Aldeyra Therapeutics Announces Last Patient Dosed in Dry Eye Disease Phase 2b Clinical Trial

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LEXINGTON, Mass., July 12, 2018 /PRNewswire/ -- Aldeyra Therapeutics, Inc. (NASDAQ: ALDX) (Aldeyra), a biotechnology company devoted to the development of next-generation medicines to improve the lives of patients with immune-mediated diseases, announced that the last patient has completed dosing in Aldeyra's randomized, double-masked, vehicle-controlled, multi-center, parallel-group Phase 2b clinical trial of topical ocular reproxalap in dry eye disease.

"Dry eye disease, a persistently disturbing ocular inflammatory condition, represents one of the largest ophthalmic markets worldwide," commented Todd C. Brady, M.D., Ph.D., President and CEO of Aldeyra. "Based on the positive results of our Phase 2a dry eye disease clinical trial, as well as our Phase 2 clinical successes in other ocular inflammatory disorders, we are pleased to complete dosing in our Phase 2b dry eye disease trial, which is designed to establish the drug concentration and patient group sizes for Phase 3 testing. We look forward to providing the top-line results from the trial later this year."

The Phase 2b clinical trial tested two concentrations of topical ocular reproxalap (0.1% and 0.25%) against vehicle over 12 weeks of treatment in 300 dry eye disease patients. The primary objective of the trial is to select a drug concentration for Phase 3 clinical testing, and to determine appropriate patient numbers for Phase 3 clinical testing, based on the activity of drug versus vehicle on standard dry eye disease signs and symptoms.

In September 2017, Aldeyra announced that the results of a randomized, double-masked, parallel-group Phase 2a clinical trial of topical ocular reproxalap demonstrated statistically and clinically relevant improvement from baseline in multiple signs and symptoms associated with dry eye disease. Improvement in symptoms was noted as soon as one week following initiation of therapy. Tear RASP (pro-inflammatory reactive aldehyde species) biomarkers diminished over the course of treatment, and greater RASP reduction generally correlated with clinical response.

Results from the Phase 2b trial are expected to be announced in the second half of 2018.

About Aldeyra Therapeutics
Aldeyra Therapeutics is developing 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 and other forms of ocular inflammation. The company is also developing other product candidates for autoimmune and metabolic diseases. None of Aldeyra's product candidates have been approved for sale in the U.S. or elsewhere.

About Dry Eye Disease
Dry eye disease is a common and chronic inflammatory disease estimated to affect approximately 20 million people in the United States, and is characterized by insufficient moisture in the anterior surface of the eye, leading to dryness, inflammation, pain, discomfort, irritation, and, in severe cases, decreased vision. Among physicians and patients, existing therapy for dry eye disease is generally regarded as inadequate.

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 plans and expectations for the development of reproxalap and its other product candidates. 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. 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, completion and reporting 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, the ability to obtain and maintain regulatory approval to conduct clinical trials and to commercialize Aldeyra's product candidates, and the labeling for any approved products; the scope, progress, expansion, and costs of developing and commercializing Aldeyra's product candidates; the size and growth of the potential markets for Aldeyra's product candidates and the ability to serve those markets; Aldeyra's expectations regarding Aldeyra's expenses and revenue, the sufficiency 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 ability to establish and maintain development partnerships; 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, 2017 and Aldeyra's Quarterly Report on Form 10-Q for the quarter ended March 31, 2018, both of which are on file with the Securities and Exchange Commission(SEC) and available on the SEC's website at www.sec.gov. Additional factors may be set forth in those sections of Aldeyra's Quarterly Report on Form 10-Q for the quarter ended June 30, 2018, to be filed with the SEC in the third quarter of 2018. 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, completion or reporting of clinical trials.

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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