Aldeyra Therapeutics Announces Publication of Phase 2 Clinical Trial of Reproxalap in Allergen Chamber Model

February 1, 2022

LEXINGTON, Mass.--(BUSINESS WIRE)--Feb. 1, 2022-- Aldeyra Therapeutics, Inc. (Nasdaq: ALDX) (Aldeyra), a biotechnology company discovering and developing innovative therapies for the treatment of immune-mediated diseases, today announced that results from the randomized, double-masked, vehicle-controlled, crossover Phase 2 clinical trial of reproxalap in an allergen chamber model have been published in the peer-reviewed journal *Clinical Ophthalmology*.[1] Reproxalap, an investigational new drug, is a first-in-class reactive aldehyde species (RASP) modulator that has been shown to mitigate inflammation in patients with allergic conjunctivitis and other eye diseases.

“Although allergic conjunctivitis affects more than 20% of the U.S. population[2] and up to 60% of patients require medication other than topical antihistamines,[3] a new mechanistic pharmacologic treatment approach has not been available for decades,” stated Todd C. Brady, M.D., Ph.D., President and Chief Executive Officer of Aldeyra. “This Phase 2 allergen chamber trial suggests that treatment with reproxalap could lead to rapid and durable improvement in the symptoms and signs of allergic conjunctivitis.”

A total of 70 adult patients with a history of moderate to severe allergic conjunctivitis for two or more years, a positive skin test to ragweed pollen, and chamber-induced ocular itching and redness scores of 2.5 or more and 2 or more (both scales range from 0 to 4), respectively, were randomized 1:1:1 to one of three sequences of treatment with 0.5% reproxalap, 0.25% reproxalap, and vehicle. Test article was administered bilaterally just before and at 90 minutes after entering an allergen chamber, during which patients were exposed to aerosolized ragweed pollen (3500 grains/m^3) for 3.5 hours. Symptoms and conjunctival redness were assessed approximately every 10 minutes after entering the chamber and over an hour after chamber exit. Compared to vehicle, treatment with either concentration of reproxalap led to rapid, statistically significant improvement in patient-reported ocular itching and tearing and investigator-assessed ocular redness. Improvement in signs and symptoms persisted over the entire chamber and all post-chamber time points.

About Reproxalap

Reproxalap, an investigational new drug, 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. Reproxalap is currently in Phase 3 clinical development as a 0.25% ophthalmic solution for the treatment of dry eye disease and allergic conjunctivitis, two of the largest markets in ophthalmology.

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.[4] 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.[5] 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 Therapeutics

Aldeyra Therapeutics discovers and develops innovative therapies designed to treat immune-mediated diseases. Our approach is to develop 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. 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 Phase 3 clinical trials in patients with dry eye disease and allergic conjunctivitis. ADX-629, an orally administered RASP modulator, is in Phase 2 proof-of-concept clinical trials in psoriasis, asthma, and COVID-19. Our pipeline also includes ADX-2191 (intravitreal methotrexate 0.8%), 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 Aldeyra's strategy, future operations, prospects, plans, and objectives and Aldeyra's plans and expectations for its product candidates, including reproxalap. 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 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) 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 related 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, 2020 and Quarterly Report on Form 10-Q for the quarter ended September 30, 2021, 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 described in those sections of Aldeyra's Annual Report on Form 10-K for the year ended December 31, 2021, expected to be filed with the SEC in the first 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.

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[1] Clark D, Karpecki P, Salapatek AM, Sheppard JD, Brady TC. Reproxalap Improves Signs and Symptoms of Allergic Conjunctivitis in an Allergen Chamber: A Real-World Model of Allergen Exposure. Clin Ophthalmol. 2022;16:15-23; Originally published by and used with permission from Dove Medical Press Ltd. https://doi.org/10.2147/OPTH.S345324

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[4] The American Academy of Allergy, Asthma & Immunology (AAAAI), Allergic Conjunctivitis Defined

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Corporate:
Joshua Reed
Aldeyra Therapeutics, Inc.
Tel: 781-761-4904 ext. 218
jreed@aldeyra.com

Investor & Media:
Scott Solomon
Sharon Merrill Associates, Inc.
Tel: 617-542-5300
ALDX@investorrelations.com

Source: Aldeyra Therapeutics, Inc.