Aldeyra to Present New Reproxalap Data from Phase 2 Clinical Trial in Allergic Conjunctivitis at American Academy of Ophthalmology 2020 Annual Meeting

October 22, 2020

Rapid and Durable Clinical Response Demonstrated in Symptoms and Signs of Allergic Conjunctivitis

Clinical Relevance Demonstrated with Responder Analyses

LEXINGTON, Mass.--(BUSINESS WIRE)--Oct. 22, 2020-- Aldeyra Therapeutics, Inc. (Nasdaq: ALDX) (Aldeyra) today announced that it will present new data from the Phase 2 allergen chamber clinical trial of reproxalap ophthalmic solution (0.25% and 0.5%) in allergic conjunctivitis. The data will be presented in a poster at the American Academy of Ophthalmology 2020 Virtual Annual Meeting (AAO 2020) from November 11 through November 15, 2020.

In the randomized, double-masked, crossover, vehicle-controlled Phase 2 clinical trial, 70 subjects with allergic conjunctivitis were assessed over 3.5 hours in an allergen chamber of aerosolized ragweed pollen (3,500 grains/m³). Reproxalap or vehicle ophthalmic solution was administered bilaterally one minute before chamber entry and at 90 minutes after chamber entry, when peak symptoms typically occur. Compared to vehicle, both concentrations of reproxalap demonstrated statistically significant and clinically relevant improvements in subject-reported ocular itching and tearing and investigator-assessed ocular redness over the duration of exposure in the allergen chamber and for more than one hour after exiting the chamber ($P < 0.0001$ for all assessments), indicating both prophylactic and treatment effect of drug. In addition, time-to-event responder analyses demonstrated the clinical relevance of the superiority of reproxalap over vehicle for ocular itching and ocular redness. No safety or tolerability concerns were observed.

“The new data presented at AAO this year further support the clinical utility of reproxalap, the first novel mechanistic approach in late-stage allergic conjunctivitis clinical trials in decades, as uniquely effective,” said Todd C. Brady, M.D., Ph.D. President and CEO of Aldeyra. “The results of the allergen chamber trial suggest that reproxalap could offer durable activity with an onset of action that is essentially immediate.”

The 0.25% concentration of reproxalap was advanced to the Phase 3 INVIGORATE Trial, a randomized, double-masked, crossover, vehicle-controlled clinical trial to assess the efficacy and safety of reproxalap compared to vehicle using an allergen chamber. Consistent with prior allergic conjunctivitis trials, the primary endpoint will be subject-reported ocular itching score. Patient enrollment is ongoing, and top-line results are expected in the first half of 2021.

Details of the poster presentation:

Title:	A Phase 2 Clinical Trial of Topical Ocular Reproxalap, a Novel RASP Inhibitor, in an Allergen Chamber Model of Allergic Conjunctivitis
Session:	PO103 - Cornea, External Disease
Date/Time:	On Demand
Abstract Link:	https://bit.ly/2IU5egX

About Reproxalap

Reproxalap is a novel small-molecule immune-modulating covalent inhibitor of reactive aldehyde species (RASP), which are elevated in ocular and systemic inflammatory disease. Reproxalap’s mechanism of action has been validated with the demonstration of statistically significant and clinically relevant activity in multiple physiologically distinct late-phase clinical indications.

About Allergic Conjunctivitis

Allergic conjunctivitis affects more than 1 billion people worldwide,[1] including more than 66 million in the U.S.[2] The disease is thought to be mediated in part by reactive aldehyde species (RASP), leading to activation of intracellular inflammatory factors, including NF-κB, inflammasomes, and Scavenger Receptor A. The symptoms of allergic conjunctivitis – ocular itching and tearing – are chronic, painful, and persistent, affecting quality of life and leading to loss of work that can create a substantial economic burden for patients and their families.[3] Although allergic conjunctivitis is one of the most common diseases treated by ophthalmologists and optometrists, in many cases physicians and patients report that currently available therapy is inadequate. Today, nearly one in five allergic conjunctivitis patients utilize corticosteroids or other adjunctive therapy in addition to antihistamines.

About Aldeyra Therapeutics

Aldeyra Therapeutics is a clinical-stage biotechnology company focused on the development of novel therapies with the potential to improve the lives of patients with immune-mediated diseases. Two of the company’s lead compounds, reproxalap and ADX-629, target reactive aldehyde species (RASP), which are elevated in ocular and systemic inflammatory disease and result in cytokine release via activation of a broad array of inflammatory factors, including NF-κB, inflammasomes, and Scavenger Receptor A. Reproxalap is being evaluated in Phase 3 clinical trials in patients with dry eye disease and allergic conjunctivitis. The company’s clinical pipeline also includes ADX-2191, a dihydrofolate reductase inhibitor in Phase 3 testing for proliferative vitreoretinopathy, and ADX-1612, a chaperome inhibitor in development for COVID-19 and ovarian cancer. 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 statements regarding Aldeyra's plans and expectations for reproxalap ophthalmic solution as a potential treatment for allergic conjunctivitis. 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," "scheduled," "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 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 review and quality control analysis of clinical data, Aldeyra's ability to design clinical trials with protocols 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; 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) 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 recent COVID-19 outbreak and subsequent public health measures, 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, 2019 and Aldeyra's Quarterly Report on Form 10-Q for the quarter ended June 30, 2020, which are on file with the Securities and Exchange Commission (SEC) and available on the SEC's website at www.sec.gov. Additional factors may be described in those sections of Aldeyra's Quarterly Report on Form 10-Q for the quarter ended September 30, 2020, expected to be filed with the SEC in the fourth quarter of 2020.

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.

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[1] White Book on Allergy (2013 Update)

[2] Singh K, Axelrod S, Bielory L. The epidemiology of ocular and nasal allergy in the United States, 1988-1994. J Allergy ClinImmunol. 2010;126(4):778-783.e6

[3] 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/opep.11.1.17.26437

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