



CONFERENCE CALL

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

April 3, 2025

Nasdaq: ALDX

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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 April 03, 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 Received a Complete Response Letter for Reproxalap for the Treatment of Dry Eye Disease

The Complete Response Letter stated that the NDA “failed to demonstrate efficacy in adequate and well controlled studies in treating ocular symptoms associated with dry eyes” and that “at least one additional adequate and well controlled study to demonstrate a positive effect on the treatment of ocular symptoms of dry eye” should be conducted. The letter identified concerns with the data from the trial submitted to the NDA that may have affected interpretation of the results, which the FDA stated may be related to methodological issues, including a difference in baseline scores across treatment arms.

Results from two ongoing trials of reproxalap in dry eye disease are expected to be available this quarter. A Type A meeting with the FDA to discuss the letter and the ongoing clinical trials is expected to be held within approximately 30 days.

Per draft FDA guidance, efficacy in dry eye disease may be demonstrated with two symptom trials and two sign trials. Aldeyra previously conducted two dry eye chamber trials for ocular redness (a dry eye disease sign) and dry eye disease field trials (environmental exposure) trials for symptoms.

No manufacturing or safety issues were identified in the letter.

Aldeyra is Well Positioned to Execute on Potential NDA Resubmission Milestones

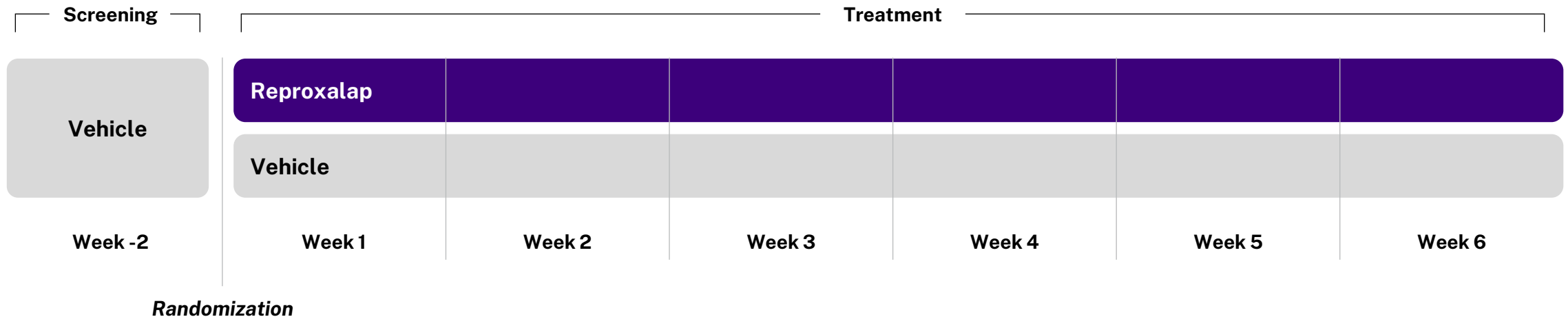
With \$101M in cash, cash equivalents, and marketable securities as of 12/31/2024, Aldeyra is well positioned to execute on potential NDA resubmission milestones.

- Top-line results from dry eye disease field and chamber clinical trials are expected in Q2 2025.
- The majority of the costs for the additional trials were incurred in 2024; total 2025 costs of trials are approximately \$6M.
- Contingent on positive results and FDA discussions, NDA resubmission is anticipated mid-2025.
- The review period for the potential NDA resubmission expected to be six months.

Dry Eye Disease Field Trial Design

Design	Randomized, double-masked, parallel group, vehicle-controlled, environmental exposure
Dosing	Reproxalap or vehicle Four-times-daily dosing for 4 weeks, followed by two-times-daily dosing for 2 weeks
Size	421 patients (approximately 210 per arm)
Primary Endpoint	Subject-reported ocular discomfort score from Week 1 to Week 6
Other Endpoints	Safety

Further information
can be found on
www.clinicaltrials.gov;
Trial #NCT0642444.



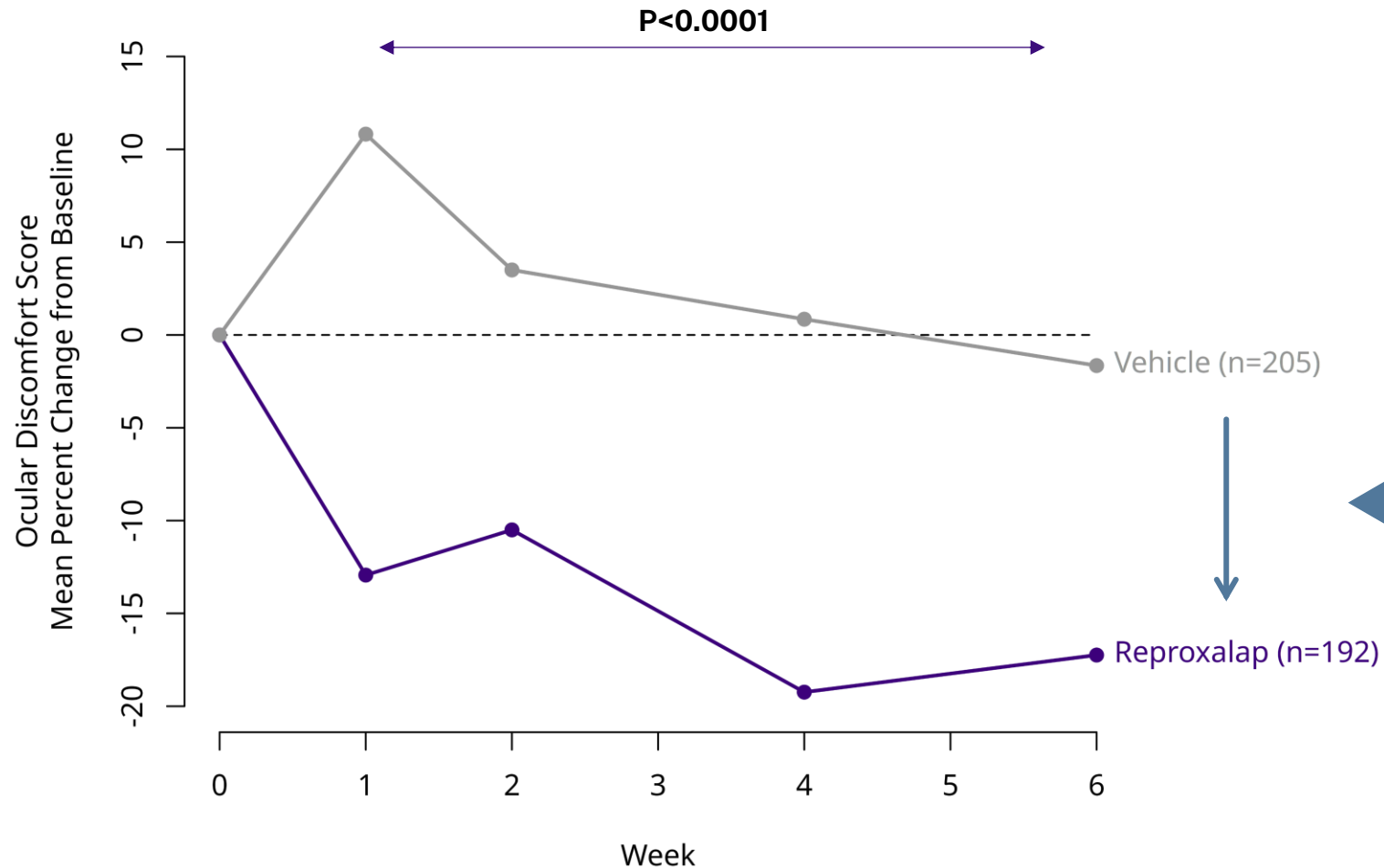
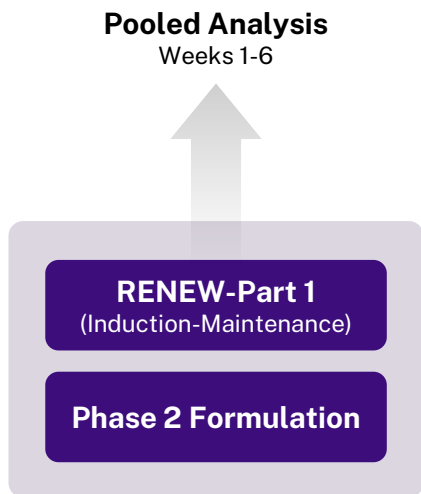
Further information can be found on www.clinicaltrials.gov: Trial #NCT0642444.



Topical ocular reproxalap is an investigational new drug candidate that has been studied in more than 2,500 patients with no observed safety concerns; mild and transient instillation site irritation is the most commonly reported adverse event in clinical trials.

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Pooled Data from Two Completed Field Trials Suggested Consistent Symptom Control Relative to Vehicle



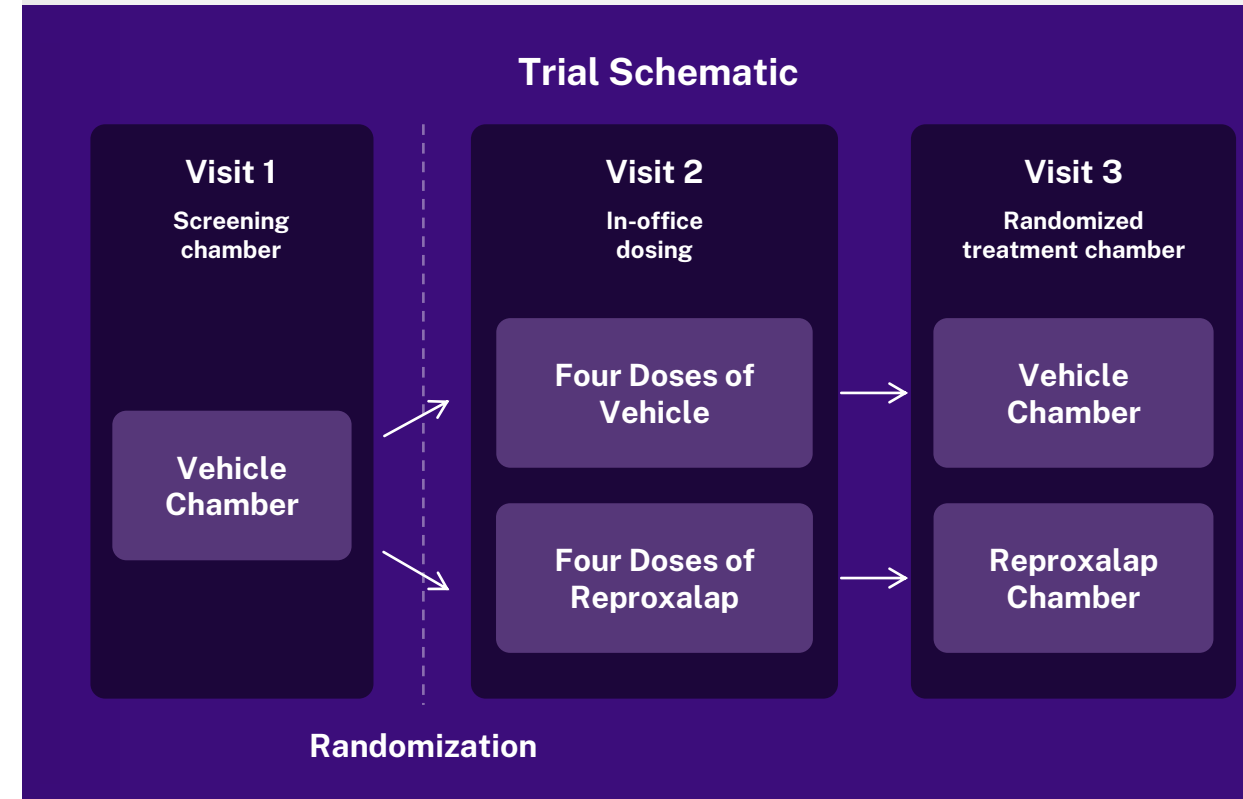
The reproxalap improvement from baseline was

10X

more than that of vehicle.

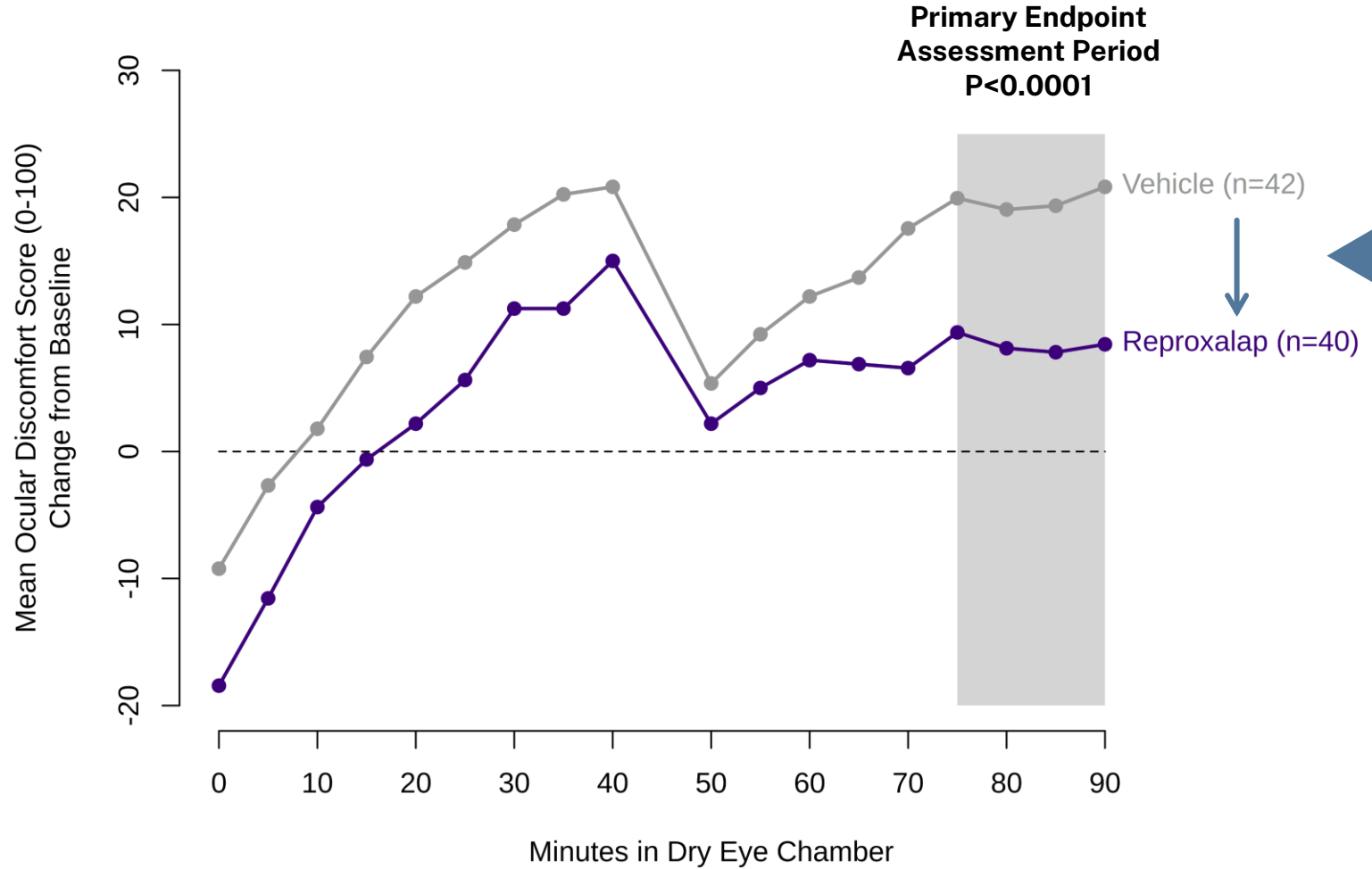
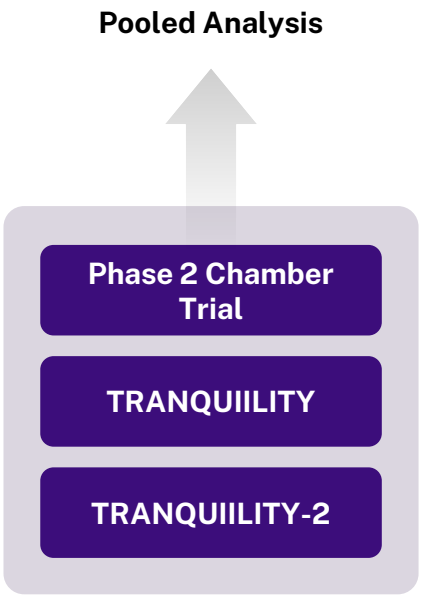
Dry Eye Disease Clinical Chamber Trial Design

Design	Randomized, double-masked, parallel-group, vehicle-controlled, dry eye chamber challenge
Dosing	<ul style="list-style-type: none"> • Visit 1: Screening vehicle dry eye chamber (dosing just before and 50 minutes after entry) • Visit 2: Four doses of randomized treatment (reproxalap or vehicle) • Visit 3: Randomized dry eye chamber (dosing just before and 50 minutes after entry)
Size	116 patients (approximately 58 per arm)
Primary Endpoint	Subject-reported ocular discomfort score from 80 to 100 minutes
Other Endpoints	Safety



Further information can be found on www.clinicaltrials.gov: Trial #NCT06389214.

Pooled Data from Three Completed Trials in the Same Chamber as the Ongoing Trial Supported Rapid Activity of Reproxalap



The vehicle increase from baseline was **148%** higher than that of reproxalap.



Topical ocular reproxalap is an investigational new drug candidate that has been studied in more than 2,500 patients with no observed safety concerns; mild and transient instillation site irritation is the most commonly reported adverse event in clinical trials. Prior results may not be indicative of results of ongoing or future trials involving our product candidates.

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 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 new drug candidate that has been studied in more than 2,500 patients with no observed safety concerns; mild and transient instillation site irritation is the most commonly reported adverse event in clinical trials.



Clinical and Regulatory Milestones

- Dry Eye Disease (Reproxalap)**
Completion of Field and Chamber Trials Expected in Q2 2025
- Dry Eye Disease (Reproxalap)**
Potential NDA Resubmission Expected Mid-2025
- Allergic Conjunctivitis (Reproxalap)**
Positive Phase 3 INVIGORATE 2 trial top-line results announced
- Atopic Dermatitis (ADX-248)**
Phase 1 clinical trial initiated[‡]
- Moderate Alcohol-Associated Hepatitis (ADX-629)**
Open-label Phase 2 clinical trial top-line results expected in 2025[‡]
- Retinitis Pigmentosa (ADX-2191)**
Phase 2/3 clinical trial initiation expected in H1 2025[‡]
- Dry Age-Related Macular Degeneration/Geographic Atrophy (ADX-631/ ADX-246)**
Investigational New Drug application expected to be submitted in 2025
- Sjögren-Larsson Syndrome (ADX-629)**
Phase 2 clinical trial pediatric cohort top-line results expected in 2025
- Obesity/Hypertriglyceridemia (ADX-743)**
Investigational New Drug application expected to be submitted in 2025

[†]Regulatory review and discussion timelines are flexible and subject to change based on the regulator's workload 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. ^{*}Investigator sponsored.

