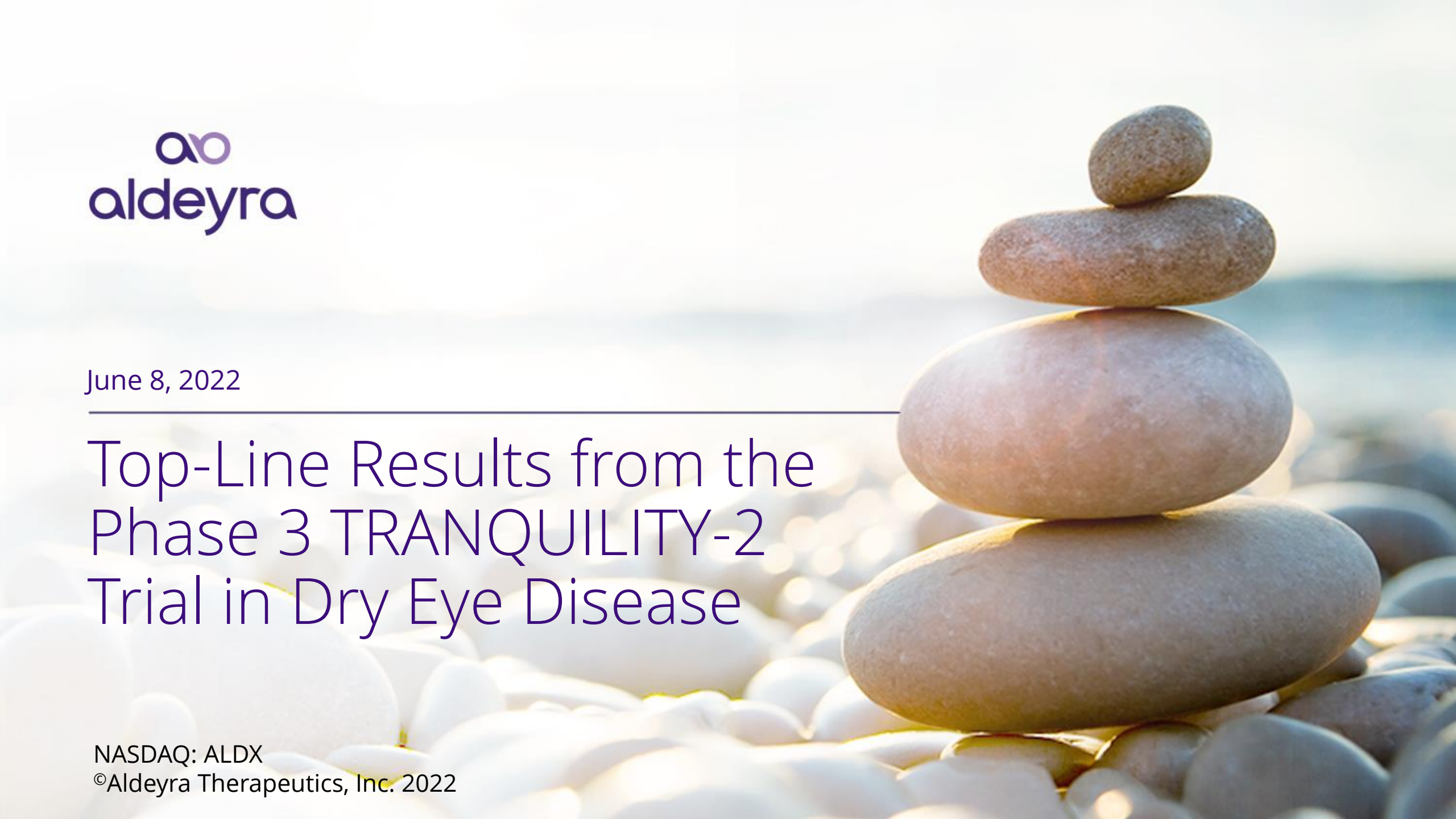

June 8, 2022

Top-Line Results from the Phase 3 TRANQUILITY-2 Trial in Dry Eye Disease

NASDAQ: ALDX

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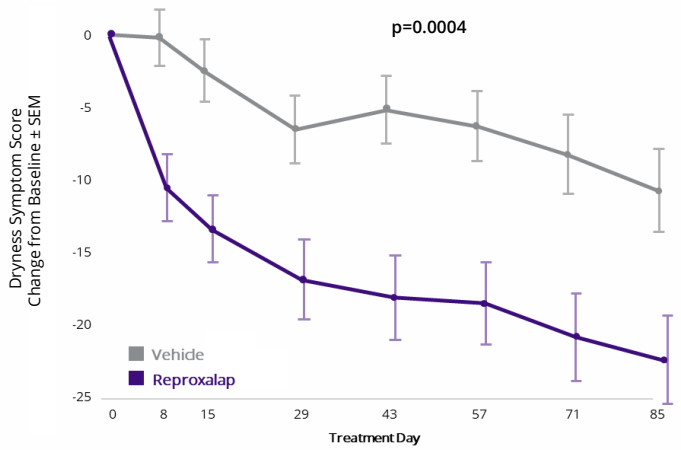
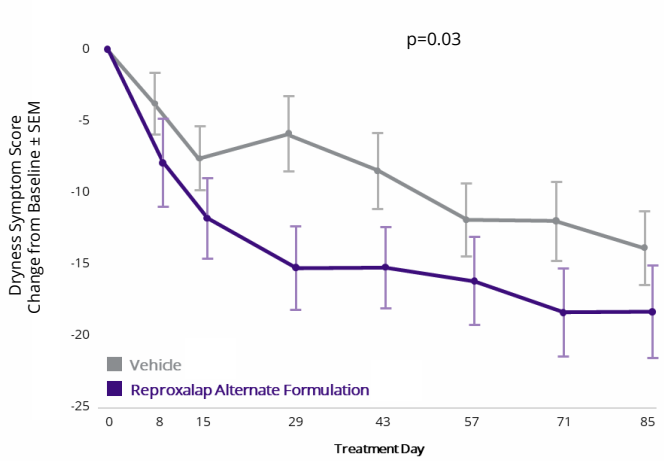
Aldeyra Previously Achieved Statistical Significance in Two Symptom and Two Sign Pivotal Trials†

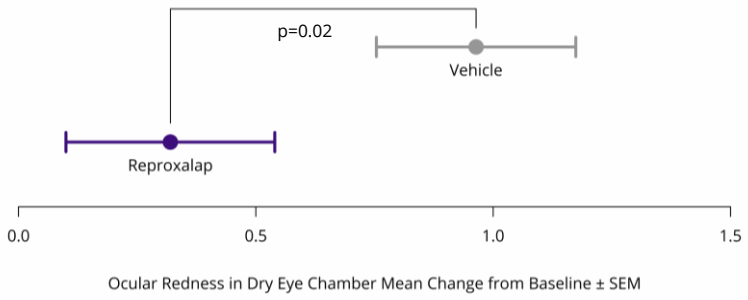
Phase 3 RENEW–Part 1



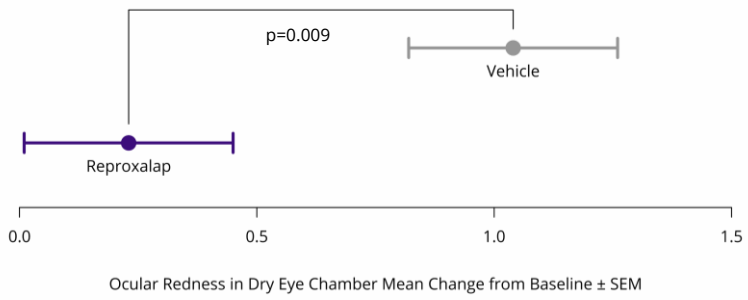
Formulation Phase 2*



Phase 3 TRANQUILITY Trial



Phase 2 Dry Eye Chamber Trial*



Symptoms

Aldeyra intends to submit two previously completed 12-week adequate and well-controlled **symptom trials** that prespecified patient-reported ocular dryness score as a primary endpoint or a co-primary endpoint.

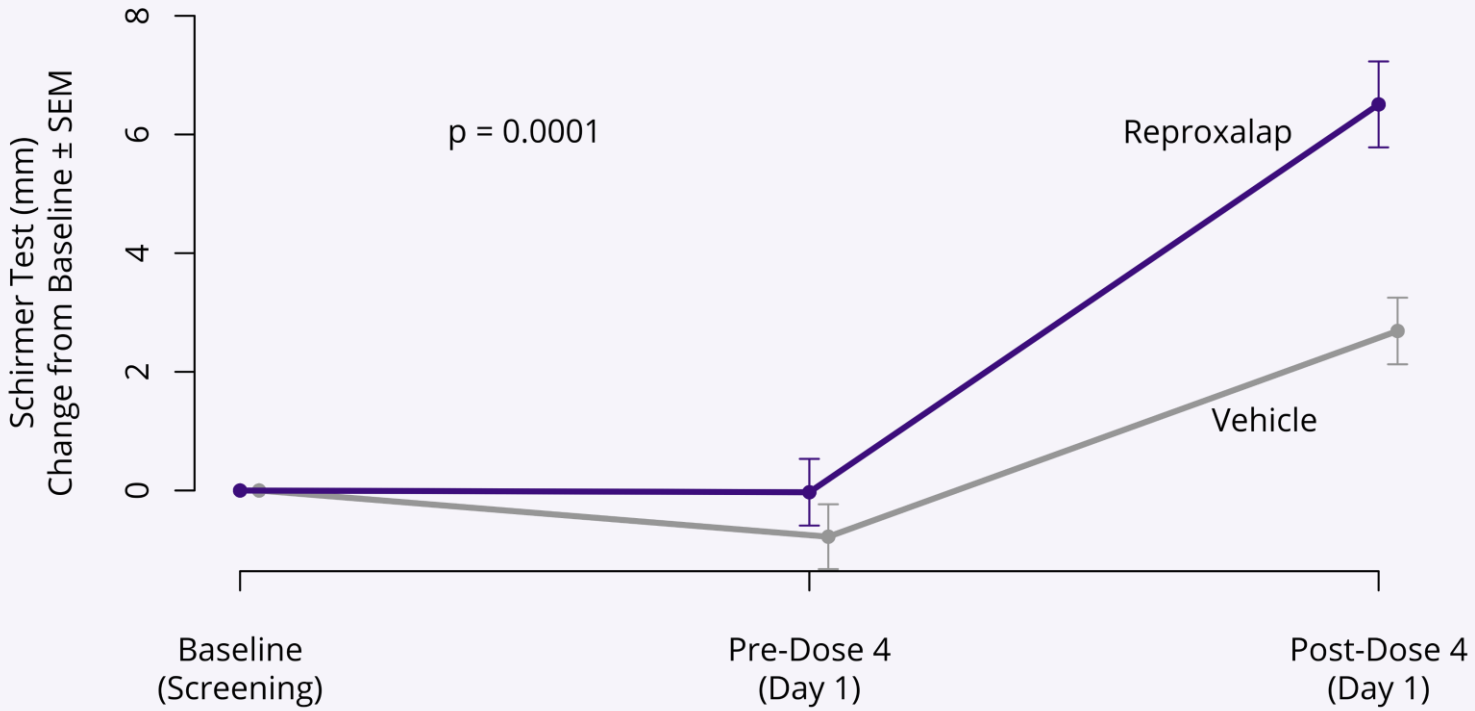
Signs

Aldeyra intends to submit two previously completed adequate and well-controlled dry eye chamber trials that prespecified **ocular redness** as a primary endpoint#. Ocular redness is an FDA-recognized, objective sign of dry eye disease.

†NDA submission requirements depend, in part, on clinical results and regulatory feedback. *Adequate and well-controlled Phase 2 or Phase 3 clinical trials can be submitted as pivotal. #Phase 2 and TRANQUILITY redness results derived from draft re-analysis using an automated assessment. **Source**: Clinical trial results on file. **SEM** = standard error of the mean. Topical ocular reproxalap is an investigational new drug candidate that has been studied in more than 1,700 patients with no observed safety concerns; mild and transient instillation site discomfort is the most commonly reported adverse event in clinical trials.

As a Secondary Endpoint, Schirmer Test Achieved in TRANQUILITY and Clinical Relevance Confirmed with Post-Hoc Responder Analysis

Schirmer Test



≥10 mm Schirmer Test Responder Analysis

	Reproxalap (n=153)	**Vehicle** (n=153)
≥10 mm increase in tear production post-Dose 4 on Day 1	31%	15%
Odds ratio (95% confidence interval) ‡	2.6 (1.7, 4.1)	
p-value‡ versus vehicle	< 0.0001	

Graph horizontal axis values offset for clarity; graph p value derived from mixed effect model of repeated measures of change from baseline over pre- and post-Dose 4 scores on Day 1.
‡ Generalized estimating equation analysis of change from baseline over pre- and post-Dose 4 scores on Day 1. **SEM** = standard error of the mean. **mm** = millimeter. **Source**: Phase 3 TRANQUILITY clinical trial results on file. Topical ocular reproxalap is an investigational new drug candidate that has been studied in more than 1,700 patients with no observed safety concerns; mild and transient instillation site discomfort is the most commonly reported adverse event in clinical trials.

To Allow for Potential Submission of Two Dry Eye Disease Signs, Schirmer Test Designated as Primary Endpoint of TRANQUILITY-2

Design	Multi-center, randomized, double-masked, parallel group, vehicle-controlled
Dosing	0.25% reproxalap or vehicle Day 1: four doses Day 2: one dose before dry eye chamber, one dose in chamber
Size	361 patients
Primary Endpoints	Schirmer test on Day 1 pre/post Dose 4 Schirmer test responders (≥10 mm)
Secondary Endpoints	Ocular redness over 90 minutes in dry eye chamber Dry eye disease symptoms

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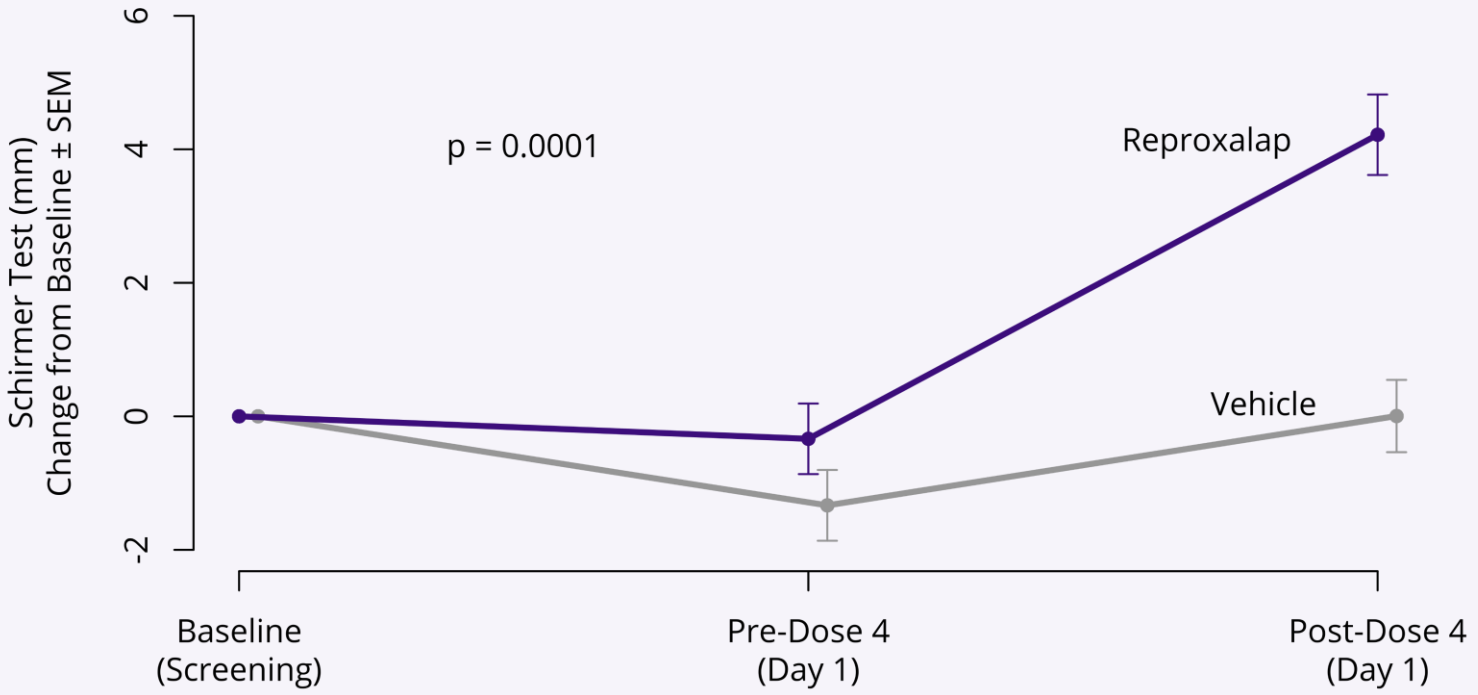
Topical ocular reproxalap is an investigational new drug candidate that has been studied in more than 1,700 patients with no observed safety concerns; mild and transient instillation site discomfort is the most commonly reported adverse event in clinical trials.

In TRANQUILITY-2, Both Primary Endpoints Were Achieved

Schirmer Test



≥10 mm Schirmer Test Responder Analysis

	Reproxalap (n=181)	**Vehicle** (n=180)
≥10 mm increase in tear production post-Dose 4 on Day 1	25%	8%
Odds ratio (95% confidence interval)‡	2.6 (1.7, 4.1)	
p-value‡ versus vehicle	< 0.0001	

Consistent with prior trials, no clinically significant safety signals were observed.

Graph horizontal axis values offset for clarity; graph p value derived from mixed effect model of repeated measures of change from baseline over pre- and post-Dose 4 scores on Day 1.
‡ Generalized estimating equation analysis of change from baseline over pre- and post-Dose 4 scores on Day 1. **SEM** = standard error of the mean. **mm** = millimeter. **Source**: Phase 3 TRANQUILITY-2 clinical trial results on file. Topical ocular reproxalap is an investigational new drug candidate that has been studied in more than 1,700 patients with no observed safety concerns; mild and transient instillation site discomfort is the most commonly reported adverse event in clinical trials.

The TRANQUILITY-2 Results May Allow for the Most Comprehensive Dry Eye Disease NDA Submitted to Date†

- Aldeyra believes that the clinical efficacy requirements for dry eye disease NDA submission have been met.
- We intend to submit an NDA covering symptoms (ocular dryness) and three sign endpoints (ocular redness, Schirmer test, and Schirmer test responder proportions) across five adequate and well-controlled clinical trials.
- Submitted clinical data is expected to encompass acute (single-day dosing, dry eye chamber) and chronic (12-week) assessments, offering unparalleled analysis of rapid and sustained activity across a combination of challenge and field-based assessments.
- If approved, reproxalap has the potential to be the first dry eye disease drug with at least two labeled objective signs.
- A Type B Pre-NDA meeting is expected to be held with the FDA in the third quarter of 2022, followed by a potential NDA submission.
- Enrollment is substantially complete in a crossover dry eye chamber trial that is intended to be adequate and well-controlled, and, pending the results, is expected to be submitted to the NDA as a supportive trial.

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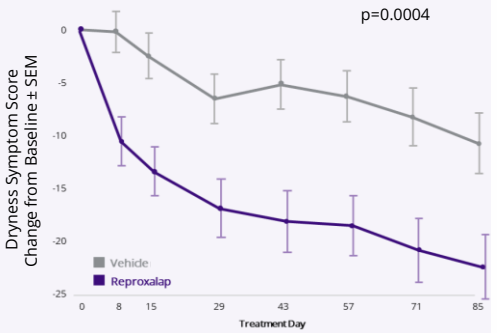
†NDA submission requirements depend, in part, on clinical results and regulatory feedback. The NDA submission is expected to include a combination of prespecified, post-hoc, primary, secondary, multiplicity-adjusted, and nominal p-value endpoints. Topical ocular reproxalap is an investigational new drug candidate that has been studied in more than 1,700 patients with no observed safety concerns; mild and transient instillation site discomfort is the most commonly reported adverse event in clinical trials

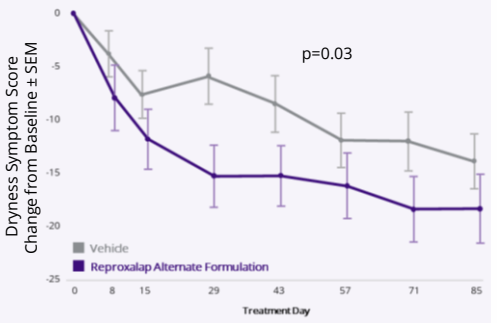
Aldeyra Intends to Submit Symptom and Three Sign Endpoints for Satisfaction of Dry Eye Disease NDA Efficacy Requirements†

Ocular Dryness Symptom Score

Phase 3 RENEW–Part 1

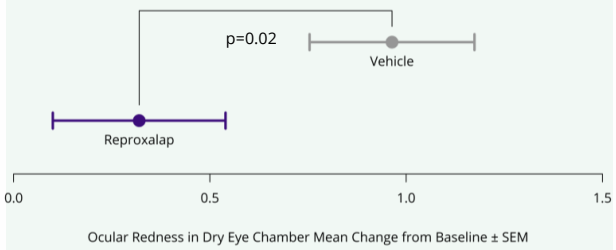


Formulation Phase 2*

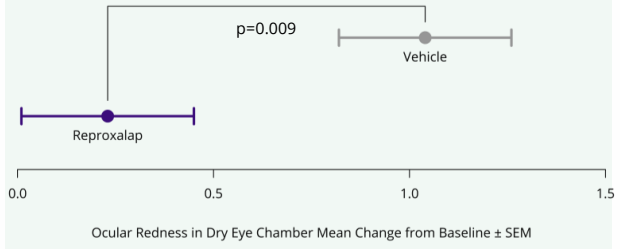


Ocular Redness#

Phase 3 TRANQUILITY Trial

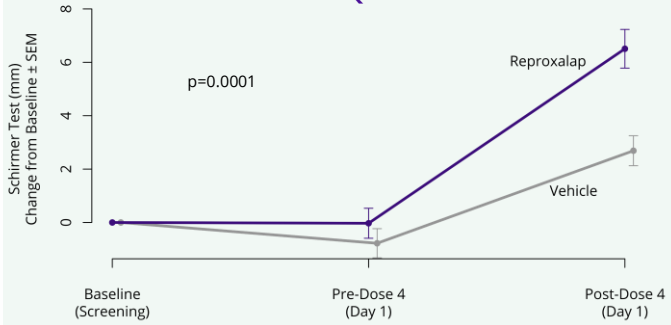


Phase 2 Dry Eye Chamber Trial*

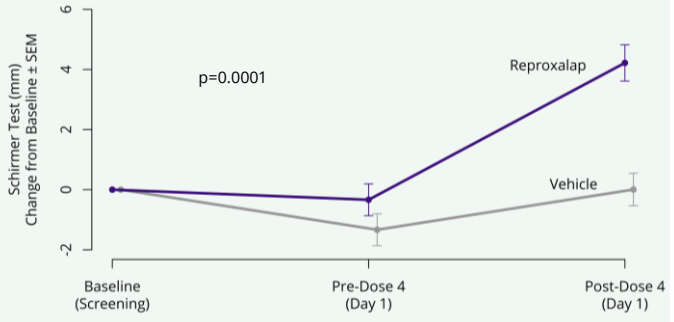


Schirmer Test

Phase 3 TRANQUILITY Trial

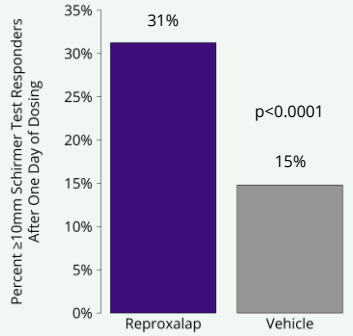


Phase 3 TRANQUILITY-2 Trial

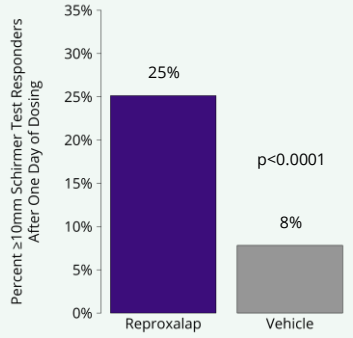


≥10 mm Schirmer Test Responder Analysis

Phase 3 TRANQUILITY Trial



Phase 3 TRANQUILITY-2 Trial



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