



## Aldeyra Therapeutics Announces Last Patient Dosed in the SOLACE Phase 3 Clinical Trial

April 30, 2019

LEXINGTON, Mass., April 30, 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 that the last patient has completed dosing in the SOLACE Phase 3 clinical trial of topical ocular reproxalap in patients with noninfectious anterior uveitis.

"We look forward to announcing the results of the SOLACE trial, our second Phase 3 clinical trial to complete this year," stated Todd C. Brady, M.D., Ph.D., President and CEO of Aldeyra. "Noninfectious anterior uveitis is a rare but severe inflammatory ocular disease characterized by pain, photophobia, and, in some cases, vision loss. An estimated 50% of patients suffer from recurrent or chronic episodes, increasing the risk of serious ocular toxicity caused by prolonged exposure to corticosteroids, the current standard of care. As a first-in-class novel compound with a unique product profile, reproxalap has the potential to treat patients without the toxicities commonly associated with corticosteroids."

The SOLACE trial is a randomized, multi-center, double-masked, parallel-group, vehicle-controlled Phase 3 clinical trial of 0.5% topical ocular reproxalap in patients with noninfectious anterior uveitis. The primary outcome measure is time-to-cure without rescue therapy.

Results from the SOLACE trial are expected to be announced in the second half of 2019.

### **About Noninfectious Anterior Uveitis**

Noninfectious anterior uveitis is a rare, potentially blinding disease characterized by inflammation in the front of the eye, pain, impaired vision, and photophobia. Topical corticosteroids are the only approved therapies for resolution of inflammation associated with noninfectious anterior uveitis, but can lead to serious ocular complications, including glaucoma, infection, and cataract formation.

### **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.

**Corporate Contact:**

David McMullin  
Aldeyra Therapeutics, Inc.  
Tel: 781-761-4904 ext. 218  
[dcmullin@aldeyra.com](mailto:dcmullin@aldeyra.com)

**Investor Contact:**

Chris Brinzey  
Westwicke, an ICR Company  
Tel: 339-970-2843  
[Chris.brinzey@westwicke.com](mailto:Chris.brinzey@westwicke.com)

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