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Aldeyra Therapeutics Announces First Patient Enrolled in Dry Eye Disease Phase 2b Clinical Trial

LEXINGTON, Mass., Jan. 30, 2018 /PRNewswire/ -- Aldeyra Therapeutics, Inc. (NASDAQ: ALDX) (Aldeyra), a clinical-stage biotechnology company devoted to treating inflammation and inborn errors of metabolism, today announced that it has enrolled the first patient in a Phase 2b clinical trial of topical ocular reproxalap for the treatment of dry eye disease (DED).

"Existing therapy for dry eye disease, a common inflammatory condition that leads to persistently disturbing ocular irritation, is generally considered by physicians and patients to be inadequate, but 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 from the Phase 2a dry eye disease clinical trial with our topical ocular product candidate reproxalap announced in September 2017, we are pleased to begin enrolling our Phase 2b clinical trial, and expect to report results in the second half of this year."

Reproxalap and other product candidates generated from Aldeyra's aldehyde trap platform sequester and facilitate the degradation of pro-inflammatory aldehyde mediators, a class of small molecule therapeutic targets that are elevated in DED patients. The Phase 2b clinical trial will test two concentrations of topical reproxalap (0.1% and 0.25%) against vehicle over 12 weeks of treatment in 300 patients with moderate dry eye disease. Consistent with the Phase 2a clinical trial, endpoints will include standard signs and symptoms characteristic of DED.

A clinical trial synopsis can be found on clinicaltrials.gov (#NCT03404115).

About Aldeyra Therapeutics

Aldeyra Therapeutics, Inc. is a biotechnology company devoted to improving lives by inventing, developing, and commercializing products that treat inflammation and inborn errors of metabolism. Aldeyra's lead product candidate, reproxalap (formerly known as ADX-102), is a small molecule aldehyde sequestering agent in Phase 2b clinical development for the treatment of dry eye disease, and Phase 3 clinical development for the treatment of allergic conjunctivitis, noninfectious anterior uveitis, and Sjögren-Larsson Syndrome. Reproxalap has not 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 and lubrication 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. In patients with dry eye disease, pro-inflammatory aldehyde mediators may contribute to ocular inflammation. By diminishing aldehyde levels, Aldeyra's topical ocular aldehyde trap platform represents a novel and differentiated approach for the treatment of dry eye disease.

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 the potential of reproxalap as an agent for the treatment of dry eye disease. 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 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 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, 2016 and Quarterly Report on Form 10-Q for the quarter ended September 30, 2017, 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 described in those sections of Aldeyra's Annual Report on Form 10-K for the year ended December 31, 2017, expected to be filed with the SEC in the first 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 or completion 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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