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## **Aldeyra Therapeutics Presents Dry Eye Disease Phase 2a Clinical Trial Results at the Association for Research in Vision and Ophthalmology 2018 Annual Meeting**

### **Data Demonstrate Statistically and Clinically Significant Activity of Topical Ocular 0.1% Reproxalap Across a Broad Array of Signs and Symptoms Safety and Tolerability Consistent with Standard of Care**

LEXINGTON, Mass., May 1, 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 immune-mediated diseases, presented the results of a randomized, double-masked, parallel-group Phase 2a dry eye disease clinical trial of topical ocular reproxalap at the Association for Research in Vision and Ophthalmology (ARVO) 2018 Annual Meeting. The primary objective of the trial, to select a formulation for Phase 2b clinical testing, was achieved with the advancement of 0.1% reproxalap. Relative to baseline, dry eye disease patients treated with 0.1% reproxalap demonstrated statistically significant improvement from baseline in tear volume (Schirmer test) as well as statistically and clinically significant improvement in the Overall 4-Symptom Score and the Ocular Discomfort Score. Tear levels of pro-inflammatory reactive aldehyde species (RASP), which are sequestered by reproxalap, were significantly decreased following treatment. Aldeyra released top-line results from the trial in September 2017. Dr. David Clark, Chief Medical Officer at Aldeyra, gave the presentation, which is available on the investor relations page of the Aldeyra Therapeutics corporate website at [ir.aldeyra.com](http://ir.aldeyra.com).

"Reproxalap could represent an important treatment for many patients that suffer from dry eye disease," commented Gary Foulks, M.D., F.A.C.S. Professor Emeritus, Department of Ophthalmology & Visual Sciences at the University of Louisville. "The activity demonstrated within one week of therapy in the Phase 2a clinical trial presented today suggests that reproxalap could have significant potential for the treatment of dry eye disease."

Fifty-one subjects with active dry eye disease were randomized equally to receive either topical ocular 0.1% reproxalap, 0.5% reproxalap, or 0.5% lipid formulation reproxalap four times daily. Results pooled from all drug groups indicated statistically significant changes in the Symptom Assessment in Dry Eye (SANDE) score, the ocular discomfort score, the overall 4-symptom score, tear volume (Schirmer test), osmolarity, and corneal staining (Lissamine Green). A modest dose response was observed, and improvement in symptoms was noted by one week of therapy. Improvement in corneal staining and osmolarity correlated with reduction in tear RASP levels. The tolerability of topical ocular 0.1% reproxalap was consistent with standard of care in dry eye disease patients, and there were no observed safety concerns, consistent with previous Phase 1 and Phase 2 clinical trials.

In January 2018, Aldeyra announced the initiation of a Phase 2b clinical trial of topical ocular reproxalap in dry eye disease. The Phase 2b trial is expected to enroll 300 patients with active disease, randomized equally to receive either 0.1% reproxalap, 0.25% reproxalap, or vehicle for three months. Results of the trial are expected to be announced in the second half of 2018.

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

Aldeyra Therapeutics is developing next-generation medicines to improve the lives of patients with immune-mediated 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 Dry Eye Disease***

Dry eye disease is a common and chronic inflammatory disease estimated to affect approximately 20 million people in the United States, and is characterized by insufficient moisture in the anterior surface of the eye, leading to dryness, inflammation, pain, discomfort, irritation, and, in severe cases, decreased vision. Among physicians and patients, existing therapy for dry eye disease is generally regarded as inadequate.

#### ***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 dry eye disease. 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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