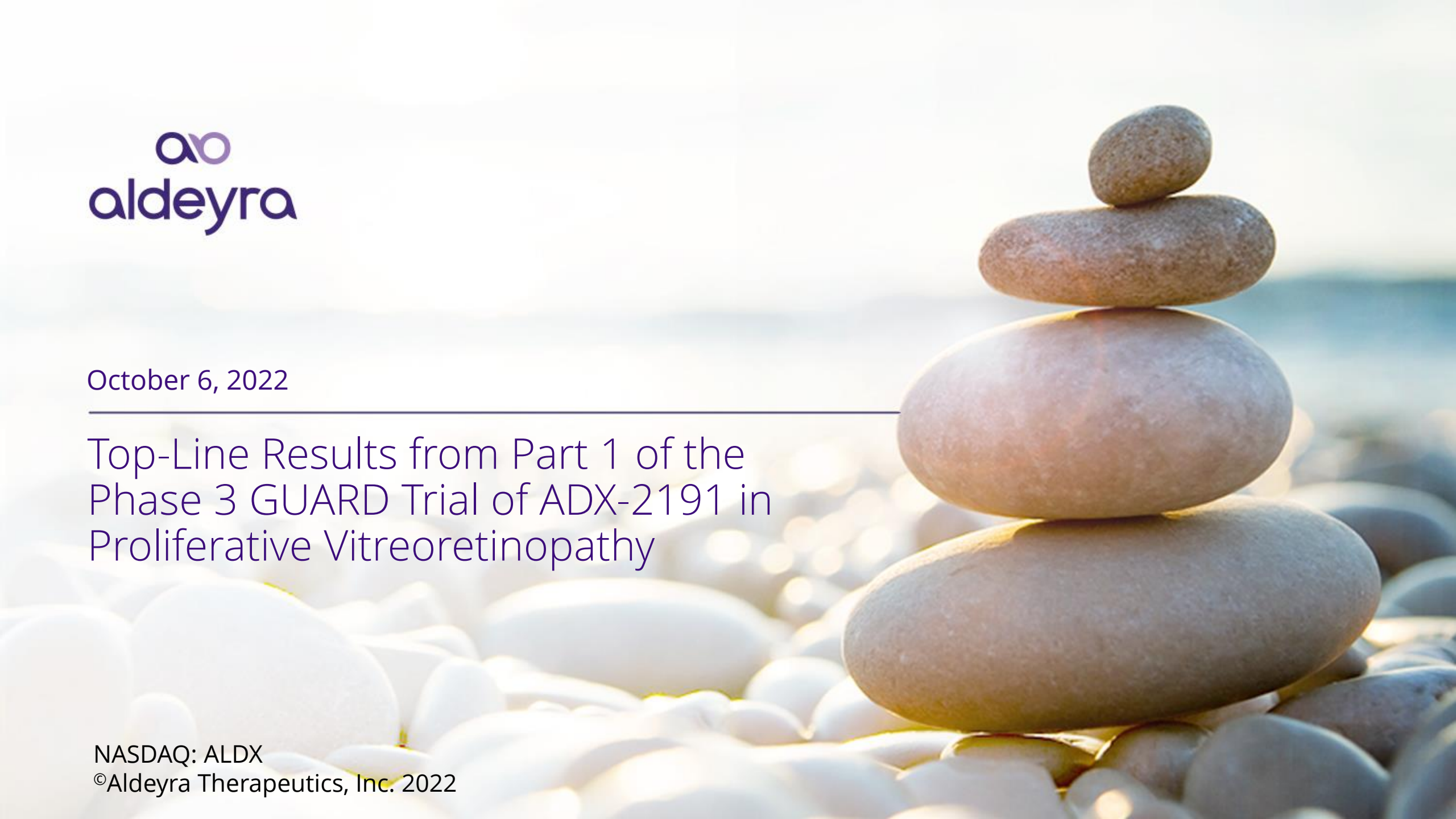

October 6, 2022

Top-Line Results from Part 1 of the Phase 3 GUARD Trial of ADX-2191 in Proliferative Vitreoretinopathy

NASDAQ: ALDX

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The Phase 3 GUARD Trial of ADX-2191 in Proliferative Vitreoretinopathy Met the Primary Endpoint

- The primary endpoint of reduction of retinal detachment over 6 months in ADX-2191-treated patients vs. historical control* was achieved (P=0.024).
- Numerical superiority of ADX-2191 over routine surgical care was demonstrated for multiple secondary and exploratory endpoints, none of which were statistically powered, which in aggregate reached statistical significance (P=0.047).
- ADX-2191 was well tolerated with no observed safety concerns. Numerical superiority of ADX-2191 over routine surgical care was demonstrated for multiple safety endpoints, which in aggregate reached statistical significance (P=0.0002).

*Ophthalmology 124(6):757-767, 2017; Archives of Ophthalmology 25(9):1161-7, 2007.

ADX-2191 (methotrexate injection, USP) for intravitreal administration is an investigational drug candidate.

USP = United States Pharmacopeia

ADX-2191, an Investigational Vitreous-Compatible Formulation of Methotrexate, Represents a Platform Approach for Rare Retinal Diseases

- ADX-2191 (methotrexate injection, USP) is the first sterile, non-compounded formulation of methotrexate designed to meet the unique requirements of intravitreal administration for specific rare retinal diseases, including primary vitreoretinal lymphoma and proliferative vitreoretinopathy.
- The ADX-2191 intravitreal formulation is designed to be vitreous-compatible and optimized for excipient composition, viscosity, density, tonicity, pH, active ingredient concentration, and volume of administration.
- ADX-2191, if approved, will be the first cGMP manufactured methotrexate drug product for intravitreal administration.
- ADX-2191 has received U.S. FDA Orphan Drug Designation for proliferative vitreoretinopathy, primary vitreoretinal lymphoma, and retinitis pigmentosa.

USP = United States Pharmacopeia; **cGMP** = current good manufacturing practices.
ADX-2191 (methotrexate injection, USP) for intravitreal administration is an investigational drug candidate.

ADX-2191 Represents a Novel Potential Therapeutic Option For the Prevention of Proliferative Vitreoretinopathy

PROLIFERATIVE VITREORETINOPATHY (PVR)

PVR is a rare disease, with ~4,000 patients per year in the U.S.

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 one of the main courses of action.

ADX-2191

ADX-2191 was granted **U.S. FDA Orphan Drug Designation and U.S. FDA Fast Track Designation** for the prevention of PVR, and **EU Orphan Medicinal Product Designation** for the treatment of retinal detachment.

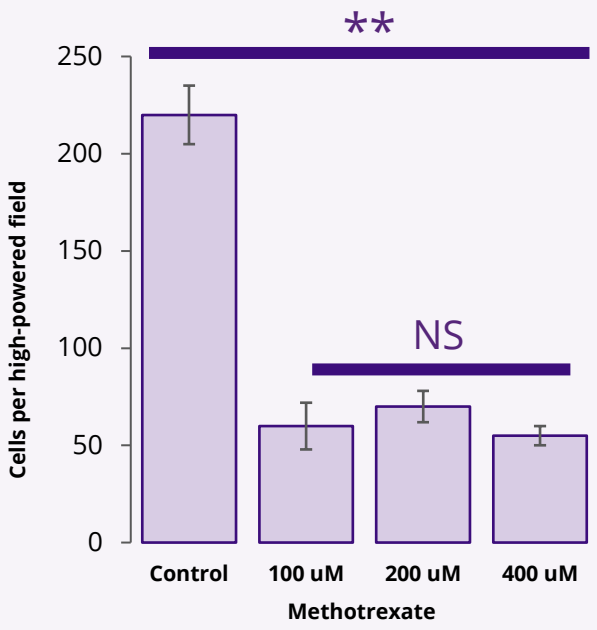
Tolerability and reattachment success demonstrated in Phase 1b open-label investigator sponsored clinical trial.

Published clinical data support the use of methotrexate for the prevention of recurrent retinal detachment due to PVR.

Source: Aldeyra internal estimates. Data on file. **PVR** = proliferative vitreoretinopathy.
ADX-2191 (methotrexate injection, USP) for intravitreal administration is an investigational drug candidate.

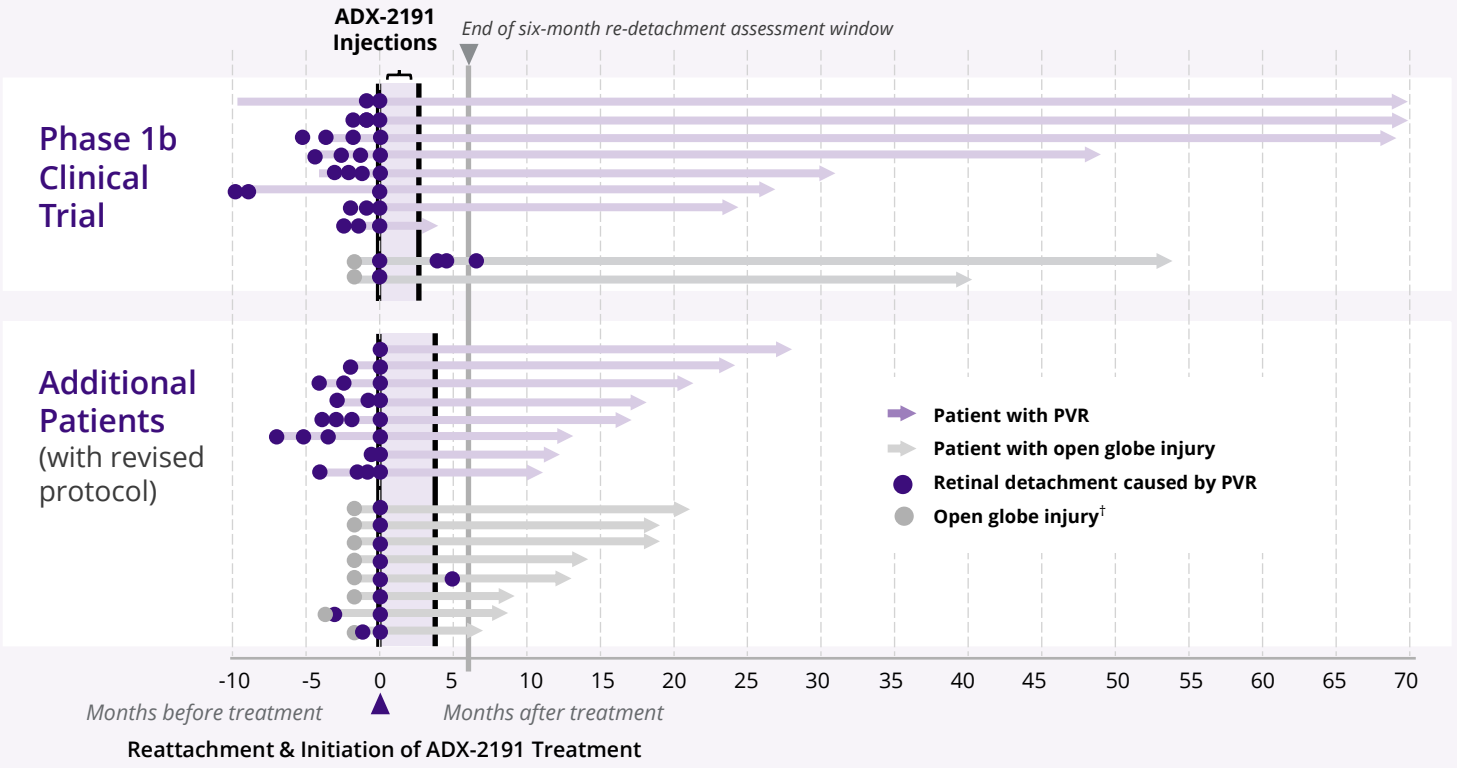
Preclinical and Clinical Results Support the Anti-Proliferative Activity of Methotrexate for the Prevention of Proliferative Vitreoretinopathy

Preclinical reduction in cellular proliferation



Clinical reduction in retinal detachment

Retinal Detachments Over Time by Patient



Sources: ADX-2191 PVR Phase 1b investigator sponsored clinical trial (n=10) results and additional in-practice use (n=16); Invest Ophthalmol Vis. Sci. 2017; 58:3940–3949. †Timing of open globe injury as shown is estimated. 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. ****** = $p \leq 0.01$. **NS** = not significant, **PVR** = proliferative vitreoretinopathy.

The Activity of Methotrexate for the Prevention of Proliferative Vitreoretinopathy is Supported by Peer-Reviewed Publications

RETINAL CASES & BRIEF REPORTS – JANUARY 2022

Rescue Intravitreal Methotrexate Treatment Following Early Recognition of Proliferative Vitreoretinopathy

Alabi R, et al

AMERICAN SOCIETY OF RETINAL SPECIALISTS 2022 MEETING

Management of Proliferative Vitreoretinopathy with Intravitreal Methotrexate using a Treat-and-Extend Protocol

Walter S, et al

AMERICAN SOCIETY OF RETINAL SPECIALISTS 2022 MEETING

Intravitreal methotrexate reduces reoperation rate and improves vision after vitrectomy for retinal detachment, trauma, and proliferative diabetic retinopathy

Franklin A, et al

GRAEFE'S ARCHIVE FOR CLINICAL AND EXPERIMENTAL OPHTHALMOLOGY, OCTOBER 2021

Adjunctive serial post-operative intravitreal methotrexate injections in the management of advanced proliferative vitreoretinopathy

Roca J, et al

ARVO ANNUAL MEETING ABSTRACT – JUNE 2020

Post-operative Intravitreal Methotrexate Injections after Recurrent Retinal Detachment Repair Can Reduce the Risk and Progression of Proliferative Vitreoretinopathy

Wa C, et al

ADX-2191: Design of Part 1 of the Adaptive Phase 3 GUARD Trial in Proliferative Vitreoretinopathy

Primary Objective
Evaluate efficacy of intravitreal ADX-2191 injections for prevention of PVR-associated retinal detachment to estimate statistical power for Part 2 of GUARD

Design
Multi-center Phase 3 clinical trial of ADX-2191 vs. historical control* and routine surgical care

Inclusion Highlights
- Recurrent retinal detachment due to PVR, or
- Retinal detachment associated with open-globe injury

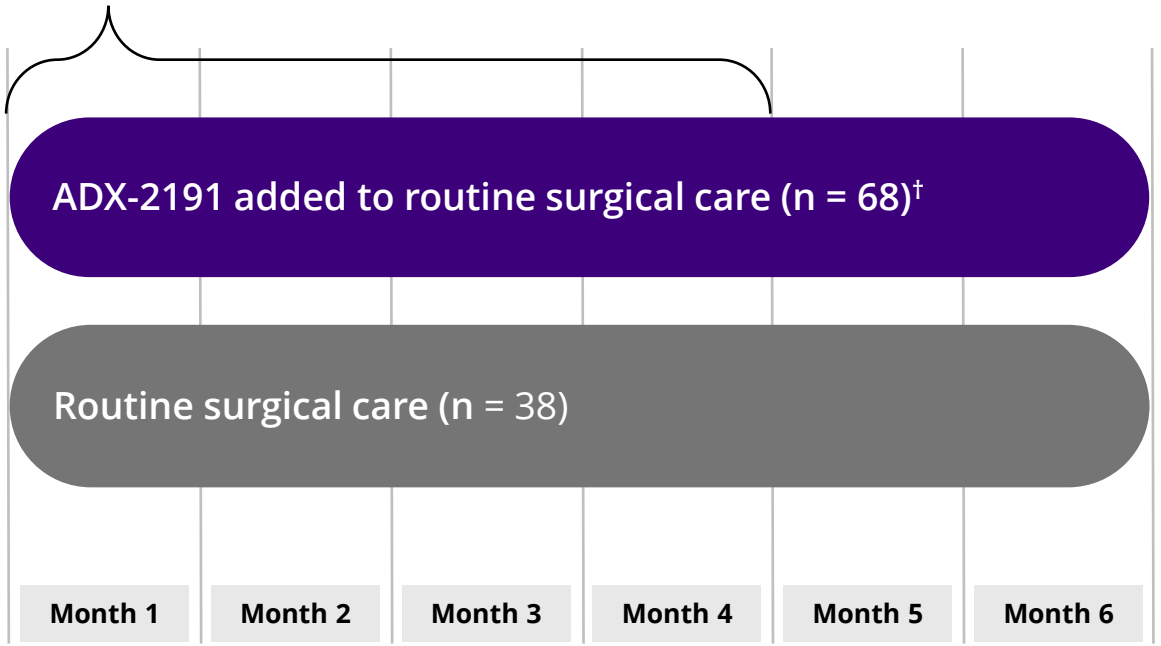
Dosing Regimen
At surgery, weekly (x8), and then every other week (x4) intravitreal injections

Primary Endpoint
Retinal re-detachments due to PVR requiring re-operation within 6 months vs. historical control

Secondary Endpoints
- Retinal re-detachments due to PVR vs. routine surgical care
- Visual acuity vs. routine surgical care

Exploratory Endpoints
Macular thickness, epiretinal membrane formation, hypotony vs. routine surgical care

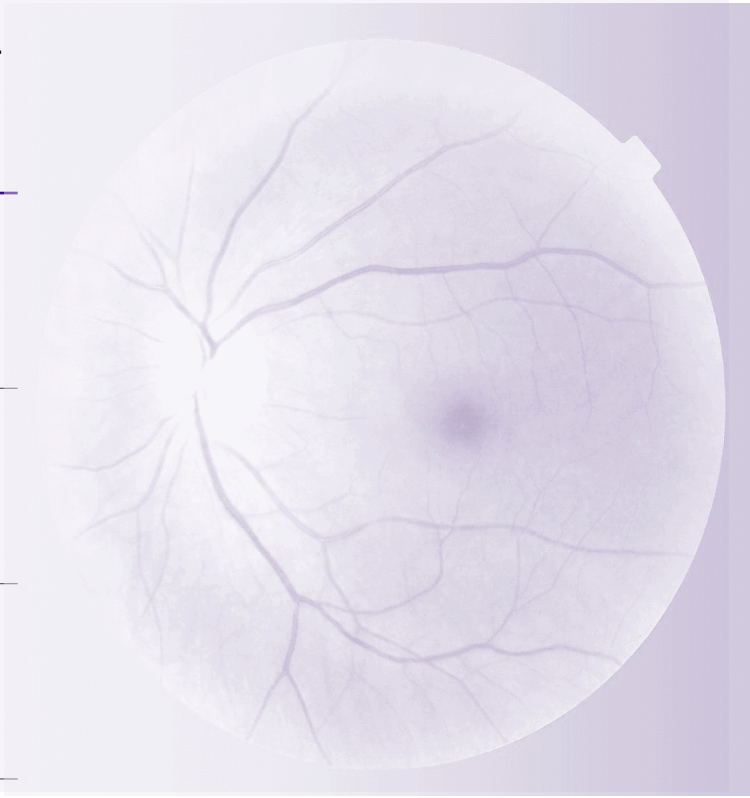
ADAPTIVE PHASE 3 PVR CLINICAL TRIAL DESIGN: PART 1



†Includes 41 subjects enrolled under the open-label portion of the protocol. *Ophthalmology 124(6):757-767, 2017; Archives of Ophthalmology 25(9):1161-7, 2007.
PVR = proliferative vitreoretinopathy. **Hypotony** = intraocular pressure less than 5 mm Hg.
ADX-2191 (methotrexate injection, USP) for intravitreal administration is an investigational drug candidate.

The Primary Endpoint of Reduction of Retinal Detachment vs. Historical Control Was Achieved

	ADX-2191 (n=68)	Historical Control† (n=292)
Patients with retinal detachment within 6 months of surgery	16	113
Odds ratio (95% CI) vs. historical control	0.49 (0.26, 0.89)	
P value vs. historical control*	0.024	



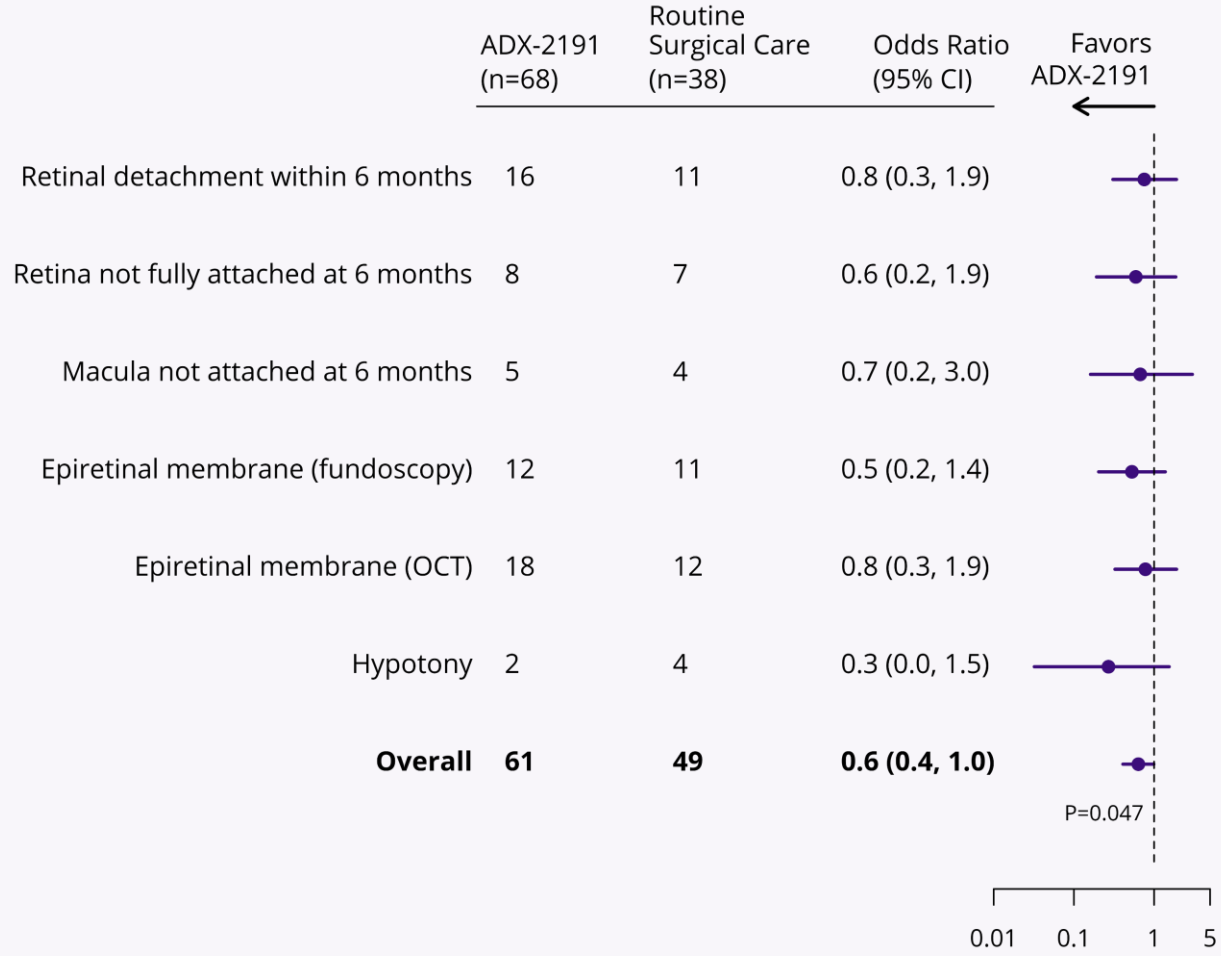
†Ophthalmology 124(6):757-767, 2017; Archives of Ophthalmology 25(9):1161-7, 2007. *Fisher exact test. **CI** = confidence interval.
ADX-2191 (methotrexate injection, USP) for intravitreal administration is an investigational drug candidate.

The Majority of Secondary and Exploratory Endpoints, While Not Statistically Powered, Were Numerically in Favor of ADX-2191

Continuous Endpoints

	ADX-2191 (n=68)	Routine Surgical Care (n=38)
Letters of visual acuity (SD)	32.9 (19.7)	36.5 (25.0)
Central macular subfield thickness (μM, SD)	382 (182)	484 (233)

Dichotomous Endpoints



SD = standard deviation. **CI** = confidence interval. **Hypotony** = intraocular pressure less than 5 mm Hg. **OCT** = optical coherence tomography. P value derived from random effect meta-analysis. ADX-2191 (methotrexate injection, USP) for intravitreal administration is an investigational drug candidate.

ADX-2191 Was Well Tolerated and No Safety Concerns Were Observed

- The most common adverse event associated with ADX-2191 administration was punctate keratitis (n=11, 16%), a well-known side effect of intravitreal methotrexate. Nine events were mild; two were moderate.
- The incidence of punctate keratitis was substantially less than that previously reported (58%)[†] for intravitreal methotrexate.
- ADX-2191 treatment was discontinued in one (1%) patient, due to scheduling difficulty.

[†]Annals of Hematology, 95(4), 593–601, 2016.
ADX-2191 (methotrexate injection, USP) for intravitreal administration is an investigational drug candidate.

ADX-2191 Was Numerically Favorable to Routine Surgical Care for Additional Key Safety Endpoints

All treatment-emergent adverse events affecting at least 10% of patients in either treatment group

	ADX-2191 (n=68)	Routine Surgical Care (n=38)	Odds Ratio (95% CI)
Ocular pain	9	9	0.5 (0.2, 1.4)
Cystoid macular edema	5	5	0.5 (0.1, 2.1)
Corneal edema	4	4	0.5 (0.1, 2.5)
Macular fibrosis	4	6	0.3 (0.1, 1.3)
Corneal epithelial defect	2	4	0.3 (0.0, 1.5)
Anterior uveitis	1	4	0.1 (0.0, 1.1)
Ocular hypertension	2	8	0.1 (0.0, 0.5)
Post-operative inflammation	1	5	0.1 (0.0, 0.8)
Overall	**28**	**45**	**0.3 (0.2, 0.6)**

CI = confidence interval. P value derived from random effect meta-analysis.
ADX-2191 (methotrexate injection, USP) for intravitreal administration is an investigational drug candidate.

Upcoming Planned Clinical Milestones for ADX-2191*

Primary Vitreoretinal Lymphoma

Pre-NDA meeting scheduled for Q4 2022

Proliferative Vitreoretinopathy

Planned Type C meeting with FDA in H1 2023 to discuss completion of clinical development

Retinitis Pigmentosa

Phase 2 clinical trial results expected in H1 2023

*The timing of ongoing clinical trials depends, in part, on the availability of clinical research facilities and staffing, and the ability to recruit patients.