Oculis | Rethinking Ophthalmology

Licaminlimab in Dry Eye Disease

Relief

Topline Results

10 June 2024

Safe Harbor Statements

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RELIEF Phase 2b Topline Results – Speakers

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RELIEF Ph2b Successfully Executed with Positive Results in DED

EFFICACY

- ☑ Licaminlimab showed rapid onset and meaningful improvements in multiple sign efficacy endpoints in full trial population
- ☑ TNFR1 genetic biomarker, previously identified in Ph2 symptom trial, showed a predictive and pronounced effect in signs, paving the way for precision medicine in Ophthalmology

SAFETY

- ☑ Licaminlimab was well-tolerated with a low incidence of adverse events like vehicle
- ☑ No burning or blurred vision events reported in the treatment group

Positive Phase 2b RELIEF trial defines clear pathway for licaminlimab to advance to Phase 3 as potentially the first precision medicine to address both signs and symptoms of DED

Data, analysis and conclusions are preliminary, and subject to change as full analysis is ongoing.

Three Positive Phase 2 Trials Now Completed in DED

First time precision medicine approach applied to DED, significantly de-risking Phase 3 clinical program and offering a transformative product profile

Phase 2 Randomized Controlled Studies in DED	Consistent positive results across studies (signs and symptoms) and unique precision medicine strategy
DED#1 Symptoms 85 patients Phase 2 PoC	**Improvement in Symptoms**: Ocular Discomfort
DED#2 Symptoms 134 patients Phase 2 PoC	**Improvement in Symptoms**: Ocular Discomfort + **Identification** of TNFR1 genetic biomarker
DED#3 (RELIEF) Signs 122 patients Phase 2b	**Improvement in Signs**: Corneal/ Conjunctival Staining + **Validation** of TNFR1 genetic biomarker

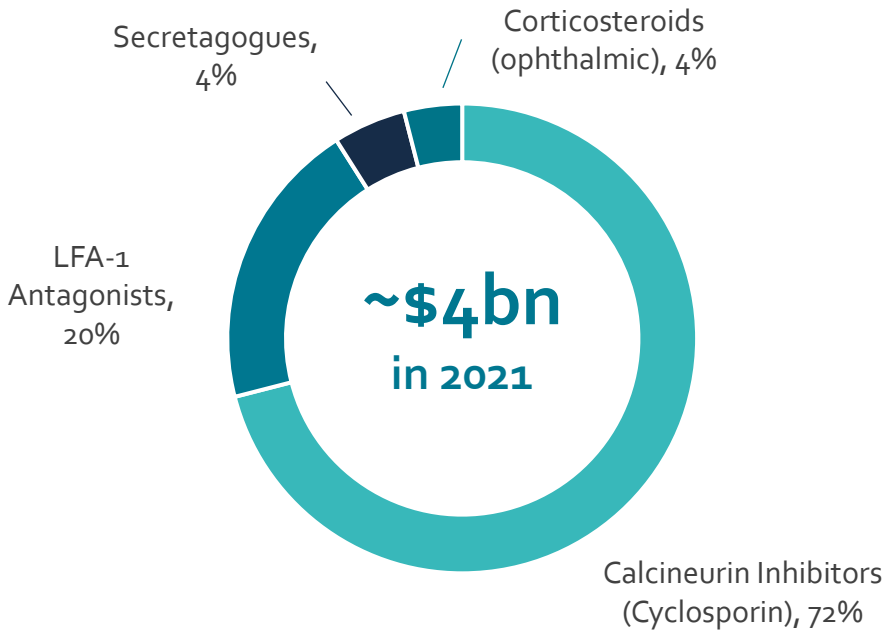
DED#1 and DED#3: Data on file
DED #2: Lee Sheetle et al. *Topical Anti-TNFα Agent Licaminlimab (OCS-02) Relieves Persistent Ocular Discomfort in Severe Dry Eye Disease: A Randomized Phase II Study,* Clinical Ophthalmology July 2022

Dry Eye Market and Unmet Needs

Large and Growing DED Opportunity

Market still underpenetrated and unsatisfied

Dry Eye Rx drug market in G7 countries in 2021[1]



Significant unmet need and market opportunity

- **Large and growing unmet medical need with ~10 million** diagnosed moderate to severe DED patients in the U.S.[1,2] with a G7 market forecasted to **reach ~$7bn** in 2029[1]
- **Most patients are treated with anti-inflammatory agents**; ~95% of the market is captured by cyclosporin and lifitigrast[3]
- **As reported in 2024 by AAO, 87% unsatisfied** patient population with only 13% of patients experiencing lasting relief [4]

1. DRG Dry Eye Disease Landscape and Forecast 2020.
2. Downs P. 2023. Dry Eye Products Market Report, Global Analysis for 2022 to 2028. Market Scope.
3. IQVIA Prescriptions volume in DED from April 2023 to March2024.
4. https://www.aao.org/eye-health/tips-prevention/fix-dry-eye-treatment-eyedrops

Despite New Treatment Options, Unsatisfied Market with Only 13% of Patients Experiencing Lasting Relief [1]

Several cyclosporines approved:

Restasis® (Cyclosporine Ophthalmic Emulsion) 0.05%

Cequa® (cyclosporine ophthalmic solution) 0.09%

vevye® (cyclosporine ophthalmic solution) 0.1%

Rx Treatments[2]

2002 | 2016 | 2018 | 2020 | 2021 | 2023

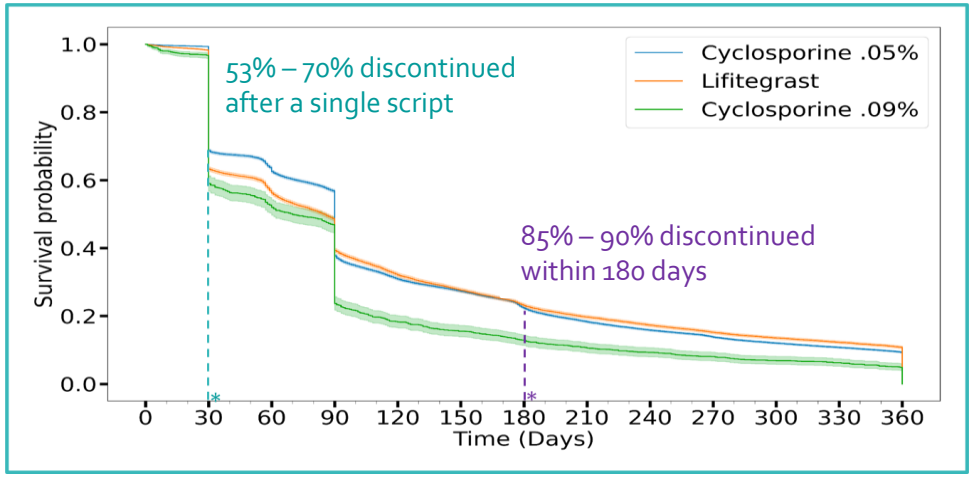
xiidra® (lifitegrast ophthalmic solution) 5%

EYSUVIS® (loteprednol etabonate ophthalmic suspension) 0.25%

tyrvaya® (varenicline solution) nasal spray 0.03 mg

NEW! Miebo™ (perfluorohexyloctane ophthalmic solution)

Discontinuation & switching is commonplace in DED[3]



- 85%- 90% of discontinuations occurred within 6 months
- Primary documented reasons for switching cited were lack of efficacy (45.1%) and adverse events (26.4%)[4]
- "Subtype specific therapeutics" rated as no. 1 need for the future in DED[4] given highly heterogeneous patient population[5]

DED (Dry eye disease).

1. https://www.aao.org/eye-health/tips-prevention/fix-dry-eye-treatment-eyedrops.
2. Downs P. *2023 Dry Eye Products Market Report, Global Analysis for 2022 to 2028.* Market Scope; 2023. 2. IQVIA TRx data from April 2023 to March 2024.
3. Mbagwu M, et al. Characterization of Discontinuation and Switching Patterns of Dry Eye Disease Medications Using Linked EHR Registry and Claims Data. Presented at: ASCRS Annual Meeting 2024.
4. https://ophthalmology360.com/study-finds-high-discontinuation-rate-of-dry-eye-medications/ 5. Audience survey during a meeting at ASCRS 2024.

Novel Anti-TNF-α Eye Drop for Ocular Inflammation

Clinically proven MoA with potential transformative impact in ocular inflammation

Topical Biologic Candidate

Licaminlimab is an **anti-TNF-α antibody fragment specifically formulated for topical delivery**

Clinically proven MoA

Anti-inflammation and anti-apoptosis MoA approved as systemic treatment for ocular disease and with **transformative impact** in other areas

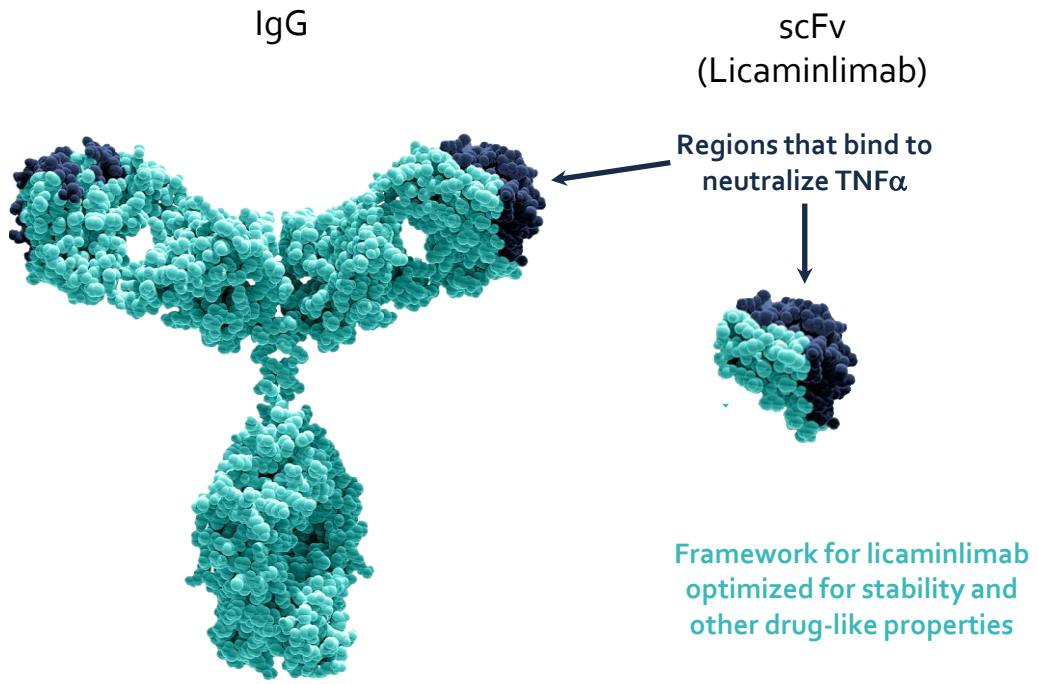
Enhanced ocular penetration

Lower molecular weight**, enhanced ocular penetration and higher concentration**

Proprietary genetic biomarker

Associated with licaminlimab response highlighting opportunity for a **precision treatment** in DED

Innovative Antibody Fragment Technology



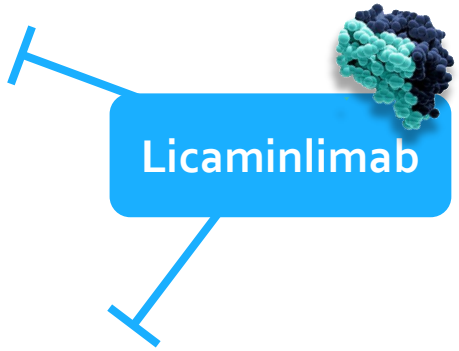
Licaminlimab Dual MoA and Potent Inhibitor of TNF-α

DUAL MoA:
ANTI-INFLAMMATORY & ANTI-APOPTOTIC

Inflammation

Inhibits release of inflammatory factor (IFN-γ, TNF-α, ILs) and MMP

Inhibits activation, recruitment, and infiltration of immune cells (primarily T-cells)



Apoptosis

Inhibits nerve stimulation and cell death in conjunctival epithelium

TNF-α inhibitor potencies	
Compound	**IC50**
Licaminlimab	**1.2 ng/mL**
Adalimumab	9.2 ng/mL
Infliximab	15.0 ng/mL

IL (Interleukin); MMP (Matrix metalloproteinase), IFN (Interferon), TNF (Tumor necrosis factor); MOA (Mechanism of action).
Oculis. Data on file.

Two Prior Successful Phase 2 Trials Showed Improvements on Symptoms and Identified TNFR1 Genetic Biomarker

EFFICACY

- ☑ Significantly reduced ocular discomfort in patients treated with licaminlimab vs. vehicle at Day 29
- ☑ Rapid onset of action with relief of symptoms starting on Day 15

SAFETY

- ☑ Well-tolerated with a low incidence of adverse events related to study treatment, similar to vehicle

PRECISION MEDICINE POTENTIAL

- ☑ Pharmacogenomic identified TNFR1 genetic biomarker showing:
  - Significant association with licaminlimab response on ocular discomfort (7-fold improvement vs. full population)
  - Reduced inflammatory cytokines in tear film observed in licaminlimab treated patients

DED#1 Phase 2 on symptoms: Data on file
DED #2: Lee Sheetle et al. *Topical Anti-TNFα Agent Licaminlimab (OCS-02) Relieves Persistent Ocular Discomfort in Severe Dry Eye Disease: A Randomized Phase II Study,* Clinical Ophthalmology July 2022

Phase 2b RELIEF Study Design and Topline Results

Trial Objectives

Designed to address three goals of licaminlimab development plan

1. Evaluate efficacy of licaminlimab in the treatment of signs of DED
2. Confirm differentiated response to licaminlimab in subjects with the TNFR1 genetic biomarker in signs of DED
3. Select primary sign efficacy endpoint for Phase 3 and inform the overall development plan

RELIEF Phase 2b in Signs of DED

Designed to identify the most relevant endpoint in signs and assess TNFR1 genetic biomarker in signs in DED

Phase 2b study design:

- Randomized, masked, vehicle-controlled study
- Multi-center, 10-week trial stratification based on TNFR1-related genotype ~20% patients

Primary Objective:

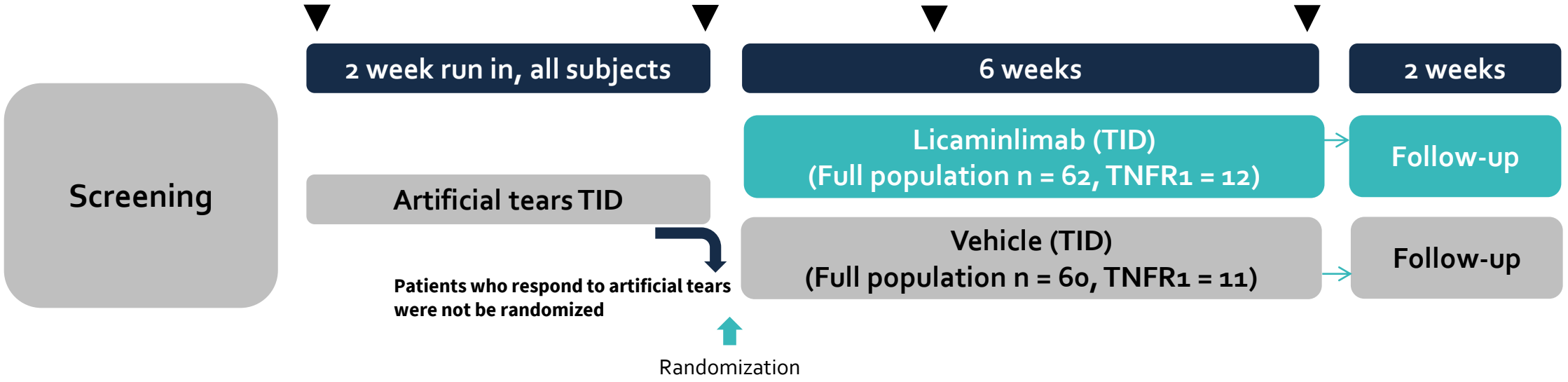
- Evaluate efficacy and safety in subjects with signs of dry eye disease

Endpoints:

- Corneal / Conjunctival Staining, Redness and Schirmer's

Patient Population:

- Moderate to severe corneal staining
- Susceptible to corneal damage of the inferior region under stressed conditions
- Decreased tear production (Schirmer's test at baseline)



▼ CAE = Controlled Adverse Environment

Secondary Trial Objective

Confirm the TNFR1 genetic biomarker as a predictor of response to licaminlimab

Simple genetic testing procedure:

1. Patient supplies saliva sample which is shipped to lab
2. Lab runs commercial identification assay on saliva for TNFR1 genetic biomarker
3. Assay uses TaqMan genotyping

Qualitative PCR (qPCR) tests:

- Widely available, affordable, and can be performed quickly in a qualified laboratory or doctor's office
- Easy to interpret binary result (Yes/No)

Aligned with FDA Guidance on Developing Drugs for DED

TRIAL DESIGN CONSIDERATIONS

- Safety and efficacy should be demonstrated in at least two adequate and well-controlled, multicenter independent trials
- Efficacy for a sign and efficacy for a symptom do not have to be demonstrated in the same trial, but each should be demonstrated in more than one trial

SIGNS OF DED CAN INCLUDE:

- **Corneal staining**
- Conjunctival staining
- Schirmer's test
- Conjunctival redness

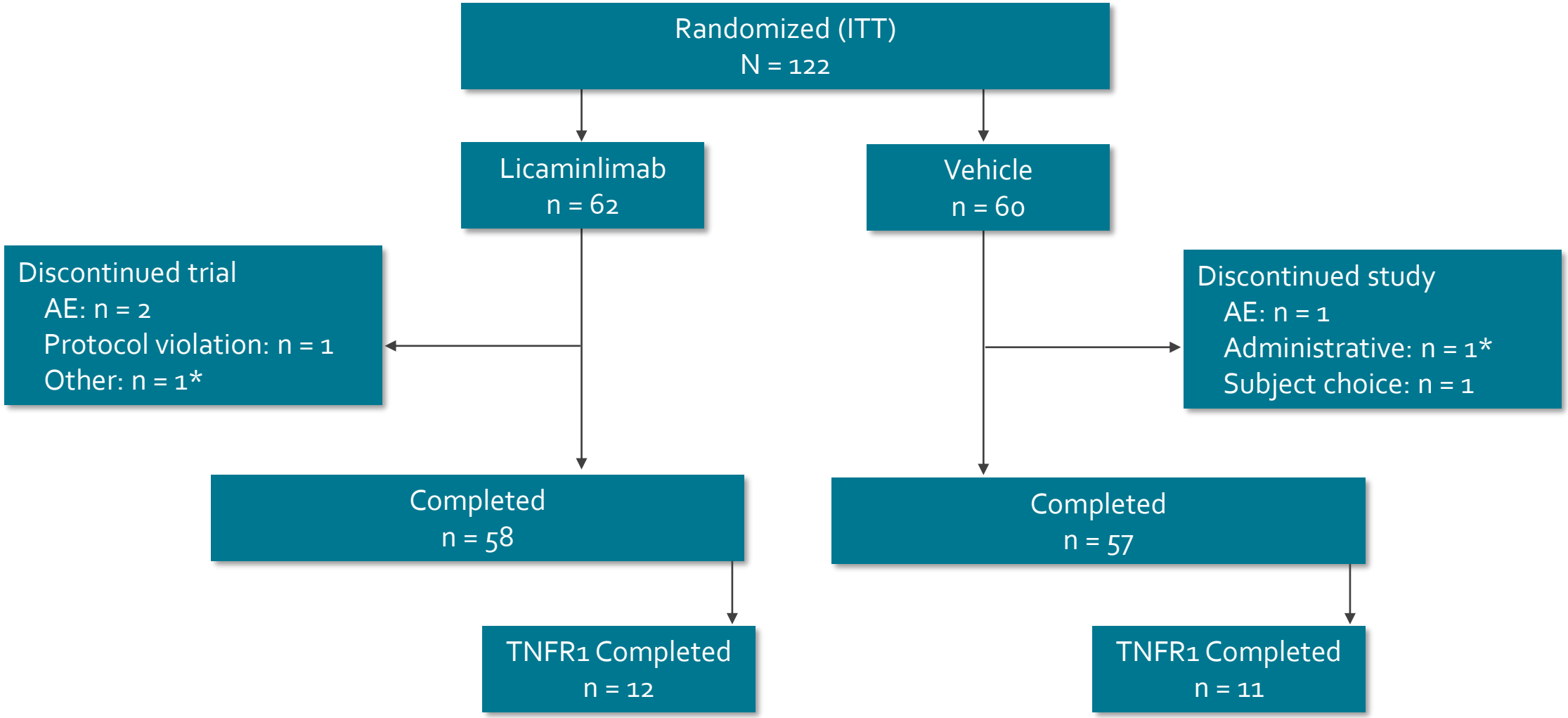
SYMPTOMS OF DED CAN INCLUDE:

- **Ocular discomfort**
- Ocular pain
- Blurred vision
- Light sensitivity
- Ocular itching
- Sandy or gritty feeling

DED (Dry eye disease).
FDA Guidance Document, December 2020: Dry Eye: Developing Drugs for Treatment Guidance for Industry

Subject Disposition

Full analysis population



AE, adverse event; ITT, intention-to-treat.
*Subject not dosed. Data, analysis and conclusions are preliminary, and subject to change as full analysis is ongoing.

Subject Demographics

Parameter	Licaminlimab (n = 62)	Vehicle (n = 60)
Mean age, years	62.4	63.1
Age ≥ 65 years, n (%)	35 (56.5)	28 (46.7)
Female, n (%)	46 (74.2)	42 (70.0)
Race, n (%)		
White	57 (91.9)	53 (88.3)
Black or African American	3 (4.8)	3 (5.0)
Asian	1 (1.6)	2 (3.3)
American Indian or Alaska Native	1 (1.6)	1 (1.7)
Unknown	0 (0.0)	1 (1.7)

TNFR1 genetic biomarker

Parameter	Licaminlimab (n = 62)	Vehicle (n = 60)
TNFR1-related genotype, n (%)		
Positive	12 (19.4)	11 (18.3)
Negative	50 (80.6)	49 (81.7)

Data, analysis and conclusions are preliminary, and subject to change as full analysis is ongoing.

Baseline Values for DED Signs

Well-balanced between treatment and vehicle in both populations

	Full population		TNFR1 Genotype group	
Efficacy Measures Mean Baseline Values	**Licaminlimab (n = 62)**	**Vehicle (n = 60)**	**Licaminlimab (n = 12)**	**Vehicle (n = 11)**
Inferior Corneal Staining	1.79	1.82	1.71	1.86
Total Corneal Staining	5.65	5.59	5.46	5.86
Schirmer's Test	4.4	5.2	4.3	4.7
Conjunctival Redness	1.53	1.62	1.5	1.64

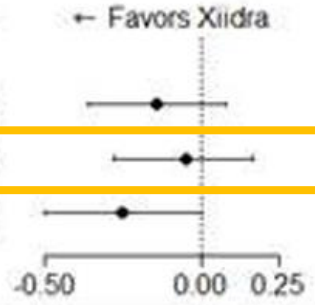
Total Corneal Staining is the sum of Inferior, Superior, and Central regions.
For Schirmer's Test, shorter lengths (in mm) indicate worse symptomology.
Conjunctival Redness is measured on a 0 to 4 scale with half-unit increments, where higher scores indicate more redness.
Data, analysis and conclusions are preliminary, and subject to change as full analysis is ongoing.

Lifitegrast Approval Endpoint

Mean change (SD) from baseline and treatment difference (lifitegrast – vehicle) in inferior corneal staining score in 12-week studies in patients with DED

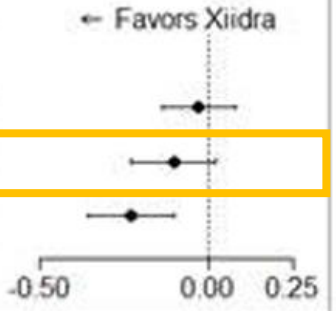
Study 1

Visit	Vehicle (N = 58)	Xiidra (N = 58)	Difference[1] (95% CI)
Baseline	1.65 (0.513)	1.77 (0.515)	
Day 14	0.24 (0.709)	0.06 (0.522)	-0.14 (-0.36, 0.08)
Day 42	0.19 (0.694)	0.08 (0.591)	-0.05 (-0.28, 0.17)
Day 84	0.38 (0.785)	0.04 (0.745)	-0.25 (-0.50, -0.00)



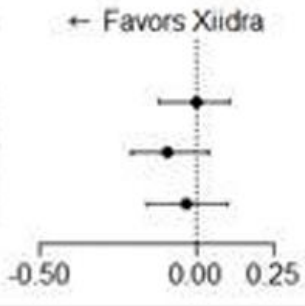
Study 2

Visit	Vehicle (N = 295)	Xiidra (N = 293)	Difference[1] (95% CI)
Baseline	1.81 (0.599)	1.84 (0.597)	
Day 14	0.08 (0.771)	0.04 (0.734)	-0.03 (-0.14, 0.08)
Day 42	-0.02 (0.893)	-0.14 (0.861)	-0.10 (-0.23, 0.02)
Day 84	0.17 (0.819)	-0.07 (0.868)	-0.23 (-0.36, -0.10)



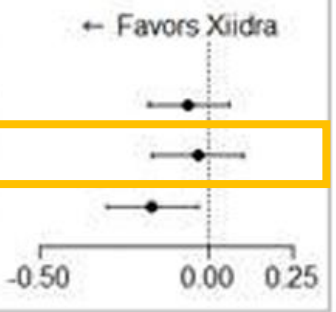
Study 3

Visit	Vehicle (N = 360)	Xiidra (N = 358)	Difference[1] (95% CI)
Baseline	2.40 (0.722)	2.39 (0.763)	
Day 14	-0.48 (0.798)	-0.48 (0.802)	-0.00 (-0.11, 0.11)
Day 42	-0.60 (0.899)	-0.69 (0.918)	-0.09 (-0.22, 0.04)
Day 84	-0.71 (0.943)	-0.73 (0.926)	-0.03 (-0.16, 0.10)



Study 4

Visit	Vehicle (N = 356)	Xiidra (N = 355)	Difference[1] (95% CI)
Baseline	2.46 (0.746)	2.46 (0.681)	
Day 14	-0.44 (0.775)	-0.49 (0.914)	-0.05 (-0.17, 0.07)
Day 42	-0.66 (0.927)	-0.69 (0.941)	-0.03 (-0.16, 0.10)
Day 84	-0.63 (0.911)	-0.80 (0.939)	-0.17 (-0.30, -0.03)



Effect size of lifitegrast on inferior corneal staining from vehicle (regulatory endpoint) ranged from -0.03 to -0.10 at day 42

Source: Lifitegrast U.S. FDA label
Based on ANCOVA model adjusted for baseline value in Study 1, and ANCOVA model adjusted for baseline value and randomization stratification factors in Studies 2-4.
All randomized and treated patients were included in the analysis and missing data were imputed using last available data. In Study 2, one vehicle-treated subject who did not have a study eye designated was excluded from analysis.

Licaminlimab Effect on Inferior Corneal Staining

Meaningful treatment effect in the full population and more pronounced in TNFR1-related genotype group

	Pre- to Post-CAE change from baseline at Day 43 Difference in means of OCS-02 vs Vehicle			
Efficacy Measures (accepted by regulators)	**Full Population Licaminlimab (n=62); Vehicle (n=60)**	**TNFR1 Genotype Licaminlimab (n=12); Vehicle (n=11)**	**Treatment Effect Favors Licaminlimab over Vehicle in Full population**	**Treatment Effect Favors Licaminlimab over Vehicle More Pronounced in TNFR1 Genotype Group**
Inferior Corneal Staining	**-0.12** (-0.378, 0.134)	**-0.59** (-1.165, -0.017)	✓	✓ ✓

*90% CI for Difference in Means based on the t-distribution; sample t-test: directional nominal p-value

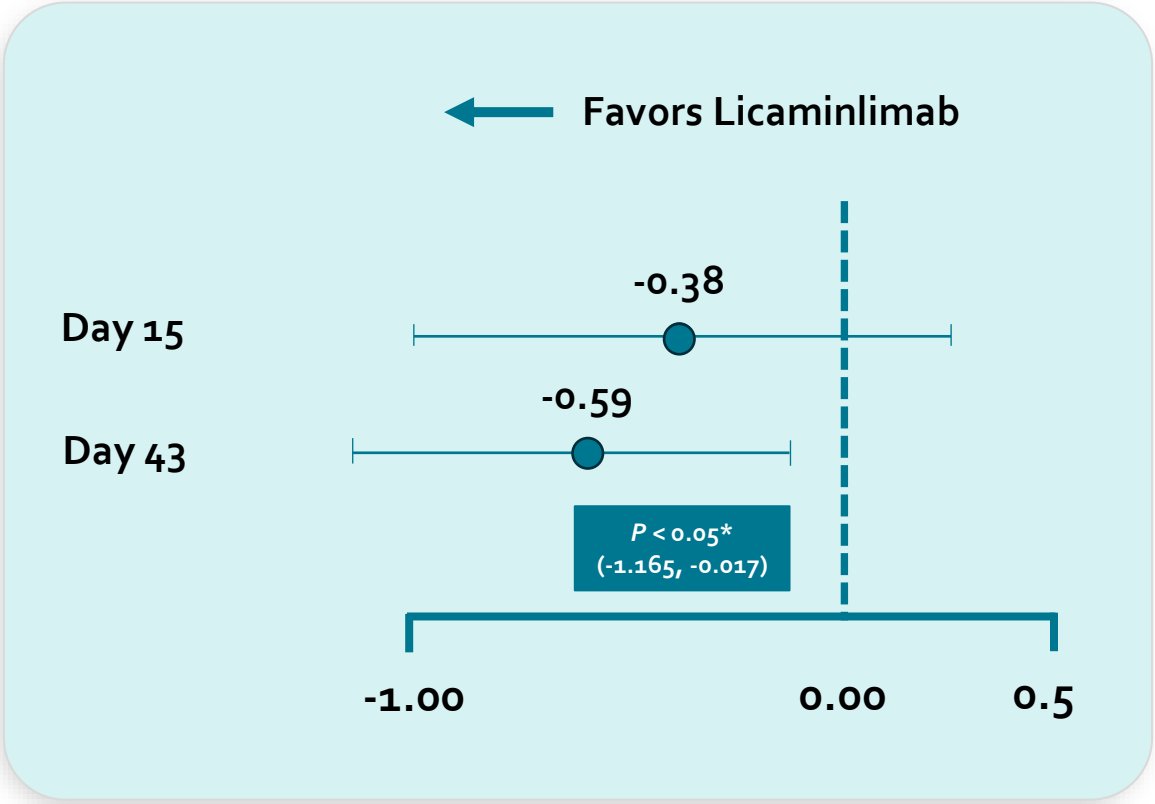
- Corneal staining is reflective of inflammation and apoptosis which play crucial roles in DED
- Corneal staining, mainly the inferior part (given its exposure), is also the most commonly assessed sign in clinical practice as it can affect quality of vision

Data, analysis and conclusions are preliminary, and subject to change as full analysis is ongoing.

Licaminlimab Effect on Inferior Corneal Staining TNFR1 Genetic Biomarker Population

Mean change from baseline (Pre- to Post-CAE)

Visit	Licaminlimab (N = 12)	Vehicle (N = 11)	Difference (90% CI)
Baseline	1.46	1.23	
Day 15	-0.29	+0.09	-0.38 (-1.012, 0.247)
Day 43	-0.50	+0.09	-0.59 (-1.165, -0.017)



*90% CI for Difference in Means based on the t-distribution; sample t-test: directional nominal p-value

Data, analysis and conclusions are preliminary, and subject to change as full analysis is ongoing.
*90% CI for Difference in Means based on the t-distribution; sample t-test: directional nominal p-value (calculated as half the t-test two-sided p-value)

Both Groups Showed Positive and Meaningful Improvements on Multiple Signs

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Efficacy Measures (accepted by regulators)	Pre- to Post-CAE change from baseline at Day 43 Difference in means of OCS-02 vs Vehicle; (CI)* Full Population Licaminlimab (n=62); Vehicle (n=60)	TNFR1 Genotype Licaminlimab (n=12); Vehicle (n=11)	Treatment Effect Favors Licaminlimab over Vehicle in Full population	Treatment Effect Favors Licaminlimab over Vehicle more pronounced in TNFR1 Genotype Group
Inferior Corneal Staining	**-0.12** (-0.378, 0.134)	**-0.59** (-1.165, -0.017)	✓	✓ ✓
Central Corneal Staining	**-0.02** (-0.251, 0.213)	**-0.05** (-0.572, 0.474)	✓	✓ ✓
Nasal Conjunctival Staining	**-0.04** (-0.328, 0.245)	**-0.58** (-1.345, 0.193)	✓	✓ ✓
Total Corneal Staining	**-0.13** (-0.620, 0.351)	**-0.61** (-1.731, 0.503)	✓	✓ ✓
Total Conjunctival Staining	**0.22** (-0.213, 0.660)	**-0.57** (-1.692, 0.555)	–	✓ ✓
Total Ocular Surface Staining	**0.09** (-0.593, 0.770)	**-1.18** (-2.875, 0.511)	–	✓ ✓
Schirmer's Test**	**0.90 [or 20%]** (-0.59, 2.35)	**1.1 [or 26%]** (-1.09, 3.36)	✓	✓ ✓
Conjunctival Redness	**0.01** (-0.168, 0.190)	**-0.04** (-0.357, 0.281)	–	✓ ✓

Data, analysis and conclusions are preliminary, and subject to change as full analysis is ongoing.
*90% CI for Difference in Means based on the t-distribution; sample t-test: directional nominal p-value; **Schirmer's Test performed Pre-CAE only (w/o anesthesia) [% improvement over baseline calculated as day 43 change from baseline / baseline]

Efficacy Summary

All study goals achieved

1 Evaluated efficacy of licaminlimab in the treatment of signs of DED

- Treatment in favor of licaminlimab observed in multiple signs, with rapid onset which continued to increase over time

2 Confirmed response to licaminlimab in subjects with TNFR1 genetic biomarker in signs of DED

- TNFR1 genetic biomarker had more pronounced and predictive treatment response on multiple signs consistent with the previous symptom trial

3 Selected primary sign efficacy endpoint for Phase 3 and de-risked the overall development plan

- Corneal staining is an approvable endpoint by FDA and a commonly assessed sign in clinical practice as it can affect quality of vision
- Licaminlimab has the potential to be disease-modifying with its dual MoA, as inflammation and apoptosis are directly linked to the pathogenesis of DED

First time precision medicine applied to DED in a clinical trial, offering a potentially transformative product profile and significantly de-risking development program

Safety Overview

Safety population	Licaminlimab (n=61)	Vehicle (n=59)
Patients with Any Ocular TEAEs (Study Eye)*, n (%)	7 (11.5%)	6 (10.2%)
Patients with Any Ocular TEAEs (Fellow Eye)*, n (%)	9 (14.8%)	7(11.9%)
Patients with any serious ocular TEAEs+, n (%)	0 (0%)	1 (1.7%)
Retinal detachment	0 (0%)	1 (1.7%)
Death	0 (0%)	0 (0%)
Patients with TEAE leading to study drug discontinuation, n (%)	2 (3.3%)	1 (1.7%)
Related to study treatment	0 (0%)	0 (0%)
TEAE ≥2% (Study Eye), n (%)		
Instillation site irritation	5 (8.2%)	1 (1.7%)
Instillation site pruritus	2 (3.3%)	0 (0%)

*SAEs were reported as unrelated to treatment.
+All Ocular TEAEs in the study eye were reported as 'mild'
TEAE = Treatment-emergent adverse event
Data, analysis and conclusions are preliminary, and subject to change as full analysis is ongoing.

Safety Summary

SAFETY

Low incidence of adverse events reported with licaminlimab similar to vehicle

- Ocular TEAEs were similar across treatment groups : 7 (11.5%) with licaminlimab versus 6 (10.2%) with vehicle
- No ocular SAEs were reported with licaminlimab

The most frequently reported (>2%) ocular TEAE

- All reported as mild and transient
- Instillation site irritation: 5 (8.2%) with licaminlimab versus 1 (1.7%) with vehicle
- Instillation site pruritus: 2 (3.3%) with licaminlimab versus 0 (zero) with vehicle

No TEAE related burning or blurred vision, similar to the previous symptoms study

Data, analysis and conclusions are preliminary, and subject to change as full analysis is ongoing.

Drop Comfort Scale & Attributes

Licaminlimab eye drop comfort consistent with artificial tears*

Drop Comfort Score

Day 43 (Post-CAE)	Licaminlimab (n = 61)	Vehicle (n = 59)
Upon instillation	2.6	1.1
1 minute post instillation	1.8	1.1
2 minutes post instillation	1.4	1.1

Drop Attributes

Day 43 (Post-CAE)	Licaminlimab (n = 61) %	Vehicle (n = 59) %
Any Positive Responses	84.5%	91.2%
Comfortable	69.0%	71.9%
Cool	41.4%	40.4%
Refreshing	46.6%	40.4%
Smooth	39.7%	40.4%
Soothing	53.4%	61.4%

* 2.05 for Rohto Dry Aid, and 1.96 for Systane Ultra; Torkildsen G., et al., Clinical Ophthalmology October 2017

Data, analysis and conclusions are preliminary, and subject to change as full analysis is ongoing.

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Summary

Opportunity for Highly Differentiated Product Profile

Licaminlimab has potential to address key unmet needs and transform the treatment paradigm of DED

UNMET NEEDS IN DED[1]	LICAMINLIMAB
New MoA targeting both signs and symptoms	Meaningful treatment effect in both signs and symptoms with a potential disease-modifying TNFα inhibitor.
Rapid onset of action	Symptoms improvement seen as early as 2 weeks
Good tolerability and drop comfort	Mild and transient AEs reported with drop comfort consistent with artificial tears
Ability to predict treatment response	TNFR1 Response was 5-fold higher in signs and 7-fold in symptoms

1. DRG Dry Eye Disease Landscape and Forecast 2020.

Conclusions and Next Steps

RELIEF trial showed positive results on signs in full population with 5x improvements in TNFR1-genotype group

Phase 2b RELIEF study in signs along with the previously completed Phase 2 study in symptoms:

- ✓ Provided consistent and meaningful results from two randomized controlled studies (DED #2 and DED #3 RELIEF)
  - Fast acting, meaningful treatment effect on ocular discomfort and corneal staining and well-tolerated
- ✓ Identified sign and symptom primary endpoints for Phase 3
  - Inferior corneal staining
  - Ocular discomfort
- ✓ Confirmed novel precision medicine approach targeting patient population with a TNFR1-related genotype
  - Identifies high responders to licaminlimab: 5 to 7-fold improvement in the treatment effects for signs and symptoms
  - Significantly de-risking Phase 3 development, while achieving time and cost efficiency
  - Potentially transformative commercial product profile for a potential disease-modifying precision medicine

Immediate Next Steps

- Conduct an End-of-Phase 2 meeting with FDA to finalize Phase 3 development plan


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Thank you