Aldeyra Therapeutics to Present Phase 3 ALLEVIATE Trial Results in Allergic Conjunctivitis at American Academy of Ophthalmology 2019 Annual Meeting

September 26, 2019

LEXINGTON, Mass.--(BUSINESS WIRE)--Sep. 26, 2019-- Aldeyra Therapeutics, Inc. (Nasdaq: ALDX) (Aldeyra) today announced that it will host an ePoster presentation and discussion of the company's ALLEVIATE Phase 3 clinical trial of reproxalap in patients with allergic conjunctivitis at the American Academy of Ophthalmology 2019 Annual Meeting, which takes place October 12-15, 2019 at the Moscone Center in San Francisco, California.

In the ALLEVIATE trial, 318 patients were topically challenged with seasonal allergen and randomized to 0.25% or 0.5% reproxalap topical ophthalmic solution, or vehicle ophthalmic solution. The trial achieved the primary endpoint of reduction in patient-reported ocular itching relative to vehicle, as assessed by area under the ocular itch score curve. Two-point responder rates and rates of complete resolution of itch in patients treated with 0.25% and 0.5% reproxalap were statistically greater than that of vehicle-treated patients, confirming the clinical relevance of the improvement of drug over vehicle in the primary endpoint.

Topical ocular reproxalap, a novel Reactive Aldehyde Species (RASP) inhibitor, has been administered to over 800 patients across ten completed clinical trials with no observed safety or tolerability concerns. In June 2019, Aldeyra announced results of topical ocular reproxalap in an allergen chamber trial, which demonstrated that ocular itching and redness in reproxalap-treated patients were statistically lower than that of vehicle-treated patients.

"The immune-modulating profile exhibited by both concentrations of reproxalap is distinct from standard-of-care antihistamine therapy," said Todd Brady, M.D., Ph.D., President and CEO of Aldeyra. "Reproxalap represents a fundamentally different mechanism of action that we believe has the potential to be the first new approach in allergic conjunctivitis in more than 40 years."

Aldeyra plans to initiate a second Phase 3 trial of topical ocular reproxalap in patients with allergic conjunctivitis following feedback from the U.S. Food and Drug Administration, which is expected in the fourth quarter of this year.

Poster presentation details:

Title:	The ALLEVIATE Phase 3 Allergic Conjunctivitis Clinical Trial of Topical Ocular Reproxalap, a Novel RASP Inhibitor
Session:	PD45 Cornea, External Disease ePoster Discussion
Date/Time:	Monday, October 14, 2019, 1:15 PM to 1:45 PM (PT)
Location:	ePoster Lounge, Station 3

About Aldeyra Therapeutics

Aldeyra Therapeutics is a biotechnology company devoted to developing and commercializing next-generation medicines to improve the lives of patients with immune-mediated diseases. Aldeyra's lead investigational drug product candidates are first-in-class potential treatments in development for dry eye disease, allergic conjunctivitis, proliferative vitreoretinopathy, and Sjögren-Larsson Syndrome. The company is also developing other product candidates for retinal and systemic inflammatory diseases.

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 financial position, projected costs and expenses, prospects, plans, and objectives and Aldeyra's plans and expectations for its product candidates, including plans relating to current or future clinical development. 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, but

not limited to, "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; delay in or failure to obtain regulatory approval of Aldeyra's product candidates; the ability to maintain regulatory approval of Aldeyra's product candidates, and the labeling for any approved products; the risk that prior results, such as signals of safety, activity or durability of effect, observed from preclinical or clinical trials, will not be replicated or will not continue in ongoing or future studies or trials involving Aldeyra's product candidates; the scope, progress, expansion, and costs of developing and commercializing Aldeyra's product candidates; uncertainty as to Aldeyra's ability to commercialize (alone or with others) Aldeyra's product candidates following regulatory approval, if any; 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 limited sales and marketing infrastructure; Aldeyra's ability to establish and maintain development partnerships; Aldeyra's ability to successfully integrate acquisitions into its business; 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, 2018 and Aldeyra's Quarterly Report on Form 10-Q for the quarter ended June 30, 2019, 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.

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