Aldeyra Therapeutics Releases Expanded Results from Allergen Chamber Trial and Announces Plans to Initiate the Phase 3 INVIGORATE Trial in Patients with Allergic Conjunctivitis

October 31, 2019

- *Highly statistically significant activity relative to vehicle across every assessed symptom and sign observed in allergen chamber clinical trial*
- *Agreement reached with U.S. FDA on design of Phase 3 INVIGORATE trial, expected to initiate in the first half of 2020*
- *Company to host conference call and webcast at 8:00 a.m. ET today*

LEXINGTON, Mass.--(BUSINESS WIRE)--Oct. 31, 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 expanded results from the company's allergen chamber clinical methods trial (#NCT03709121) of topical ocular reproxalap in patients with allergic conjunctivitis, and Phase 3 clinical trial plans based on recent feedback from the U.S. Food & Drug Administration (FDA).

"The expanded results from our allergen chamber trial demonstrate highly statistically significant activity of reproxalap relative to vehicle across all assessed symptoms and signs," commented Todd C. Brady, M.D., Ph.D., President and CEO of Aldeyra. "Based on the positive outcome of the trial, we have reached agreement with the FDA on the design and the primary endpoint for our Phase 3 INVIGORATE trial – statistical significance in ocular itching at a majority of time points over a pre-specified range. Importantly, in the completed allergen chamber trial, all time points to be pre-specified in the INVIGORATE trial were statistically significant."

The double-masked, randomized, vehicle-controlled, crossover allergen chamber clinical methods trial assessed the efficacy and safety of 0.25% and 0.5% concentrations of reproxalap topical ophthalmic solution compared with vehicle in 70 patients with ocular allergy to ragweed. Patient-reported ocular itching and tearing, and investigator-assessed ocular redness, were recorded at various intervals over approximately 3.5 hours during exposure to a standardized amount of ragweed pollen. Test article was administered before chamber entry and at 90 minutes post-entry, near the peak of allergy symptoms and signs.

Relative to patients treated with vehicle, patients treated with 0.25% or 0.5% reproxalap demonstrated statistically significant reduction in ocular itching ($p<0.0001$), redness ($p<0.0001$), and tearing ($p<0.0001$). The total ocular symptom score, a combination of itching, redness, and tearing, was also significantly lower in reproxalap-treated subjects than in vehicle-treated subjects ($p<0.0001$ for both concentrations). Consistent with the positive results from the ALLEVIATE Phase 3 clinical trial in allergic conjunctivitis released earlier this year, there was no statistical difference between the activity of 0.25% and 0.5% reproxalap. Consistent with all prior clinical experience with topical ocular reproxalap in over 1,000 patients across 12 clinical trials, there were no observed safety or tolerability concerns, and the most common treatment-emergent adverse event was transient instillation site irritation.

"We believe that the allergic conjunctivitis results released today, in aggregate, represent the first rigorous demonstration of activity of a late-stage, novel immune-modulating agent in an allergen chamber," stated David J. Clark, M.D., M.R.C.P., Chief Medical Officer of Aldeyra. "The allergen chamber is an innovative and demanding assessment that combines real-world applicability with controlled allergen exposure. The results from the trial indicated distinct prophylactic and treatment activity of reproxalap in reducing all of the primary signs and symptoms of allergic conjunctivitis: ocular itching, redness, and tearing."

The Phase 3 INVIGORATE trial, which is expected to initiate in the first half of 2020, will evaluate 0.25% reproxalap versus vehicle in an allergen chamber. The primary endpoint will be achieved if statistically significant reduction in ocular itching between drug and vehicle is demonstrated at the majority of eleven time points in a pre-specified range from 110 to 210 minutes following chamber entry. In the completed allergen chamber trial, reproxalap was statistically superior to vehicle at every time point to be pre-specified in INVIGORATE.

Conference Call

Aldeyra will host a conference call to discuss this announcement today, October 31, 2019, at 8:00 a.m. ET. The dial-in numbers are (866) 211-4098 for domestic callers and (647) 689-6613 for international callers. The Conference ID is 4695959. 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. Presentation slides will be available on the investor relations page approximately 30 minutes prior to the start of the conference call and webcast.

After the live webcast, the event will remain archived on the Aldeyra Therapeutics website for thirty days.

About Reproxalap

Reproxalap is a novel, small-molecule immune-modulating covalent inhibitor of reactive aldehyde species (RASP), which are elevated in ocular and systemic inflammatory disease. Reproxalap's mechanism of action has been validated with the demonstration of statistically significant and clinically relevant activity in multiple physiologically distinct late-phase clinical indications.

About Allergic Conjunctivitis

Allergic conjunctivitis affects more than 1 billion people worldwide,[1] including more than 100 million in the U.S.[2] The disease is thought to be mediated in part by reactive aldehyde species (RASP), leading to activation of intracellular inflammatory factors, including NF-kB, inflammasomes, and Scavenger Receptor A. The symptoms of allergic conjunctivitis – ocular itching and tearing – are chronic, painful, and persistent, affecting quality of life and leading to loss of work that can create a substantial economic burden for patients and their families.[3] Allergic conjunctivitis is hyperendemic and

prevalence is increasing. Although allergic conjunctivitis is one of the most common diseases treated by ophthalmologists and optometrists, in many cases physicians and patients report that currently available therapy is inadequate. Today nearly one in five allergic conjunctivitis patients utilize corticosteroids or other adjunctive therapy in addition to antihistamines.

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 investigational drug product candidates are first-in-class potential 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.

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 development plans and expectations for reproxalap and 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 relating to current or future clinical development. 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, but not limited to, "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 safety and efficacy results of later phase or larger clinical trials confirming the results of Aldeyra's earlier trials; 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 June 30, 2019, 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 September 30, 2019, expected to be filed with the SEC in the fourth 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.

[1] White Book on Allergy (2013 Update)

[2] Singh K, Axelrod S, Bielory L. The epidemiology of ocular and nasal allergy in the United States, 1988-1994.J Allergy ClinImmunol.2010;126(4):778-783.e6

[3] Andrew D. Pitt, Andrew F. Smith, Lynda Lindsell, Li Wern Voon, Peter W. Rose & Anthony J. Bron (2004) Economic and quality-of-life impact of seasonal allergic conjunctivitis in Oxfordshire, Ophthalmic Epidemiology, 11:1, 17-33, DOI: 10.1076/opep.11.1.17.26437

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