Aldeyra Therapeutics Completes Enrollment in Phase 3 INVIGORATE-2 Clinical Trial in Allergic Conjunctivitis

April 13, 2023

Top-Line Results Expected in the First Half of 2023

LEXINGTON, Mass.--(BUSINESS WIRE)--Apr. 13, 2023-- Aldeyra Therapeutics, Inc. (Nasdaq: ALDX) (Aldeyra) today announced completion of enrollment in the Phase 3 INVIGORATE-2 clinical trial of topical ocular reproxalap, a first-in-class investigational new drug candidate, for the treatment of allergic conjunctivitis.

“Today, millions of allergic conjunctivitis patients rely on therapies that may not provide sufficient relief or cannot be used chronically due to serious side effects,” stated Todd C. Brady, M.D., Ph.D., President and Chief Executive Officer of Aldeyra. “Reproxalap, which has demonstrated rapid and durable improvement in the symptoms and signs of allergic conjunctivitis across a number of clinical trials, could signify the first new therapeutic mechanism of action in decades for patients suffering from this persistently disturbing condition.”

The randomized, double-masked, crossover, vehicle-controlled Phase 3 clinical trial enrolled 131 seasonal allergic conjunctivitis patients who were evaluated for 3.5 hours in an allergen chamber designed to simulate real-world pollen exposure. Consistent with pivotal trials of approved allergic conjunctivitis products, the primary endpoint of INVIGORATE-2 is patient-reported ocular itching. Top-line results from the trial are expected in the first half of 2023.

The protocol of INVIGORATE-2 is substantially identical to that of the Phase 3 INVIGORATE clinical trial and a Phase 2 clinical trial,[1] both of which achieved the ocular itching endpoint ($P<0.001$).

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. The mechanism of action of reproxalap has been supported by the demonstration of statistically significant and clinically relevant activity in multiple physiologically distinct late-phase clinical indications. Reproxalap has been studied in more than 2,300 patients with no observed clinically significant safety concerns; mild and transient instillation site irritation is the most commonly reported adverse event in clinical trials.

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.[2] 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.[3] Although allergic conjunctivitis is commonly treated with antihistamines, up to 60% of patients require adjunctive therapy and up to 40% of patients require corticosteroids,[4] which can lead to significant ocular toxicity.

About Aldeyra

Aldeyra Therapeutics is a biotechnology company devoted to discovering innovative therapies designed to treat immune-mediated diseases. Our approach is to develop 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. Our product candidates include RASP (reactive aldehyde species) modulators ADX-629, ADX-246, ADX-248, and chemically related molecules for the potential treatment of systemic and retinal immune-mediated diseases. Our pre-commercial product candidates are reproxalap, a RASP modulator for the potential treatment of dry eye disease (under U.S. Food and Drug Administration New Drug Application Review) and allergic conjunctivitis, and ADX-2191, a novel formulation of intravitreal methotrexate for the potential treatment of primary vitreoretinal lymphoma (under U.S. Food and Drug Administration New Drug Application Priority Review), proliferative vitreoretinopathy, and other rare sight-threatening retinal diseases. 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 expected timing of top-line results of the Phase 3 INVIGORATE-2 clinical trial of reproxalap for the treatment of 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,” “contemplates,” “likely,” “potential,” “continue,” “ongoing,” “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, funding, 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; delay in or failure to obtain regulatory approval of Aldeyra's product candidates, including as a result of the FDA not accepting Aldeyra's regulatory filings, requiring additional clinical trials or data prior to review or approval of such filings; 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 different indications; the scope, progress, expansion, and costs of developing and commercializing Aldeyra's product candidates; the current and potential future impact of the COVID-19 pandemic on Aldeyra's business, results of operations, and financial position; 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 future revenue, the timing of future revenue, the sufficiency or use of Aldeyra's cash resources and needs for additional financing; 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 commercialization, marketing and manufacturing capabilities and strategy; 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; 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; 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, 2022, which is 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 Quarterly Report on Form 10-Q for the quarter ended March 31, 2023, expected to be filed with the SEC in the second quarter of 2023.

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] 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 Jan 4;16:15-23.

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

[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.

[4] Leonardi A, Piliego F, Castegnaro A, et al. Allergic conjunctivitis: a cross-sectional study. Clin Exp Allergy. 2015;45(6):1118–1125.

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Investor & Media
Scott Solomon
Sharon Merrill Associates, Inc.
Senior Vice President
(857) 383-2409
ALDX@investorrelations.com

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