently no approved therapy for the treatment of PVR.

About Aldeyra

Aldeyra is a clinical-stage biotechnology company developing innovative therapies designed to treat immune-mediated diseases. Our approach is to discover 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. Two of our lead product candidates, reproxalap and ADX-629, target pre-cytokine, systems-based mediators of inflammation known as RASP (reactive aldehyde species). Reproxalap is in late-stage clinical trials in patients with dry eye disease and allergic conjunctivitis. ADX-629, an orally administered RASP modulator, is in Phase 2 clinical testing for the treatment of systemic immune-mediated diseases. Our pipeline also includes ADX-2191 (methotrexate injection) for intravitreal administration, in development for the prevention of proliferative vitreoretinopathy and the treatment of retinitis pigmentosa and primary vitreoretinal lymphoma. 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 Aldeyra's future expectations, plans, and prospects, including without limitation statements regarding: the potential regulatory approval of ADX-2191 and Aldeyra's goals as to timing; the potential profile and benefit of ADX-2191; and other statements regarding the goals, opportunity and potential for ADX-2191, anticipated clinical or regulatory milestones for ADX-2191, including expectations regarding timing and results of meetings with the FDA, including scheduled Type C and pre-NDA meetings, and submissions to the FDA. 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," "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, 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; updated or refined data based on Aldeyra's continuing or post-hoc review and quality control analysis of clinical data, Aldeyra's ability to design clinical trials with protocols, data analysis methodologies, 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 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; 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) 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 revenue, the sufficiency or use of Aldeyra's cash resources and needs for additional financing; 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; 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, 2021, and Aldeyra's Quarterly Report on Form 10-Q for the quarter ended June 30, 2022, 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 set forth in those sections of Aldeyra's Quarterly Report on Form 10-Q for the quarter ended September 30, 2022, expected to be filed with the SEC in the fourth quarter of 2022.

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] United States Pharmacopeia
[2] Ophthalmology 124(6):757-767, 2017; Archives of Ophthalmology 25(9):1161-7, 2007.

Contacts

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