Aldeyra Therapeutics Announces First Patient Enrolled in the Phase 3 INVIGORATE Trial in Allergic Conjunctivitis

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LEXINGTON, Mass.--(BUSINESS WIRE)--Jan. 21, 2020-- Aldeyra Therapeutics, Inc. (Nasdaq: ALDX) (Aldeyra), a biotechnology company devoted to developing and commercializing next-generation medicines to improve the lives of patients with immune-mediated diseases, today announced enrollment of the first patient into the Phase 3 INVIGORATE Trial of topical ocular reproxalap in patients with allergic conjunctivitis.

“Initiating enrollment in the INVIGORATE Trial moves us closer to our goal of providing allergic conjunctivitis patients with a new treatment option for one of the world’s most common ocular conditions,” said Todd C. Brady, M.D., Ph.D., President and CEO of Aldeyra. “Standard of care antihistamines are ineffective in nearly a quarter of all allergic conjunctivitis patients, many of whom require adjunct therapy, including corticosteroids, which cannot be used chronically due to toxicity. We believe that reproxalap may offer a durable and highly differentiated approach for the treatment of ocular allergy, a condition that is increasing in prevalence but has not benefited from the introduction of a novel therapeutic approach in decades.”

The INVIGORATE Trial, which will enroll approximately 120 patients, is a randomized, double-masked, crossover vehicle-controlled Phase 3 clinical trial to assess the efficacy and safety of reproxalap ophthalmic solution (0.25%) compared with vehicle using an allergen chamber. Consistent with prior allergic conjunctivitis trials, the primary endpoint will be subject-reported ocular itching score.

In Aldeyra’s Phase 2 allergen chamber clinical methods trial, completed in March 2019, 0.25% reproxalap demonstrated highly statistically significant reductions from vehicle in ocular itching and redness.

More information about the INVIGORATE Trial is available on www.clinicaltrials.gov (NCT04207736).

About Reproxalap

Reproxalap is a novel, small-molecule immune-modulating covalent inhibitor of RASP (reactive aldehyde species), which are elevated in ocular and systemic inflammatory disease, and lead to activation of intracellular inflammatory factors, including NF-kB, inflammasomes, and Scavenger Receptor A. 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 100 million in the U.S.[2] The disease is thought to be mediated in part by RASP. The signs and symptoms of allergic conjunctivitis – ocular itching, redness, and tearing – are persistently disturbing, affecting quality of life and leading to loss of work that can create a substantial economic burden for patients and families.[3] Allergic conjunctivitis is hyperendemic and prevalence is increasing. 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 requires corticosteroids or other adjunctive therapy in addition to antihistamines.

About Aldeyra Therapeutics

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, proliferative vitreoretinopathy, and Sjögren-Larsson Syndrome. The company is also developing other product candidates for retinal and systemic inflammatory diseases.

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 strategy, future operations, future financial position, projected costs and expenses, prospects, plans, and objectives and Aldeyra's plans and expectations for its product candidates, including plans relating to the clinical development or commercial potential of 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; 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; 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, 2018 and Aldeyra's Quarterly Report on Form 10-Q for the quarter ended September 30, 2019, 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 set forth in those sections of Aldeyra's Annual Report on Form 10-K for the year ended December 31, 2019, expected to be filed with the SEC in the first 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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