



April 24, 2018

## **Aldeyra Therapeutics Announces First Patient Enrolled in Allergic Conjunctivitis Phase 3 Clinical Trial**

LEXINGTON, Mass., April 24, 2018 /PRNewswire/ -- Aldeyra Therapeutics, Inc. (NASDAQ: ALDX) (Aldeyra), a biotechnology company devoted to development of next-generation medicines to improve the lives of patients with inflammatory diseases, today announced that it has enrolled the first patient in a Phase 3 clinical trial of topical ocular reproxalap for the treatment of allergic conjunctivitis.

"We are pleased to advance our allergic conjunctivitis program to Phase 3 clinical testing," commented Todd C. Brady, M.D., Ph.D., President and CEO of Aldeyra. "With clinically demonstrated post-histaminic activity, reproxalap could represent the first mechanistically differentiated product in decades for the treatment of allergic conjunctivitis, a chronic disease that affects approximately 100 million patients in the United States. We look forward to presenting the results of the trial in the second half of 2018 or early 2019."

The multi-center, double-masked, parallel-group, vehicle-controlled Phase 3 clinical trial is expected to enroll 300 allergic conjunctivitis patients, randomized equally to receive either topical ocular 0.25% reproxalap, 0.5% reproxalap, or vehicle in a conjunctival allergen challenge model of acute allergic conjunctivitis. The primary outcome measure will be patient-reported ocular itching.

A clinical trial synopsis can be found on [clinicaltrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT03494504) (#NCT03494504).

### ***About Aldeyra Therapeutics***

Aldeyra Therapeutics is developing next-generation medicines to improve the lives of patients with inflammatory diseases. Aldeyra's lead product candidate, reproxalap, is a first-in-class treatment in late-stage development for dry eye disease and other forms of ocular inflammation. Aldeyra is leveraging its experience in ocular inflammation to develop other product candidates for systemic inflammatory disease. None of Aldeyra's product candidates have been approved for sale in the U.S. or elsewhere.

### ***About Allergic Conjunctivitis***

Allergic conjunctivitis is a common allergic disease that affects 20% or more of the population worldwide. The disease is characterized by inflammation of the conjunctiva (a membrane covering part of the front of the eye), resulting in ocular itching, excessive tear production, lid swelling, and redness. Antihistamines are commonly used to treat allergic conjunctivitis, but use is limited by lack of durable activity and ocular dryness.

### ***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 the development of reproxalap; and the potential of reproxalap as an agent 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 "may," "might," "will," "objective," "intend," "should," "could," "can," "would," "expect," "believe," "anticipate," "project," "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. 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, completion and reporting 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, the ability to obtain and maintain regulatory approval to conduct clinical trials and to commercialize Aldeyra's product candidates, and the labeling for any approved products; the scope, progress, expansion, and costs of developing and commercializing Aldeyra's product candidates; the size and growth of the potential markets for Aldeyra's product candidates and the ability to serve those markets; Aldeyra's expectations regarding Aldeyra's expenses and revenue, the sufficiency 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 ability to establish and maintain development partnerships; 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, 2017, which is on file with the Securities and Exchange Commission (SEC) and available on the SEC's website at [www.sec.gov](http://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, 2018, which is expected to be filed with the SEC in the second quarter of 2018. 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, completion or reporting of clinical trials.

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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