Aldeyra Therapeutics Announces Results from the SOLACE Trial in Noninfectious Anterior Uveitis

June 25, 2019

- Statistical Significance Not Achieved for Primary or Secondary Endpoints Due to High Rates of Disease Resolution in Vehicle-Treated Patients, but Activity of Reproxalap Observed to be Consistently Greater than Vehicle
- Noninfectious Anterior Uveitis Program to be Discontinued
- Company Plans to Prioritize Phase 3 Ocular Pipeline Programs in Dry Eye Disease, Allergic Conjunctivitis, and Proliferative Vitreoretinopathy

LEXINGTON, Mass.--(BUSINESS WIRE)--Jun. 25, 2019-- 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 results from the noninfectious anterior uveitis SOLACE Trial. Statistical significance was not achieved for the primary or secondary endpoints, due to high rates of disease resolution in vehicle-treated patients, but activity of reproxalap was consistently greater than that of vehicle.

“The results of the SOLACE Trial confirm the potential of reproxalap to treat ocular inflammation, and further validate the novel mechanism of action of reproxalap, which demonstrated highly statistically significant immune-modulating activity in the Phase 3 ALLEVIATE Trial and Phase 2b Dry Eye Disease trial,” stated Todd C. Brady, M.D., Ph.D., President and Chief Executive Officer of Aldeyra. “We look forward to aggressively prioritizing advancement of high-value ocular programs in dry eye disease, allergic conjunctivitis, and proliferative vitreoretinopathy.”

Topical ocular reproxalap was observed to be safe and well-tolerated. Reproxalap ophthalmic solution, in various concentrations, has now been administered to over 800 patients in nine clinical trials for ocular inflammation.

Conference Call
Aldeyra will hold a conference call on June 25, 2019 at 8:00 a.m. Eastern Time. The dial-in numbers are (866) 211-4098 for domestic callers and (647) 689-6613 for international callers. The Conference ID is 8856138. A live, listen-only audio webcast of the conference call can be accessed on the investor relations page of Aldeyra's corporate website at ir.aldeyra.com. After the live webcast, the event will remain archived on the Aldeyra Therapeutics website for thirty days.

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 candidates are first-in-class 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. 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 and Aldeyra's Quarterly Report on Form 10-Q for the quarter ended March 31, 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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