# aldeyra

April 2022

#### **CORPORATE OVERVIEW**

## Innovative Therapeutics to Treat Immune-Mediated Diseases

Nasdaq: ALDX © Aldeyra Therapeutics, Inc. 2022

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**ALDEYRA'S MISSION** is to discover and develop innovative medicines that improve the lives of patients who suffer from immune-mediated diseases.

**OUR APPROACH** is to create therapies that modulate immunological systems, instead of directly inhibiting or activating single protein targets, with the goal of optimizing multiple pathways at once while minimizing toxicity.

Front of the end Back of the Drug Development Platform VISION

Systemic Disease

Eye

## Aldeyra is a Well-Capitalized Biotechnology Company with a Broad Immunology Pipeline and Near-Term Catalysts

| PRODUCT CANDIDATES  | DISEASE TARGETS  | DEVELOPMENT STAGE | NEXT EXPECTED MILESTONE              |  |
|---|--|-------------------|--------------------------------------|--|
| RASP PLATFORM FOR OCULAR AND SYSTEMIC IMMUNE-MEDIATED DISEASES        |  |                   |                                      |  |
| Reproxalap<br>(ophthalmic solution)                                   | Dry Eye Disease  | Phase 3           | Q2 2022: Final Pivotal Trial Results |  |
|   | Allergic Conjunctivitis  | Phase 3           | 2023: Final Pivotal Trial Results    |  |
| ADX-629<br>(oral administration)                                      | Ethanol Toxicity, Chronic Cough, Sjögren-Larsson<br>Syndrome, Minimal Change Disease | Phase 2a          | 2022 and 2023: Trial Completions     |  |
| RASP-Modulator<br>Discovery Platform                                  | Multiple Immune-Mediated<br>Retinal and Systemic Indications                         | Preclinical       | 2023: IND Submissions                |  |
| VITREOUS METHOTREXATE PLATFORM FOR RARE RETINAL INFLAMMATORY DISEASES |  |                   |                                      |  |
| ADX-2191<br>(intravitreal injection)                                  | Primary Vitreoretinal Lymphoma<br>(U.S. FDA Orphan Drug Designation)                 | Pre-NDA           | H2 2022: Regulatory Update           |  |
|   | Proliferative Vitreoretinopathy<br>(U.S. FDA Orphan Drug and Fast Track Designation) | Phase 3           | H2 2022: Part 1 GUARD Trial Results  |  |
|   | Retinitis Pigmentosa<br>(U.S. FDA Orphan Drug Designation)                           | Phase 2           | H2 2022: Trial Results               |  |

As of 12/31/2021, cash and cash equivalents were \$229.8M, which is expected to be sufficient to fund operations through the end of 2023, based on projected operating expenses.<sup>†</sup>

<sup>†</sup>Company guidance as of March 17, 2022. **IND** = Investigational New Drug. **NDA** = New Drug Application.

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April 2022

**REPROXALAP, ADX-629, AND NOVEL RASP MODULATORS** 

Modulating RASP – A First-in-Class, Systems-Based Therapeutic Approach

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## Aldeyra is the Leading Developer of RASP Modulators: A Novel Approach Supported by Late-Stage Trials

Reproxalap, ADX-629 LPS Animal Model of Cytokine Storm RASP 700% Cytokine Levels Percent Change vs. Vehicle **Scavenger** \*\* p < 0.01 NF-KB \*\*\* p < 0.001 receptor A \*\*\*\* p <0.0001 translocation binding 0 \*\* \*\* Inflammasome -25 TNF-∝ activation -50 -75 **Cytokine Release** 

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#### **Preclinical Broad-Based Cytokine Reduction**



#### **Broad-Based** Symptom Reduction

#### RENEW-Part 1 Phase 3 Dry Eye Disease Trial

Symptom Treatment Difference<sup>†</sup> (Reproxalap-Vehicle) Weeks 2 -12

NS

0-100 Ocular Symptom Scales VAS: Ocular Dryness (Co-Primary) 0.0004 VAS: Eye Discomfort VAS: Photophobia 0.0041 VAS: Foreign Body Sensation VAS: Itching VAS: Pain 0.0268 VAS: Burning/Stinging NS **OSDI** (Total)



#### 0-4 & 0-5 Ocular Symptom Scales

**OD4S:** Grittiness OD4S: Dryness **OD4S: Ocular Discomfort OD4S: Burning OD4S: Stinging** CAC Ocular Itching Scale **Ocular Discomfort Scale** 



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<sup>†</sup>Treatment difference of induction-maintenance dosing, defined as the difference between the changes from baseline for the evaluated drug minus vehicle (least squares mean difference ± 95%) confidence interval). Ocular Dryness Score co-primary endpoint assessed in pre-specified patient population having an OD4S dryness baseline score of ≥ 3 (N=170). Sources: Cullen, et al. The Small Molecule Aldehyde Trap NS2 Exhibits Potent Anti-Inflammatory Activity in Three Murine Models of Inflammation [abstract]. In: The Journal of Allergy and Clinical Immunology. Volume 135, Issue 2, AB384, Feb 2015; Reproxalap RENEW-Part 1 clinical trial results. RASP = reactive aldehyde species. VAS = visual analog scale. OSDI = Ocular Surface Disease Index. NS = not significant. OD4S = Ocular Discomfort & 4-Symptom Scale. **CAC** = conjunctival allergen challenge.

## The Activity of Lead RASP Modulator Reproxalap is Supported by Marquee Peer-Reviewed Publications



Topical ocular reproxalap is an investigational drug candidate that has been studied in over more than 1,500 patients with no observed safety concerns; mild and transient instillation site discomfort is the most commonly reported adverse event in clinical trials.

## Reproxalap is Now in Two Phase 3 Programs for Ocular Inflammation

#### **DRY EYE DISEASE**



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**39 million** or more adults in the U.S.<sup>1</sup>

Currently available topical therapy often requires months to demonstrate even modest efficacy.

#### ALLERGIC CONJUNCTIVITIS



66 million or more adults in the U.S.<sup>2</sup>

For patients that do not respond to over-the-counter antihistamine eyedrops, therapeutic options are limited. Reproxalap is poised to potentially be the next novel entrant in the dry eye disease and allergic conjunctivitis markets.

Sources: <sup>1</sup>Company estimates and Paulsen AJ, Cruickshanks KJ, Fischer ME, et al. Dry eye in the beaver dam offspring study: prevalence, risk factors, and health-related quality of life. Am J Ophthalmol. 2014;157(4):799-806; <sup>2</sup>Company estimates and Singh K, Axelrod S, Bielory L. The epidemiology of ocular and nasal allergy in the United States, 1988-1994. J Allergy Clin Immunol. 2010;126(4):778-783. Topical ocular reproxalap is an investigational drug candidate that has been studied in more than 1,500 patients with no observed safety concerns; mild and transient instillation site discomfort is the most commonly reported adverse event in clinical trials.

## Reproxalap Represents a Novel, Rapid-Onset Potential Therapeutic Approach in Dry Eye Disease

Potential advantages for patients and healthcare providers could effect a paradigm shift relative to standard of care.



Rapid symptom improvement



Broad symptomatic activity



Acute increase in tear production and reduction of ocular redness



Topical ocular reproxalap has been studied in more than 1,500 patients with no observed safety concerns; mild and transient instillation site discomfort is the most commonly reported adverse event in clinical trials.

### Aldeyra is One Pivotal Clinical Trial Away from NDA Submission of Reproxalap for Dry Eye Disease<sup>†</sup>

To satisfy efficacy requirements for dry eye disease, the FDA requires two positive trials with the same symptom and two positive trials with the same sign.<sup>‡</sup>



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#### Symptoms

Aldeyra intends to submit two previously completed 12-week adequate and well-controlled **symptom trials** that pre-specified patient-reported ocular dryness score as a primary endpoint or a co-primary endpoint.

Aldeyra has shown statistically significant results in ocular redness in the Phase 2<sup>\*</sup> dry eye chamber trial and in Schirmer test in the Phase 3 TRANQUILITY Trial<sup>#</sup>. Both ocular redness and Schirmer test are FDAsanctioned, objective signs of dry eye.

\*NDA submission requirements depend, in part, on clinical results and regulatory feedback. \*Draft U.S. Food and Drug Administration (FDA) guidance. \*Adequate and well-controlled Phase 2 or Phase 3 clinical trials can be submitted as pivotal. #Schirmer test was a secondary endpoint in the TRANQUILITY Trial. Sources: Clinical trial results on file. MMRM = mixed model repeated measures. SEM = standard error of the mean. Topical ocular reproxalap is an investigational drug candidate that has been studied in more than 1,500 patients with no observed safety concerns; mild and transient instillation site discomfort is the most commonly reported adverse event in clinical trials.

## The Phase 3 TRANQUILITY-2 Trial is Designed to Serve as Pivotal if Either Ocular Redness or Schirmer Test Achieved

- Results are expected Q2 2022.
- Using an alpha sharing approach, TRANQUILITY-2 is expected to be submitted as pivotal for either ocular redness or Schirmer test if the primary endpoint is met.
- Based on data from Phase 2 and TRANQUILITY clinical trials, simulation modeling indicated that more than 90% of outcomes achieved for either ocular redness or Schirmer test primary endpoints.

| Design                 | Multi-center, randomized, double-masked,<br>parallel group, vehicle-controlled        |
|------------------------|---|
| Dosing                 | 0.25% reproxalap or vehicle   |
|                        | Day 1: four doses<br>Day 2: one dose before dry eye chamber,<br>one dose in chamber   |
| Size                   | Up to 200 patients per arm  |
| Primary<br>Endpoint    | Ocular redness over 90 minutes in dry eye<br>chamber <b>or</b> Schirmer test on Day 1 |
| Secondary<br>Endpoints | Dry eye disease symptoms on Day 1   |

### Ocular Discomfort Score, Blurry Vision, and Dysgeusia were Statistically Lower with Reproxalap than with Xiidra<sup>®</sup> in a Post-Acute Ocular Tolerability Clinical Trial



Source: McMullin D, Clark D, Cavanagh B, Karpecki P, Brady TC. A Post-Acute Ocular Tolerability Comparison of Topical Reproxalap 0.25% and Lifitegrast 5% in Patients with Dry Eye Disease. Clin Ophthalmol. 2021 Sep 22;15:3889-3900. AUC = area under the curve. p-values represent MMRM of vehicle area under the curve vs. pooled reproxalap AUC. Topical ocular reproxalap is an investigational drug candidate that has been studied in more than 1,500 patients with no observed safety concerns; mild and transient instillation site discomfort is the most commonly reported adverse event in clinical trials.

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### Patient-Reported Ocular Discomfort and Ocular Itching were Statistically Lower with Reproxalap than with Xiidra<sup>®</sup> in a Phase 2 Dry Eye Chamber **Clinical Trial**





Source: Clinical trial results on file. MMRM = mixed model repeated measures. Topical ocular reproxalap has been studied in more than 1,500 patients with no observed safety concerns; mild and transient instillation site discomfort is the most commonly reported adverse event in clinical trials.

### Aldeyra is One Pivotal Trial Away from NDA Submission of Reproxalap for Allergic Conjunctivitis<sup>†</sup>

#### The Phase 3 INVIGORATE Allergen Chamber Trial



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<sup>†</sup>NDA submission requirements depend, in part, on clinical results and regulatory feedback. **Source**: INVIGORATE clinical trial results. Topical ocular reproxalap has been studied in more than 1,500 patients with no observed safety concerns; mild and transient instillation site discomfort is the most commonly reported adverse event in clinical trials. **MMRM** = mixed model repeated measures.

## The Phase 3 INVIGORATE-2 Trial is Designed to be Substantially Identical to INVIGORATE

- Results are expected 2023.
- Enrollment criteria, endpoints, trial design, and study conduct are substantially identical to INVIGORATE.
- Based on data from INVIGORATE, simulation modeling indicates that more than 90% of outcomes achieved for the primary endpoint of patientreported ocular itching.

| Design                    | Randomized, double-masked, crossover, vehicle-<br>controlled allergen chamber exposure to aerosolized<br>pollen over 3.5 hours |
|---------------------------|--|
| Dosing                    | 0.25% reproxalap or vehicle  |
|                           | One dose just prior to chamber entry, one dose 90 minutes after chamber entry  |
| Size                      | Approximately 50 patients  |
| Primary<br>Endpoint       | Patient-reported ocular itching score  |
| Key Secondary<br>Endpoint | Investigator-assessed ocular redness score   |

## ADX-629, a RASP Modulator for Oral Administration, Is a First-in-Class Pharmacologic Approach With Activity in Phase 2 Clinical Trials



**SEM** = standard error of the mean. P values derived from mixed model for repeated measures analysis of comparison to 0 (no change).

P values are derived from mixed model for repeated measures analysis of placebo group comparison to 0 (no change).

**NIAID** = National Institute of Allergy and Infectious Diseases. **LOCF** = Last Observation Carried Forward.

## New Clinical Development Indications for ADX-629 Feature Multiple Systemic Diseases Associated With RASP

Ethanol Toxicity



Up to 10% of adults in the U.S. abuse ethanol, which can lead to the development of hepatitis.

Approximately 12 million adults in the U.S. have alcoholic fatty liver disease (AFLD). Chronic Cough



Approximately ~13M adults in the U.S., and up to 10% of people worldwide, have chronic cough.

RASP are increased in the lungs of patients with chronic cough.<sup>†</sup>

Sjögren-Larsson Syndrome

Sjögren-Larsson

Syndrome is an

oxidation.

impacted.

autosomal recessive

error of metabolism

involving fatty alcohol

Approximately 1,300

U.S. patients are

neurocutaneous inborn



Minimal Change Disease



Minimal Change Disease is an **orphan kidney disease** that primarily afflicts children.

Treatment involves corticosteroids and other immunosuppressant alternatives that may lead to toxicity.

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Sources: Company estimates; UpToDate (Ethanol toxicity in adults updated 03/19/20). Wong et al. JAMA. 2019;321(17):1723-25. Neuman et al. Exp Mol Pathol. 2014;97(3):492-510; Singh et al. World J Gastroenterol. 2017;23:6549-6570; Meltzer et al. J Allergy Clin Immunol Pract. 2021;9:4037-4044. Arinze et al. ERJ Open Res. 2021;6:00300-2019; ; Vivarelli et al. Clin J Am Soc Nephrol. 2017;2:332-345. UpToDate (Minimal Change Disease updated 12/3/21). <sup>†</sup>Data on file.

## ADX-629 Phase 2a Trials Initiating in 2022 Represent Varied Trial Designs and Are Expected to Complete in 2022 and 2023<sup>†</sup>

| INDICATION                  | PLANNED DESIGN   | PLANNED ENDPOINTS  | EXPECTED COMPLETION |
|-----------------------------|--|--|---------------------|
| Ethanol Toxicity            | Crossover, ethanol<br>challenge, acute<br>dosing, ~20 subjects | Symptoms, plasma<br>chemistry, flushing                              | H2 2022             |
| Chronic Cough               | Crossover, 28-day dosing,<br>~50 subjects                      | Cough frequency, symptoms  | 2023                |
| Sjögren-Larsson<br>Syndrome | Baseline-controlled,<br>~6 subjects                            | Plasma biomarkers,<br>magnetic resonance<br>imaging, quality of life | 2023                |
| Minimal Change<br>Disease   | Baseline-controlled,<br>~ 6 subjects                           | Relapse (corticosteroid<br>dependency, proteinuria)                  | 2023                |

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### New Candidates for Systemic and Retinal Diseases Expected to be Advanced to Clinical Trials in 2023



Aldeyra has developed the leading RASP modulation discovery platform.

LPS = lipopolysaccharide. ADMET = absorption, distribution, metabolism, excretion, and toxicity. IND = Investigational New Drug.

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April 2022

ADX-2191 (METHOTREXATE FOR INTRAVITREAL INJECTION)

## A Platform Approach to Treat Rare Inflammatory Retinal Diseases

Nasdaq: ALDX © Aldeyra Therapeutics, Inc. 2022

## ADX-2191, a New Vitreous-Compatible Formulation of Methotrexate, Represents a Clinically Tested Systems Modulating Approach





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. <sup>†</sup>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 ≤ 0.01. **NS** = not significant, **PVR** = proliferative vitreoretinopathy.

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## 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. 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 one of the main courses of action.

#### ADX-2191

**Granted U.S. FDA orphan drug designation, U.S. FDA fast track designation, and EU orphan drug designation** for the prevention of PVR

Tolerability and reattachment success 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



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

#### Results Expected H2 2022<sup>†</sup>

#### **Primary Objective**

Evaluate efficacy of intravitreal ADX-2191 injections for prevention of recurrent retinal detachment due to PVR

#### Design

Multi-center, two-part, adaptive Phase 3 clinical trial (N  $\cong$  100)

#### **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

#### ADX-2191 intravitreal injections



# Subjects include n  $\cong$  30 subjects recruited under open label portion of protocol.



<sup>†</sup>The timing of ongoing clinical trials depends, in part, on restrictions related to the COVID-19 pandemic, the availability of clinical research facilities and staffing, and the ability to recruit patients. **PVR** = proliferative vitreoretinopathy. **OCT** = optical coherence tomography.

## ADX-2191 Has the Potential to be the First Approved Drug for Primary Vitreoretinal Lymphoma (PVRL), a Rare but Serious Retinal Cancer





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

OC

A rare, aggressive, high-grade cancer, PVRL arises in the vitreous and retina.

Approximately **2,900 patients** in the United States suffer from PVRL.

Approximately **600 new cases** of PVRL are diagnosed in the United States per year. **4.83 years is the median survival** for newly diagnosed patients.

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, though methotrexate represents current standard of care.

#### U.S. FDA Orphan Drug Designation Received in July 2021

## ADX-2191 Has the Potential to be the First Approved Drug for Retinitis Pigmentosa (RP), a Clinical Group of Rare Genetic Eye Diseases

RP refers to a group of inherited retinal diseases characterized by cell death and loss of vision.



Affects an estimated 82,000-110,000 individuals in the United States, and approximately 1 in 4,000 people worldwide.

Forms of RP and related diseases include usher syndrome, Leber's congenital amaurosis, and Bardet-Biedl syndrome, among others.



Preclinical evidence in a P23H rhodopsin mutation mouse model of RP suggests that methotrexate improves retinal function.

#### U.S. FDA Orphan Drug Designation Received in August 2021

## ADX-2191: Phase 2 Clinical Trial Design in Retinitis Pigmentosa

#### Results Expected H2 2022<sup>†</sup>

#### **Primary Objective**

To evaluate the safety and efficacy of ADX-2191 in patients with RP

#### Design

Single-center, open label study (N = 8)

#### **Inclusion Highlights**

Diagnosis of RP due to rhodopsin gene mutations, including P23H

#### **Dosing Regimen**

Cohort A (n = 4): Monthly injections Cohort B (n = 4): Twice-monthly injections

#### Primary Endpoint

Safety and tolerability of ADX-2191 in RP subjects

#### Secondary Endpoints

- 1. Change in visual acuity assessed by ETDRS
- 2. Central retinal sensitivity assessed by MAIA microperimetry
- 3. Change in dark-adapted flash analyzed by ffERG
- 4. Change in dark-adapted retinal sensitivity
- OCT assessment for change in central subfield foveal thickness and ellipsoid zone area/width

#### RETINITIS PIGMENTOSA CLINICAL TRIAL DESIGN





<sup>†</sup>The timing of ongoing clinical trials depends, in part, on restrictions related to the COVID-19 pandemic, the availability of clinical research facilities and staffing, and the ability to recruit patients. **RP** = retinitis pigmentosa. **OCT** = optical coherence tomography. **ETDRS** = Early Treatment Diabetic Retinopathy Study. **MAIA** = Macular Integrity Assessment. **ffERG** = full field electroretinography.

## Experienced Management Team and Board of Directors

#### MANAGEMENT TEAM

**Todd Brady**, M.D., Ph.D. President, CEO & Director



Joshua Reed, M.B.A. Chief Financial Officer Bristol-Myers Squibb J.P.Morgan

**Stephen Machatha**, Ph.D. Chief Development Officer



#### **BOARD OF DIRECTORS**

| <b>Richard Douglas,</b> Ph.D.<br>Chairman | Former SVP Corporate<br>Development at Genzyme      |
|---|---|
| Ben Bronstein, M.D.                       | Former CEO Peptimmune <sup>6</sup>                  |
| Marty Joyce, M.B.A.                       | Former CFO of Serono USA                            |
| Nancy Miller-Rich                         | Former SVP BD&L and<br>Commercial Strategy at Merck |
| Gary Phillips, M.D.                       | CEO OrphoMed  |
| Neal Walker, D.O.                         | CEO Aclaris Therapeutics                            |
| Todd Brady, M.D., Ph.D.                   | CEO Aldeyra Therapeutics                            |



### Upcoming Planned Clinical Milestones\*



Phase 3 TRANQUILITY-2 Trial of reproxalap in dry eye disease

Top-line results expected Q2 2022 Part 1 of Phase 3 GUARD Trial of ADX-2191 in proliferative vitreoretinopathy Results expected H2 2022 Burn

Phase 2 clinical trial of ADX-2191 in retinitis pigmentosa Results expected H2 2022

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Phase 2a clinical trials of ADX-629 in ethanol toxicity, chronic cough, Sjögren-Larsson Syndrome, and minimal change disease Expected completion

in 2022 and 2023



## We Are Creating What We Believe Are Best-in-Class Therapeutic Platforms for Modulation of Inflammatory Disease

Unparalleled drug discovery and development engine targeting RASP, with multiple early and late-stage milestones expected over the next two years<sup>†</sup>

- Reproxalap NDA submission in dry eye disease expected mid-2022
- ADX-629 advancing to Phase 2 trials in four new indications
- New compounds for systemic and retinal disease expected to begin clinical trials in 2023

Novel intravitreal methotrexate formulation with orphan drug status in three rare retinal diseases

• ADX-2191 could be the first approved therapy for proliferative vitreoretinopathy, retinitis pigmentosa, and primary vitreoretinal lymphoma.



<sup>†</sup>Timing depends, in part, on restrictions related to the COVID-19 pandemic, the availability of clinical research facilities and staffing, the ability to recruit patients, and regulatory feedback. <sup>‡</sup>NDA submission requirements depend, in part, on clinical results and regulatory feedback. **NDA** = New Drug Application.

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