



July 16, 2020

OIS VIRTUAL PUBLIC COMPANY SHOWCASE

Novel Pharmaceutical Approaches for the Treatment of Ocular Disease

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Aldeyra is Developing Technology Designed to Modulate Biological *Systems* ... Not Single Targets

Traditional



Most immunological drugs shut down **specific molecules**, obstructing the immune system, and leading to toxicity.

The traditional approach is limited to two outcomes.

In contrast, **modulation** of the immune **system** maintains immune function, but allows for lower levels of inflammation.

A systems-based approach allows for infinite control.

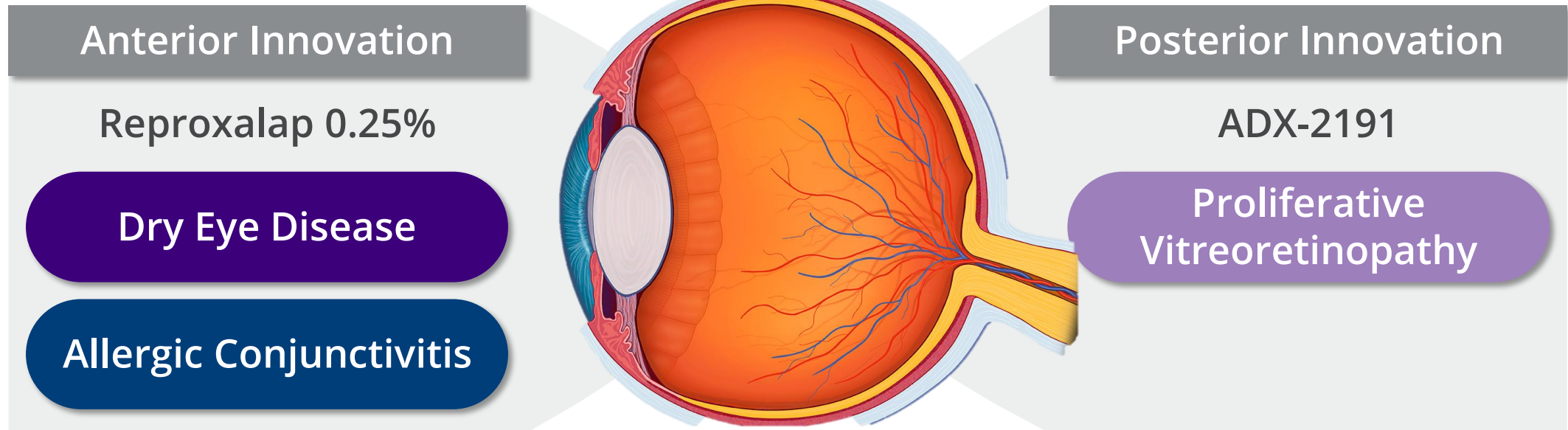
Systems-Based



Innovative Pipeline Addressing Immunological Disease

Disease Area	Compound	Mechanism	Indication	Preclinical	Phase 1	Phase 2	Phase 3
Ocular Diseases	Reproxalap	RASP	Dry Eye Disease				
			Allergic Conjunctivitis				
	ADX-2191	DHFR	Proliferative Vitreoretinopathy				
			Intraocular Lymphoma				
	ADX-103/10X	RASP	Retinal Disease				
	Undisclosed	RASP	Ocular Inflammatory Diseases	Research Collaboration (undisclosed)			
Systemic Diseases	ADX-1612	CHP	Ovarian Cancer	Investigator-Sponsored Trial			
			SARS-CoV2 Antiviral (COVID-19)				
	ADX-629	RASP	Cytokine Release Syndrome (COVID-19)				
			Autoimmune Disease (Psoriasis)				
			Allergy (Atopic Asthma)				

Novel Ocular Phase 3 Programs Targeting Unmet Medical Needs



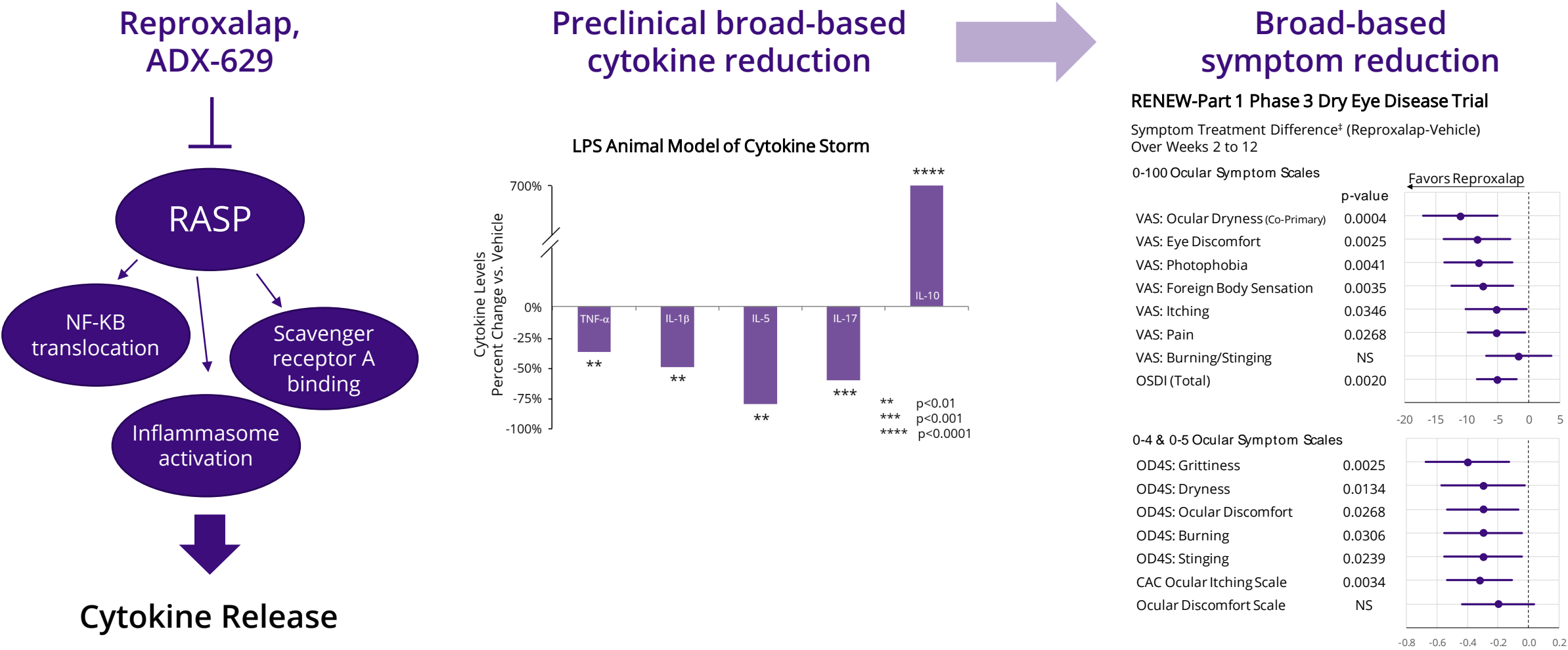


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Reactive Aldehyde Species (RASP) Inhibition

RASP Inhibition is a Pre-Cytokine, Systems-Based Approach that Has Been Clinically Validated in Late-Stage Trials



Lead RASP Inhibitor Reproxalap, a Novel Topical Ocular Drug, Now in Two Phase 3 Programs for Ocular Inflammation

Dry Eye Disease



Often months to demonstrate even modest efficacy with current Rx

34 million or more adults in the U.S.

Allergic Conjunctivitis



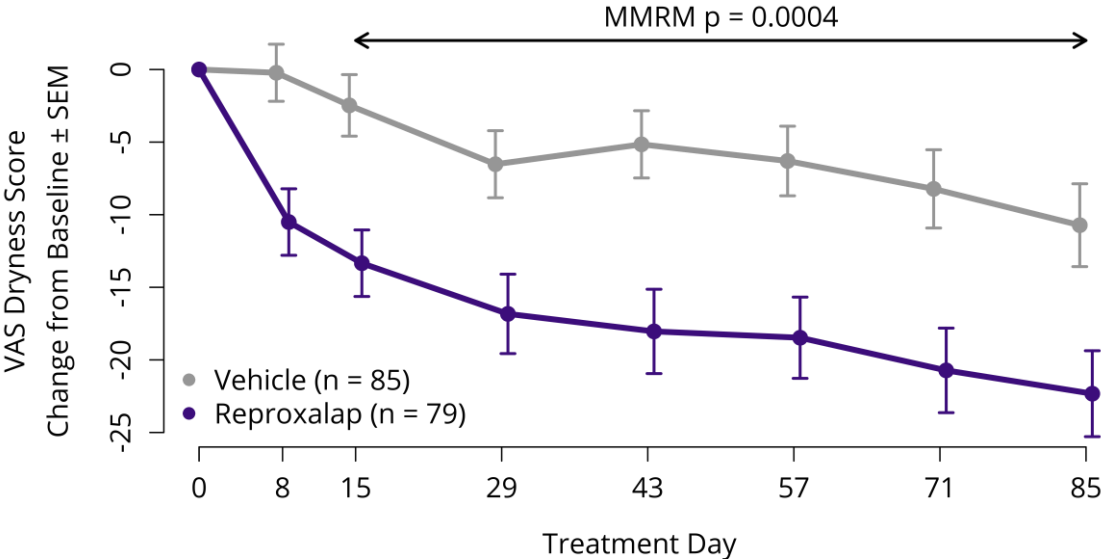
Unchecked growing disease burden and limited options beyond OTC/Rx antihistamines

66 million or more adults in the U.S.

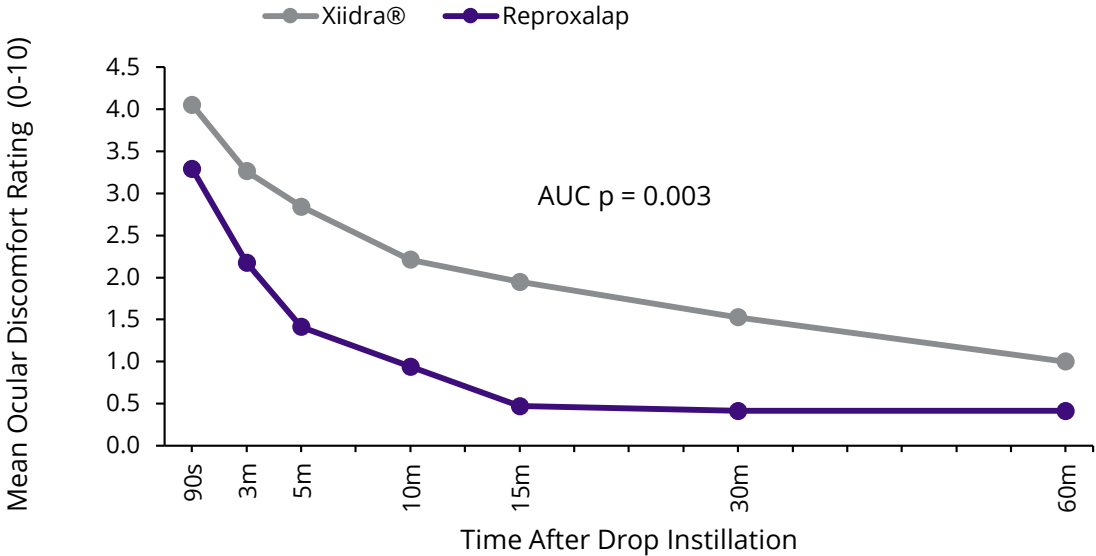
Reproxalap poised to potentially be the next novel entrant in the dry eye disease and allergic conjunctivitis markets.

Reproxalap Exhibited First-Line Symptom Control and Tolerability in Dry Eye Disease Clinical Trials

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



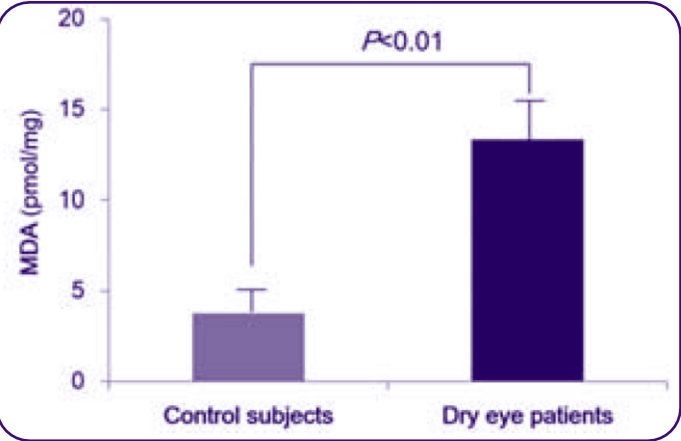
Head-to-Head Tolerability Trial vs. Xiidra®



Reproxalap's Mechanism of Action Reduces RASP, a Novel Dry Eye Disease Sign

RASP in Dry Eye Disease

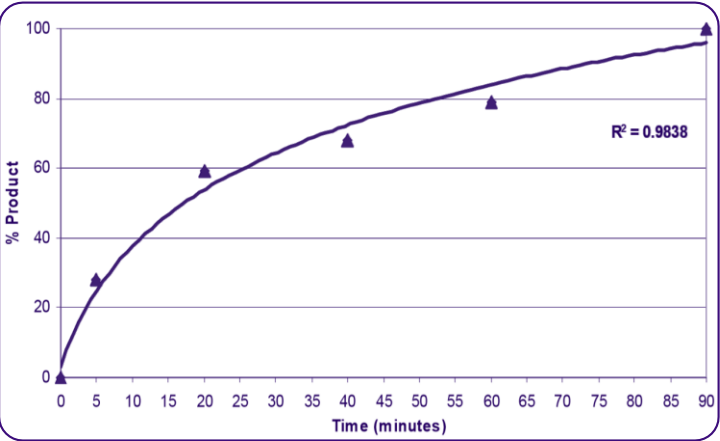
- RASP markers are upregulated in dry eye disease.
- RASP levels have been shown to correlate with worsening symptoms and signs.



Source: Curr Eye Res. 2016, 41(9):1143-9

Preclinical rapid and complete RASP binding

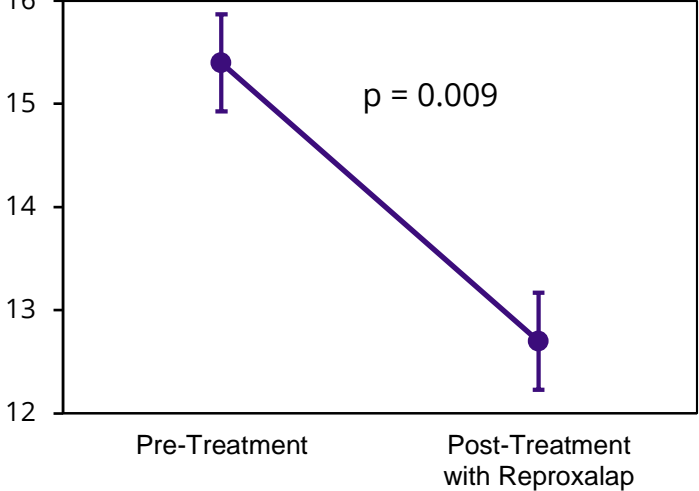
In vitro Reproxalap-Malondialdehyde (MDA) adduct formation over time
(% of MDA bound by reproxalap)



Reproxalap

Clinical reduction in RASP adducts

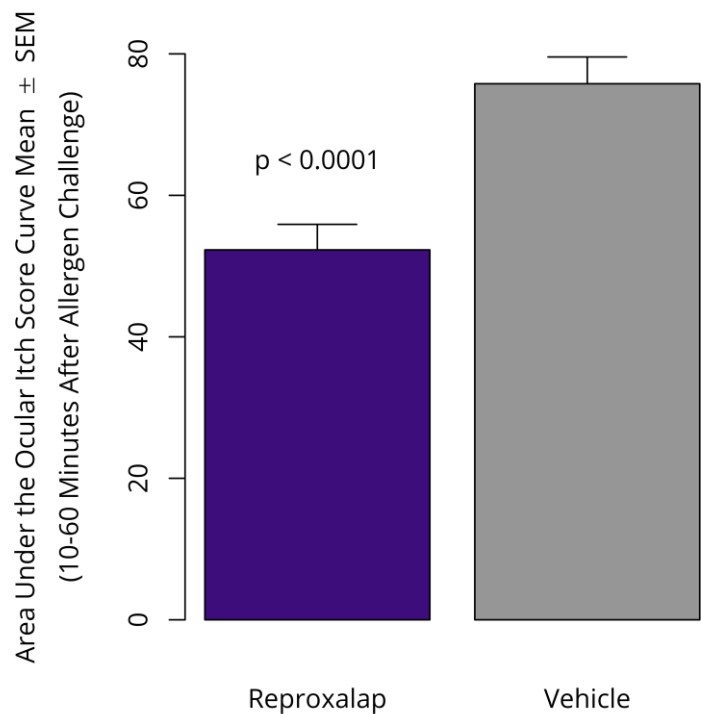
Phase 2a
Tear RASP Levels in Dry Eye Disease Patients
(μ M Malondialdehyde Adduct; Mean \pm Within-Subject SEM)



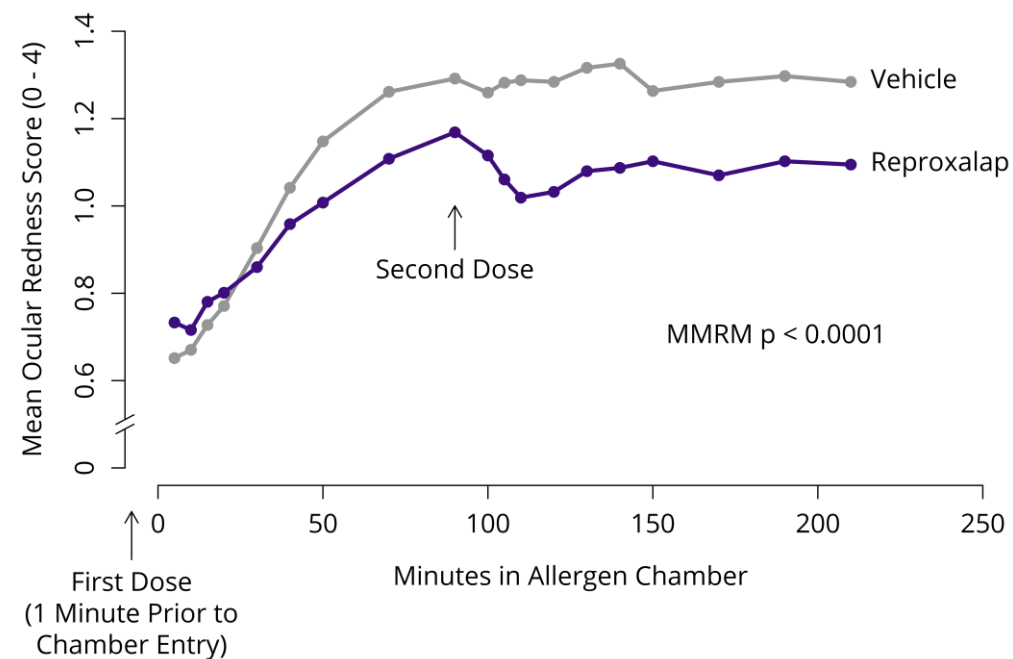
RASP is a novel and FDA approvable dry eye disease sign

Reproxalap Reduced Itching and Redness in Late-Stage Clinical Trials for Allergic Conjunctivitis

ALLEVIATE Phase 3 Trial



Phase 2 Allergen Chamber Trial

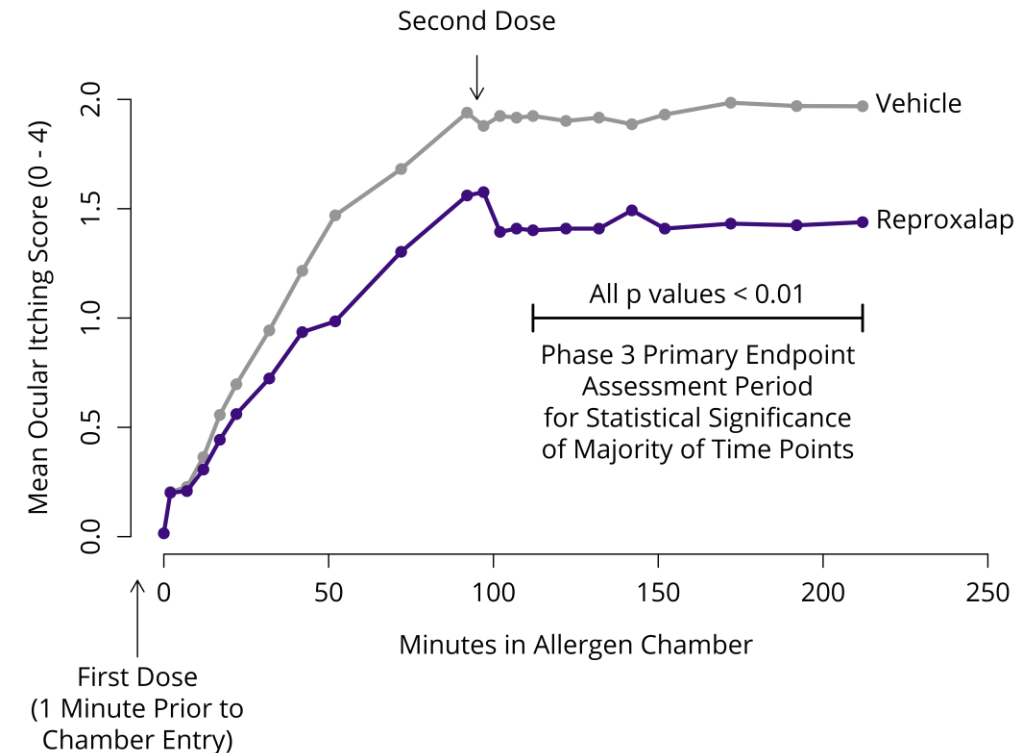


Results from the INVIGORATE Phase 3 Trial in Allergic Conjunctivitis Expected in H1 2021

- **Design:**
 - Two-way randomized crossover, ~100 patients total
- **Primary endpoint:**
 - Statistical significance in ocular itch (0-4 scale) at a majority of eleven time points between 110 and 210 minutes
- **Secondary endpoints:**
 - Investigator-assessed ocular redness score
 - Patient-reported ocular tearing score
 - Total ocular symptom score
- **Inclusion/exclusion criteria:**
 - History of moderate to severe allergic conjunctivitis to ragweed pollen
 - Itching score of ≥ 2.5 or redness score ≥ 2 in baseline chamber test
- **Chamber exposure and dosing schedule:**
 - 3.5 hours continuous allergen exposure
 - First dose 5 minutes before chamber entry
 - Second dose 90 minutes after entry (when non-treated patients reach peak allergy symptoms)



Phase 2 Results Were Statistically Significant During Phase 3 Primary Endpoint Time Points*





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Dihydrofolate Reductase Inhibition

ADX-2191: A Potential Therapeutic Breakthrough in the Treatment of Proliferative Vitreoretinopathy

Proliferative vitreoretinopathy

ADX-2191

4,000
U.S.

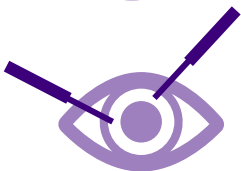
PVR is a **rare disease**, with ~4,000 patients per year in the U.S. and nearly twice as many in Europe and Japan combined.



Left untreated, retinal detachment due to PVR can **progress to permanent blindness**.



There is currently **No FDA- or EMA-approved therapy**.



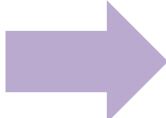
Repeat surgery, which can lead to **vision loss**, is currently the only possible course of action.

ADX-2191

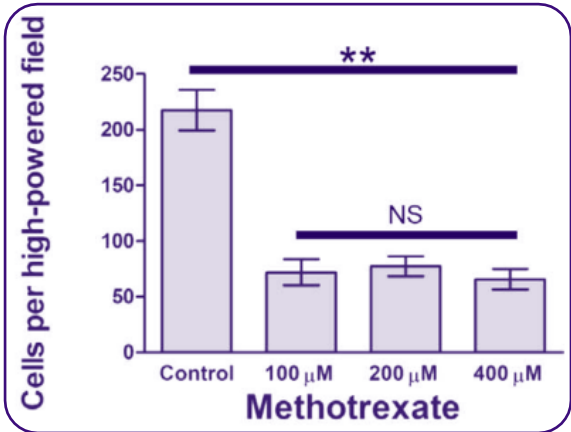
- A potential therapeutic breakthrough in PVR treatment
- **Granted U.S. orphan designation and FDA fast track designation** for the prevention of PVR
- **Tolerability and reattachment success** during study period **demonstrated in Phase 1b** open-label investigator sponsored clinical trial
- **GUARD adaptive Phase 3 clinical trial** for the prevention of recurrent retinal detachment due to PVR ongoing
- **Exploring additional indications**, including primary intraocular lymphoma

ADX-2191, a Novel Intravitreal Formulation of Methotrexate, Represents a Clinically Proven Systems Modulating Approach

Preclinical reduction in cellular proliferation

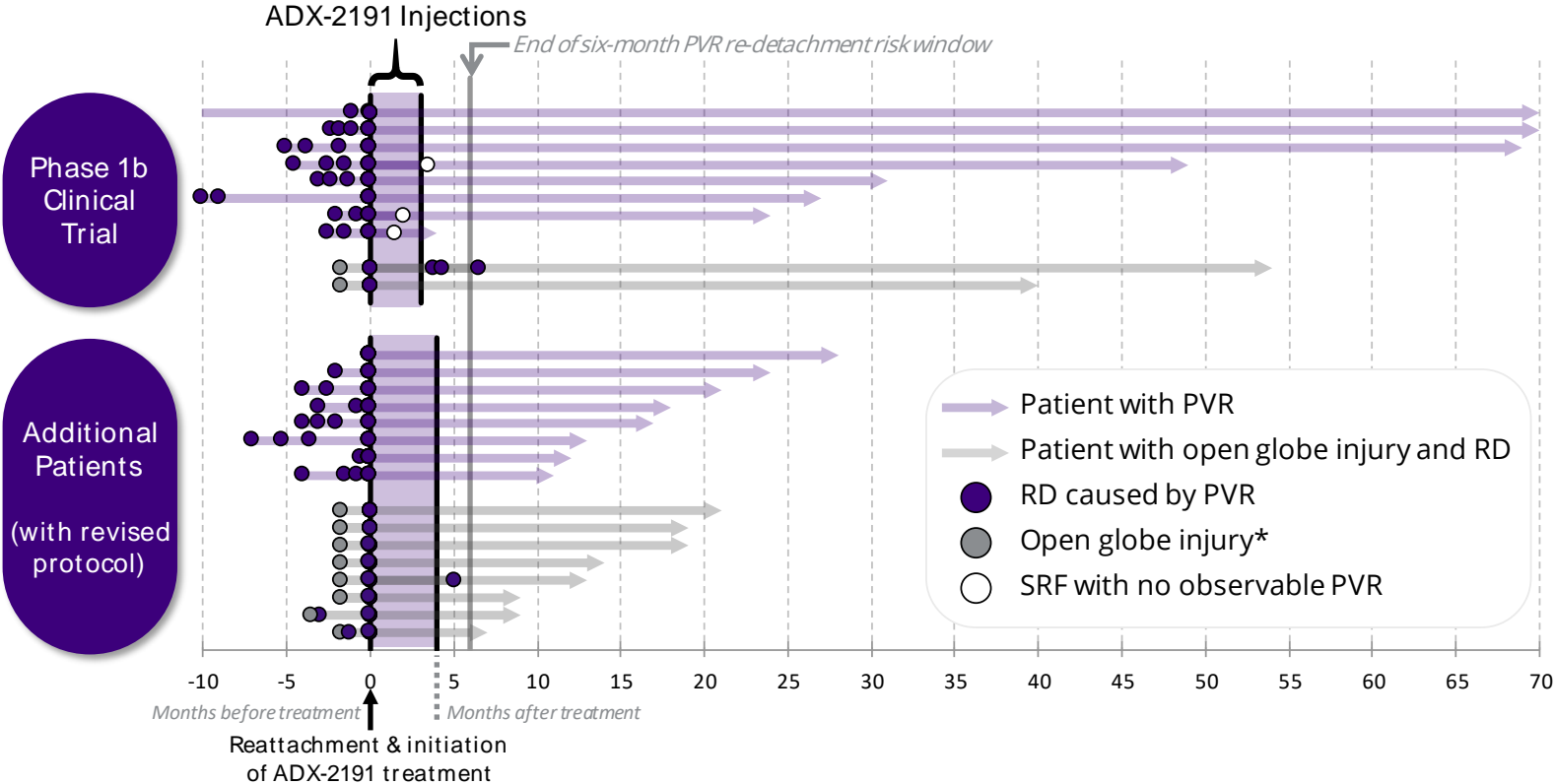


Clinical reduction in retinal detachment



Source: Invest Ophthalmol Vis. Sci. 2017; 58:3940–3949

Retinal Detachments Over Time by Patient



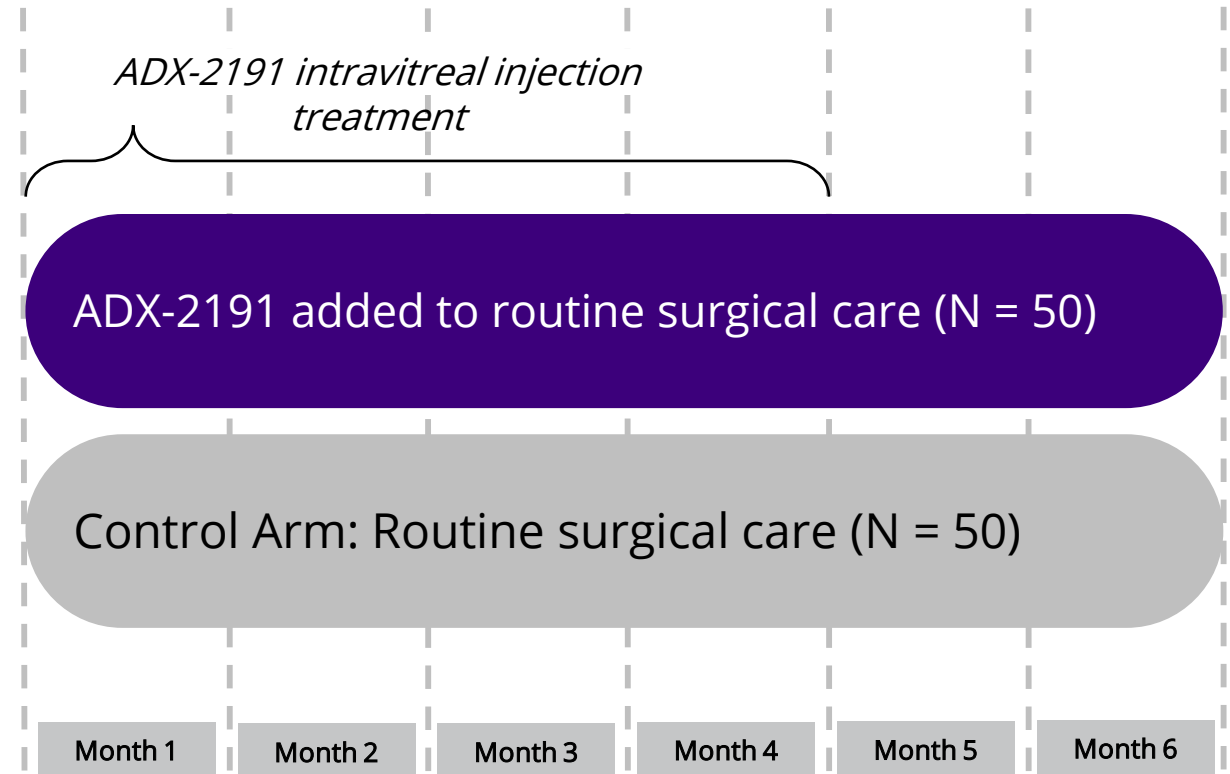
*Timing of open globe injury as shown is estimated. Typically 6-8 weeks prior to reattachment & initiation of ADX-2191. There is no assurance that prior results, such as signals of safety, activity or durability of effect, observed from this open label investigator sponsored trial will be replicated in more rigorous clinical trials involving ADX-2191. Source: ADX-2191 PVR Phase 1b investigator sponsored clinical trial (n=10) results and additional in-practice use (n=16)

ADX-2191: GUARD Trial Design in Proliferative Vitreoretinopathy

Adaptive Phase 3 (Part 1) Clinical Trial Design

- **Primary objective:**
 - Evaluate efficacy of intravitreal ADX-2191 injections for prevention of recurrent retinal detachment due to proliferative vitreoretinopathy (PVR)
- **Design:**
 - Multi-center, randomized, controlled, two- part, adaptive Phase 3 clinical trial
- **Inclusion highlights:**
 - Recurrent retinal detachment due to PVR, or
 - Retinal detachment associated with open-globe injury
- **Dosing regimen:**
 - At surgery, weekly (x8), and then every other week (x4) intravitreal ADX-2191 injections
- **Endpoint:**
 - Retinal re-detachments due to PVR requiring re-operation within 6 months:
 1. OCT demonstrating fovea-off retinal detachment
 2. Photographic documentation retinal detachment

Adaptive Phase 3 PVR Clinical Trial Design: Part 1



Progress Update Expected H2 2020*

ADX-2191 Also Has the Potential to be the Only Approved Drug for Primary Vitreoretinal Lymphoma, a Rare but Serious Retinal Cancer



Small (top) and large (bottom) subretinal infiltrates in patients with primary vitreoretinal lymphoma

- Primary vitreoretinal lymphoma (PVRL) is a rare, aggressive, high-grade non-Hodgkin's lymphoma that arises in the vitreous and retina.
- Approximately 2,900 people in the United States suffer from PVRL.
- Approximately 600 new cases of PVRL are diagnosed in the United States per year.
- The median survival for newly diagnosed patients is 4.83 years.
- The most common ocular complaints reported by patients include blurred vision, painless loss of vision, floaters, red eye, and photophobia.
- No approved treatments are currently available.



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Upcoming Development Milestones

Upcoming Development Milestones in Ocular Disease

- ☒ Reproxalap dry eye disease subsequent development plans update following June Type C FDA meeting final minutes July 2020
- ☐ Reproxalap dry eye disease tear level RASP reduction clinical trial initiation H2 2020
- ☐ Reproxalap allergic conjunctivitis INVIGORATE Phase 3 study results H1 2021
- ☐ ADX-2191 - Intraocular lymphoma orphan designation H2 2020
- ☐ ADX 2191 - GUARD Phase 3 Trial enrollment update H2 2020*



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