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

December 20, 2018

LEXINGTON, Mass., Dec. 20, 2018 /PRNewswire/ -- Aldeyra Therapeutics, Inc. (NASDAQ: ALDX) (Aldeyra), a biotechnology company devoted to development of next-generation medicines to improve the lives of patients with immune-mediated diseases, today announced that the last patient has completed dosing in the ALLEVIATE Phase 3 clinical trial of topical ocular reproxalap in patients with allergic conjunctivitis.

"We look forward to announcing the results of the ALLEVIATE clinical trial in early 2019 as the first of three Phase 3 readouts expected next year," stated Todd C. Brady, M.D., Ph.D., President and CEO of Aldeyra. "Affecting approximately 20% of the population worldwide, allergic conjunctivitis is a common disease that can cause persistently disturbing symptoms, and is often associated with dry eye disease. Reproxalap's novel mechanism has the potential to be uniquely effective in allergic conjunctivitis, and may offer increased durability of activity relative to standard of care."

The ALLEVIATE trial is a multi-center, double-masked, parallel-group, vehicle-controlled Phase 3 clinical trial that enrolled over 300 allergic conjunctivitis patients, randomized equally to receive either topical ocular 0.25% reproxalap, 0.5% reproxalap, or vehicle in a conjunctival allergen challenge model of acute allergic conjunctivitis. The primary outcome measure will be patient-reported ocular itching.

Results from the Phase 3 clinical trial are expected to be announced in early 2019.

About Allergic Conjunctivitis
Allergic conjunctivitis is a common disease that affects 20% or more of the population worldwide. The disease is mediated in part by RASP (Reactive Aldehyde Species) and is characterized by inflammation of the conjunctiva (a membrane covering part of the front of the eye), resulting in ocular itching, excessive tear production, lid swelling, and redness. Allergic conjunctivitis is often associated with dry eye disease. Antihistamines are commonly prescribed for allergic conjunctivitis, but compliance is limited by ocular dryness and lack of effect on non-histaminic pathways involving RASP.

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, allergic conjunctivitis, noninfectious anterior uveitis, and Sjögren-Larsson Syndrome. The company is also developing other product candidates for autoimmune disease, post-transplant lymphoproliferative disease, retinal inflammation, 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, prospects, plans, and objectives and Aldeyra's plans and expectations for its product candidates, including plans to initiate further clinical testing. 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, the ability to obtain and maintain regulatory approval of 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 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 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 September 30, 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.

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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