Aldeyra Therapeutics Announces Positive Top-Line Results from the Phase 3 ALLEVIATE Trial in Patients with Allergic Conjunctivitis

March 26, 2019

- Primary endpoint of ocular itch score area under the curve achieved for both tested reproxalap concentrations

- Key secondary endpoint of clinically relevant two-point ocular itch score improvement achieved for both tested reproxalap concentrations

- Company closed on $60 million term loan facility

LEXINGTON, Mass., March 26, 2019 /PRNewswire/ -- Aldeyra Therapeutics, Inc. (Nasdaq: ALDX) (Aldeyra), a biotechnology company devoted to developing and commercializing next-generation medicines to improve the lives of patients with immune-mediated diseases, today announced positive results from the Phase 3 ALLEVIATE Trial of 0.25% and 0.5% reproxalap topical ophthalmic solution in patients with allergic conjunctivitis. The clinical trial met the primary endpoint and the key secondary endpoint for both concentrations of reproxalap.

"We are thrilled to announce positive results from ALLEVIATE, our first completed Phase 3 clinical trial," commented Todd C. Brady, M.D., Ph.D., President and CEO of Aldeyra. "Consistent with positive results from five prior Phase 2 clinical trials in ocular inflammation, today's announcement confirms the potential of reproxalap as a novel and clinically meaningful approach for the treatment of allergic conjunctivitis. Given that approximately half of allergic conjunctivitis patients also suffer from ocular dryness, we believe the ALLEVIATE results highlight the relevance of reproxalap to our current Phase 3 program in dry eye disease."

The double-masked, randomized, vehicle-controlled, multi-center, parallel-group conjunctival allergen challenge Phase 3 ALLEVIATE trial assessed the efficacy and safety of 0.25% and 0.5% concentrations of reproxalap topical ophthalmic solutions compared to vehicle in 318 patients (approximately 100 per arm) with seasonal allergic conjunctivitis. The primary efficacy endpoint was the evaluation of ocular itch score (0 to 4 scale) area under the curve from 10 to 60 minutes after allergen challenge, and the key secondary endpoint was two-point responder rate, a measure of clinical relevance.

Relative to patients treated with vehicle, patients treated with 0.25% and 0.5% reproxalap demonstrated statistically significant reduction in ocular itching ($p < 0.0001$ and $p = 0.0025$, respectively), as assessed by area under the ocular itch score curve. Two-point responder rates for 0.25% and 0.5% reproxalap were statistically greater than that of vehicle-treated patients ($p = 0.0005$ and $p = 0.0169$, respectively), confirming the clinical relevance of the observed primary endpoint improvements. Both concentrations of reproxalap exhibited an anti-inflammatory profile that is distinct from standard-of-care antihistamine therapy and supports a differentiated mechanism of action for the treatment of allergic conjunctivitis.

Topical ocular reproxalap has now been administered to over 700 patients across seven completed clinical trials. Consistent with prior clinical experience, in the ALLEVIATE trial there were no observed safety or tolerability concerns and no observed adverse events other than mild and transient instillation site irritation.

"There is a large allergic conjunctivitis patient population that is underserved by currently available medications," stated David J. Clark, M.D., M.R.C.P., Chief Medical Officer of Aldeyra. "The ALLEVIATE results suggest the potential of topical ocular reproxalap as a novel, safe, and effective therapeutic option that could be used to complement existing therapy before resorting to corticosteroids, which can lead to serious ocular toxicity."

In preparation for subsequent clinical testing, Aldeyra is conducting clinical method development studies to assess the feasibility of measuring ocular itching induced by environmental exposure to allergen. In the second half of 2019, Aldeyra plans to meet with regulatory authorities to discuss the ALLEVIATE results and remaining clinical requirements for a potential submission of a New Drug Application to the U.S. Food and Drug Administration.

In addition to announcing the positive Phase 3 top-line results from the ALLEVIATE trial, the Company entered into a Loan and Security Agreement with Hercules Capital, Inc. that provides up to $60 million in non-dilutive financing. The facility advances capital at the Company's option based upon certain funding conditions.

Conference Call

Aldeyra will hold a conference call on March 26, 2019 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 a biotechnology company devoted to developing and commercializing 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, allergic conjunctivitis, noninfectious anterior uveitis, and Sjögren-Larsson Syndrome. The company is also developing other product candidates for proliferative vitreoretinopathy and other retinal diseases, post-transplant lymphoproliferative disease, autoimmune disease, metabolic disease, and cancer. None of Aldeyra's product candidates have been approved for sale in the U.S. or elsewhere.

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 to initiate further clinical testing, the timing of results from clinical programs, and its regulatory plans. 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, 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 which is 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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