



September 2019

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BIOCENTURY NEWSMAKERS 2019

Innovating Transformative Therapies

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Our Mission and Value Proposition

Developing Next-Generation Medicines to Improve the Lives of Patients with Immune-Mediated Diseases



Deep and Innovative Pipeline Focused on Immune-Mediated Diseases

Disease Area	Compound	[Mechanism]	Indication	Preclinical	Phase 1	Phase 2	Phase 3	Next Anticipated Milestone
Ocular Diseases	Reproxalap	[RASP]	Dry Eye Disease					Phase 3-Part 1 completion Q4 2019
			Allergic Conjunctivitis					
	ADX-2191	[DHFR]	Proliferative Vitreoretinopathy					Phase 3-Part 1 initiation Q4 2019
	ADX-103/10X	[RASP]	Retinal Disease					Phase 1/2 initiation 2020
	Undisclosed		Ocular Inflammation	Research Collaboration (undisclosed)				
Systemic Diseases	Reproxalap	[RASP]	Sjögren-Larsson Syndrome					
	ADX-1612	[CHP]	PTLD					Phase 2 initiation H2 2019
			Mesothelioma	Investigator-Sponsored Trial				
			Ovarian Cancer	Investigator-Sponsored Trial				
	ADX-629	[RASP]	Autoimmune / Metabolic Disease					Phase 1 initiation H2 2019
	ADX-1615	[CHP]	Autoimmune Disease / Cancer					
	Undisclosed	[RASP]	Systemic Inflammatory Disease	Research Collaboration				

Our Lead Programs Represent Compelling Commercial Opportunities

Late Stage Programs	Estimated U.S. Population [†]	Current Standard of Care	Drug Candidate and Dev. Stage	Potential Competitive Advantages [†]
<i>Ocular Diseases</i>				
Dry Eye Disease	20 million DED Up to 10 million with DED & AC	Xiidra®, Restasis®	Reproxalap: Phase 3	Rapid onset, broad activity, reduction in itch
Allergic Conjunctivitis	30 million AC	Antihistamines	Reproxalap: Phase 3	Non-drying, durable activity; Responder superiority vs. vehicle
Proliferative Vitreoretinopathy	4,000	None (repeat surgeries)	ADX-2191: Phase 3	Clinically demonstrated activity; Currently no FDA- or EMA-approved therapy
<i>Systemic Diseases</i>				
Sjögren-Larsson Syndrome	1,000	None (manage symptoms)	Reproxalap: Phase 3	Clinically demonstrated activity; Currently no FDA- or EMA-approved therapy

[†]Pending clinical data, regulatory discussions, payor negotiations, competition, potential legislative changes, and other factors, which may not be in Aldeyra's control. Preliminary assumptions are subject to change.

Source: Aldeyra internal estimates based on primary and secondary market research; published literature

Recent and Expected Development Milestones:*

Novel Approaches to Address Immune-Mediated Disease

○ = Ocular Diseases
○ = Systemic Diseases



Positive reproxalap allergic conjunctivitis
ALLEVIATE Phase 3 trial results March 2019



Reproxalap dry eye disease **RENEW Phase 3 - Part 1 clinical trial initiation April 2019**



Positive reproxalap allergic conjunctivitis
environmental chamber trial results June 2019



Reproxalap Sjögren-Larsson Syndrome
RESET Phase 3 - Part 1 completion Q2 2019



ADX-2191 proliferative vitreoretinopathy **GUARD Phase 3 - Part 1 clinical trial initiation Q4 2019**



Reproxalap allergic conjunctivitis design for potential
second Phase 3 to be confirmed Q4 2019



Reproxalap dry eye disease **RENEW Phase 3 - Part 1 completion Q4 2019**



ADX-629 systemic **Phase 1 clinical trial initiation H2 2019**



ADX-1612 post-transplant lymphoproliferative disorder **Phase 2 clinical trial initiation H2 2019**



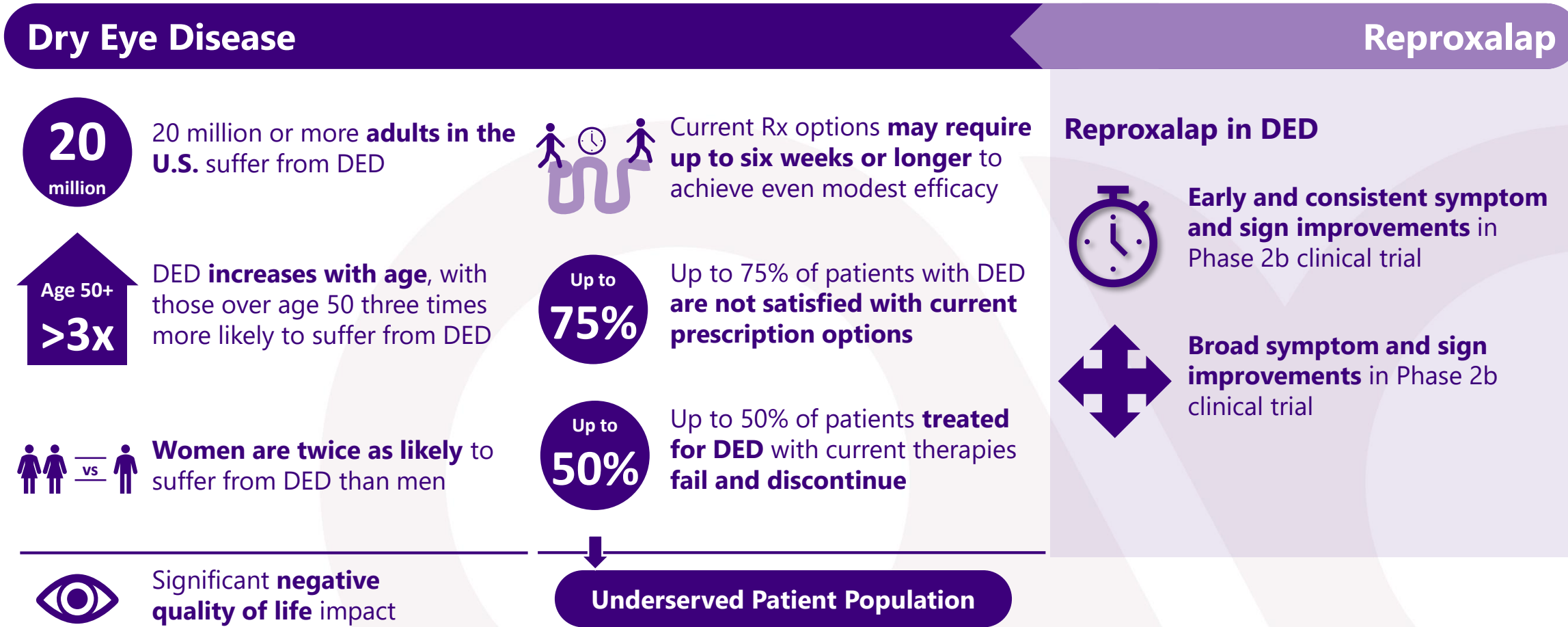
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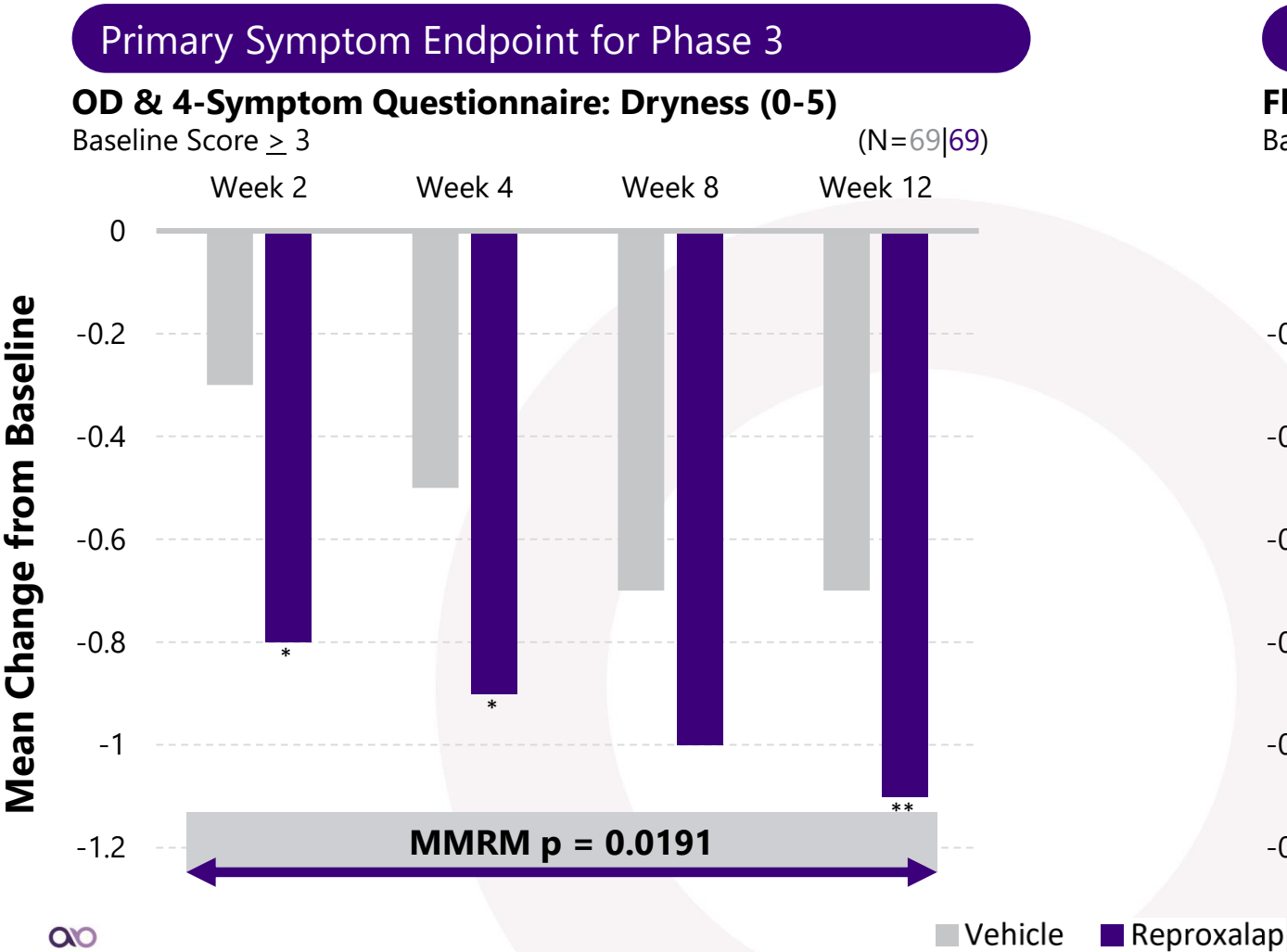
- **DRY EYE DISEASE**
- ALLERGIC CONJUNCTIVITIS
- PROLIFERATIVE VITREORETINOPATHY

Ocular Disease Area

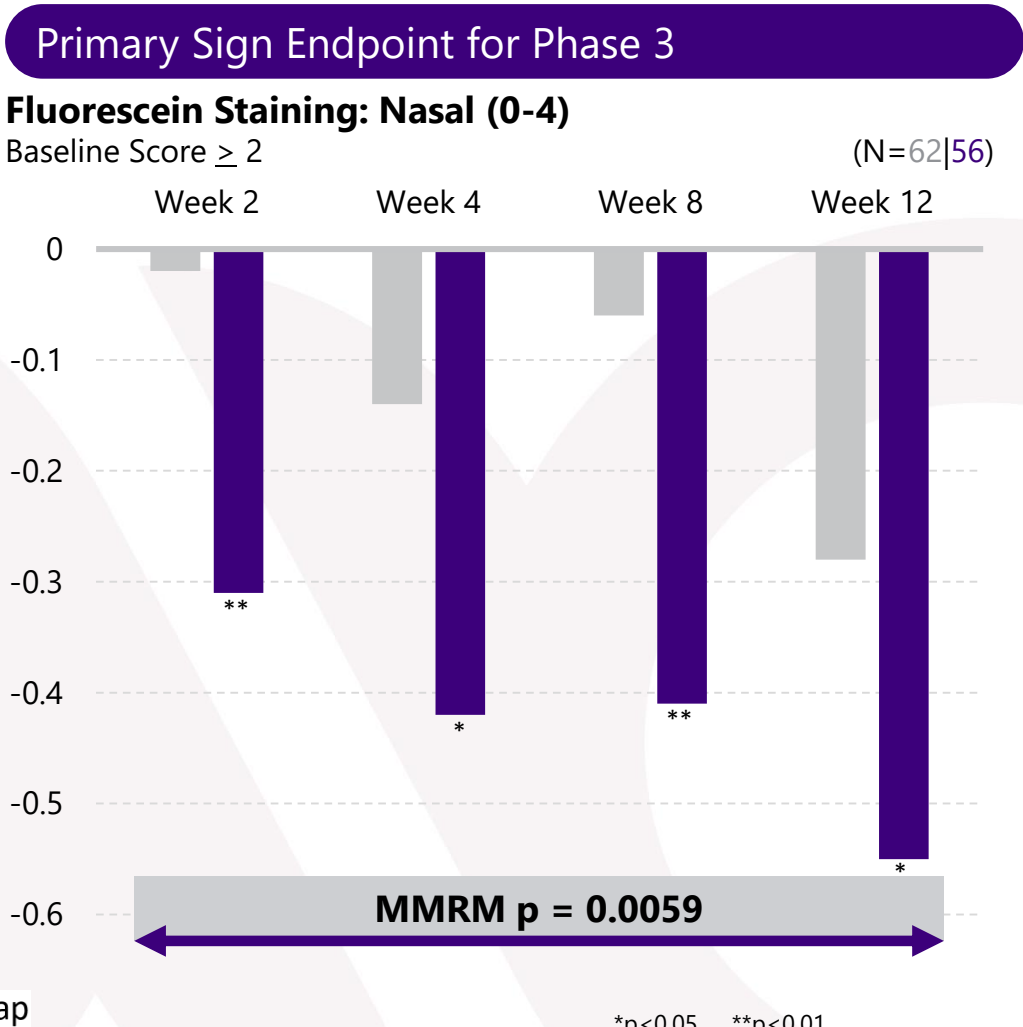
Dry Eye Disease: A Persistently Disturbing Condition Inadequately Treated with Currently Available Therapy



Phase 3 Dry Eye Disease Symptom and Sign Endpoints Achieved in Phase 2b Clinical Trial



Source: Reproxalap DED Phase 2b clinical trial results (reproxalap 0.25%);
p values shown represent reproxalap effect versus vehicle.



* $p < 0.05$ ** $p < 0.01$
OD = Ocular Discomfort
MMRM = Mixed Effect Model Repeated Measures (across 12 weeks)

Broad Drug Activity Across All Measured Dry Eye Disease Symptoms and Signs in Phase 2b Clinical Trial Supports Differentiated Product Profile

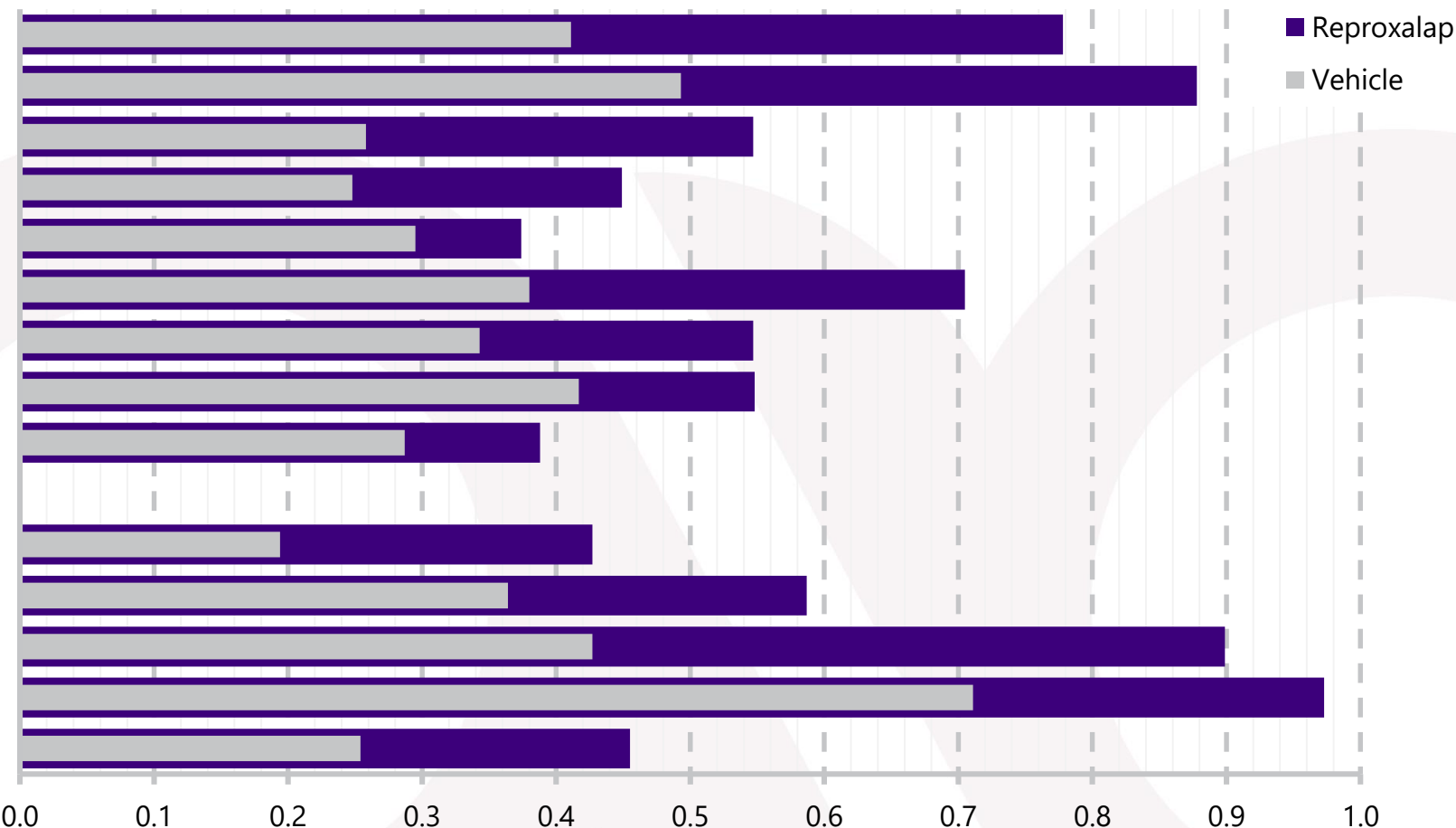
Improvement Effect Size at Week 12

Dry Eye Disease Symptoms

- 4-Symptom: Ocular Discomfort
- 4-Symptom: Dryness
- 4-Symptom: Grittiness
- 4-Symptom: Stinging
- 4-Symptom: Burning
- SANDE: Severity
- SANDE: Frequency
- Ocular Discomfort Scale
- Ocular Surface Disease Index

Dry Eye Disease Signs

- Fluorescein Stain (Nasal)
- Lissamine Green Stain (Nasal)
- Schirmer's Test
- Tear Film Break-Up Time
- Osmolarity



Adaptive Phase 3 Dry Eye Disease Clinical Program

Adaptive Phase 3 Program

- ✓ Confirm symptom and sign endpoints from Phase 2b trial
- ✓ Confirm dosing regimen (QID vs. QID to BID taper)
- ✓ Confirm sample size for subsequent trial

Dry Eye Disease

Clinical Program to NDA Submission

Initiated April 2019

RENEW
Phase 3 (Part 1)

RENEW
Phase 3 (Part 2)

Confirmatory DED
Phase 3

NDA*

Initiated April 2019

Formulation Trial

DED Safety Study

Adaptive design, co-primary endpoints, and innovative analysis strategy confirmed with FDA at EOP2 Meeting

The RENEW Phase 3 Clinical Trial in Dry Eye Disease

Part 1 Initiated April 2019

- **Primary objective:**

- Evaluate efficacy of reproxalap ophthalmic solution (0.25%) vs. vehicle to confirm dosing regimen and sample size for Part 2

- **Inclusion/exclusion criteria:**

- Same as used for Phase 2b
- Moderate to severe dry eye disease

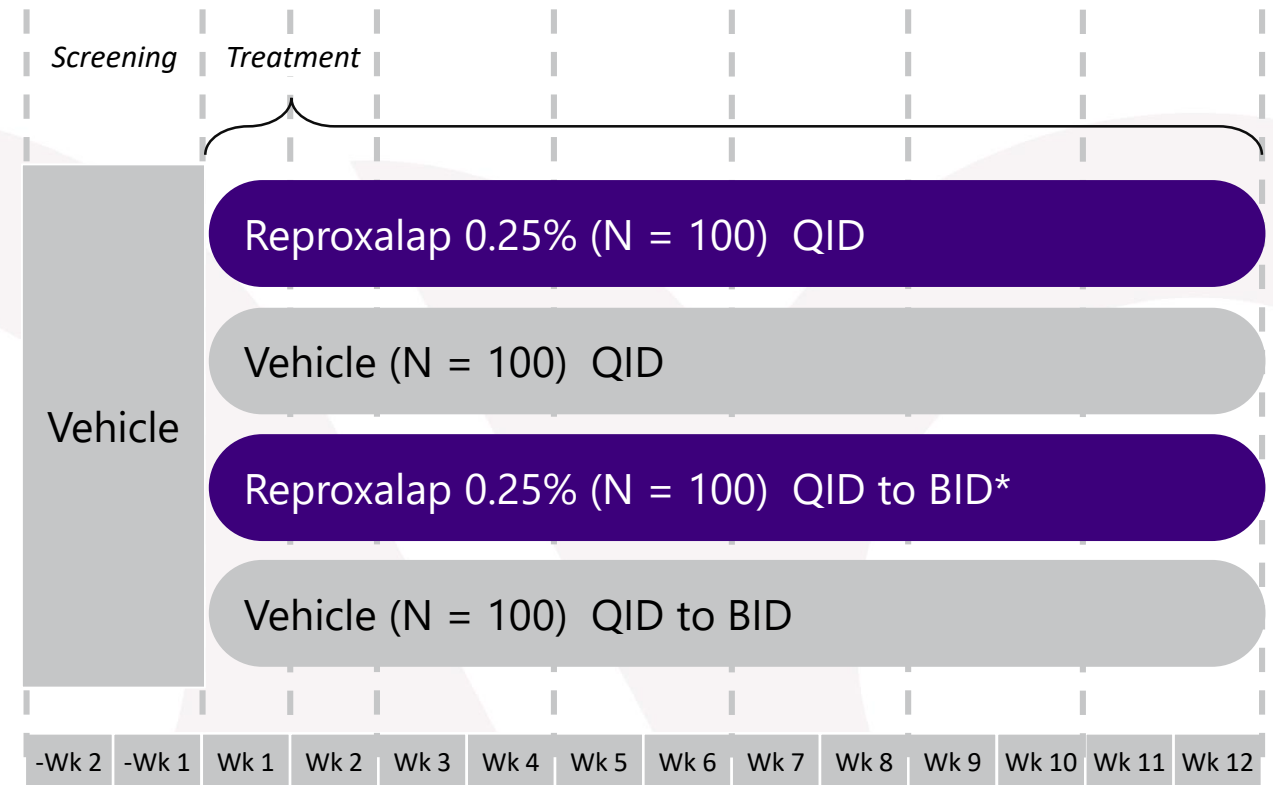
- **Co-primary endpoints:**

- Ocular dryness score (0-100mm VAS) and fluorescein nasal region staining

- **Analysis strategy:**

- Both co-primary endpoints will be assessed using Mixed Model Repeated Measures (MMRM) from week 2 to 12
- Both co-primary endpoints will be assessed in separate pre-specified patient populations
 - Ocular dryness score (OD4SS): baseline score of ≥ 3
 - Fluorescein nasal staining: baseline score ≥ 2

Phase 3 Dry Eye Disease Clinical Trial: Part 1





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- DRY EYE DISEASE
- **ALLERGIC CONJUNCTIVITIS**
- PROLIFERATIVE VITREORETINOPATHY

Ocular Disease Area

Allergic Conjunctivitis: A Common Disease with Unmet Medical Need

Allergic Conjunctivitis

30

million

Up to 30 million of **AC sufferers** in the U.S. **do not respond adequately** to or are **dissatisfied with antihistamines**



Many AC **patients make significant sacrifices** due to lack of drug activity



AC patients experience symptoms throughout **all decades of adult life**

24%

Antihistamines are not effective in an estimated 24% of treated AC patients



AC can result in **acute, intermittent, and chronic** symptoms

2%

~2% of AC patients have severe symptoms and **may be corticosteroid-dependent**



Significant **negative quality of life** impact

Underserved Patient Population

Reproxalap

Reproxalap in AC

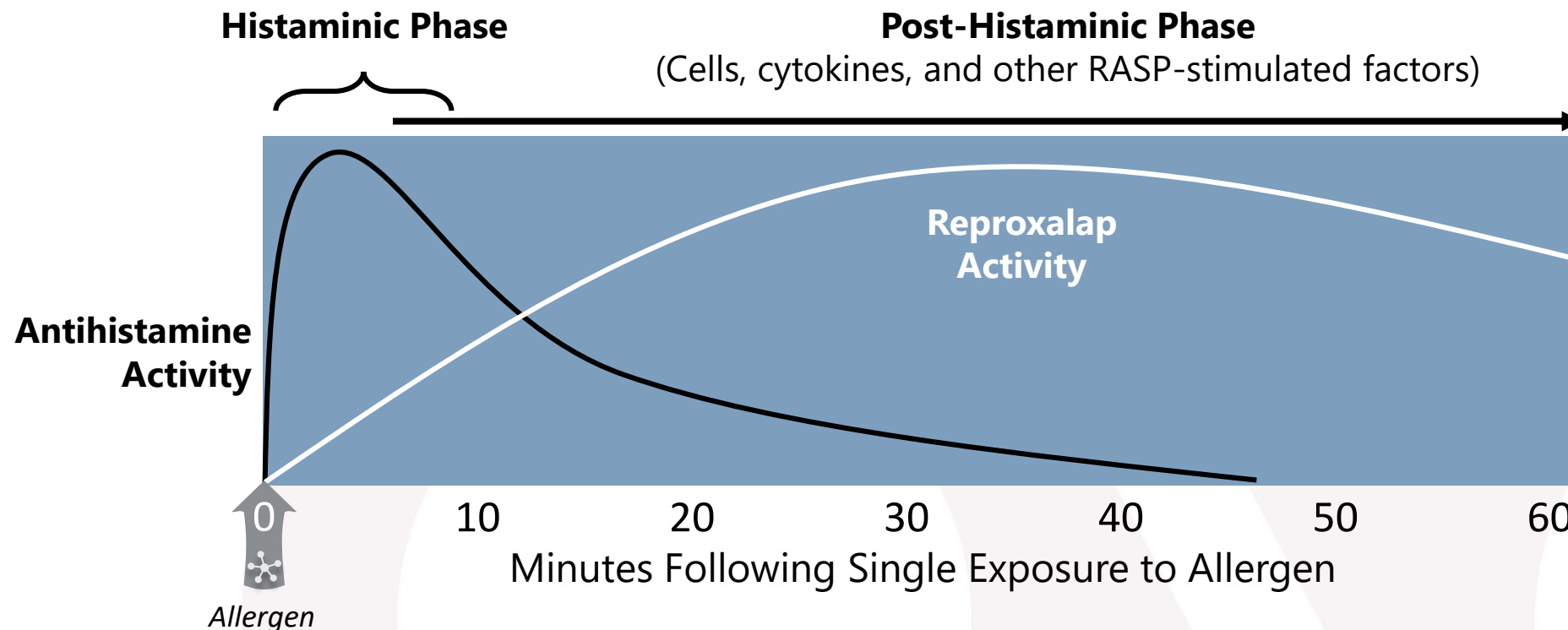


Clinically significant and durable symptom response in Phase 3 clinical trial



Active in post-histaminic allergy, for which no drug is approved

Reproxalap's Novel Mechanism of Action has the Potential to Provide Differentiated Activity Versus Antihistamines

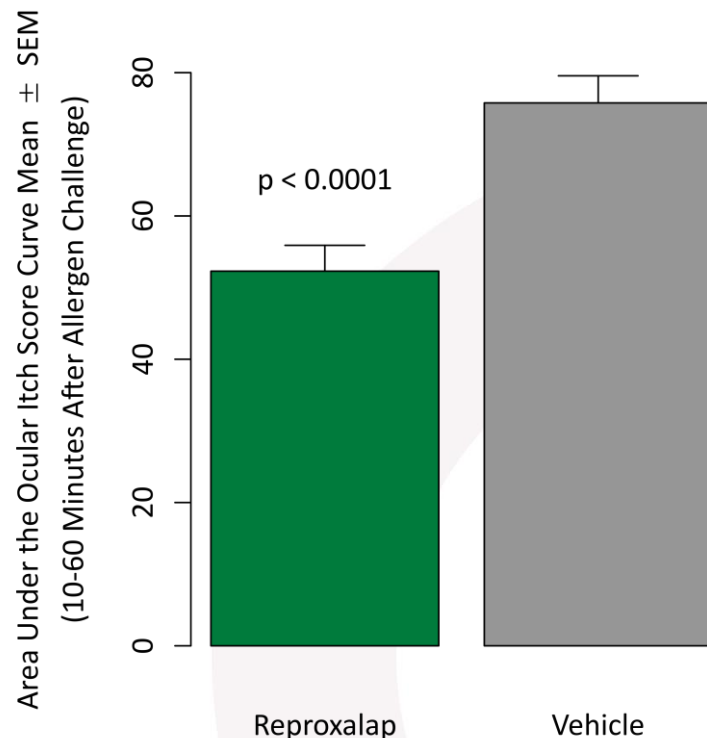


Reproxalap has the potential to be uniquely effective in post-histaminic allergy, which affects all allergic conjunctivitis patients

Reproxalap Achieved Primary and Key Secondary Endpoints in ALLEVIATE Phase 3 Clinical Trial

Primary Endpoint

Area Under the Curve: Ocular Itch Score (0-4) 10 to 60 Minutes After Allergen Challenge

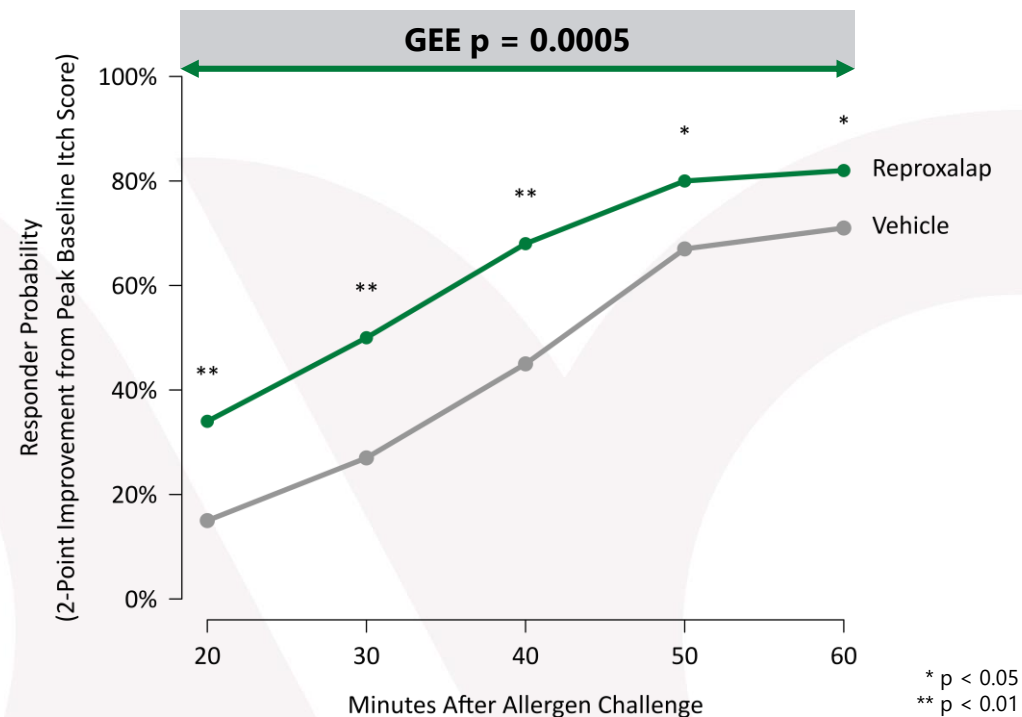


Improvement in itch score over one hour after allergen exposure statistically greater for reproxalap vs. vehicle

SEM = Standard error of the mean

Key Secondary Endpoint

Probability of Two-Point Response: Ocular Itch Score (0-4)

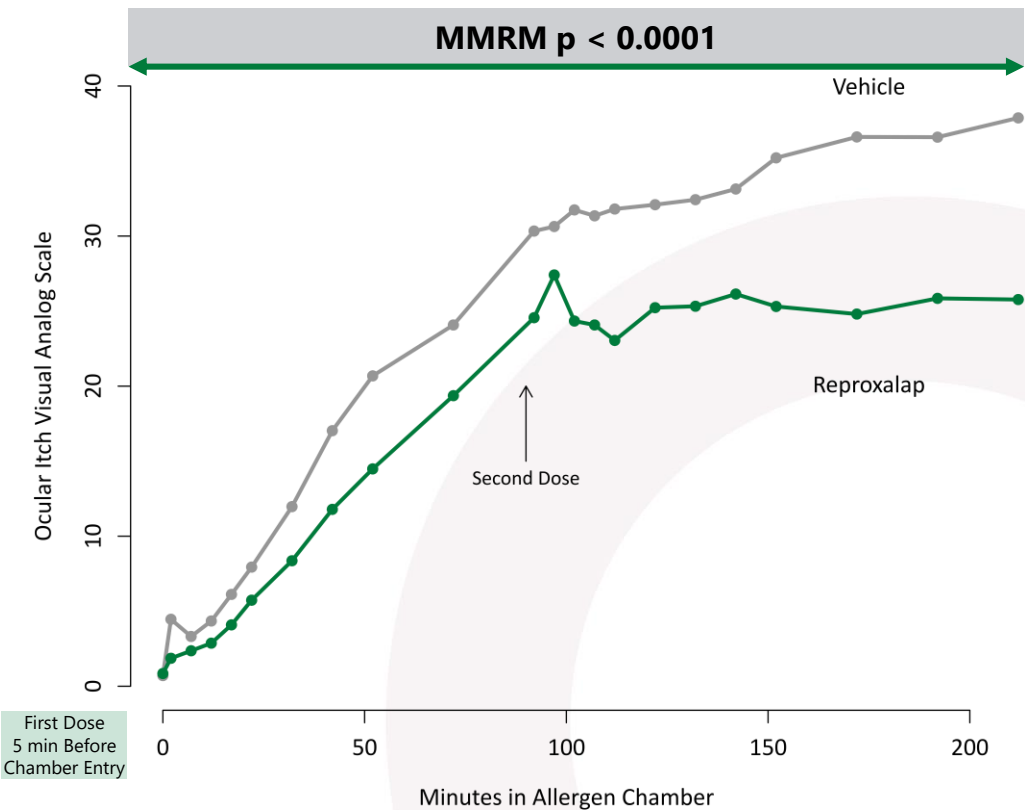


Clinically significant response rate of reproxalap statistically higher than that of vehicle

GEE = Generalized estimating equation analysis

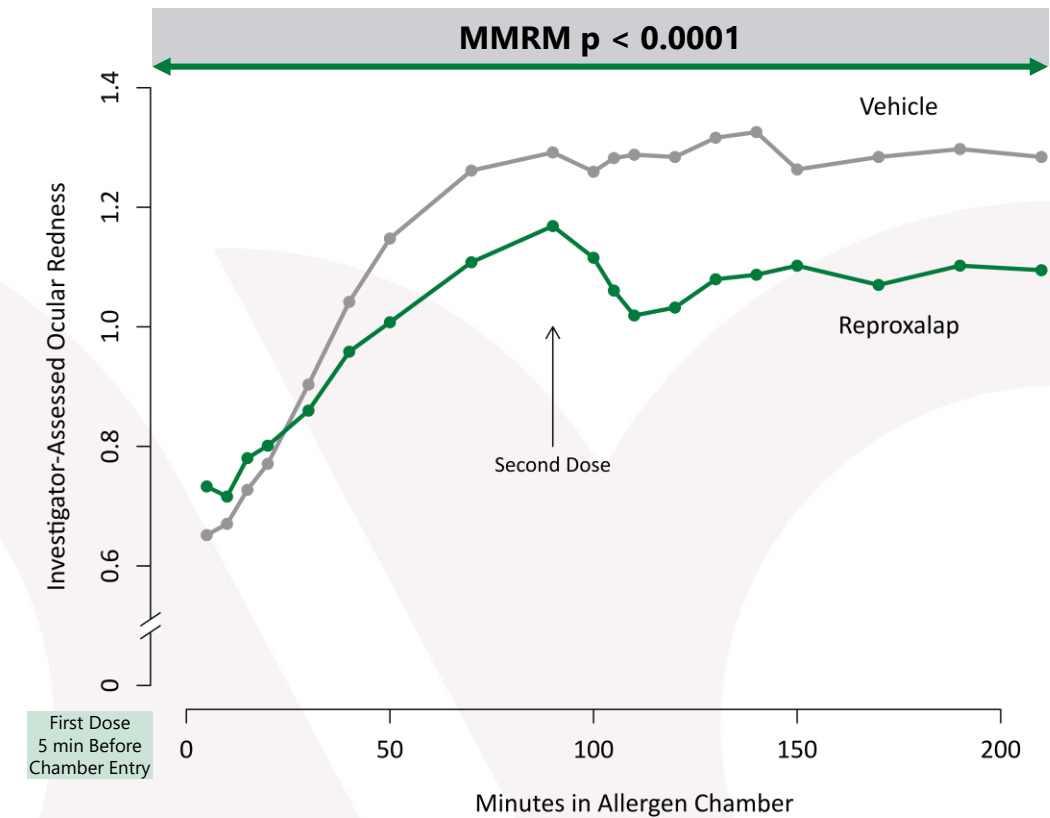
Reproxalap Treatment Led to Durable Reduction in Ocular Itch and Redness in Allergen Chamber Clinical Trial

Ocular Itch Score (0-100) During 3.5 Hours of Allergen Exposure



Statistically significant reduction in ocular itch vs. vehicle for more than three hours of exposure to allergen

Ocular Redness Score (0-4) During 3.5 Hours of Allergen Exposure



Statistically significant reduction in ocular redness vs. vehicle for more than three hours of exposure to allergen

Allergic Conjunctivitis Phase 3 Clinical Program

Allergic Conjunctivitis

Clinical Program to NDA Submission

**Results Announced
March 2019**

ALLEVIATE Phase 3 (CAC)

Type C
FDA Meeting

Additional AC Phase 3

NDA*

**Methods Development Trials
(Environment / Chamber)**

AC Safety Study

**Results Announced
June 2019**



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- DRY EYE DISEASE
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- **PROLIFERATIVE VITREORETINOPATHY**

Ocular Disease Area

Proliferative Vitreoretinopathy: A Rare Sight-Threatening Retinal Disease With No Approved Therapy

Proliferative vitreoretinopathy

ADX-2191

4,000
U.S.

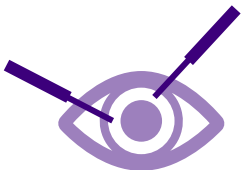
PVR is a **rare disease**, with ~4,000 patients per year in the U.S. and nearly twice as many in Europe and Japan.



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



No FDA- or EMA-approved therapy



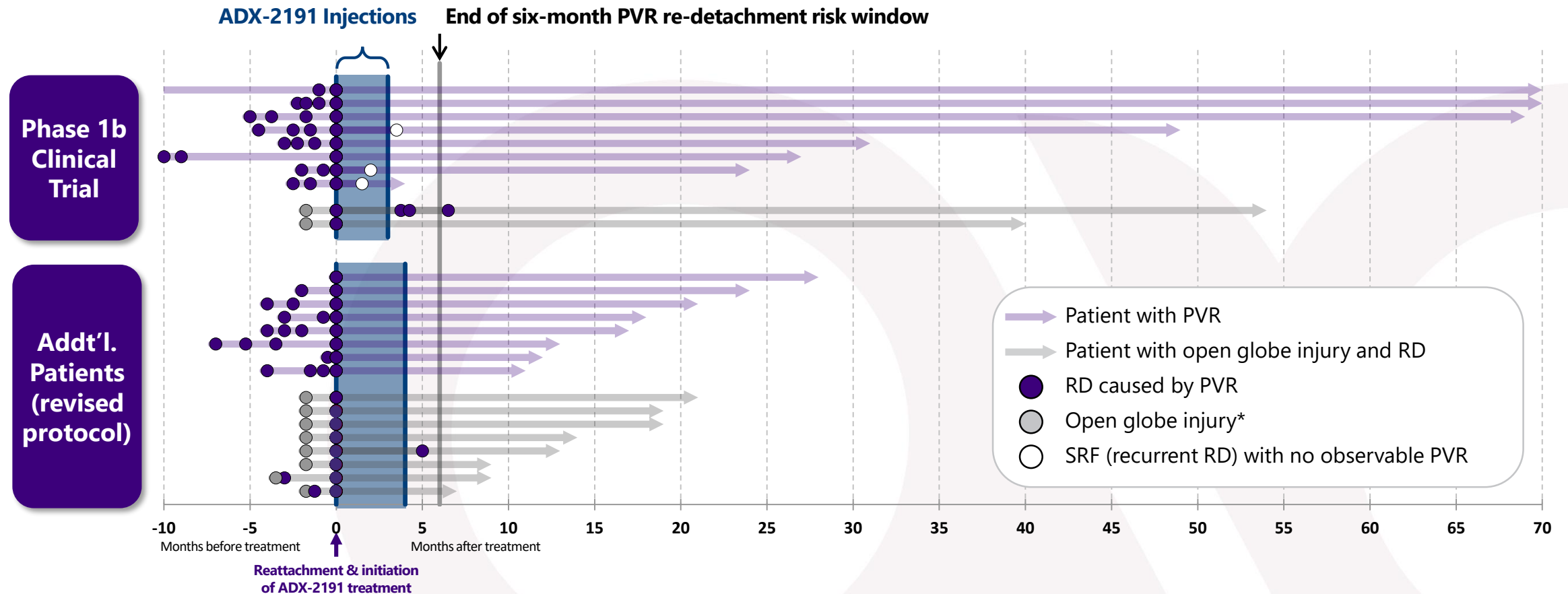
Repeat surgery, which can lead to **vision loss**, is currently the only possible course of action.

ADX-2191

- A **novel approach and potential therapeutic breakthrough** in PVR treatment
- **Granted U.S. orphan 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 **expected to initiate Q4 2019**

ADX-2191 Reduced Recurrent Retinal Detachment in Investigator Sponsored Phase 1b Clinical Trial and in Additional In-Practice Use

Retinal Detachments Over Time by Patient

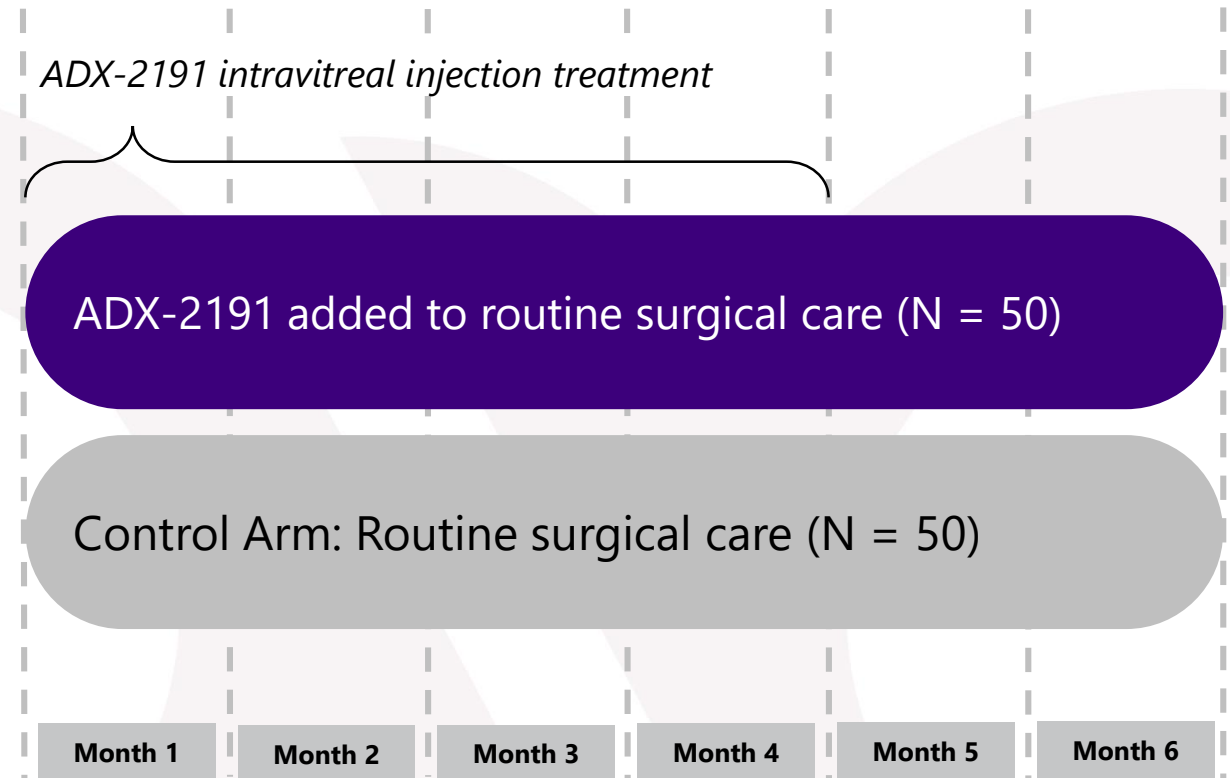


ADX-2191: GUARD Trial Design in Proliferative Vitreoretinopathy

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





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