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

Statistically and Clinically Significant Improvement Across Multiple Sign and Symptom Endpoints
Onset of Action Observed Within One Week of Therapy
Phase 2b Clinical Trial Expected to be Initiated in the First Half of 2018

LEXINGTON, Mass., Sept. 12, 2017 /PRNewswire/ -- Aldeyra Therapeutics, Inc. (NASDAQ: ALDX) (Aldeyra), a clinical-stage biotechnology company devoted to treating inflammation, inborn errors of metabolism, and other diseases related to endogenous aldehyde toxicity, today announced positive results from a Phase 2a clinical trial of topical ocular ADX-102 in patients with dry eye disease.

"ADX-102 is a promising agent for the treatment of dry eye disease, a persistently challenging condition for many people worldwide," commented John Sheppard, M.D., Professor of Ophthalmology, Eastern Virginia Medical School. "The evidence of rapid-onset activity and the tolerability profile demonstrated in the Phase 2a clinical trial suggests that ADX-102 could provide important patient benefits relative to existing therapies."

The randomized, dose-ranging, parallel-group, double-masked Phase 2a clinical trial investigated three formulations of ADX-102 (0.1% ophthalmic solution, 0.5% ophthalmic solution, and 0.5% lipid formulation) in 51 dry eye disease patients (17 per arm) treated for 28 days. The results from the pooled data over the 28-day treatment period demonstrated statistically significant improvement from baseline in Symptom Assessment in Dry Eye (SANDE) Score (p=0.003), Ocular Discomfort Score (p=0.00002), Overall Four-Symptom Score (p=0.0004), Schirmer (tear volume) Test (p=0.008), tear osmolarity (p=0.003), and Lissamine Green ocular surface staining score (p=0.002). Improvements in dry eye disease signs and symptoms were evident within one week of therapy. A modest dose-response was observed, and activity increased over the duration of therapy, supporting evidence of the effect of drug. Levels of malondialdehyde, a pro-inflammatory aldehyde mediator sequestered by ADX-102, were significantly reduced in the tears of patients (p=0.009), supporting the differentiated mechanism of action relative to other therapies in dry eye disease.

The primary objective of the trial was to select a formulation and dose range for a Phase 2b clinical trial. Based on consistent statistically and clinically significant activity across multiple sign and symptom endpoints, and tolerability consistent with that of standard of care, 0.1% ADX-102 was nominated for advancement. Relative to baseline, improvement after 28 days of 0.1% ADX-102 therapy was statistically significant or approached statistical significance for Ocular Discomfort Score (p=0.002), the dryness component of the Four-Symptom Score (p=0.01), Overall Four-Symptom Score (p=0.048), SANDE Score (p=0.09), Schirmer Test (p=0.04), tear osmolarity (p=0.06), and tear aldehyde levels (p=0.007). Effect sizes generally correlated with clinical significance for patient-reported outcomes.

There were no safety concerns observed for any of the formulations of ADX-102, and no serious adverse events were reported.

"These data represent the fourth set of positive Phase 2 results with ADX-102 in ocular inflammation. The breadth of activity across noninfectious anterior uveitis, allergic conjunctivitis, and now dry eye disease confirms the potential of ADX-102 as an important and differentiated therapy in ophthalmology," commented Todd C. Brady, M.D., Ph.D., President and Chief Executive Officer of Aldeyra. "We are particularly excited about the potential of ADX-102 in the dry eye disease population, which is generally perceived to be inadequately treated but accounted for approximately $1.8 billion in prescription sales in the United States in 2016. We look forward to the initiation of a Phase 2b clinical trial in dry eye disease in the first half of 2018."

Conference Call
Aldeyra will hold a conference call on September 12, 2017 at 8:00 a.m. ET to discuss results of the clinical trial. The dial-in numbers are 1-877-870-4263 for domestic callers and 1-412-317-0790 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, Inc. is a biotechnology company devoted to improving lives by inventing, developing and

commercializing products that treat diseases thought to be related to endogenous aldehydes, a naturally occurring class of pro-inflammatory and toxic molecules. Aldeyra's lead product candidate, ADX-102, is an aldehyde trap in development as topical eye drops for the treatment of ocular inflammation. ADX-102 has now been tested in over 250 patients in Phase 2 clinical trials in dry eye disease, allergic conjunctivitis, and noninfectious anterior uveitis. A dermatologic form of ADX-102 is in late-stage clinical development for the treatment of ichthyosis due to Sjögren-Larsson Syndrome, an inborn error of aldehyde metabolism. ADX-102 has not 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, and is characterized by insufficient moisture and lubrication 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. In patients with dry eye disease, pro-inflammatory aldehyde mediators may contribute to ocular inflammation. By diminishing aldehyde levels, Aldeyra's topical ocular aldehyde trap platform represents a novel and differentiated approach for the treatment 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 plans and expectations for the development of ADX-102 and the timing thereof; the potential of ADX-102 as an agent for the treatment of dry eye disease; the ability of ADX-102 to provide important patient benefits and a differentiated mechanism of action relative to existing therapies; and estimates of the market size for 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 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 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, 2016 and Quarterly Report on Form 10-Q for the quarter ended June 30, 2017, which are on file with the Securities and Exchange Commission(SEC) and available on the SEC's website at www.sec.gov. 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.

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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