January 7, 2021

DATA RELEASE

Initial Symptom and Sign Results From Run-In Cohort of Phase 3 TRANQUILITY Trial in Dry Eye Disease

Nasdaq: ALDX

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Initial Results From Run-In Cohort of Phase 3 TRANQUILITY Trial Support First-Line Potential of Reproxalap in Dry Eye Disease

- Statistical significance achieved for both sign and symptoms in dry eye chamber:*
  - Reproxalap demonstrated statistically significant improvement over vehicle in ocular redness (p=0.03), an FDA-approvable objective sign.
  - Reproxalap demonstrated statistically significant improvement over vehicle for the two assessed clinical symptoms: VAS Ocular Dryness (p=0.001) and Ocular Discomfort Score (p<0.0001).
- Acute improvements in ocular symptoms and objective sign within minutes of reproxalap administration in a dry eye chamber.
- 24-hour environmental results supportive of reproxalap's rapid and broad efficacy, with consistent directional improvements over vehicle across symptoms and Schirmer's test, and statistical significance vs. vehicle achieved in four of eight assessed outcome measurements.
- The main cohort of TRANQUILITY is expected to begin enrollment in February 2021, following completion of tear RASP analysis from the run-in cohort and confirmation of endpoints and patient numbers.

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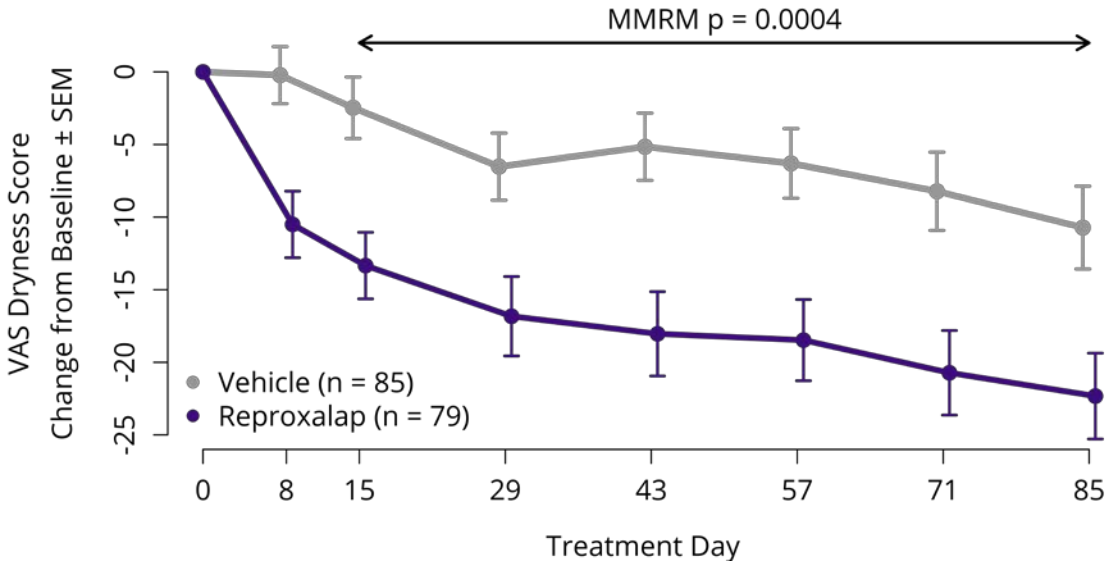
*Based on Mixed Model Repeated Measures (MMRM p values shown above). Topical ocular reproxalap has been studied in over 1,100 patients thus far with no observed safety concerns; mild instillation site irritation is the most commonly reported adverse event in clinical trials. Mixed effect model of repeated measures (MMRM) for change from baseline (Time 0).
Source: TRANQUILITY Run-In Cohort initial results

VAS = Visual Analog Scale
RASP = Reactive Aldehyde Species

Reproxalap Demonstrated Rapid, Broad, and Durable Symptom Improvement Over 12 Weeks of Chronic Therapy in Prior Trials

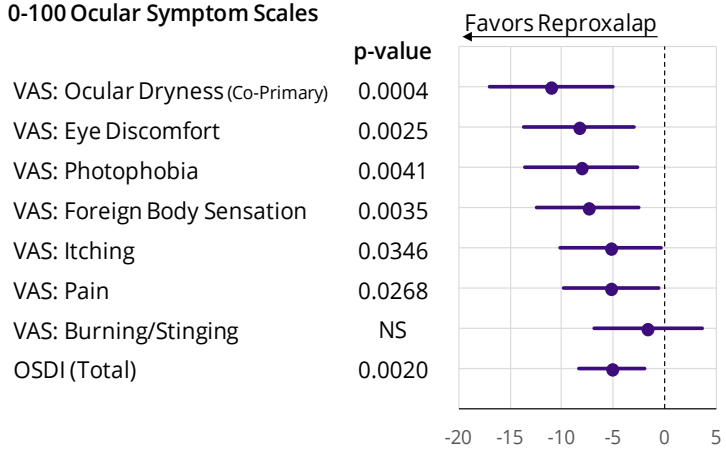
RENEW-Part 1 Phase 3 Trial
(Induction-Maintenance Dosing)



Reproxalap demonstrated statistically significant symptom improvements over vehicle as early as one week after treatment initiation.

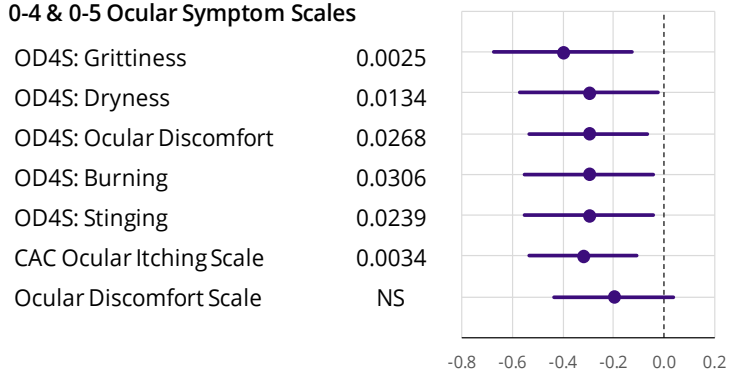
Symptom Treatment Difference‡ (Reproxalap-Vehicle) Over Weeks 2 to 12

0-100 Ocular Symptom Scales



	p-value
VAS: Ocular Dryness (Co-Primary)	0.0004
VAS: Eye Discomfort	0.0025
VAS: Photophobia	0.0041
VAS: Foreign Body Sensation	0.0035
VAS: Itching	0.0346
VAS: Pain	0.0268
VAS: Burning/Stinging	NS
OSDI (Total)	0.0020

0-4 & 0-5 Ocular Symptom Scales



OD4S: Grittiness	0.0025
OD4S: Dryness	0.0134
OD4S: Ocular Discomfort	0.0268
OD4S: Burning	0.0306
OD4S: Stinging	0.0239
CAC Ocular Itching Scale	0.0034
Ocular Discomfort Scale	NS

‡Treatment Difference of induction-maintenance dosing, defined as the difference between the changes from baseline for the evaluated drug vs. vehicle (LS Mean Difference ± 95% CI). Ocular Dryness Score co-primary endpoint assessed in pre-specified patient population having an OD4S dryness baseline score of ≥ 3 (N=170). Topical ocular reproxalap has been studied in over 1,100 patients with no observed safety concerns; mild instillation site irritation is the most commonly reported adverse event in clinical trials.
Induction-Maintenance dosing defined as QID dosing (4x daily) for weeks 1-4 followed by BID dosing (2x daily) for weeks 5-12.
Source: Reproxalap RENEW-Part 1 clinical trial results and TRANQUILITY Run-In Cohort initial results.

VAS = Visual Analog Scale
OD4S = Ocular Discomfort & 4-Symptom
CAC = Conjunctival Allergen Challenge
MMRM = Mixed Effect Model Repeated Measures

TRANQUILITY Run-In Cohort Evaluated Acute Effects of Reproxalap in Dry Eye Disease Patients

Run-In cohort objective:

- Evaluate efficacy of reproxalap compared to vehicle in dry eye disease after single and multiple doses, and after exposure to a dry eye chamber.
- Power and confirm primary and secondary endpoints for the main cohort of the Phase 3 TRANQUILITY clinical trial.

Initial Results Available Today

Day 1 (24 hour)
- Dry Eye Symptoms
- Schirmer's Test

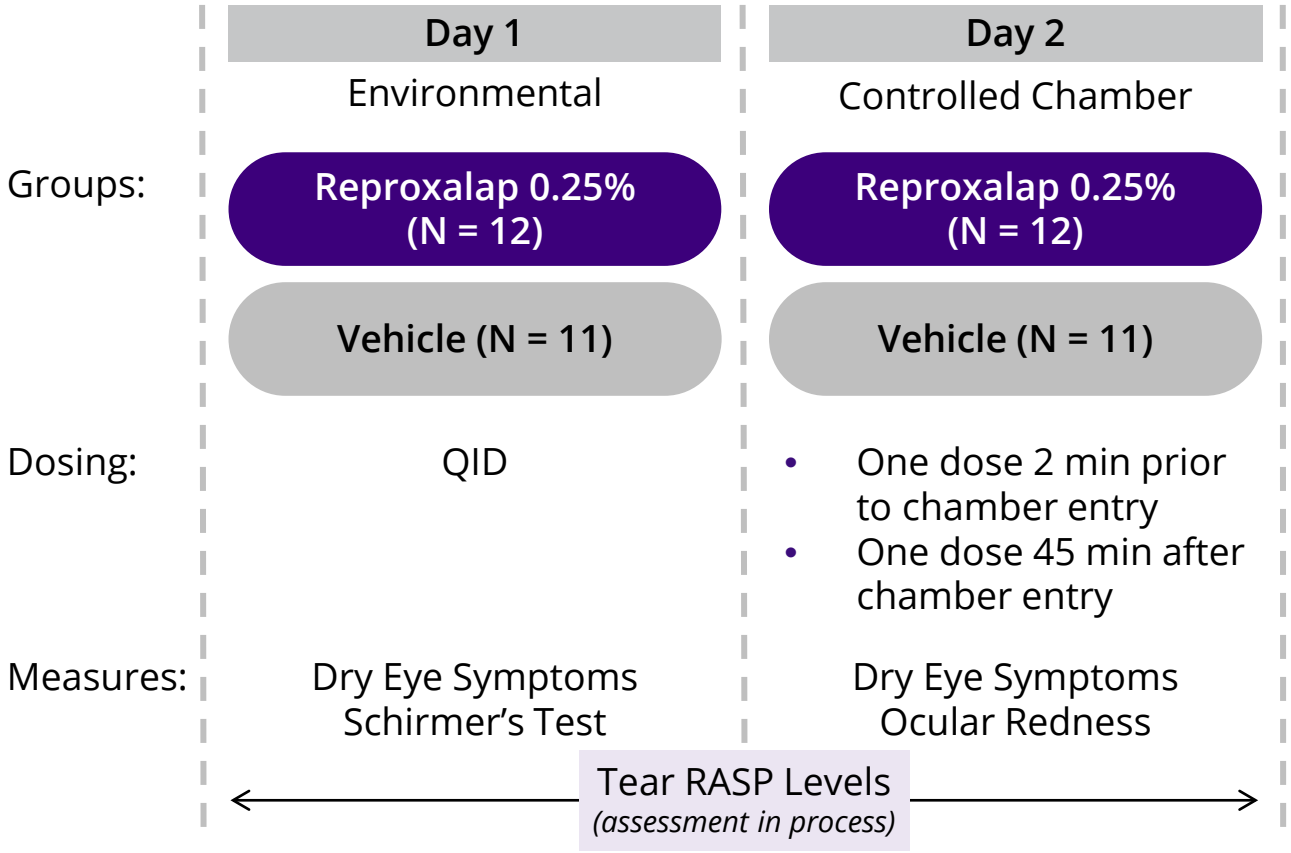
Day 2 (Chamber)
- Dry Eye Symptoms
- Ocular Redness

Assessment Currently In Process

Day 1 – Day 2
- Tear RASP Levels

Main cohort expected to begin enrollment in February 2021, following completion of tear RASP analysis from run-in cohort and confirmation of endpoints and patient numbers.

TRANQUILITY Run-In Cohort Design



QID = Four times daily

Reproxalap Demonstrated Rapid And Broad Improvements After Only One Day of Treatment in TRANQUILITY Run-In Cohort

TRANQUILITY Run-In Cohort Day 1 (24 Hours) Results:*

Dry Eye Assessment (Scale) After Environmental Dosing	Change From Baseline		P-Value
	Reproxalap (N = 12)	Vehicle (N = 11)	
VAS Dryness (0-100)	-26	+2	**0.003**
OD4S: Discomfort (0-5)	-0.7	+0.4	**0.003**
OD4S: Dryness (0-5)	-1.2	+0.1	**0.006**
OD4S: Grittiness (0-5)	-1.1	+0.1	**0.006**
OD4S: Burn (0-5)	-0.1	+0.8	0.07
OD4S: Sting (0-5)	-0.1	+0.4	0.23
Ocular Discomfort Scale (0-4)	-0.7	+0.4	0.07
Schirmer's Test (mm)*	+3.4	+1.3	0.30

*Day 1 Schirmer's Test results based on improvement after a single dose; all other Day 1 assessments performed over 24 hours of QID dosing. Topical ocular reproxalap has been studied in over 1,100 patients thus far with no observed safety concerns; mild instillation site irritation is the most commonly reported adverse event in clinical trials.
Source: TRANQUILITY Run-In Cohort initial results

VAS = Visual Analog Scale
OD4S = Ocular Discomfort & 4-Symptom Questionnaire
QID = Four times daily

The Dry Eye Chamber:
A Demanding Real-World Drug Assessment of Dry Eye Disease

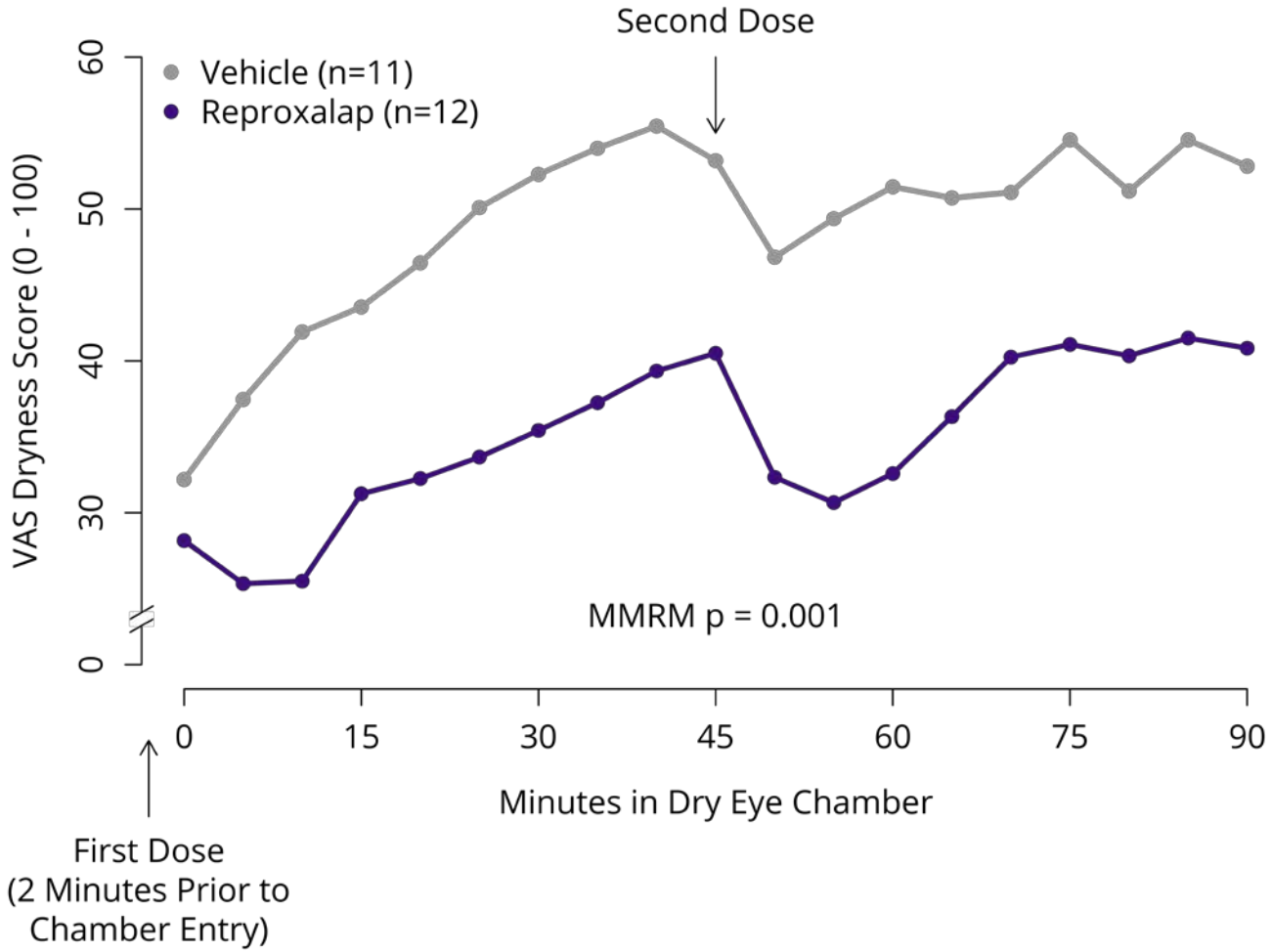
- Challenge-model trials utilizing a controlled chamber are an FDA accepted design for pivotal endpoints.*
- Dry eye chambers control relative humidity, temperature, airflow, and visual tasking in order to stress the ocular surface.
  - Chambers simulate a “bad day” scenario in the life of a dry eye disease sufferer.
- Trial designs utilizing chambers are able to confirm the utility of drugs with rapid onset of action during an acute ocular surface challenge.

*FDA published “Dry Eye: Developing Drugs for Treatment” draft guidance; December 2020.

Reproxalap Demonstrated Acute and Durable Improvements in Ocular Dryness in TRANQUILITY Run-In Dry Eye Chamber

TRANQUILITY Run-In Cohort Day 2 Results: Ocular Dryness Score (VAS) in Dry Eye Chamber

- Drug effect over vehicle observed upon entry and sustained throughout duration of exposure.
- Therapeutic activity demonstrated after first and second doses, representing near-immediate (within minutes) and statistically significant symptom relief vs. vehicle.
- Consistent and statistically significant improvements over vehicle observed across all symptoms evaluated in the chamber.



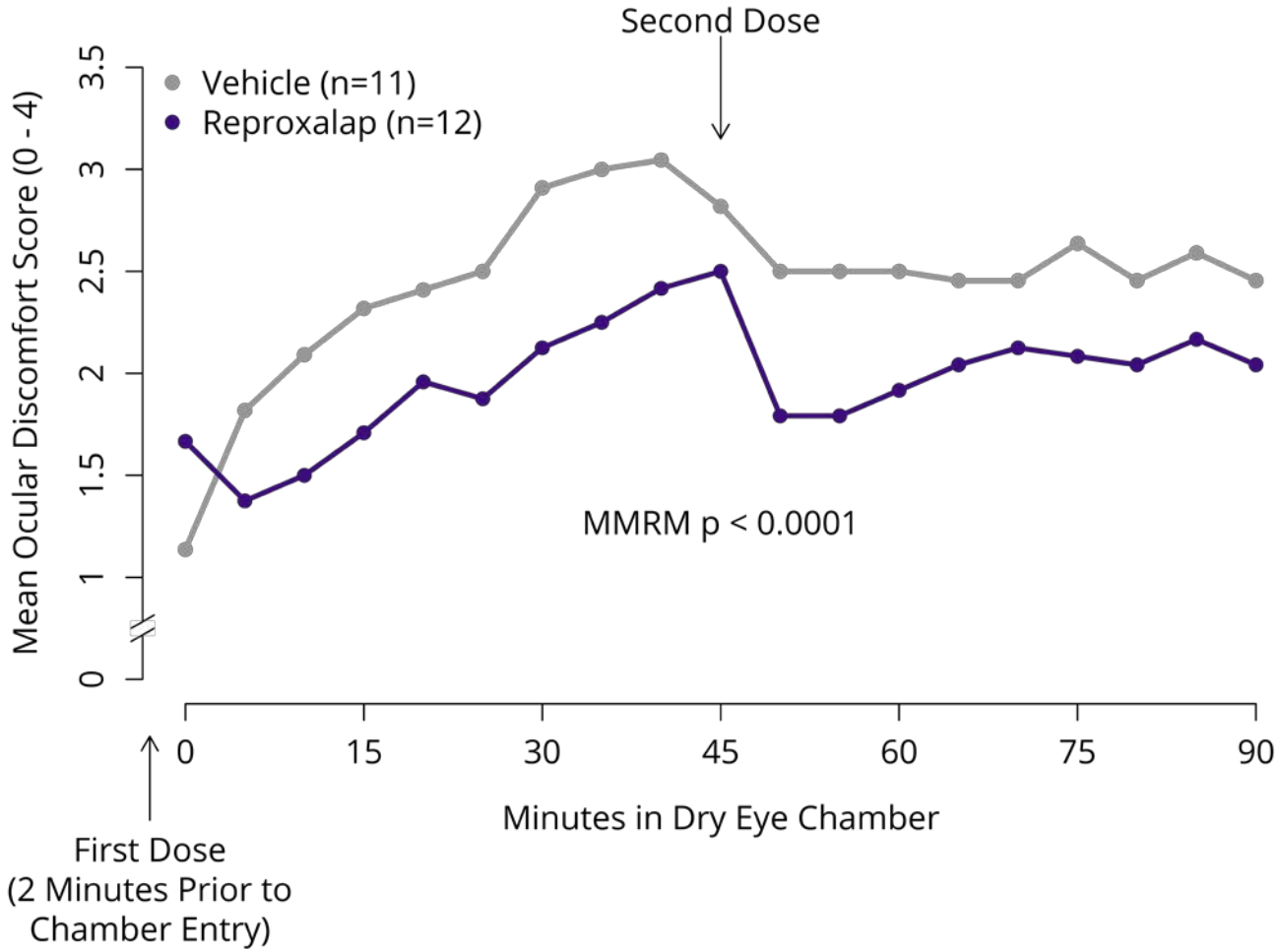
Mixed effect model of repeated measures (MMRM) for change from baseline (Time 0). Topical ocular reproxalap has been studied in over 1,100 patients thus far with no observed safety concerns; mild instillation site irritation is the most commonly reported adverse event in clinical trials.
Source: TRANQUILITY Run-In Cohort initial results

VAS = Visual Analog Scale
MMRM = Mixed Model Repeated Measures

Reproxalap Demonstrated Acute and Durable Improvements in Ocular Discomfort in TRANQUILITY Run-In Dry Eye Chamber

TRANQUILITY Run-In Cohort Day 2 Results: Ocular Discomfort Scale (0-4) in Dry Eye Chamber

- Drug effect over vehicle observed upon entry and sustained throughout duration of exposure.
- Therapeutic activity demonstrated after first and second doses, representing near-immediate (within minutes) and statistically significant symptom relief vs. vehicle.
- Consistent and statistically significant improvements over vehicle observed across all symptoms evaluated in the chamber.



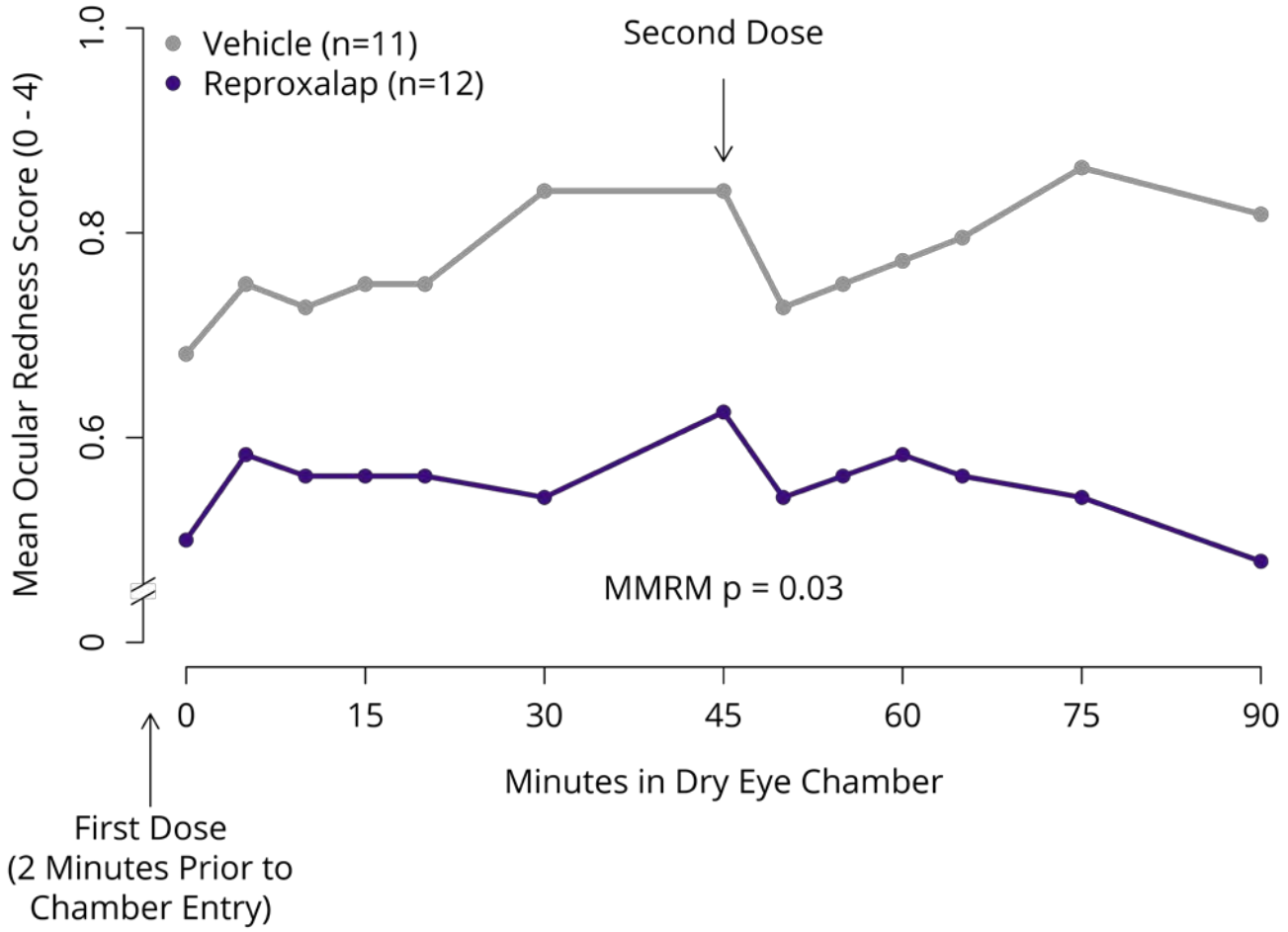
Mixed effect model of repeated measures (MMRM) for change from baseline (Time 0). Topical ocular reproxalap has been studied in over 1,100 patients thus far with no observed safety concerns; mild instillation site irritation is the most commonly reported adverse event in clinical trials.
Source: TRANQUILITY Run-In Cohort initial results

VAS = Visual Analog Scale
MMRM = Mixed Model Repeated Measures

Reproxalap Demonstrated Acute and Durable Improvements in Ocular Redness in TRANQUILITY Run-In Dry Eye Chamber

TRANQUILITY Run-In Cohort Day 2 Results: Ocular Redness Score (0-4) in Dry Eye Chamber

- Drug effect over vehicle observed upon entry and sustained throughout duration of exposure.
- Therapeutic activity demonstrated after first and second dose, representing near-immediate (within minutes) and statistically significant objective sign relief vs. vehicle.
- Ocular redness is an FDA-approvable objective sign endpoint for dry eye disease.*



*Currently FDA approved dry eye products have utilized Schirmer's Test, corneal staining, and conjunctival hyperemia (redness) as objective sign measures.
Mixed effect model of repeated measures (MMRM) for change from baseline (Time 0). Topical ocular reproxalap has been studied in over 1,100 patients thus far with no observed safety concerns; mild instillation site irritation is the most commonly reported adverse event in clinical trials.
Source: TRANQUILITY Run-In Cohort initial results

VAS = Visual Analog Scale
MMRM = Mixed Model Repeated Measures

Reproxalap Has Demonstrated Consistent Symptom and Sign Results Across Two Chamber Challenge Models in Ocular Surface Diseases

TRANQUILITY Run-In Cohort

Phase 2 Allergic Conjunctivitis Chamber Trial

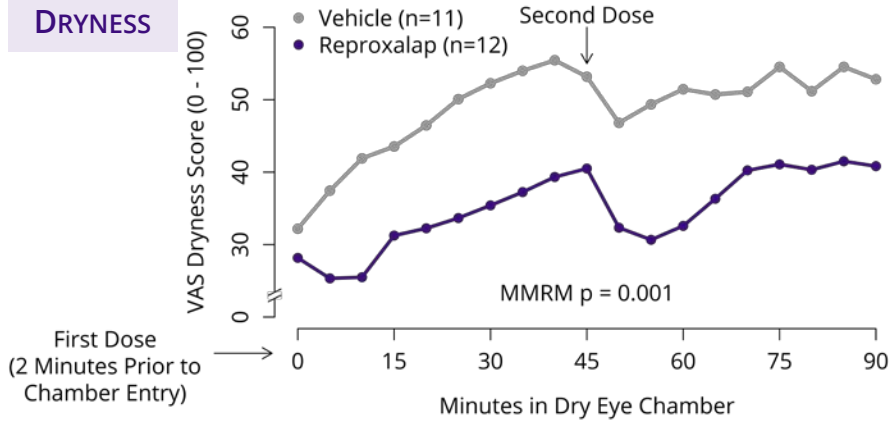
Disease Symptom

Disease Sign

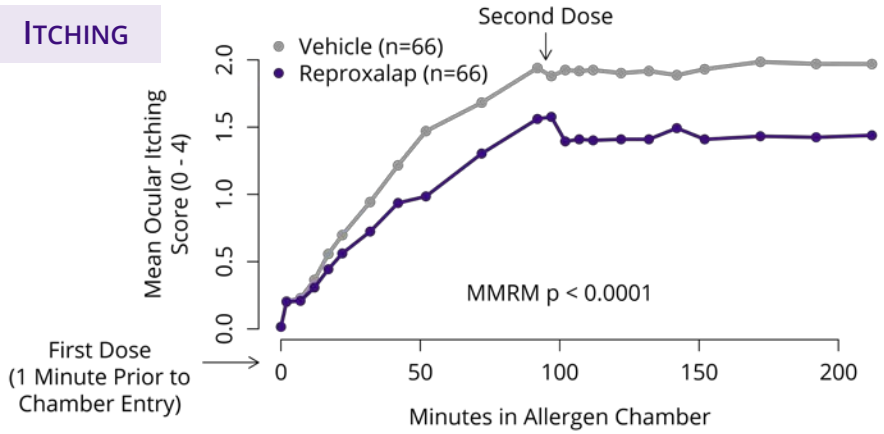
Dry Eye Chamber

Allergen Chamber

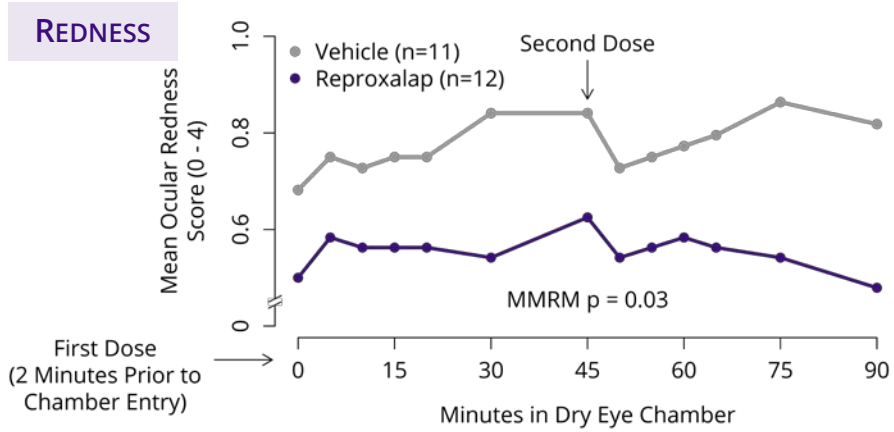
DRYNESS



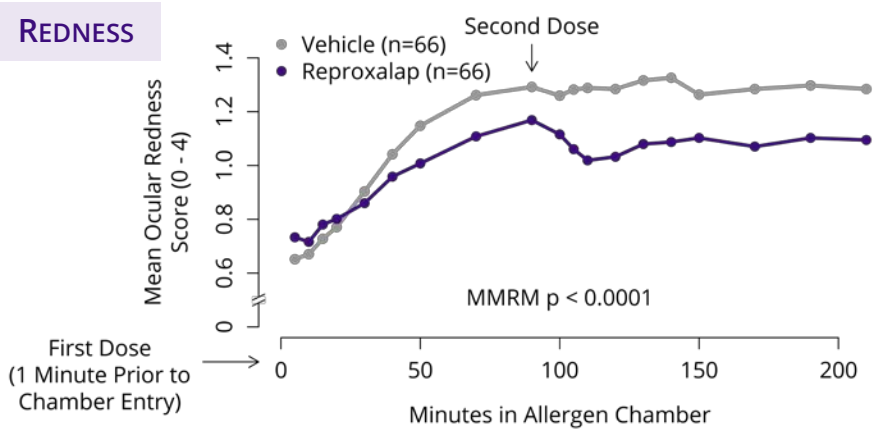
ITCHING



REDNESS



REDNESS



Topical ocular reproxalap has been studied in over 1,100 patients thus far with no observed safety concerns; mild instillation site irritation is the most commonly reported adverse event in clinical trials.
Source: TRANQUILITY Run-In Cohort initial results; Phase 2 Allergen Chamber clinical trial – reproxalap 0.25% (ClinicalTrials.gov #NCT03709121)

VAS = Visual Analog Scale
MMRM = Mixed Model Repeated Measures

TRANQUILITY Main Cohort Clinical Trial Design

- Main cohort trial design, endpoints, and patient numbers to be confirmed following completion of tear RASP analysis from the run-in cohort.
- TRANQUILITY main cohort design options:

Trial Design Option:

Challenge-Model

Duration:	**Two days**
Size:	**~200 patients total***
Primary endpoint:	Objective DED Sign
Secondary endpoints:	Additional DED Sign and DED Symptoms
Design:	Multi-center randomized, double-masked, parallel design, vehicle-controlled clinical trial

Trial Design Option:

Challenge-Model + Environmental Exposure

Duration:	**Four weeks**
Size:	**~200 patients total***
Primary endpoint:	Objective DED Sign
Secondary endpoints:	Additional DED Sign and DED Symptoms
Design:	Multi-center randomized, double-masked, parallel design, vehicle-controlled clinical trial

Main cohort expected to begin enrollment in February 2021.

*Pending final powering based on final run-in cohort results.

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Upcoming Expected Reproxalap Development Milestones*

- Reproxalap dry eye disease
  Phase 3 TRANQUILITY main cohort enrollment initiation February 2021
- Reproxalap dry eye disease
  Phase 3 TRANQUILITY-2 initiation Q1 2021
- Reproxalap allergic conjunctivitis
  Phase 3 INVIGORATE study top-line results H1 2021

*The timing of clinical trial initiation and completion depends, in part, on restrictions related to COVID-19, the availability of clinical research facilities and staffing, the ability to recruit patients, and regulatory feedback.