# Efficacy and Safety of 0.25% Reproxalap Ophthalmic Solution in Patients With Dry Eye Disease: Results From a Dry Eye Chamber Trial

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Reproxalap is an investigational therapy that has not received FDA (or any regulatory authority) approval and has not been demonstrated safe or effective for any use.

Reproxalap is owned by Aldeyra Therapeutics and subject to option exercise pursuant to an agreement between Aldeyra Therapeutics and AbbVie.

# Introduction

**Objective:**

To evaluate the efficacy and safety of reproxalap compared with a vehicle ophthalmic solution in improving ocular discomfort in patients with dry eye disease (DED)

DED is a common ocular condition that is characterized in part by ocular discomfort

- Many current therapeutic options for DED require weeks or months of treatment to achieve noticeable levels of activity, and may lead to adverse events such as installation site pain, ocular burning, temporary blurring of vision, and dysgeusia[1]

- Reproxalap, a novel reactive aldehyde species inhibitor in development for the treatment of DED, has demonstrated improvement in DED symptoms within minutes of administration, without clinically significant safety concerns

1. Jones L, et al. Am J Ophthalmol. 2025;279:289-386.

# Methods

**Study Design:** Randomized, double-masked, vehicle-controlled, parallel group, Phase 3 clinical trial that was conducted in a dry eye chamber and included 4 visits

### Visit 1: Screening
Medical screening and administration of vehicle treatment

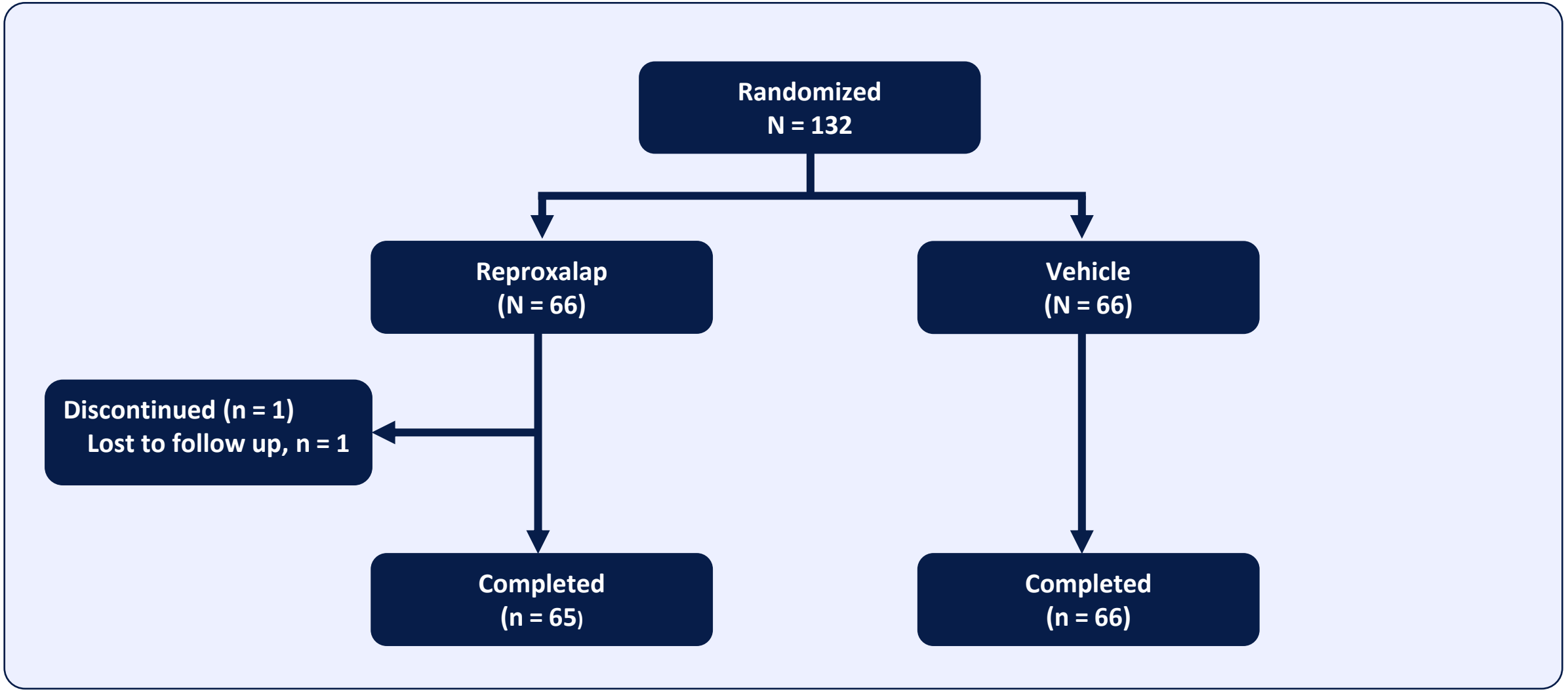
### Visit 2: Vehicle Chamber Visit
All patients received vehicle ~ 5 minutes before and 50 minutes after entry to the dry eye chamber

### Visit 3: Randomization
Patients were randomized 1:1 to receive four doses of reproxalap or vehicle

### Visit 4: Treatment Chamber Visit
The same treatment was administered the following day, during which patients received treatment ~ 5 minutes before and 50 minutes after entry to the dry eye chamber

- The **primary endpoint** of ocular discomfort symptom score (visual analogue score of 0 to 100; Treatment Chamber – Vehicle Chamber) was assessed from 80 to 100 minutes after chamber entry
- Ocular discomfort was recorded at -12 and -7 minutes before chamber entry and every 5 minutes after chamber entry from 10 to 100 minutes

## Figure 1. Patient Disposition



# Baseline characteristics were similar for both groups

## Table 1. Baseline Characteristics

| Outcome | Reproxalap N = 66 | Vehicle N = 66 |
|---|---|---|
| **Age, mean (SD)** | 49.6 (11.9) | 46.5 (11.5) |
| **Age ≥ 65, n (%)** | 6 (9.1) | 5 (7.6) |
| **Female, n (%)** | 53 (80.3) | 41 (62.1) |
| **Ethnicity, n (%)** | | |
| Hispanic or Latino | 10 (15.2) | 16 (24.2) |
| Not Hispanic or Latino | 54 (81.8) | 50 (75.8) |
| Not reported | 2 (3.0) | 0 |
| **Race, n (%)** | | |
| Asian | 11 (16.7) | 14 (21.2) |
| Black or African American | 7 (10.6) | 10 (15.2) |
| White | 46 (69.7) | 40 (60.6) |
| Other or not reported | 2 (3.0) | 2 (3.0) |
| **Eye disorders other than DED, n (%)** | | |
| Myopia | 23 (34.8) | 23 (34.8) |
| Presbyopia | 21 (31.8) | 15 (22.7) |
| Hypermetropia | 11 (16.7) | 7 (10.6) |
| Astigmatism | 2 (3.0) | 0 |
| Amblyopia | 0 | 1 (0.5) |
| Lagophthalmos | 0 | 1 (0.5) |
| Pterygium | 1 (0.5) | 0 |
| Visual impairment | 1 (0.5) | 0 |
| Vitreous floaters | 0 | 1 (0.5) |
| **Mean ocular discomfort score** | 43 | 36 |

Ocular discomfort score ranges from 0 to 100, with lower scores indicating less severe symptoms.
Abbreviation: DED, dry eye disease.

# Reproxalap-treated patients experienced significantly less ocular discomfort

**Table 2. Primary Efficacy Analysis of Ocular Discomfort Symptom Score (ITT Population): Treatment Chamber vs Vehicle Chamber for Time Points of ≥ 80 Minutes After Chamber Entry**

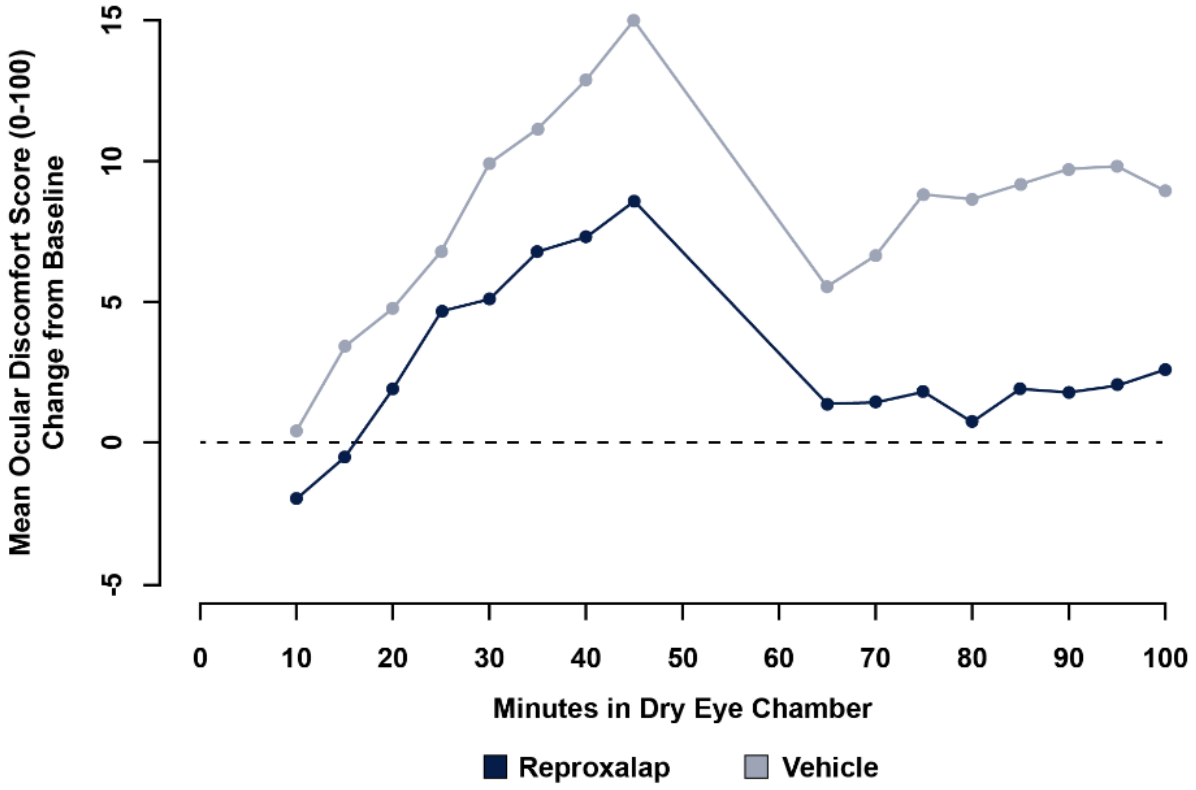
| Outcome | Reproxalap N = 66 | Vehicle N = 66 |
|---|---|---|
| Mean (SD) | -13.97 (18.49) | -10.67 (20.40) |
| LS mean (SE) | -16.87 (1.32) | -11.65 (1.28) |
| 95 % CI for LS mean | -19.46, -14.27 | -14.17, -9.14 |
| *P* Value | < .0001 | < .0001 |
| | | |
| LS mean difference vs vehicle (SE) | -5.21 (1.82) | - |
| 95 % CI for LS mean difference | -8.79, -1.63 | - |
| *P* Value | .0044 | - |

- Compared with Vehicle Chamber, adjusted patient-reported ocular discomfort at Treatment Chamber was significantly lower in reproxalap-treated patients from 80 to 100 minutes after chamber entry (LS mean difference [95% CI]: -5.21 [-8.79, -1.63]; *P* = .0044) (**Table 2**)

Abbreviations: CI, confidence interval; ITT, intention-to-treat; LS, least squares.

# Ocular discomfort remained lower in reproxalap-treated patients for the entirety of the chamber

**Figure 2. Mean Change from Baseline for Ocular Discomfort Score at Each Timepoint in the Randomized Treatment Dry Eye Chamber (Treatment Chamber) (ITT Population)**

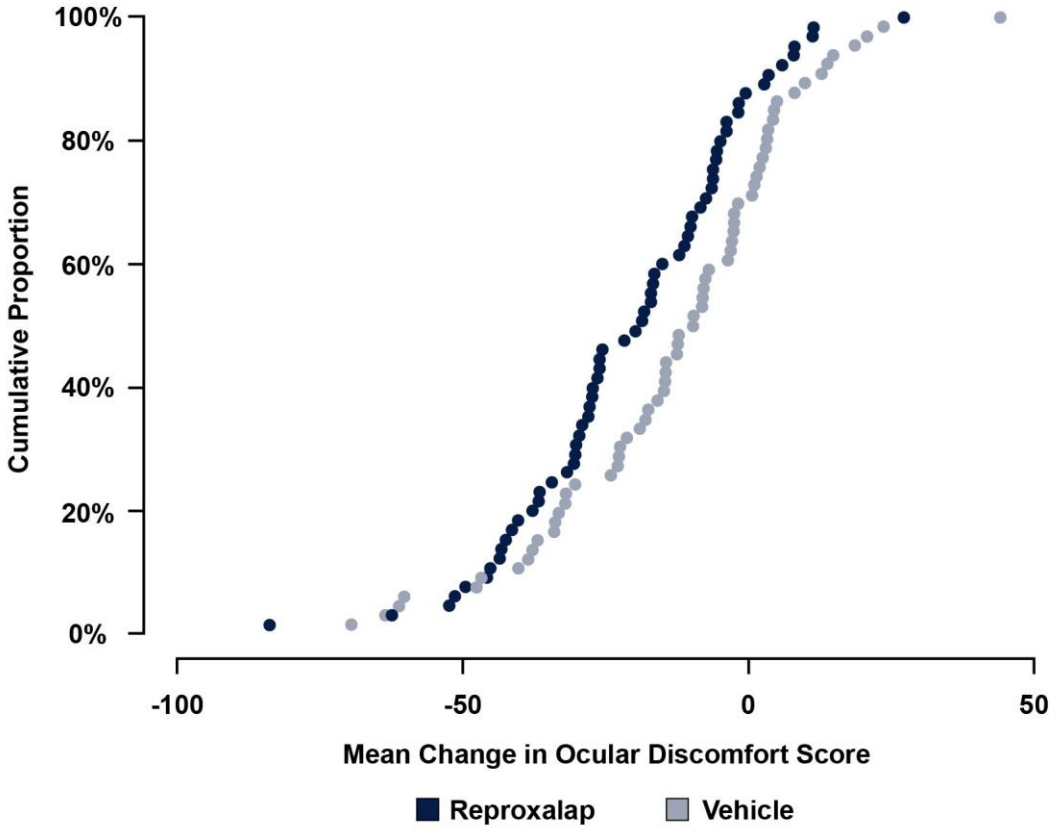



- Change from baseline in ocular discomfort was numerically lower with reproxalap than with vehicle at every time point in the dry eye chamber
- In contrast to vehicle-treated patients, mean ocular discomfort scores from patients treated with reproxalap approached baseline by the end of the chamber

Abbreviation: ITT, intention-to-treat.

# Ocular discomfort scores were lower for a greater proportion of reproxalap-treated patients

**Figure 3. Distribution Function of Time-Matched Change from Baseline in Ocular Discomfort Dry Eye Chamber Score (Treatment Chamber- Vehicle Chamber) Averaged Across Eyes and Primary Endpoint Contrast Timepoints (80-100 Minutes)**




- The cumulative distribution function of time-matched change from baseline in ocular discomfort score (Treatment Chamber – Vehicle Chamber), averaged across both eyes and all prespecified contrast timepoints (80-100 minutes after chamber entry), indicated that reproxalap was superior to vehicle across nearly all thresholds

- From 80 to 100 minutes after chamber entry, ocular discomfort scores of approximately 89% of patients in the reproxalap treatment arm were lower in Treatment Chamber than in Vehicle Chamber vs approximately 70% in the vehicle treatment arm

# Most ocular TEAEs were mild or moderate for reproxalap-treated patients

## Table 3. All Treatment and Ocular Treatment-Emergent Adverse Events (Safety Population)

| TEAEs | Reproxalap N = 66 N (%) [# of events] | Vehicle N = 66 N (%) [# of events] |
|---|---|---|
| **Any TEAE** | 60 (90.9) [299] | 20 (15.2) [31] |
| **Any TEAE related to study intervention** | 60 (90.9) [299] | 20 (15.2) [31] |
| **Any ocular TEAE** | 60 (90.9) [298] | 14 (10.6) [24] |
| **Eye disorders** | 2 (3.0) [3] | 4 (3.0) [7] |
| Abnormal sensation in eye | 1 (1.5) [2] | 0 |
| Asthenopia | 0 | 1 (0.8) [3] |
| Eye pain | 0 | 1 (0.8) [1] |
| Eye pruritus | 0 | 1 (0.8) [1] |
| Foreign body sensation in eye | 0 | 1 (0.8) [1] |
| Swelling of eyelid | 0 | 1 (0.8) [1] |
| Vision blurred | 1 (1.5) [1] | 0 |
| **General disorders and administration site conditions** | 60 (90.9) [295] | 10 (7.6) [17] |
| Instillation site irritation | 60 (90.9) [291] | 10 (7.6) [17] |
| Instillation site pruritus | 3 (4.5) [4] | 0 |

- 60 (90.9%) of patients in the reproxalap group experienced 299 TEAEs compared with 20 (15.2%) of patients in the vehicle group that experienced 31 TEAEs. All were considered related to the test article
  - The majority of TEAEs (reproxalap: n = 59 [89.4%]; vehicle: n = 18 [13.6%]) were mild in severity; no serious or severe TEAEs were reported, and no TEAE led to withdrawal or death
- Ocular TEAEs occurred in 60 (90.9%) patients who received reproxalap and 14 (10.6%) who received vehicle
- Ocular TEAEs were mild in 59 (89.4%) patients who received reproxalap and in 18 (13.6%) patients who received vehicle
- Ocular TEAE's were moderate in 1 (1.5%) patient who received reproxalap (instillation site irritation), and 2 (1.5%) patients who received vehicle (eye pain; swelling of eyelid)
- The most common ocular TEAE in both treatment groups was instillation site irritation, which was almost always mild (reproxalap: n = 59 [89.4%]; vehicle: n = 10 [7.6%]) and most commonly lasted < 1 minute

Abbreviations: #, number; TEAE, treatment-emergent adverse event.

## Limitations

- Interpretation of this study is limited by several factors, including:
  - Single-center design
  - Small number of patients included
  - Long-term effects not assessed

# Conclusions

- Patient-reported ocular discomfort scores from Vehicle Chamber to Treatment Chamber for 80 to 100 minutes after dry eye chamber entry were significantly lower in reproxalap-treated patients compared with vehicle-treated patients
- The primary endpoint of ocular discomfort symptom score was achieved, indicating the rapid activity of reproxalap in reducing ocular discomfort associated with DED in a challenge model designed to mimic dry eye flare, the most described aspect of DED for most patients
- No patients discontinued from the trial due to adverse events, nor were there any serious adverse events, which is consistent with previous studies

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