



CONFERENCE CALL

Reproxalap for the Potential Treatment of Dry Eye Disease: Regulatory Update

September 29, 2026

Nasdaq: ALDX

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Aldeyra Intends to Submit a Formal Dispute Resolution Request Regarding Reproxalap for the Treatment of Dry Eye Disease

Following a New Drug Application (NDA) submission and two NDA resubmissions of reproxalap for the treatment of dry eye disease, Aldeyra has received three Complete Response Letters, the first two of which recommended an additional clinical trial to “demonstrate a positive effect on the treatment of ocular symptoms of dry eye” and the most recent of which did not request further clinical trials but stated that the “totality of evidence from the completed clinical trials does not support the effectiveness of the product.”

Over the course of the three NDA submissions, Aldeyra has provided data from nine adequate and well-controlled clinical trials, five of which achieved all multiplicity-controlled primary endpoints, consistent with or greater than the success rates of clinical trials conducted for approved dry eye disease products.

Aldeyra met with the Division of Ophthalmology and the Office of Specialty Medicine at an End of Review Type A meeting and again at a Type D meeting to present arguments supportive of the totality of evidence. Based on the outcome of the meetings, Aldeyra intends to submit a Formal Dispute Resolution Request (FDRR) to the Office of New Drugs (OND).

Based on established timelines for FDRR, Aldeyra expects to meet with OND in the fourth quarter of 2026. The timing of the OND FDRR decision will depend on a number of factors, including whether the deciding official requests additional information or determines there is a need to discuss the FDRR with internal or external experts or convene an advisory panel, and other factors, the occurrence and timing of which are uncertain.

FDRR is an Established Process with Uncertain Timelines

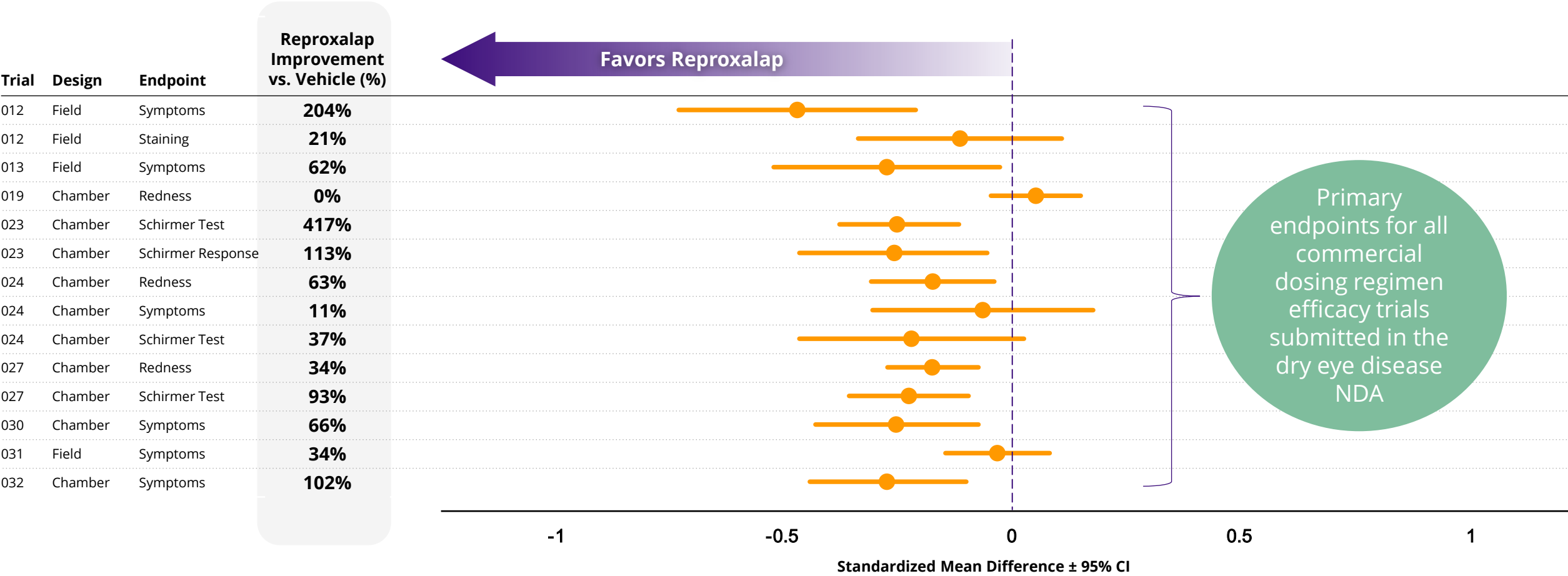
The FDRR process is subject to PDUFA goals. FDRR guidance[†] states that a meeting requested as part of the FDRR should be treated as a Type A meeting and held within 30 days after submission of the FDRR. The decision on the FDRR should be made by the deciding official within 30 days after the meeting unless there is an interim response by the deciding official, such as a request for information or a decision by the deciding official that additional discussion is needed, in which case the decision should be made within 30 days after the requested information is provided or discussion occurs.

Following the FDRR decision, the NDA must be resubmitted with the additional information, if any, required by the decision.

We are aware of two FDRRs in 2026 for ophthalmological drug products: one FDRR resulted in an Appeal Granted decision, and one FDRR is awaiting an advisory panel.

[†]Dry Eye: Developing Drugs for Treatment Guidance for Industry, www.fda.gov/media/85613/download

Aldeyra Believes That the Totality of Evidence Indicates a Clear Pattern of Superiority of Reproxalap over the Vehicle Control



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. Vehicle is the drug product without reproxalap. Trials 012, 013, and 031 were field trials; other trials were single-day exposures (Day 1, Schirmer Test) followed by a dry eye chamber (Day 2, redness and symptoms). Trial 012 reflects the proposed commercial dosing regimen. For the plot, continuous outcomes from the prespecified MMRM differences are standardized by the pooled standard deviation across treatment groups. Schirmer response is analyzed as difference in response rates, standardized using a Bernoulli standard deviation. Treatment comparisons are reproxalap minus vehicle, except Schirmer score, which is vehicle minus reproxalap. The table represents unadjusted mean treatment comparisons as a percentage of vehicle mean. Trials=ADX-102-DED-xxx where xxx is the trial number, Symptoms=patient-reported dryness or discomfort, Staining=nasal fluorescein staining, Redness=investigator-assessed ocular redness, Schirmer=tear production score, Schirmer response= ≥ 10 mm response, CI=confidence interval, MMRM=mixed models for repeated measures, NDA=New Drug Application for reproxalap for the treatment of the signs and symptoms dry eye disease



The Majority of Reproxalap Dry Eye Trials Submitted to the Dry Eye Disease NDA Achieved Primary Endpoints Supporting Efficacy

TRIAL	PRIMARY ENDPOINT(S)	P<0.05	FDA POSITION	ALDEYRA POSITION
012	Symptoms Staining	✓	Co-primary not met	Supportive for symptoms
013	Symptoms	✓	Endpoint met	Endpoint met
019	Redness		Endpoint not met	Supportive for Schirmer Test (secondary P<0.0001), Schirmer Response (post-hoc P<0.0001)
023	Schirmer Test Schirmer Response	✓ ✓	Methodological issues	Endpoints met, methodological sensitivity testing supportive of outcome
024	Redness Symptoms Schirmer Test	✓	Redness endpoint met	Redness endpoint met; Symptoms and Schirmer Test numerically supportive
027	Redness Schirmer Test	✓ ✓	Redness met, Schirmer Test methodological issues	Both endpoints met, methodological sensitivity testing supportive of outcome for Schirmer Test
030	Symptoms	✓	Methodological issues	Endpoint met, methodological sensitivity testing supportive of outcome
031	Symptoms		Not statistically significant	Results numerically favored reproxalap
032	Symptoms	✓	Endpoint met	Endpoint met

Five of the nine

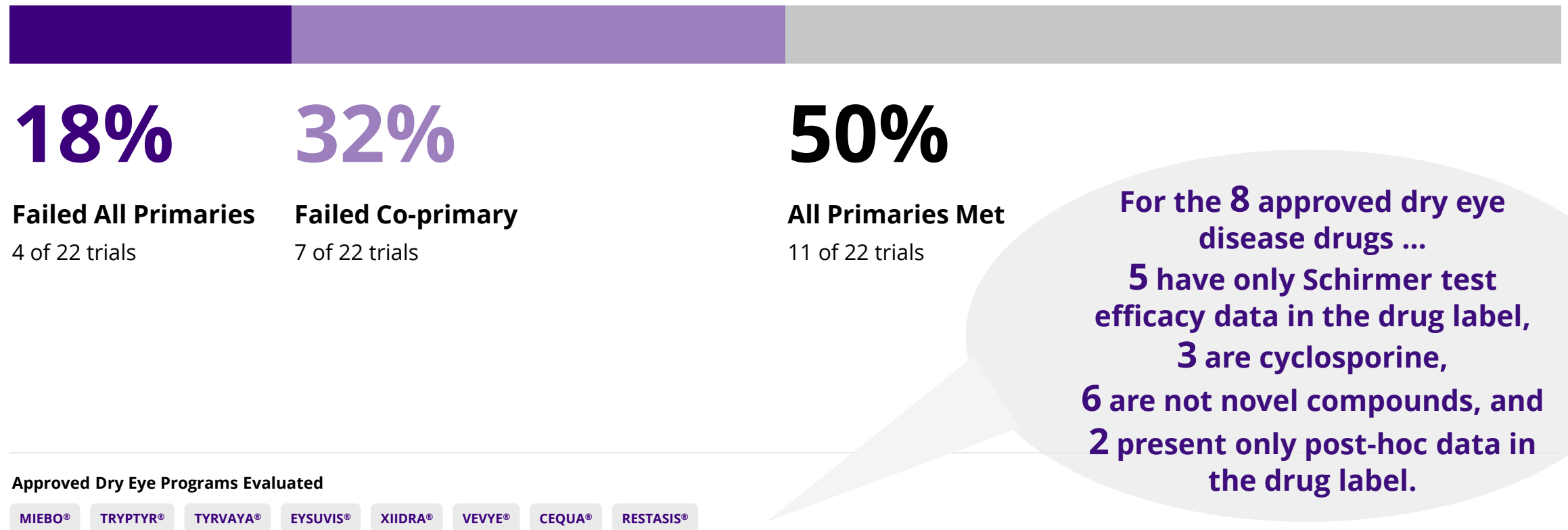
efficacy trials submitted in the NDA achieved all primary endpoints, and the P values for 9 of 14 endpoints were less than 0.05.

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. The table presents the primary endpoints from all proposed commercial dosing regimen efficacy trials of reproxalap that were submitted to the dry eye disease NDA. FDA position is Aldeyra's abbreviated interpretation of FDA review. Trials=ADX-102-DED-xxx where xxx is the trial number, Symptoms=patient-reported dryness (Trials 012 and 013) or discomfort (Trials 030, 031, and 032), Staining=nasal region fluorescein staining, Redness=investigator-assessed ocular redness, Schirmer Test=tear production score, Schirmer Response= ≥ 10 mm response, FDA=US Food and Drug Administration, NDA=New Drug Application for reproxalap for the treatment of the signs and symptoms dry eye disease



Half of Trials Supporting Dry Eye Drug Approvals Fail to Meet All Primary Endpoints

Across pivotal trials for approved dry eye drugs, 11 of 22 (50%) met all prespecified endpoints.



"All primaries met" = every primary endpoint met; "Partial / Failed Co-Primary" = some but not all met; "Failed All Primaries" = none met; dose-ranging and safety-only trials excluded.

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

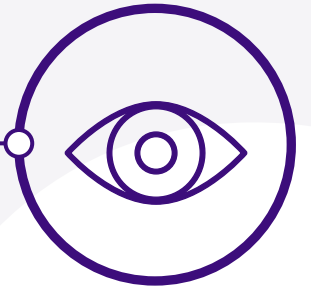
Potential advantages for patients and healthcare providers could effect a paradigm shift relative to standard of care.



Rapid and sustained symptom improvement



Broad symptomatic activity



Acute tear production and reduction of ocular redness

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

Aldeyra is Well Positioned to Execute on the FDRR Process and Continue Pipeline Advancement

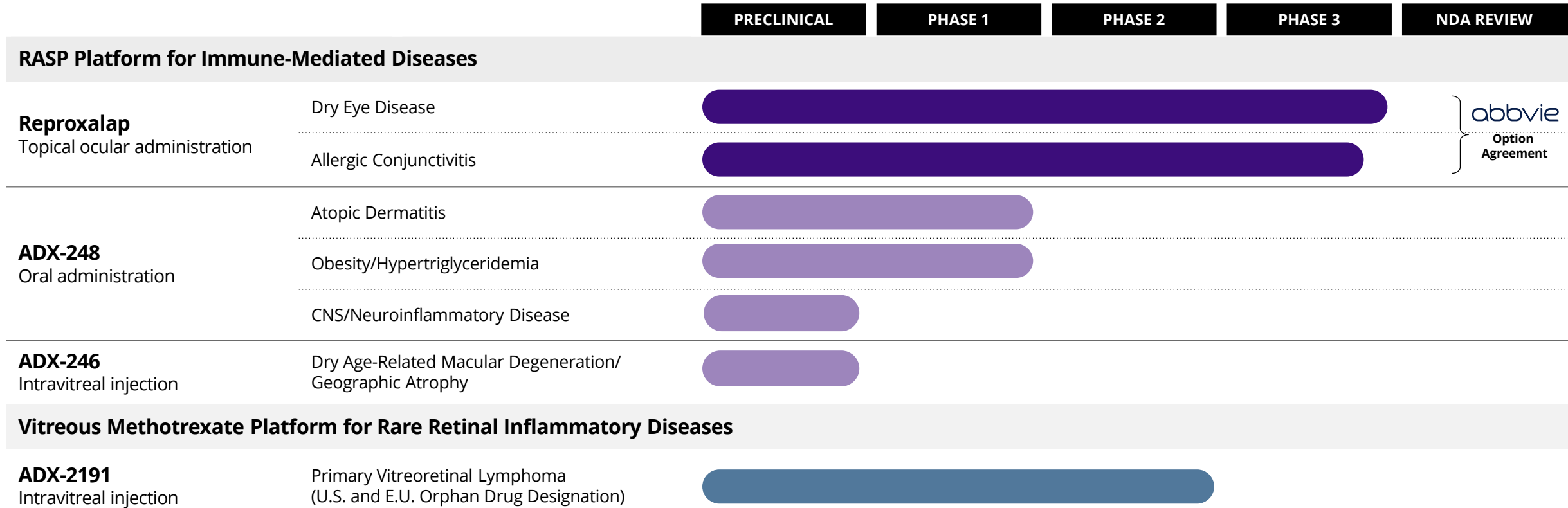
With \$45.1M in cash and cash equivalents as of 6/30/2026, Aldeyra is well positioned to execute on the FDRR process for reproxalap and advance ADX-2191 for primary vitreoretinal lymphoma (PVRL), with operational cash runway into 2029.[†]

- FDRR submission and meeting with OND expected in Q4 2026.
- Phase 3 clinical trial initiation expected in 2027.[‡]

Regulatory review timelines are flexible and subject to change based on the regulator's workload and other potential review issues. [†]Company guidance as of September 29, 2026, which has not been updated or confirmed since such date and does not include any potential licensing or product revenue associated with reproxalap. CNS=central nervous system, NDA=New Drug Application. [‡]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. FDRR = Formal Dispute Resolution Request, OND = Office of New Drugs, PVRL= Primary Vitreoretinal Lymphoma



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



As of 6/30/2026, cash and cash equivalents were \$45.1M, which Aldeyra believes will be sufficient to fund the Company into 2029.[†]



[†]Company guidance as of September 29, 2026, which has not been updated or confirmed since such date and does not include any potential licensing or product revenue associated with reproxalap. CNS=central nervous system, NDA=New Drug Application.

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Clinical and Regulatory Milestones



Reproxalap



ADX-2191



ADX-248



ADX-246



Dry Eye Disease (Reproxalap)

FDRR meeting with the FDA OND expected the fourth quarter of 2026[†]



Primary Vitreoretinal Lymphoma (ADX-2191)

Phase 3 clinical trial initiation expected in 2027[‡]



Atopic Dermatitis (ADX-248)

Timeline guidance to be provided when available



Obesity/Hypertryglyceridemia (ADX-248)

Timeline guidance to be provided when available



Dry Age-Related Macular Degeneration/Geographic Atrophy (ADX-246)

Timeline guidance to be provided when available

[†]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. FDRR = Formal Dispute Resolution Request, OND = Office of New Drugs