Aldeyra Therapeutics

Fact Sheet

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ALDEYRA THERAPEUTICS

QUICK REFERENCE

Aldeyra Therapeutics Inc

NASDAQ: ALDX

www.ALDEYRA.com

BUSINESS SUMMARY

Aldeyra Therapeutics is a biotechnology company devoted to developing and commercializing next-generation medicines to improve the lives of patients with immune-mediated diseases. Aldeyra's lead investigational drug product candidates are potential first-in-class treatments in development for dry eye disease, allergic conjunctivitis, and proliferative vitreoretinopathy. The company is also developing other product candidates for retinal and systemic inflammatory diseases.

PIPELINE & DISEASE AREAS - OCULAR AND INFLAMMATORY DISEASES

Dry Eye Disease

For the approximately 39 million patients in the United States with dry eye disease, the ocular pain, dryness, and gritty sensation are all too familiar and persistent symptoms of the disease. There are presently three FDA-approved products for the treatment of dry eye disease, however, a significant clinical unmet need remains. There is an opportunity for novel approaches to the treatment of Dry Eye Disease that can demonstrate improvements in the effectiveness of both the signs and symptoms of the disease as well as therapies with a more rapid onset of action.

Reproxalap: Our Novel Small Molecule Drug Candidate for Dry Eye

Allergic Conjunctivitis

Approximately 100 million patients in the United States have allergic conjunctivitis, and we estimate that up to 30 million of these patients either don't respond adequately to, or are dissatisfied with, topical antihistamines, the current standard of care. The reason: antihistamines appear to lack durable activity, which may be because histamine is only one of the biological mediators of allergic conjunctivitis and the fact that increased histamine levels persist for only up to 20 minutes after allergen exposure.

Reproxalap: Our Novel Small Molecule Drug Candidate for Allergic Conjunctivitis

Proliferative Vitreoretinopathy

Proliferative vitreoretinopathy (PVR) is a rare inflammatory disorder of the retina that leads to severe retinal scarring and blindness and is the leading cause of failure of retinal reattachment surgery. Over 50% of PVR cases result in severe uncorrectable vision loss (visual acuity of 20/320 or worse), and 76% of PVR patients suffer from at least moderate uncorrectable vision loss. PVR occurs after up to 10% of surgeries for retinal detachment and 50% or more of surgeries for open globe injury. Based on the prevalence of primary retinal detachment, in addition to retinal detachment that occurs as a result of trauma, we estimate that there are, in aggregate, more than 20,000 treatable cases of PVR in the United States, Europe, and Japan. By inhibiting cell growth and thereby diminishing scar formation, ADX-2191 has the potential to be the first FDA-approved drug for prevention of PVR. In April 2018, ADX-2191 received orphan drug designation from the FDA for the prevention of PVR.

Clinical Results in Proliferative Vitreoretinopathy - In an Investigator Sponsored Trial, led by Dr. Dean Eliott of the Massachusetts Eye and Ear Infirmary and Harvard Medical School, ADX-2191 led to rates of retinal detachment that were less than what would be expected from the standard of care (no treatment).

CONTACT INFORMATION

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Recent Press Releases *(Headlines and Excerpts)*

FDA Accepts for Priority Review ADX-2191 New Drug Application for the Treatment of Primary Vitreoretinal Lymphoma

- PDUFA Date is June 21, 2023
- Planned U.S. Launch of ADX-2191 in Second Half of 2023, Pending Approval by the FDA
- ADX-2191 with Potential to be the First FDA-Approved Drug Available for Patients Suffering from Primary Vitreoretinal Lymphoma

Mar. 2, 2023-- Aldeyra Therapeutics, Inc. announced that the U.S. Food and Drug Administration (FDA) accepted for Priority Review the New Drug Application (NDA) for ADX-2191 (methotrexate injection, USP), an investigational drug candidate, for the treatment of primary vitreoretinal lymphoma. The FDA assigned a Prescription Drug User Fee Act (PDUFA) date of June 21, 2023. The FDA noted that no potential filing review issues have been identified.

The NDA submission is supported by a combination of more than three decades of published literature on the safety and efficacy of methotrexate, the active ingredient of ADX-2191, for the treatment of primary vitreoretinal lymphoma, in addition to safety data from the recently completed Phase 3 GUARD Trial of ADX-2191 in patients with proliferative vitreoretinopathy. During the Phase 3 GUARD Trial, no safety signals were observed, and ADX-2191 was well tolerated; there were no observed treatment-emergent serious adverse events. The most common adverse event associated with ADX-2191 treatment was punctate keratitis, a frequently observed side effect of intravitreal methotrexate, that was most commonly mild in severity.

About ADX-2191
ADX-2191 (methotrexate injection, USP) is a sterile, non-compounded intravitreal formulation of methotrexate for the potential prevention or treatment of specific rare retinal diseases, including primary vitreoretinal lymphoma, proliferative vitreoretinopathy, and retinitis pigmentosa. The ADX-2191 intravitreal formulation is preservative-free, is designed to be vitreous-compatible, and is optimized for excipient composition, viscosity, density, tonicity, pH, concentration, and volume of administration. ADX-2191 has received FDA Orphan Drug Designation for the prevention of proliferative vitreoretinopathy, and for the treatment of primary vitreoretinal lymphoma and retinitis pigmentosa.

Aldeyra Therapeutics Schedules Webcast and Conference Call to Report Full-Year 2022 Financial Results and Discuss Recent Corporate Highlights

Mar. 1, 2023-- Aldeyra Therapeutics, Inc. will host a conference call at 8:00 a.m. ET Thursday, March 9, 2023 to report financial results for the year ended December 31, 2022 and discuss recent corporate highlights.

The dial-in numbers are (833) 470-1428 for domestic callers and (404) 975-4839 for international callers. The access code is 202679. A live audio webcast of the conference call also will be accessible from the "Investors & Media" section of Aldeyra's website at https://ir.aldeyra.com/.
After the live webcast, the event will remain archived on Aldeyra's website for 90 days.

Aldeyra Therapeutics Announces Positive Top-Line Results from 12-Month Safety Clinical Trial of Reproxalap in Patients with Dry Eye Disease

- Primary Endpoints of Treatment-Related Serious Adverse Events in Ocular Safety Parameters Were Not Observed
- Ocular Safety Events Were Similar Across Reproxalap and Vehicle Groups
- In Post-Hoc Analysis, Reproxalap Potentially the First Chronically Administered Topical Ocular Therapy to Demonstrate Distance Visual Acuity Improvement in Adults

Feb. 28, 2023-- Aldeyra Therapeutics, Inc. announced top-line results from a 12-month, vehicle-controlled, multicenter, parallel-group safety clinical trial of reproxalap, an investigational new drug, in dry eye disease patients. The primary endpoints of treatment-related serious adverse events in ocular safety were not observed in any patient. Ocular safety events were similar across reproxalap and vehicle treatment groups. In a post-hoc analysis, reproxalap was statistically superior to vehicle in improvement from baseline in distance visual acuity, potentially representing the first demonstration of improvement in distance visual acuity with a topically administered therapy.

The 12-month safety clinical trial population was comprised of 447 dry eye disease patients; 299 patients were treated with reproxalap and 148 patients were treated with vehicle. Visual acuity and ocular safety assessments, including assessment of intraocular pressure, slit-lamp examination, corneal endothelial cell density, and dilated fundoscopy, were performed at baseline, and after 4 weeks, 6 weeks, 3 months, 6 months, and one year of treatment. The primary endpoints were the proportion of treatment-related ocular safety events related to visual acuity, intraocular pressure, slit-lamp examination, and dilated fundoscopy in reproxalap-treated patients compared to vehicle-treated patients. Change from baseline in visual acuity, as assessed by the logarithm of the minimum angle of resolution (logMAR, lower values indicate better visual acuity), was analyzed post-hoc over 12 months using a repeated measures analysis.

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