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Pooled Fluorescein Staining Results from Two Dry Eye Disease Trials with Reproxalap, a Novel RASP Modulator for the Treatment of Dry Eye Disease

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OBJECTIVE

To evaluate the efficacy of reproxalap in improving total corneal fluorescein staining scores in patients with dry eye disease (DED)

CONCLUSIONS

Reproxalap demonstrated rapid onset of action, achieving statistically significant improvements in total corneal fluorescein staining scores by Week 2 and sustained through Week 12 in patients with DED

Reproxalap treatment was safe and well tolerated, with mild-to-moderate instillation site irritation reported as the most common adverse event

Reproxalap is an innovative and rapidly acting therapeutic option for patients with DED

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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.

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PURPOSE

- Dry eye disease (DED) is a chronic ocular surface condition associated with ocular inflammation that can compromise the integrity of the corneal epithelium, damaging the cornea[1,2]
- Corneal fluorescein staining is a common efficacy endpoint in clinical trials for DED, providing an objective measure for corneal epithelial barrier disruption[3]
- Reproxalap, a novel reactive aldehyde species (RASP) inhibitor, targets ocular inflammation associated with corneal barrier disruption and may improve corneal epithelial barrier integrity
- This post-hoc analysis evaluated corneal fluorescein staining scores following treatment with reproxalap in individuals with DED

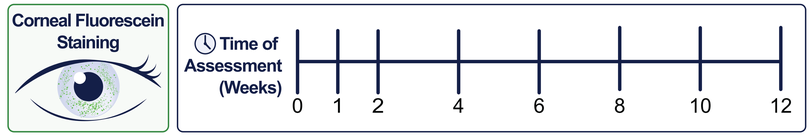
METHODS

- In this post-hoc analysis, data was pooled from two 12-week, multicenter, randomized, double-masked, parallel-group, vehicle-controlled trials that investigated the efficacy of reproxalap at improving corneal fluorescein staining scores
  - ► ADX-102-DED-012 (NCT03879863): Adaptive Phase 3 clinical trial
  - ► ADX-102-DED-013 (NCT03916042): Phase 2 clinical trial
- Patients with DED received reproxalap 0.25% four times daily for one month and twice daily thereafter

METHODS (CONT'D.)

- Total corneal fluorescein staining scores (0-12) were evaluated as a sum of superior, central, and inferior regions and were assessed from baseline through Week 12
- Fluorescein staining was graded using the Ora Calibra Corneal Staining Scale evaluating staining severity (0=none, 4=severe)
- Change from baseline following reproxalap treatment was analyzed using a mixed model for repeated measures, with baseline score included as a covariate and visit as a fixed effect
- Clinical relevance was evaluated using an exact binomial test, comparing the proportion of patients achieving ≥3-point improvement from baseline with an assumed spontaneous improvement rate of 10%

Study Design



RESULTS

Participants

- Across both studies, a total of 207 patients received treatment with reproxalap, the majority of which were White females
- Patient demographics were comparable between those receiving reproxalap and those receiving vehicle

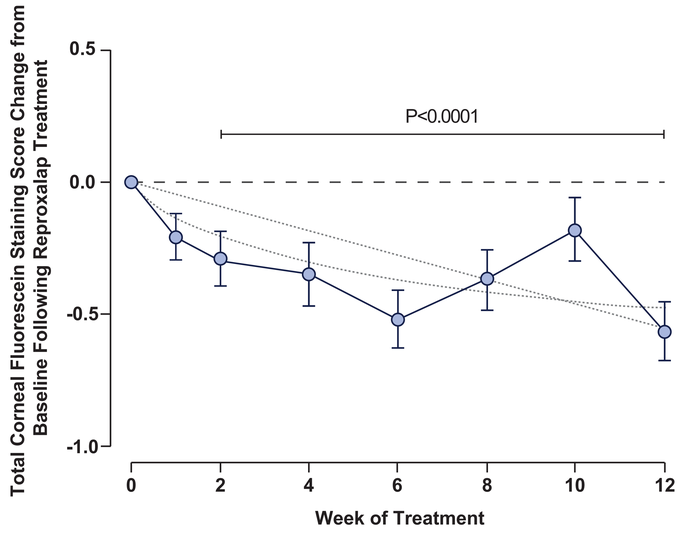
Efficacy

- Least-squares mean change from baseline in overall total fluorescein staining score through Week 12 was -0.36 (95% confidence interval: -0.48, -0.24, P<0.0001)
  - ► Both linear and logarithmic models demonstrated an acceptable fit (R^2 = 0.77 and 0.88, respectively)
- In the reproxalap treatment group, significant improvements from baseline were observed as early as Week 2 (P=0.006)
- The ≥3-point responder rate was significantly higher with reproxalap (P<0.0001)

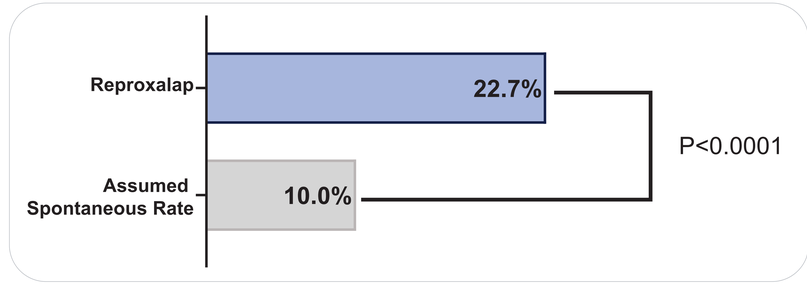
Baseline Demographics

Demographics	Reproxalap (n=207)
Age, mean years	64.8
Sex, n (%)	
Male	50 (24.2)
Female	157 (75.8)
Race, n (%)	
American Indian or Alaskan Native	2 (1.0)
Asian	9 (4.3)
Black or African American	16 (7.7)
White	179 (86.5)
Multiple	0 (0.0)
Other	1 (0.5)

Change from Baseline Through Week 12 in Total Corneal Fluorescein Staining Score Following Reproxalap Treatment



≥3-Point Responder Rate Among Reproxalap-Treated Patients



Safety

- The most common adverse event reported was mild-to-moderate instillation site irritation
- No serious treatment emergent adverse events (TEAEs) were deemed related to reproxalap treatment

Adverse Events

Safety Endpoint, n (%)	Reproxalap (n=207)
Patients with ≥1 TEAE	184 (88.9)
Mild	148 (71.5)
Moderate	35 (16.9)
Severe	1 (0.5)
Patients with ≥1 Ocular TEAE	182 (87.9)
Patients with ≥1 Non-Ocular TEAE	33 (15.9)
General Disorders & Administration Site Conditions	176 (85.0)
Instillation Site Irritation	108 (52.2)
Patients with ≥1 TE-SAE	2 (1.0)
TEAEs Leading to Study Discontinuation	13 (6.3)
TEAEs or SAEs Resulting in Death	0 (0.0)

Abbreviations: SAE, serious adverse event; TEAE, treatment-emergent adverse event; TE-SAE, treatment-emergent serious adverse event.

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