



Aldeyra Therapeutics Announces Oral Presentation of Phase 3 Data at the American Academy of Optometry 2022 Annual Meeting

October 26, 2022

LEXINGTON, Mass.--(BUSINESS WIRE)--Oct. 26, 2022-- [Aldeyra Therapeutics, Inc.](#) (Nasdaq: ALDX) (Aldeyra) today announced that an oral presentation highlighting clinical data from the Phase 3 INVIGORATE allergen chamber trial of reproxalap in allergic conjunctivitis will be presented at the American Academy of Optometry 2022 Annual Meeting, taking place in San Diego October 26-29, 2022.

Oral Presentation

Abstract Title: Clinically Relevant Activity of Reproxalap in an Allergen Chamber Model of Allergic Conjunctivitis: The Phase 3 INVIGORATE Trial

Presenter: Jacob R. Lang, O.D., F.A.A.O., Medical Director of Dry Eye Services, Associated Eye Care, St. Paul, Minnesota

Date: Wednesday, October 26, 2022

Location: Room 29AB

"Reproxalap demonstrated statistically significant and clinically relevant reductions relative to vehicle in ocular itching and redness in the INVIGORATE Trial," Dr. Lang stated. "Given the strong overlap between allergic conjunctivitis and dry eye disease, the findings being presented at the Academy's Annual Meeting further highlight the potential benefits of Aldeyra's novel RASP modulator to improve treatment outcomes for patients with anterior segment inflammation."

About Reproxalap

Reproxalap, an investigational new drug candidate, is a first-in-class small-molecule modulator of RASP (reactive aldehyde species), which are elevated in ocular and systemic inflammatory disease. Reproxalap's mechanism of action has been supported by the demonstration of statistically significant and clinically relevant activity in multiple physiologically distinct late-phase clinical indications.

About Allergic Conjunctivitis

Allergic conjunctivitis is the most common inflammatory disease that affects the front of the eye, and is characterized by itching, redness, and tearing.¹ The signs and symptoms of allergic conjunctivitis are persistently disturbing, affecting quality of life and leading to loss of work that can create a substantial economic burden for patients and their families.² Although allergic conjunctivitis is commonly treated with antihistamines, up to 60% of patients require adjunctive therapy and up to 40% of patients require corticosteroids, which can lead to significant ocular toxicity.³

About Aldeyra

Aldeyra is a clinical-stage biotechnology company developing innovative therapies designed to treat immune-mediated diseases. Our approach is to discover pharmaceuticals 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. Two of our lead product candidates, reproxalap and ADX-629, target pre-cytokine, systems-based mediators of inflammation known as RASP (reactive aldehyde species). Reproxalap is in late-stage clinical trials in patients with dry eye disease and allergic conjunctivitis. ADX-629, an orally administered RASP modulator, is in Phase 2 clinical testing for the treatment of systemic immune-mediated diseases. Our pipeline also includes ADX-2191 (methotrexate injection) for intravitreal administration, in development for the prevention of proliferative vitreoretinopathy and the treatment of retinitis pigmentosa and primary vitreoretinal lymphoma. For more information, visit <https://www.aldeyra.com/> and follow us on [LinkedIn](#), [Facebook](#), and [Twitter](#).

Safe Harbor Statement

This release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including, but not limited to, statements regarding the potential benefits of reproxalap in improving treatment outcomes for patients with anterior segment inflammation. Aldeyra intends such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 21E of the Securities Exchange Act of 1934 and the Private Securities Litigation Reform Act of 1995. In some cases, you can identify forward-looking statements by terms such as, but not limited to, "may," "might," "will," "objective," "intend," "should," "could," "can," "would," "expect," "believe," "anticipate," "project," "on track," "on schedule," "target," "design," "estimate," "predict," "potential," "aim," "plan," or the negative of these terms, and similar expressions intended to identify forward-looking statements. Such forward-looking statements are based upon current expectations that involve risks, changes in circumstances, assumptions, and uncertainties. Aldeyra is at an early stage of development and may not ever have any products that generate significant revenue. All of Aldeyra's development timelines may be subject to adjustment depending on recruitment rate, regulatory review, preclinical and clinical results, and other factors that could delay the initiation, enrollment or completion of clinical trials. Important factors that could cause actual results to differ materially from those reflected in Aldeyra's forward-looking statements include, among others, the timing of enrollment, commencement and completion of Aldeyra's clinical trials, the timing and success of preclinical studies and clinical trials conducted by Aldeyra and its development partners; updated or refined data based on Aldeyra's continuing or post-hoc review and quality control analysis of clinical data, Aldeyra's ability to design clinical trials with protocols, data analysis methodologies, and endpoints acceptable to applicable regulatory authorities; delay in or failure to obtain regulatory approval of Aldeyra's product candidates; the ability to maintain regulatory approval of Aldeyra's product candidates, and the labeling for any approved products; the risk that prior results, such as signals of safety, activity, or durability of effect, observed from preclinical or clinical trials, will not be replicated or will not continue in ongoing or future studies or clinical trials involving Aldeyra's product candidates in clinical trials focused on the same or on different indications; the risk that the results from earlier clinical trials, portions of clinical trials, or pooled clinical data may not accurately predict results of subsequent trials or the remainder of a clinical trial; the scope, progress, expansion, and costs of developing and commercializing Aldeyra's product candidates; uncertainty as to Aldeyra's ability to commercialize (alone or with others) and obtain reimbursement for Aldeyra's product candidates following regulatory approval, if any; the size and growth of the potential markets and pricing for Aldeyra's product candidates and the ability to serve those markets; Aldeyra's expectations regarding Aldeyra's expenses and revenue, the sufficiency or use of

Aldeyra's cash resources and needs for additional financing; political, economic, legal, social, and health risks, including the COVID-19 pandemic and subsequent public health measures, and war or other military actions, that may affect Aldeyra's business or the global economy; the rate and degree of market acceptance of any of Aldeyra's product candidates; Aldeyra's expectations regarding competition; Aldeyra's anticipated growth strategies; Aldeyra's ability to attract or retain key personnel; Aldeyra's limited sales and marketing infrastructure; Aldeyra's ability to establish and maintain development partnerships; Aldeyra's ability to successfully integrate acquisitions into its business; Aldeyra's expectations regarding federal, state, and foreign regulatory requirements; regulatory developments in the United States and foreign countries; Aldeyra's ability to obtain and maintain intellectual property protection for its product candidates; the anticipated trends and challenges in Aldeyra's business and the market in which it operates; and other factors that are described in the "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of Aldeyra's Annual Report on Form 10-K for the year ended December 31, 2021, and Aldeyra's Quarterly Report on Form 10-Q for the quarter ended June 30, 2022, which are on file with the Securities and Exchange Commission (SEC) and available on the SEC's website at <https://www.sec.gov/>. Additional factors may be set forth in those sections of Aldeyra's Quarterly Report on Form 10-Q for the quarter ended September 30, 2022, expected to be filed with the SEC in the fourth quarter of 2022.

In addition to the risks described above and in Aldeyra's other filings with the SEC, other unknown or unpredictable factors also could affect Aldeyra's results. No forward-looking statements can be guaranteed and actual results may differ materially from such statements. The information in this release is provided only as of the date of this release, and Aldeyra undertakes no obligation to update any forward-looking statements contained in this release on account of new information, future events, or otherwise, except as required by law.

¹ The American Academy of Allergy, Asthma & Immunology (AAAAI), Allergic Conjunctivitis Defined

² Andrew D. Pitt, Andrew F. Smith, Lynda Lindsell, Li Wern Voon, Peter W. Rose & Anthony J. Bron (2004) Economic and quality-of-life impact of seasonal allergic conjunctivitis in Oxfordshire, *Ophthalmic Epidemiology*, 11:1, 17-33, doi: 10.1076/oep.11.1.17.26437

³ Leonardi A, Piliego F, Castegnaro A, et al. Allergic conjunctivitis: a cross-sectional study. *Clin Exp Allergy*. 2015;45(6):1118–1125. doi:10.1111/cea.12536

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