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Aldeyra Therapeutics Announces Results from Allergic Conjunctivitis Phase 2b Clinical Trial and Plans for Phase 3 Clinical Testing

One-Point Reduction vs. Control Component of Primary Endpoint Not Met but 0.5% ADX-102 Statistically Superior to Control and Demonstrates Late-Phase Anti-Inflammatory Activity Differentiated from Standard of Care
Clear Evidence of ADX-102 Dose Response
Phase 3 Clinical Testing Planned Following End of Phase 2 Discussion with Regulatory Authorities in the Second Half of 2017

LEXINGTON, Mass., June 14, 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 aldehyde toxicity, today announced results from a Phase 2b clinical trial of topical ocular ADX-102 in patients with allergic conjunctivitis. Based on the data from the trial and the differentiated late-phase anti-inflammatory profile of ADX-102 that could apply to a large underserved population with allergic conjunctivitis, Aldeyra currently plans to initiate Phase 3 clinical testing with 0.5% ADX-102 following discussion with the regulatory authorities in the second half of this year.

"The consistent statistically significant reductions in ocular itching scores during the late phase of ocular allergy observed in Phase 2a and Phase 2b clinical trials have confirmed the clinical activity of our lead aldehyde trap, ADX-102, and strengthened our confidence in continued clinical development as a potentially differentiated product for the large worldwide market of allergic conjunctivitis patients whose symptoms are not relieved by standard of care antihistamines," commented Todd C. Brady, M.D., Ph.D., President and Chief Executive Officer of Aldeyra Therapeutics. "While the one-point improvement relative to control component of the primary endpoint was not met, the threshold was approached in seasonal allergy patients, with peak changes of 0.8, and was exceeded on a percent change basis in this population 30 to 60 minutes after allergen challenge, which we believe represents a novel activity profile that addresses late phase inflammation generally not affected by antihistamines."

The randomized, dose-ranging, parallel-group, double-masked, vehicle-controlled, conjunctival allergen challenge (ORA-CAC®) Phase 2b clinical trial of 0.1% and 0.5% ADX-102 ophthalmic solution enrolled 154 patients (approximately 50 per arm) with allergic conjunctivitis, including subjects with seasonal and perennial allergies. Relative to levels of ocular itching in the control group, the primary endpoint required statistically significant improvement, and absolute levels of improvement of at least one point on a patient-reported scale of 0 to 4. The trial demonstrated statistically significant efficacy of 0.5% ADX-102 over vehicle in reducing ocular itching over one hour post-challenge ($p < 0.03$), and effect sizes were generally larger than those observed in the prior Phase 2a clinical trial. Relative to vehicle, 0.5% ADX-102 achieved statistically significant reduction in itching at 10, 20 and 30 minutes post-challenge (p values of 0.02, 0.04, and 0.03, respectively), exhibiting a late-phase anti-inflammatory profile that was differentiated from standard-of-care antihistamines, which are active around 5 minutes post-allergen challenge. In subjects with seasonal allergy, reductions in itching were up to 0.8 points over vehicle (on a 0 to 4 point scale, $p=0.002$), approaching the one-point threshold of activity required for achievement of the primary endpoint of the trial.

A one-point difference at 5 minutes post-challenge, which has been typically used in antihistamine and corticosteroid allergic conjunctivitis studies for endpoint assessment, represents a 38% improvement in itch score relative to that of the vehicle values observed in the trial. Observed percent improvements in itch score for 0.5% ADX-102 versus vehicle were 23%, 37%, 55%, and 65% at 10, 20, 30, and 60 minutes post-challenge in seasonal allergy patients. The data suggest that the 38% one-point equivalent threshold was met or exceeded 20 minutes post-challenge and later.

Aldeyra is not aware of any therapy that has demonstrated activity during the late phase allergy response, which is responsible for persistent disease in patients with serious and chronic forms of allergic conjunctivitis that do not respond optimally to antihistamines. This population is estimated to represent approximately one-third of allergic conjunctivitis patients.

"The clinical data announced today represent a unique activity profile that is distinguished from antihistamines, the standard of care in allergic conjunctivitis. This is a clear demonstration of efficacy with a novel anti-inflammatory mechanism in the Ora-CAC®," commented David A. Hollander, M.D., M.B.A, Chief Medical Officer of Ora, Inc. (the clinical research

organization that performed the trial). "In our experience, the rate of sub-optimal response to antihistamines is up to 30 to 40 percent, a significant unmet medical need that has the potential to be addressed by ADX-102."

0.1% ADX-102 also reduced itching, but generally to a lesser degree than 0.5% ADX-102, suggesting a dose-related efficacy response that confirms the biological effect of drug. Both concentrations of ADX-102 were generally well tolerated and there were no safety concerns observed during the trial.

Conference Call
Aldeyra will hold a conference call on June 14, 2017 at 8:00 A.M. EDT 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. Please reference the Aldeyra Therapeutics call to the operator. 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 for ocular inflammation, as well as for Sjögren-Larsson Syndrome and Succinic Semi-Aldehyde Dehydrogenase Deficiency, two inborn errors of aldehyde metabolism. ADX-102 has not been approved for sale in the U.S. or elsewhere.

About Allergic Conjunctivitis
Allergic conjunctivitis is a common allergic disease that is thought to be mediated in part by pro-inflammatory aldehydes, and 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.

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. 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 March 31, 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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