# Aldeyra Therapeutics Announces Positive Results from Phase 2b Dry Eye Disease Clinical Trial

September 26, 2018

**Statistically Significant Improvement Across Multiple Symptom and Sign Measures**
**Early Onset and Broad Range of Activity Supports Differentiated Product Profile**
**Pivotal Clinical Testing Expected to Begin in 2019 Following Discussion with Regulatory Authorities**

LEXINGTON, Mass., Sept. 26, 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, today announced positive results from its Phase 2b clinical trial of topical ocular reproxalap in patients with dry eye disease.

"The early onset and broad activity observed in the Phase 2b clinical trial suggests that reproxalap could be an important treatment option relative to existing therapies," commented John Sheppard, M.D., Professor of Ophthalmology, Eastern Virginia Medical School. "The results announced today confirm the potential of reproxalap, a drug with a novel mechanism of action, as a promising and differentiated therapeutic agent for dry eye disease, which remains a persistently challenging condition for large numbers of patients worldwide."

The randomized, vehicle-controlled, parallel-group, multi-center, double-masked Phase 2b clinical trial investigated 0.1% and 0.25% concentrations of reproxalap topical ophthalmic solution versus vehicle. Relative to patients treated with vehicle, patients treated with the 0.25% concentration of reproxalap had statistically significant and clinically relevant reductions in the Four-Symptom Ocular Dryness Score ($p<0.05$) and the Overall Ocular Discomfort Symptom Score ($p<0.05$). Symptom improvement greater than that of vehicle was consistently observed across all measures, and activity versus vehicle was demonstrated as early as two weeks (the first assessment following initiation of therapy). The early onset of symptomatic improvement is consistent with the Phase 2a clinical trial of topical ocular reproxalap in dry eye disease, and is supportive of a differentiated product profile relative to current standard of care. Patients treated with the 0.25% concentration of reproxalap also demonstrated reductions in ocular fluorescein staining score that were statistically superior to those of patients treated with vehicle ($p<0.05$).

Both 0.1% and 0.25% reproxalap concentrations demonstrated activity relative to vehicle, and a clear dose response was observed. Consistent with previous clinical trials, topical ocular reproxalap was well tolerated, and reported adverse events were generally mild.

Three hundred patients with dry eye disease were randomized equally to receive 0.1%, 0.25%, or vehicle for 12 weeks. The primary objective of the trial was to evaluate the safety and efficacy of reproxalap for the treatment of the symptoms and signs of dry eye disease in order to select a drug concentration, confirm endpoint selection, and determine sample size for a pivotal Phase 3 clinical program.

"Based on the successful Phase 2b results, we look forward to initiating a Phase 3 program in dry eye disease in 2019 following our discussion with regulatory authorities," commented Todd C. Brady, M.D., Ph.D., Chief Executive Officer of Aldeyra. "The addition of dry eye disease to our late-stage clinical portfolio, which includes Phase 3 clinical trials in allergic conjunctivitis and noninfectious anterior uveitis, highlights the potential of reproxalap as a highly differentiated and novel ophthalmic therapy."

**Conference Call**
Aldeyra will hold a conference call on September 26, 2018 at 8:00 a.m. ET to discuss results of the clinical trial. The dial-in numbers are 1-877-266-8979 for domestic callers and 1-412-317-5231 for international callers. A live webcast of the conference call will also be available on the investor relations page of Aldeyra's corporate website at ir.aldeyra.com. After the live webcast, the event will remain archived on Aldeyra's website for one year.

***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 also developing other product candidates for autoimmune disease, post-transplant lymphoproliferative disease, retinal inflammation, metabolic disease, and cancer. 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 inflammatory disease estimated to affect approximately 20 million people in the United States. The disease is characterized by insufficient moisture and lubrication in the anterior surface of the eye, leading to dryness, inflammation, pain, discomfort, irritation, diminished quality of life, and in severe cases, permanent vision impairment. Among physicians and patients, existing therapy for dry eye disease is generally regarded as inadequate. In patients with dry eye disease, pro-inflammatory RASP (Reactive Aldehyde Species) may contribute to ocular inflammation. By diminishing RASP levels, Aldeyra's RASP inhibitor platform represents a novel and differentiated approach for the treatment of the symptoms and signs of dry eye disease.

***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, prospects, plans, and objectives and Aldeyra's plans and expectations for reproxalap, including the timing of initiating a Phase 3 program, and its other product candidates. 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. 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, the ability to obtain and maintain regulatory approval of 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 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 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 and Aldeyra's Quarterly Report on Form 10-Q for the quarter ended June 30, 2018, both of which are on file with the Securities and Exchange Commission(SEC) and available on the SEC's website at www.sec.gov.*

*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.*

Corporate Contact:
David McMullin
Aldeyra Therapeutics, Inc.
Tel: 781-761-4904 ext. 218
dmcmullin@aldeyra.com

Investor Contact:
Chris Brinzey
Westwicke Partners
Tel: 339-970-2843
|Chris.brinzey@westwicke.com

Media Contact:
Cammy Duong
MacDougall Biomedical Communications
781-591-3443
cduong@macbiocom.com

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