Aldeyra Therapeutics Provides Update on Ophthalmic Programs at 2019 Research & Development Day

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Phase 3 Results from ALLEVIATE Trial in Allergic Conjunctivitis Expected in Early 2019
Co-Primary Endpoints Confirmed for Phase 3 Clinical Trial in Dry Eye Disease, Expected to Begin in First Half of 2019
Phase 3 Clinical Trial of ADX-2191 in Proliferative Vitreoretinopathy Expected to Begin in Second Half of 2019
Phase 3 Results from SOLACE Clinical Trial in Noninfectious Anterior Uveitis Expected in Second Half of 2019

LEXINGTON, Mass., Feb. 28, 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 updated progress on ophthalmic programs at a 2019 Research & Development Day in New York City. Presentations were given by members of the Aldeyra executive team along with Dean Eliott, M.D., the Stelios Evangelos Gragoudas Professor of Ophthalmology at Harvard Medical School, Director of the Retina Service at Massachusetts Eye and Ear Infirmary, and Director of the Retina Fellowship at Harvard and Massachusetts Eye and Ear Infirmary. Presentations covered the development and commercialization plans for novel product candidates in proliferative vitreoretinopathy, dry eye disease, allergic conjunctivitis, and noninfectious anterior uveitis.

A webcast of the presentation and slide deck will be available via Aldeyra's investor relations website at http://ir.aldeyra.com until February 28, 2020.

"Over the past few years, we have deliberately expanded our pipeline in support of our corporate strategic initiatives. Today, we have six different compounds in development, representing three unique mechanisms of action, targeting ten potential clinical indications," commented Todd C. Brady, M.D., Ph.D., President and CEO of Aldeyra. "With a deliberate focus on ocular disease and select systemic conditions, we now have five Phase 3 programs in progress or expected to be initiated this year. We look forward to updating investors on the first of the Phase 3 programs, the ALLEVIATE trial in allergic conjunctivitis, early this year."

R&D Day Highlights

- **ADX-2191 for Proliferative Vitreoretinopathy (PVR):** The first Phase 3 clinical trial of ADX-2191, acquired this year for the prevention of PVR, is expected to begin in 2019. PVR is a rare inflammatory fibroproliferative disorder that leads to severe retinal scarring and blindness and is the leading cause of failure of retinal reattachment surgery. Over 50% of PVR cases result in severe uncorrectable vision loss, and 75% of PVR patients suffer from at least moderate uncorrectable vision loss. With no currently approved therapy available, PVR is a serious and sight-threatening disease that effects approximately 4,000 patients in the United States and nearly twice as many in Europe and Japan. Aldeyra plans to begin a two-part, multi-center, non-masked, randomized, controlled, adaptive Phase 3 clinical program in the second half of 2019, following discussions with regulatory authorities. ADX-2191 has received Orphan Drug Designation for the prevention of PVR.

- **Reproxalap for Dry Eye Disease (DED):** In September 2018, Aldeyra reported Phase 2b results in DED that demonstrated statistical superiority of reproxalap versus vehicle across multiple DED symptoms and signs. Based on these results, Aldeyra plans to initiate Part 1 of a two-part adaptive Phase 3 clinical trial in the first half of 2019. Part 1 of the clinical trial will evaluate the efficacy of reproxalap ophthalmic solution (0.25%) vs. vehicle in 400 patients with moderate-to-severe DED. Results from Part 1 will confirm dosing and size for Part 2 of the Phase 3 clinical trial. The co-primary endpoints of this trial will be ocular dryness, and fluorescein nasal region staining in pre-specified moderate to severe patient subsets analyzed over twelve weeks of therapy using Mixed effects Model Repeated Measures (MMRM). In the Phase 2b clinical trial, the MMRM p values for the Phase 3 co-primary endpoints of dryness and staining were 0.0048 and 0.0007, respectively. DED impacts approximately 20 million adults in the United States and represents a highly underserved patient population with up to 50% of patients discontinuing treatment due to limited efficacy or slow onset with current treatment options.

- **Reproxalap for Allergic Conjunctivitis (AC):** Aldeyra expects to report results of the Phase 3 ALLEVIATE trial in early 2019. ALLEVIATE is a multi-center, double-masked, parallel-group, vehicle-controlled Phase 3 clinical trial that will measure ocular itch score area under the curve and patient responder rate. In preparation for a subsequent Phase 3 clinical trial, Aldeyra is also conducting clinical method development studies to assess the feasibility of measuring ocular itch following environmental exposure to allergen. Allergic conjunctivitis represents a large and underserved market with an estimated 30 million patients in the United States who are inadequately treated with the current standard of care. In two Phase 2 clinical trials, reproxalap was observed to be well tolerated and demonstrated the potential to be effective in post-histaminic allergy, for which no drug is approved, and which affects all patients suffering from allergic conjunctivitis.

- **Reproxalap for Overlapping Treatment of Dry Eye Disease and Allergic Conjunctivitis:** Studies have shown that DED and AC are interrelated, with up to 50% of the patient population suffering from DED/AC comorbidity. Reproxalap has demonstrated efficacy against both DED and AC in separate Phase 2b clinical trials. Aldeyra plans to advance parallel Phase 3 programs in DED and AC that could support concurrent New Drug Application filings with the U.S. Food and Drug Administration for both conditions.

- **Reproxalap for Noninfectious Anterior Uveitis (NAU):** NAU is a rare ocular disease caused by an inflammatory response that leads to surface irritation, pain, photophobia, and in some cases vision loss, and affects approximately 260,000 patients in the United States per year. An estimated 50% of patients suffer from repeat or chronic NAU episodes, increasing the risk of serious ocular toxicity as a result of prolonged exposure to corticosteroids, the current standard of care. The anti-inflammatory product profile of reproxalap has the potential to treat patients without the toxicities commonly associated with corticosteroids. The Phase 3 SOLACE clinical trial of reproxalap in NAU is currently ongoing, and results are expected to be announced in the second half of 2019.

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, 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 rgulatory 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, 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. Additional factors may be set forth in those sections of Aldeyra's Annual Report on Form 10-K for the year ended December 31, 2018, to be filed with the SEC in the first 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
dmcmullin@aldeyra.com

Investor Contact:
Chris Brinzey
Westwicke Partners
Tel: 339-970-2843
Chris.brinzey@westwicke.com