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): November 13, 2025

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.

On November 13, 2025, Aldeyra Therapeutics, Inc. ("Aldeyra") intends to make a slide presentation at its previously announced 2025 Research & Development Webcast (the "2025 Research and Development Webcast"). A copy of Aldeyra's slide presentation is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference herein.

The furnishing of the attached slide presentation is not an admission as to the materiality of any information contained therein. The information contained in the slide presentation is summary information that is intended to be considered in the context of more complete information included in Aldeyra's filings with the Securities and Exchange Commission ("SEC") and other public announcements that Aldeyra has made and may make from time to time by press release or otherwise. Aldeyra undertakes no duty or obligation to update or revise the information contained in this report, although it may do so from time to time as its management believes is appropriate.

Various statements to be made during the conference call are "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, and potential for Aldeyra's RASP modulator product candidates and pipeline; the outcome and timing of any clinical trials of Aldeyra's RASP modulator product candidates; anticipated timing of regulatory filings; and the outcome of the New Drug Application of reproxalap for the treatment of dry eye disease. 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, issuing a complete response letter, or requiring additional clinical trials or data prior to review or approval of such filings or in connection with resubmissions 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; 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, 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, 2024, and Aldeyra's Quarterly Report on Form 10-Q for the quarter ended September 30, 2025, which are on file with the Securities and Exchange Commission (SEC) and available on the SEC website at https://www.sec.gov/.

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 conveyed on the conference call is provided only as of the date of the call, and Aldeyra undertakes no obligation to update any forward-looking statements presented on the conference call on account of new information, future events, or otherwise, except as required by law.

This information in this Item 7.01 of this Current Report on Form 8-K shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that Section, or incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in any such filing.

Item 8.01 Other Events.

On November 13, 2025, Aldeyra issued a press release regarding the 2025 Research & Development Webcast (the "Press Release") including the expansion of the RASP platform to include central nervous system diseases, and manufacturing updates on reproxalap, a first-in-class investigational new drug candidate for the treatment of the signs and symptoms of dry eye disease. 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	Slide Presentation of Aldeyra Therapeutics, Inc. dated November 13, 2025.
99.2	Press Release of Aldeyra Therapeutics, Inc. dated November 13, 2025.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

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

ALDEYRA THERAPEUTICS, INC.

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

Dated: November 13, 2025

Exhibit 99.1

CORPORATE

2025 Research & Development Webcast

November 13, 2025

Nasdaq: ALDX

Disclaimers and Forward-Looking Statements

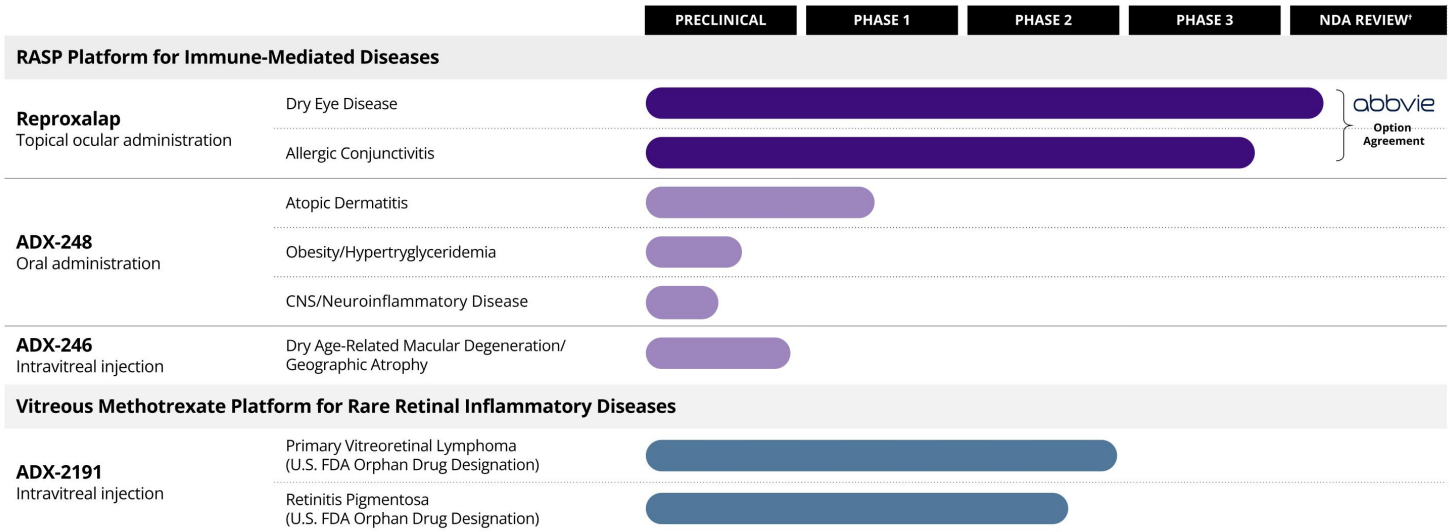
This presentation contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and Section 21E of the Securities Exchange Act of 1934, as amended, including statements regarding Aldeyra's possible or assumed future results of operations, expenses and financing needs, business strategies and plans, statements regarding Aldeyra's future expectations, plans and prospects, including, without limitation, statements regarding: Aldeyra' cash runway; the outcome and expected timing and results of ongoing or planned clinical trials; FDA agreement with the clinical development and regulatory plan for reproxalap; the outcome and expected timing and results of the clinical development and regulatory plan; the outcome and timing of the FDA's review and/or approval of the NDA resubmission for reproxalap and the adequacy of the data included in the NDA resubmission or the supplemental responses to the FDA; the potential for and timing of regulatory approval and commencement of commercialization of reproxalap; Aldeyra's expectations regarding the exercise of the AbbVie option; 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; the outcome and timing of any clinical trials with ADX-2191; the outcome and timing of the FDA's acceptance, review, or approval of a potential NDA resubmission for ADX-2191 and the adequacy of the data expected to be included in such potential resubmitted NDA; the goals, opportunity and potential for reproxalap and its other product candidates; anticipated clinical or regulatory milestones for ADX-2191, ADX-248, and ADX-246, including expectations regarding the results of scheduled FDA meetings and discussions, clinical trial initiations and completions, and the timing and nature of NDA or other submissions to the FDA; Aldeyra's business, research, development and regulatory plans or expectations; political, economic, legal, social and health risks that may affect Aldeyra's business or the global economy; the structure, timing and success of Aldeyra's planned or pending clinical trials; and 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-2191, ADX-248, and ADX-246), 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 (SEC). 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, regulatory developments in the United States and other countries, 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 November 13, 2025, 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.

aldeyra

Aldeyra Is a Well-Capitalized Biotechnology Company with a Broad Immunology Pipeline



As of 9/30/2025, cash, cash equivalents, and marketable securities were $75.3M, which Aldeyra believes will be sufficient to fund the Company into the second half of 2027.[‡]

[1]Regulatory review timelines are flexible and subject to change based on the regulator's workload and other potential review issues. [‡]Company guidance as of November 6, 2025; includes continued early and late-stage development of our product candidates in immune-mediated diseases. Guidance has not been updated or confirmed since November 6, 2025 and does not include any potential licensing or product revenue associated with reproxalap. CNS=central nervous system, NDA=New Drug Application.

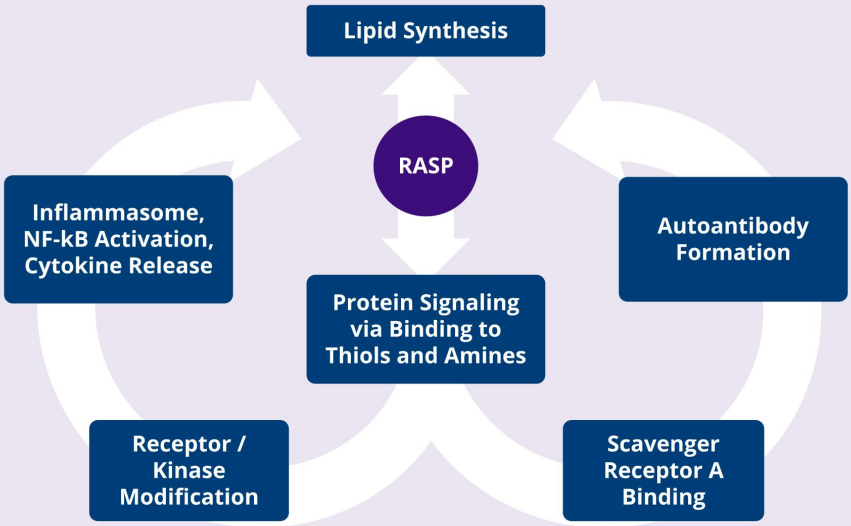
aldeyra

aldeyra

Modulating RASP – A First-in-Class, Systems-Based Therapeutic Approach

RASP Represent a Novel, Potentially Broadly Applicable Pharmaceutical Target that Modulates Many Proteins at Once

- RASP are formed by oxidation of alcohols and other metabolic processes.
- RASP bind thiol (Michael addition) and amine (Schiff base) residues on proteins, leading to conformational and functional changes in certain proteins that **initiate pro-inflammatory signaling cascades**.
- RASP are also precursors of lipids and **may contribute to obesity and dyslipidemia**.



RASP=reactive aldehyde species.

aldeyra

RASP Modulation Represents a Novel Pharmacology

Traditional pharmacology targets specific proteins and is generally limited to two actions: on or off.

Activating or inhibiting specific proteins on a sustained basis, which rarely occurs in nature, may lead to toxicity and could limit activity.

vs.

RASP modulation may allow for control of protein *systems*, without turning any single protein on or off.

Systems-based pharmacology could potentially lead to broader-based activity with less toxicity associated with activation or inhibition of specific proteins.

RASP=reactive aldehyde species.

aldeyra

Results from a Phase 2 Proof-of-Concept Trial of ADX-629, a Signal-Finding RASP Modulator, in Alcohol-Associated Hepatitis

Development of ADX-629, a Signal-Finding, First-Generation RASP Modulator, Concluded with Positive Results in Alcohol-Associated Hepatitis

ADX-629 is a first-generation RASP modulator that was tested in proof-of-concept Phase 2 clinical trials across a number of immune-mediated diseases, including:

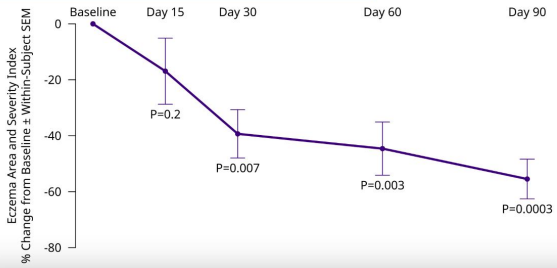
- Atopic Dermatitis
- Psoriasis
- Chronic Cough
- Alcohol-Associated Hepatitis

Across all trials in aggregate, ADX-629 was deemed to be safe and well tolerated, and demonstrated acute and chronic activity in reducing signs and symptoms of inflammation.

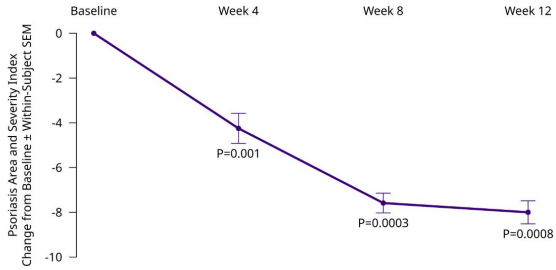
ADX-629 is an investigational drug candidate. RASP=reactive aldehyde species.

ADX-629 Consistently Demonstrated Activity in Phase 2 Clinical Trials

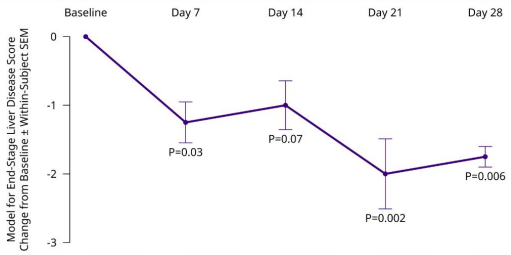
Autoimmune Disease: Atopic Dermatitis



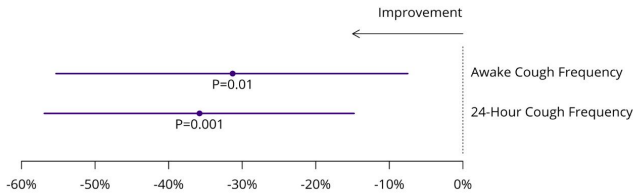
Autoimmune Disease: Psoriasis



Hepatic Inflammation: Alcohol-Associated Hepatitis



Idiopathic Inflammation: Chronic Cough

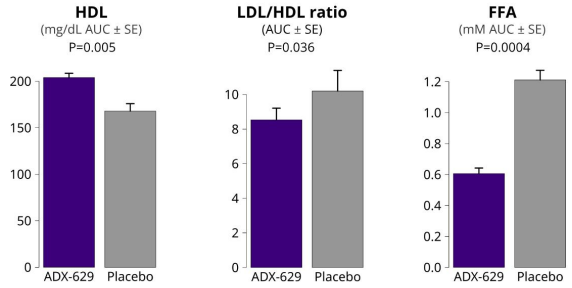


ADX-629 Placebo-Adjusted Reduction from Baseline ± 95% CI

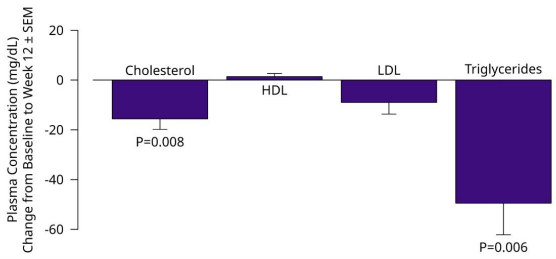
ADX-629 is an investigational drug candidate. RASP=reactive aldehyde species, SEM=standard error of the mean.

Statistically Significant Changes Observed in Lipid Profiles in Multiple Clinical Trials with ADX-629

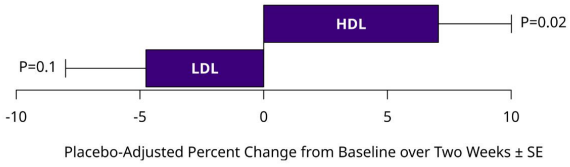
Phase 1 Clinical Trial



Phase 2 Psoriasis Clinical Trial

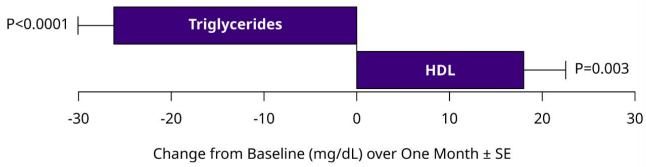


Phase 2 Chronic Cough Clinical Trial



Placebo-Adjusted Percent Change from Baseline over Two Weeks ± SE

Phase 2 Alcohol-Associated Hepatitis Clinical Trial

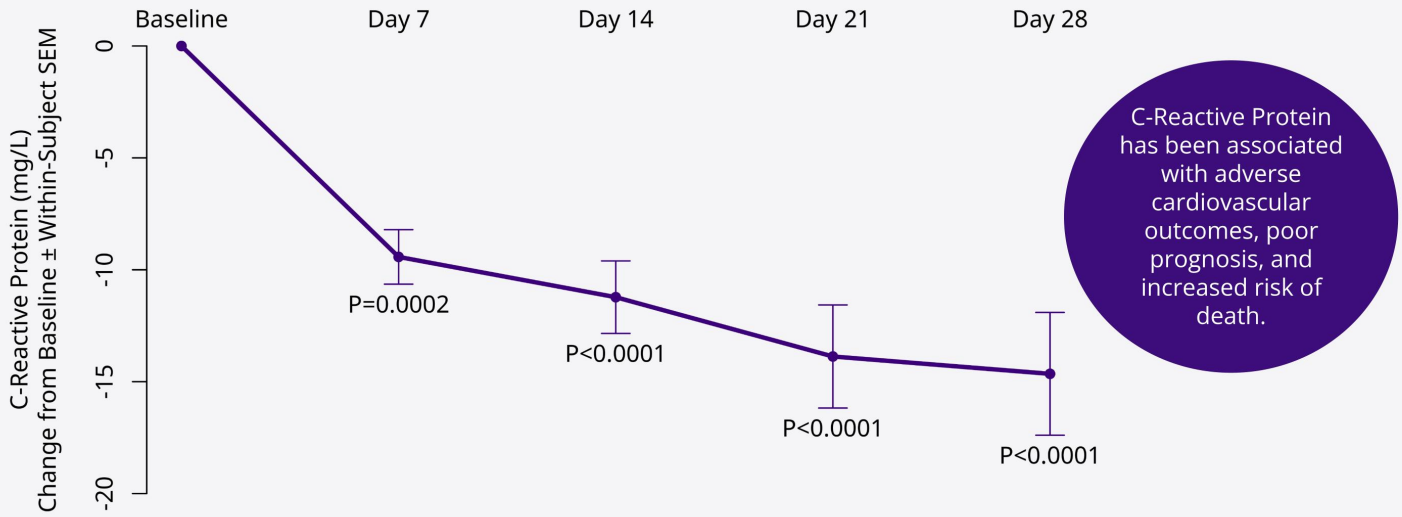


Change from Baseline (mg/dL) over One Month ± SE

ADX-629 is an investigational drug candidate. AUC=area under the curve, FFA=free fatty acids, HDL=high-density lipoprotein, LDL=low-density lipoprotein, mM=millimolar, SE=linear model standard error, RASP=reactive aldehyde species, SEM=standard error of the mean.

aldeyra

ADX-629 Reduced Levels of the Inflammation Marker C-Reactive Protein in Phase 2 Clinical Trial in Alcohol-Associated Hepatitis



ADX-629 is an investigational drug candidate. SEM=standard error of the mean.

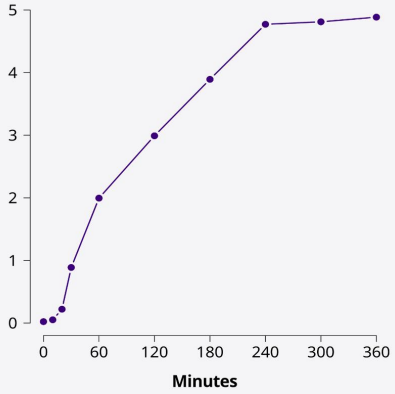
aldeyra

aldeyra

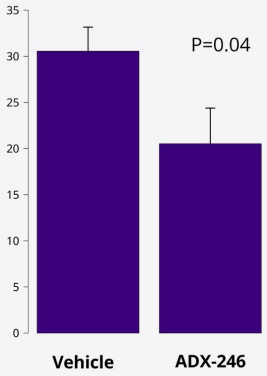
Activity of Next-Generation RASP Modulators in Preclinical Disease Models

By Binding the RASP Retinaldehyde, ADX-246 Potentially Represents a New Intravitreally Administered Therapy for the Treatment of Dry Age-Related Macular Degeneration (Dry AMD)

ADX-246 Binding to RASP Retinaldehyde (absorbance units)



Reduction in Toxic Retinaldehyde Metabolite A2E (retinal picomoles + SEM) in *Abcr* Knockout Mouse (Model of Dry AMD)



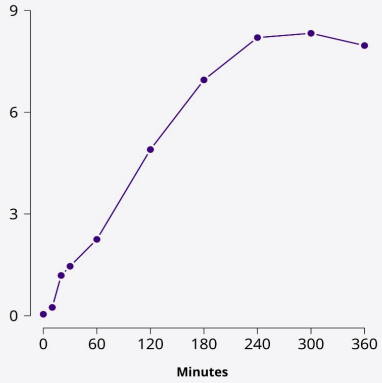
A2E is related to impairment in low-light vision,† one of the first symptoms of dry AMD.

†J Biol Chem, 297(3):101074, 2021. ADX-246 is an investigational drug candidate. A2E=bis-retinoid N-retinyl-N-retinylidene ethanolamine, RASP=reactive aldehyde species, SEM=standard error of the mean.

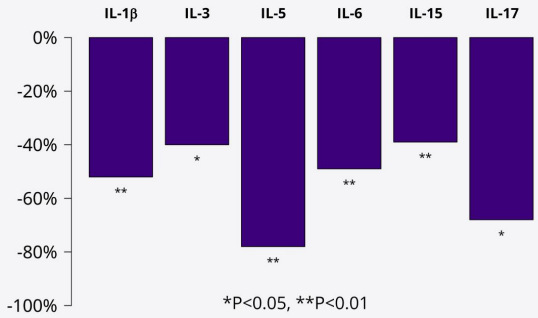
aldeyra

By Binding HNE, a Pro-Inflammatory RASP, ADX-248 Potentially Represents a New Orally Administered Therapy for the Treatment of Immune-Mediated Disease

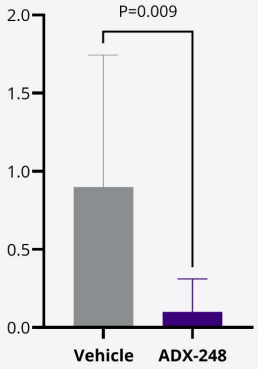
ADX-248 Binding to Pro-Inflammatory RASP HNE (absorbance units)



Cytokine Reduction vs. Vehicle Control in LPS-Challenged Mice



Epidermal Erosion Score (0-5) + SEM in Oxazolone Mouse Model of Atopic Dermatitis



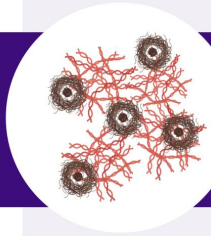
ADX-248 is an investigational drug candidate. HNE=4-hydroxynonenal, LPS=lipopolysaccharide, RASP=reactive aldehyde species, SEM=standard error of the mean.

aldeyra

RASP Are Associated with Human Neuroinflammatory Diseases that Affect the Central Nervous System

Parkinson's Disease

- Environmental toxins that promote Parkinson's disease also increase RASP.
- The RASP DOPAL cross-links α-synuclein and leads to dopaminergic neuron death.[1]



Amyotrophic Lateral Sclerosis (ALS)

- The RASP HNE is increased in the central nervous system of ALS patients.[2]
- Genetic variants associated with RASP clearance influence ALS disease progression risk.

Multiple Sclerosis

- The RASP acrolein is elevated in multiple sclerosis patients.[3]
- Acrolein inhibition reduced disease severity in a preclinical model of multiple sclerosis.[4]

[1]Plotegher, N. et al. Sci Rep 7, 40699 (2017). [2]Smith, R. G. et al. Ann Neurol 44, 696–699 (1998). [3]Tully, M. et al. Front. Neurol. 9, (2018). [4]Leung, G. et al. Neuroscience 173, 150–155 (2011).
DOPAL=3,4-dihydroxyphenylacetaldehyde, HNE=4-hydroxynonenal, RASP=reactive aldehyde species.

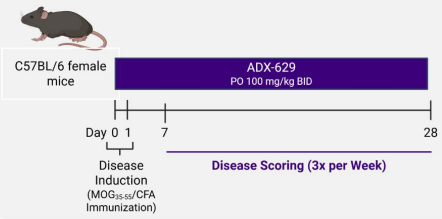
aldeyra

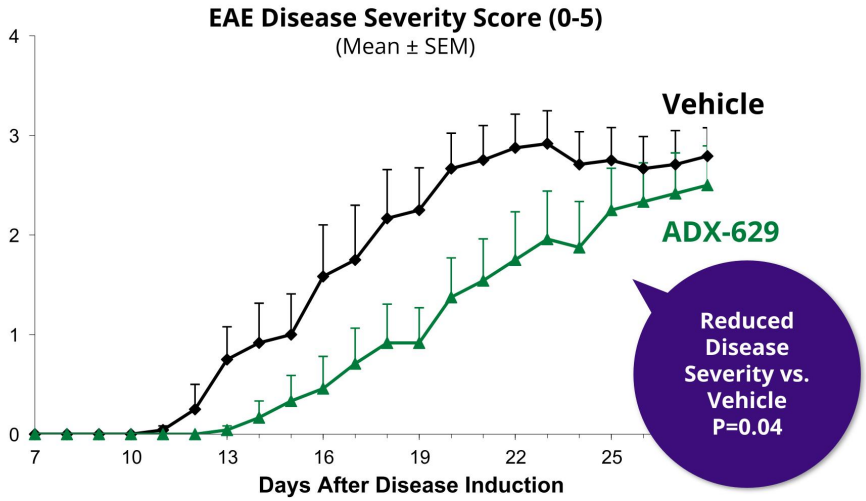
Legacy RASP Modulator ADX-629 Significantly Reduced Disease Severity in a Mouse Model of Multiple Sclerosis

EAE Disease Model

- Inducible mouse model of MS
- Characterized by increasing paralysis
- Widely accepted model of neuron demyelination

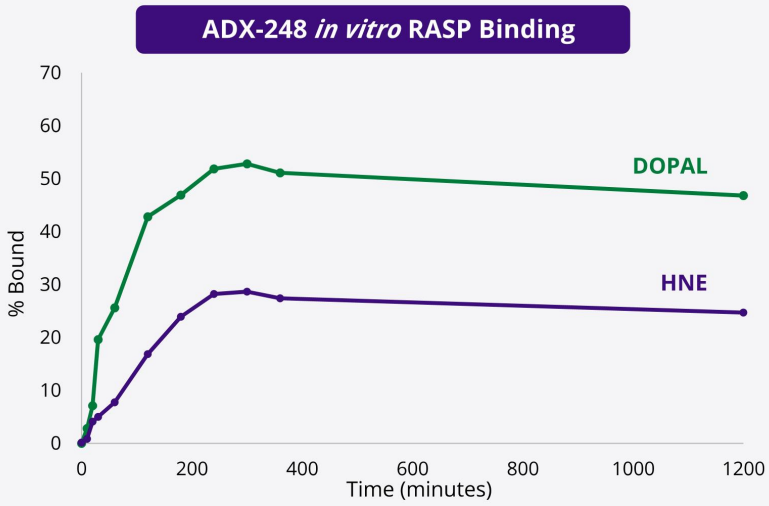
Study Design



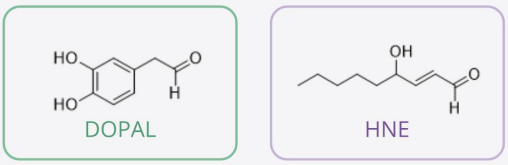


ADX-629 is an investigational drug candidate. EAE=experimental autoimmune encephalomyelitis, MS=multiple sclerosis, MOG_{35-55}=myelin oligodendrocyte glycoprotein peptide, CFA=Complete Freund's Adjuvant, BID=twice daily, SEM=standard error of mean, PO=oral administration.

ADX-248 Binds RASP Associated with CNS/Neuroinflammatory Diseases



ADX-248 binds DOPAL and HNE, neurotoxic RASP associated with neuroinflammatory diseases.



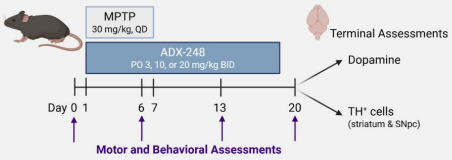
ADX-248 is an investigational drug candidate. DOPAL=3, 4-dihydroxyphenylacetaldehyde, HNE=4-hydroxynonenal, RASP=reactive aldehyde species, CNS=central nervous system.

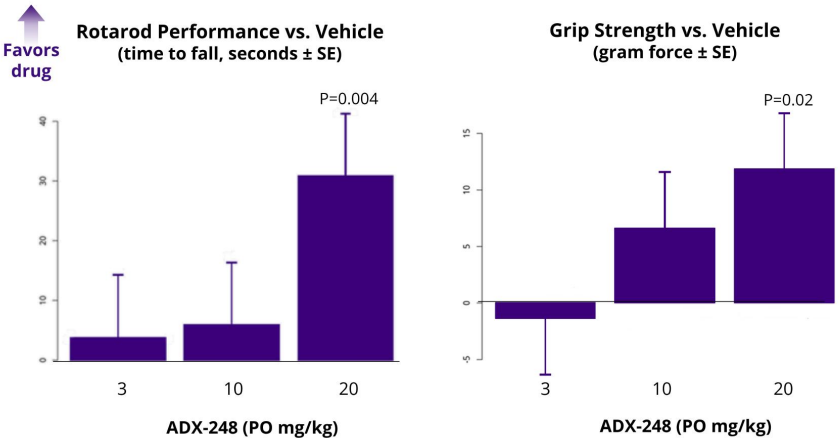
ADX-248 Significantly Improved Rotarod Performance and Grip Strength in the Mouse MPTP Parkinson's Disease Model

MPTP Parkinson's Model

- Dopaminergic neuron loss
- Parkinson's-like disease symptoms
- Widely accepted preclinical model

Study Design

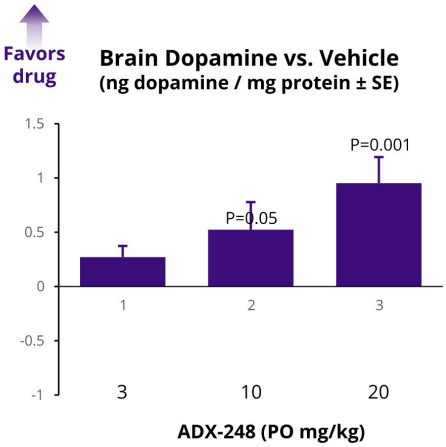


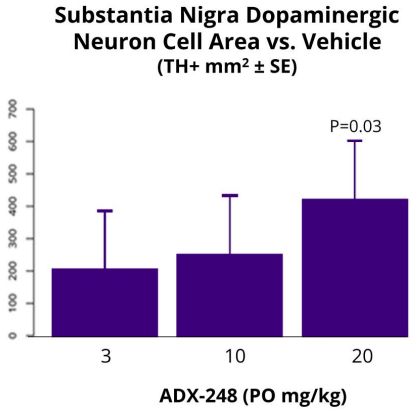


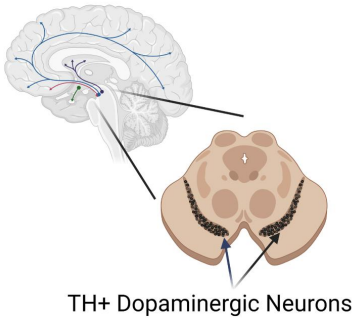
ADX-248 is an investigational drug candidate. MPTP=1-methyl-4-phenyl-1,2,3,6-tetrahydropyridine, TH+=tyrosine hydroxylase positive, QD=once daily, BID=twice daily, SE=mixed model for repeated measures standard error, PO=oral administration.

aldeyra

ADX-248 Significantly Increased Brain Dopamine and Dopaminergic Neuron Cell Area in the Mouse MPTP Parkinson's Disease Model







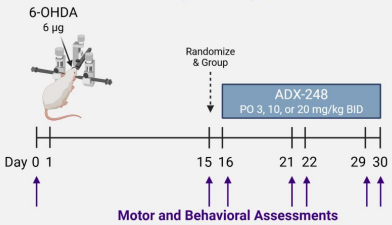
ADX-248 is an investigational drug candidate. MPTP=1-methyl-4-phenyl-1,2,3,6-tetrahydropyridine, TH+=tyrosine hydroxylase positive, ng=nanogram, SE= mixed model for repeated measures standard error, PO=oral administration.

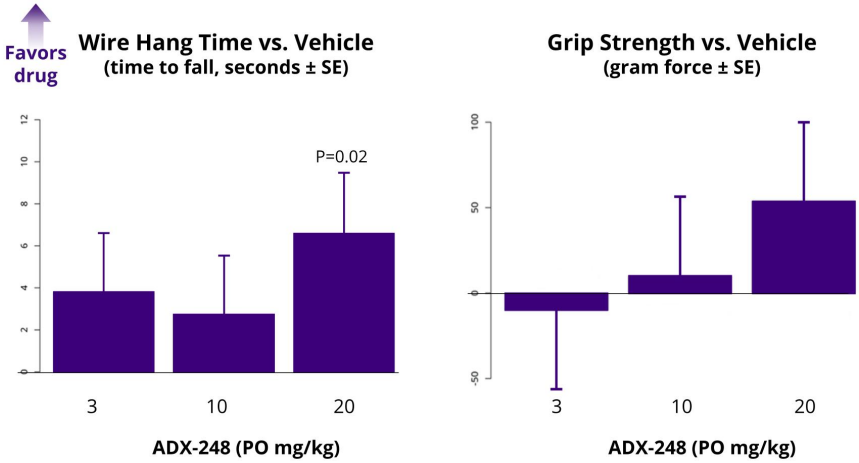
ADX-248 Significantly Improved Wire Hang Time in the Rat 6-OHDA Parkinson's Disease Model

6-OHDA Parkinson's Disease Model

- Unilateral brain damage
- Dopaminergic neuron loss in the injured hemisphere
- Widely accepted Parkinson's disease model

Study Design





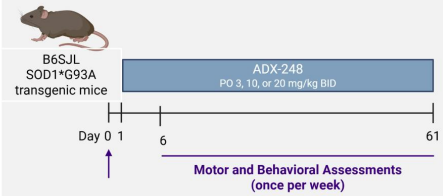
ADX-248 is an investigational drug candidate. 6-OHDA= 6-hydroxydopamine, BID=twice daily, SE= mixed model for repeated measures standard error, PO=oral administration.

ADX-248 Significantly Improved Grip Strength and Rotarod Performance in the Mouse SOD1-G93A Amyotrophic Lateral Sclerosis Disease Model

SOD1-G93A ALS Disease Model

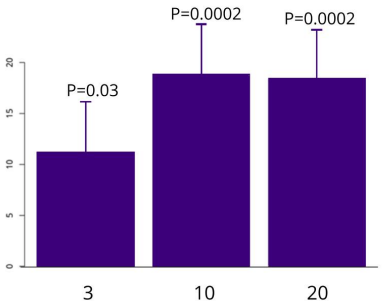
- Models familial ALS
- Translationally relevant disease pathology
- Widely accepted model

Study Design



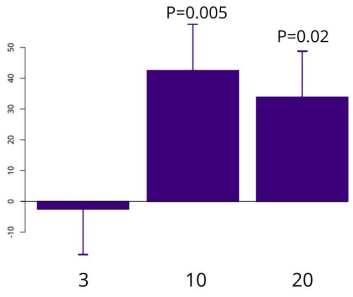
Favors drug

Grip Strength vs. Vehicle
(gram force ± SE)



ADX-248 (PO mg/kg)

Rotarod Performance vs. Vehicle
(time to fall, seconds ± SE)



ADX-248 (PO mg/kg)

ADX-248 is an investigational drug candidate. SOD1=superoxide dismutase 1, ALS=Amyotrophic lateral sclerosis, BID=twice daily, SE= mixed model for repeated measures standard error, PO=oral administration.

aldeyra

ADX-248, a Next-Generation RASP Modulator, Demonstrated Activity in Multiple Preclinical Neuroinflammatory Disease Models

ADX-248 Pharmacology

- Sequestered DOPAL and HNE, RASP associated with neuronal cell death
- Improved neuromotor function in Parkinson's and ALS disease models
- Increased brain dopamine levels and TH+ cell area in the mouse MPTP Parkinson's disease model

ADX-248 Exposure & Safety

- Mouse in vivo and cell line studies suggest achievable therapeutic brain levels in humans
- Favorable preclinical safety profile, with acceptable safety margins at potentially therapeutic human doses
- Phase 1 healthy subject dose escalation ongoing

Key Messages

1. Favorable preclinical data in Parkinson's, ALS, and MS disease models creates opportunities for **multiple neuroinflammatory disease development paths.**
2. Potential **Phase 2 trials** will be supported by the ongoing human Phase 1 clinical trial and preclinical safety studies.

ADX-248 is an investigational drug candidate. DOPAL=3,4-dihydroxyphenylacetaldehyde, HNE=4-hydroxynonenal, RASP=reactive aldehyde species, ALS=amyotrophic lateral sclerosis, MS=multiple sclerosis, TH+=tyrosine hydroxylase positive, MPTP=1-methyl-4-phenyl-1,2,3,6-tetrahydropyridine.

aldeyra

ADX-248 Preclinical Benefit Observed at Doses Predicted to be Safe and Achievable Based on Ongoing Phase 1 Clinical Trial

Preclinical Dose (PO mg/kg, BID)	Human Equivalent Dose (PO mg, QD)
3	15
10	**50**
20	**100**

↓

Neurologic improvements observed at 10 and 20 mg/kg in preclinical models

- ✓ 10x safety margin* expected for 100 mg human dose
- ✓ ADX-248 Phase 1 dose escalation in healthy subjects ongoing at doses in excess of 100 mg QD

Ongoing pivotal safety testing expected to support Phase 2 clinical trials in 2026

- 6-month rat toxicity; 9-month dog toxicity; embryo-fetal toxicity in rat and rabbit
- Phase 1 SAD/MAD clinical trial

*based on preclinical safety studies in rat and dog

ADX-248 is an investigational drug candidate. QD= once daily, BID=twice daily, SAD=single ascending dose, MAD=multiple ascending dose, PO=oral administration.

aldeyra

aldeyra

Reproxalap: A Novel RASP Modulator for the Treatment of Dry Eye Disease

Reproxalap Represents a Novel Potential Therapeutic Approach in Dry Eye Disease with Rapid Activity Observed in Clinical Trials

Potential advantages for patients and healthcare providers could effect a paradigm shift relative to standard of care.

Rapid and sustained symptom improvement

Broad symptomatic activity

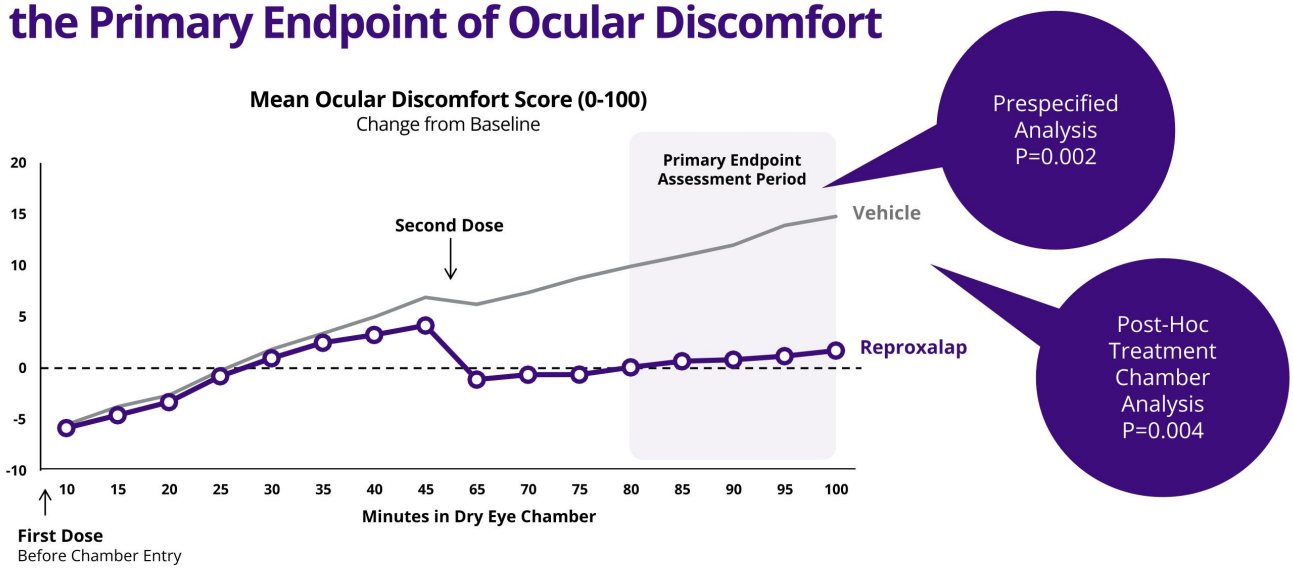
Acute reduction of ocular redness

Dry eye disease afflicts 39 million or more adults in the United States.†

†Company estimates and Am J Ophthalmol. 2014;157(4):799-806. Topical ocular reproxalap is an investigational drug candidate that has not been approved by the FDA; mild and transient instillation site irritation is the most commonly reported adverse event in clinical trials. FDA=U.S. Food & Drug Administration.

aldeyra

The Phase 3 Dry Eye Chamber Trial Achieved the Primary Endpoint of Ocular Discomfort



PDUFA Target Action Date December 16, 2025†

†Regulatory review and discussion timelines are flexible and subject to change based on the regulator's workload, governmental shutdown, and other potential review issues. P value derived from primary endpoint mixed model for repeated measures analysis. Topical ocular reproxalap is an investigational drug candidate that has not been approved by the FDA; mild and transient instillation site irritation is the most commonly reported adverse event in clinical trials. FDA=U.S. Food & Drug Administration, PDUFA=Prescription Drug User Fee Act.

Reproxalap Drug Substance and Drug Product Vendors Have Recently Been Inspected by the U.S. Food and Drug Administration

In 2025, the U.S. Food and Drug Administration (FDA) performed routine cGMP inspections of manufacturing sites associated with the production of reproxalap.

- The reproxalap drug product vendor was inspected in Q1 2025.
- The reproxalap drug substance vendor was inspected in Q3 2025.

Both inspections were classified as Voluntary Action Indicated (VAI), and the FDA has notified the manufacturers that the inspections are closed and that no further action was necessary.

cGMP=current Good Manufacturing Practices.

aldeyra

Aldeyra has Entered into an Exclusive Option Agreement with AbbVie Inc. for License to Develop and Commercialize Reproxalap

Key Terms of Reproxalap Option Agreement

Option for AbbVie to obtain:

- Co-exclusive license to develop, manufacture, and commercialize reproxalap in the U.S.
- Exclusive license to develop, manufacture, and commercialize outside the U.S.
- Option terminates on the 10th business day after Aldeyra receives approval from the U.S. FDA of the NDA for reproxalap in dry eye disease

Financial terms of license if option exercised:

- Upfront payment of $100 million less option fees
- $100 million milestone payment upon U.S. FDA approval in dry eye disease
- $200 million in additional regulatory and commercial milestones
- Profit and loss share (60% for AbbVie / 40% for Aldeyra) from commercialization in U.S.
- Tiered royalties on net sales outside of U.S.

Topical ocular reproxalap is an investigational drug candidate that has not been approved by the FDA; mild and transient instillation site irritation is the most commonly reported adverse event in clinical trials.
FDA=U.S. Food & Drug Administration, NDA=New Drug Application.

aldeyra

Milestones

Clinical and Regulatory Milestones

Dry Eye Disease (Reproxalap)
New Drug Application PDUFA date December 16, 2025†

Atopic Dermatitis (ADX-248)
Phase 2 clinical trial initiation expected in H1 2026‡

Obesity/Hypertryglyceridemia (ADX-248)
Investigational New Drug application expected to be submitted in 2026

Dry Age-Related Macular Degeneration/Geographic Atrophy (ADX-246)
Investigational New Drug application expected to be submitted in 2026

Primary Vitreoretinal Lymphoma (ADX-2191)
Phase 3 clinical trial initiation expected in H2 2025‡

Retinitis Pigmentosa (ADX-2191)
Phase 2/3 clinical trial initiation expected in H1 2026‡

†Regulatory review and discussion timelines are flexible and subject to change based on the regulator's workload, governmental shutdown, and other potential review issues. ‡The timing of clinical trials depends, in part, on the availability of clinical research facilities and staffing, the ability to recruit patients, and the number of patients in the trial. PDUFA=Prescription Drug User Fee Act.

aldeyra

News Release

Aldeyra Therapeutics Announces Expansion of RASP Platform to Include Central Nervous System Diseases and Provides Updates on Reproxalap at Research & Development Webcast

Lexington, Mass. November 13, 2025 – Aldeyra Therapeutics, Inc. (Nasdaq: ALDX) (Aldeyra), a biotechnology company devoted to discovering and developing innovative therapies designed to treat immune-mediated diseases, today announced at a research and development webcast the expansion of the RASP platform to include programs in central nervous system diseases associated with inflammation, and provided updated manufacturing information on reproxalap.

- Based on new preclinical results in models of Parkinson's disease and amyotrophic lateral sclerosis, which included improved grip strength, balance, and biomarkers of central nervous system function, potential clinical indications for the orally administered, next-generation RASP modulator ADX-248 were expanded to include neuroinflammatory diseases that affect the central nervous system.

- The U.S. Food and Drug Administration (FDA) completed routine site inspections of reproxalap drug substance and drug product manufacturing facilities in 2025. The inspections resulted in Voluntary Action Indicated (VAI) designations, and the FDA has notified the manufacturers that the inspections are closed, and that no further action was necessary.

"A testament to the growing opportunity for immune-modulating therapeutic approaches, the new results announced today in preclinical models of neurological diseases associated with inflammation highlight the potentially broad applicability of ADX-248 and other next-generation RASP modulators as novel product candidates for the treatment of a number of clinical indications," stated Todd C. Brady, M.D., Ph.D., President and Chief Executive Officer of Aldeyra. "We look forward to providing future updates on ADX-248, reproxalap, and other RASP modulators as we advance our therapeutic pipeline."

Conference Call & Webcast Information
Aldeyra will host a conference call at 8:00 a.m. ET today to discuss new preclinical results from ADX-248 in models of diseases that affect the central nervous system and provide clinical and manufacturing updates on reproxalap. The dial-in numbers are (833) 470-1428 for domestic callers and (646) 844-6383 for international callers. The access code is 663378. 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 protein 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-248, ADX-246, and chemically related molecules for the potential treatment of systemic and retinal immune-mediated diseases. Our late-stage product candidates are reproxalap, a RASP modulator for the potential treatment of dry eye disease and allergic conjunctivitis, and ADX-2191, a novel formulation of intravitreal methotrexate for the potential treatment of primary vitreoretinal lymphoma 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, and potential for Aldeyra's RASP modulator product candidates and pipeline; the outcome and timing of any clinical trials of Aldeyra's RASP modulator product candidates; anticipated timing of regulatory filings; and the outcome of the New Drug Application of reproxalap for the treatment of dry eye disease. 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, issuing a complete response letter, or requiring additional clinical trials or data prior to review or approval of such filings or in connection with resubmissions 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; 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, 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, 2024, and Aldeyra's Quarterly Report on Form 10-Q for the quarter ended September 30, 2025, which are on file with the Securities and Exchange Commission (SEC) and available on the SEC website at https://www.sec.gov/.
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.

Investor & Media Contact
Laura Nichols
(781) 257-3060
investorrelations@aldeyra.com