



## Aldeyra Therapeutics Announces First Patient Enrolled in the RENEW Phase 3 Clinical Trial for Dry Eye Disease

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LEXINGTON, Mass., April 2, 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 enrollment of the first patient into the RENEW Phase 3 clinical trial of topical ocular reproxalap for the treatment of dry eye disease.

"Based on the positive results from our Phase 2b dry eye disease clinical trial, in which reproxalap demonstrated early onset and broad activity, we are pleased to initiate the RENEW Phase 3 trial," commented Todd C. Brady, M.D., Ph.D., President and CEO of Aldeyra. "In the United States, dry eye disease affects approximately 20 million adults, a large patient population that is underserved by currently available therapies, which often require weeks of therapy to achieve modest clinical benefit."

The RENEW Trial is a two-part, multi-center, randomized, double-masked, parallel-group, vehicle-controlled, adaptive Phase 3 clinical trial evaluating the efficacy of reproxalap ophthalmic solution (0.25%) vs. vehicle in 400 patients with moderate-to-severe dry eye disease. Results from the first part of the trial will confirm the dosing regimen and sample size for the second part. The co-primary endpoints of the trial will be ocular dryness and fluorescein nasal region ocular staining in pre-specified moderate to severe patient subsets analyzed over twelve weeks of therapy using Mixed effects Model Repeated Measures (MMRM).

In September 2018, Aldeyra reported results from a Phase 2b dry eye disease clinical trial, which demonstrated statistical superiority of reproxalap versus vehicle across multiple symptoms and signs. In the Phase 2b clinical trial, the MMRM p values for the Phase 3 co-primary endpoints of dryness and staining were 0.0048 and 0.0007, respectively.

More information about the RENEW trial is available on [www.clinicaltrials.gov](http://www.clinicaltrials.gov) (NCT03879863).

### **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](http://www.sec.gov). Additional factors may be described in those sections of Aldeyra's Quarterly Report on Form 10-Q for the quarter ended March 31, 2019, to be filed with the SEC in the second quarter of 2019.

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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