Aldeyra Therapeutics Announces Clinical Development Plan for Resubmission of New Drug Application for Reproxalap in Dry Eye Disease

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LEXINGTON, Mass.--(BUSINESS WIRE)--Mar. 28, 2024-- Aldeyra Therapeutics, Inc. (Nasdaq: ALDX) (Aldeyra), a biotechnology company devoted to discovering and developing innovative therapies designed to treat immune-mediated and metabolic diseases, today announced the clinical development plan intended to enable resubmission of a New Drug Application (NDA) of topical ocular 0.25% reproxalap, an investigational RASP modulator, for the treatment of dry eye disease to the U.S. Food and Drug Administration (FDA). Following discussions with the FDA, Aldeyra intends to initiate a dry eye chamber clinical trial in the first half of 2024. Contingent on positive results from the planned clinical trial, NDA resubmission is expected in the second half of 2024. Based on FDA guidance, the planned review period for the potential NDA resubmission is expected to be six months.

“The planned dry eye chamber clinical trial, if successful, could represent the first pivotal demonstration of rapid improvement in the symptoms of dry eye disease, a potentially debilitating and increasingly pervasive condition that affects millions of patients worldwide,” stated Todd C. Brady, M.D., Ph.D., President and Chief Executive Officer of Aldeyra.

In the proposed dry eye chamber trial, patients will be administered vehicle (the drug product without the active ingredient) before and during exposure to a dry eye chamber. Qualifying patients will subsequently be randomized to receive either reproxalap or vehicle before and during exposure to an additional dry eye chamber. Approximately 100 patients are expected to be enrolled to assess the primary endpoint of ocular discomfort. The design and statistical powering for the proposed trial are derived from four previously completed dry eye chamber clinical trials with reproxalap. Based on the data from the previous clinical trials, when analyzed with the planned trial design and statistical plan, ocular discomfort in the dry eye chamber following treatment with reproxalap was statistically lower than that of vehicle (p=0.0003). The planned clinical trial is expected to be more than 90% powered to detect a difference between treatment groups.

“Affecting hundreds of millions of people globally, dry eye disease is a multifactorial progressive disease that impacts quality of life,” stated Sumit Garg, M.D., Professor of Ophthalmology at University of California Irvine. “We are excited about the novel upstream mechanism of action of RASP modulation and the potential to provide rapid relief of signs and symptoms of dry eye.”

A clinical trial at a different dry eye chamber, in addition to a traditional six-week field clinical trial, are expected to be conducted in parallel with the planned clinical trial as part of a comprehensive strategy designed to account for disease heterogeneity and potential differences in clinical sites and environment. Consistent with previously disclosed guidance and based on the current operating plan, cash and cash equivalents of $142.8 million as of December 31, 2023 are projected to be sufficient to fund operations beyond 2026.

Conference Call & Webcast Information
Aldeyra will host a conference call at 8:00 a.m. ET today, March 28, 2024, to discuss the clinical development plan for resubmission of the new drug application for reproxalap in dry eye disease. The dial-in numbers are (833) 470-1428 for domestic callers and (404) 975-4839 for international callers. The access code is 515106. A live webcast of the conference call will be available on the Investor Relations page of the company’s website at https://ir.aldeyra.com. After the live webcast, the event will remain archived on the Aldeyra Therapeutics website for 90 days.

About Aldeyra
Aldeyra Therapeutics is a biotechnology company devoted to discovering innovative therapies designed to treat immune-mediated and metabolic diseases. Our approach is to develop pharmaceuticals that modulate protein systems, instead of directly inhibiting or activating single protein targets, with the goal of optimizing multiple pathways at once while minimizing toxicity. Our product candidates include RASP (reactive aldehyde species) modulators ADX-629, ADX-246, ADX-248, and chemically related molecules for the potential treatment of systemic and retinal immune-mediated and metabolic diseases. Our late-stage product candidates are reproxalap, a RASP modulator for the potential treatment of dry eye disease and allergic conjunctivitis, and ADX-2191, a novel formulation of intravitreal methotrexate for the potential treatment of retinitis pigmentosa.

About Reproxalap
Reproxalap is an investigational new drug candidate in development for the treatment of dry eye disease and allergic conjunctivitis, two of the largest markets in ophthalmology. Reproxalap is a first-in-class small-molecule modulator of RASP, which are elevated in ocular and systemic inflammatory diseases. The mechanism of action of reproxalap has been supported by the demonstration of statistically significant and clinically relevant activity in multiple physiologically distinct late-phase clinical indications. Reproxalap has been studied in more than 2,400 patients with no observed safety concerns; mild and transient instillation site irritation is the most commonly reported adverse event in clinical trials.

Safe Harbor Statement
This release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including, but not limited to, statements regarding Aldeyra’s future expectations, plans, and prospects, including without limitation statements regarding: the goals, opportunity, and potential for reproxalap; the outcome and expected timing and the results of Aldeyra’s planned clinical trials; the outcome and timing of the FDA’s review, acceptance and/or approval of a NDA resubmission for reproxalap and the adequacy of the data included in the original NDA and the potential NDA resubmission; and Aldeyra’s projected cash runway. 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,” “on track,” “scheduled,” “target,” “design,” “estimate,” “predict,” “contemplates,” “likely,” “potential,” “continue,” “ongoing,” “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, funding, and other factors that could delay the initiation, enrollment, 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; delay in or failure to obtain regulatory approval of Aldeyra's product candidates, including as a result of the FDA not accepting Aldeyra's regulatory filings, issuing a complete response letter, or requiring additional clinical trials or data prior to review or approval of such filings or in connection with resubmissions of such filings; 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 clinical trials involving Aldeyra's product candidates in clinical trials focused on the same or different indications; 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) and obtain reimbursement for 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 future revenue, the timing of future 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 commercialization, marketing and manufacturing capabilities and strategy; 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; political, economic, legal, social, and health risks, public health measures, and war or other military actions, that may affect Aldeyra's business or the global economy; 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, 2023, which is on file with the Securities and Exchange Commission (SEC) and available on the SEC's website at https://www.sec.gov/. Additional factors may be described in those sections of Aldeyra's Quarterly Report on Form 10-Q for the quarter ended March 31, 2024, expected to be filed with the SEC in the second quarter of 2024, and Aldeyra's other filings with the SEC.

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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