# Aldeyra Therapeutics Announces PDUFA Extension of the New Drug Application of Reproxalap for the Treatment of Dry Eye Disease

December 16, 2025

LEXINGTON, Mass.--(BUSINESS WIRE)--Dec. 15, 2025-- Aldeyra Therapeutics, Inc. (Nasdaq: ALDX) (Aldeyra), a biotechnology company devoted to discovering and developing innovative therapies designed to treat immune-mediated diseases, today announced that the U.S. Food and Drug Administration (FDA) has extended the Prescription Drug User Fee Act (PDUFA) target action date for the reproxalap New Drug Application (NDA) for the treatment of dry eye disease. The extended PDUFA target action date is March 16, 2026.

Following submission on June 16, 2025, the NDA was accepted for review as a “complete class 2 response” by the FDA on July 16, 2025, with a target PDUFA action date of December 16, 2025. On December 12, 2025, the FDA met with Aldeyra to request submission to the NDA of the Clinical Study Report (CSR) for the dry eye disease field trial of reproxalap, for which top-line results were announced on May 5, 2025. The field trial, which was supportive of the activity of reproxalap relative to vehicle, did not meet the primary endpoint of improvement in dry eye symptoms relative to the vehicle control. Prior to submitting the NDA in June, the field trial was discussed with the FDA.

At the December 12 meeting, the FDA made no other requests and did not identify any other specific issues with the NDA review. The CSR, which had been previously submitted to the Investigational New Drug (IND) file for reproxalap, was submitted to the NDA the same day of the meeting and was considered a major amendment to the NDA by the FDA. Per the FDA's earlier request during the NDA review, the safety data from the field trial was submitted to the NDA on August 21, 2025. The CSR has been reviewed by the FDA under the IND.

In early December, the FDA shared with Aldeyra a draft of the prospective label, and Aldeyra has submitted a response. The FDA notified Aldeyra that if no major deficiencies are identified during the extended review, the FDA plans to communicate proposed labeling requests and, if necessary, any anticipated postmarketing requirements by February 16, 2026.

**Conference Call & Webcast Information**
Aldeyra will host a conference call at 8:00 a.m. ET tomorrow, Tuesday December 16, 2025, to discuss the PDUFA extension. The dial-in numbers are (833) 470-1428 for domestic callers and (646) 844-6383 for international callers. The access code is 438712. 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 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-248, ADX-246, and chemically related molecules for the potential treatment of systemic and retinal immune-mediated 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 primary vitreoretinal lymphoma and retinitis pigmentosa.

***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: anticipated timing of regulatory action; the outcome of the New Drug Application of reproxalap for the treatment of dry eye disease, including, if approved, the label for reproxalap; and the goals, opportunity, and commercial potential for reproxalap. 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, 2024, and Aldeyra's Quarterly Report on Form 10-Q for the quarter ended September 30, 2025, which are on file with the Securities and Exchange Commission (SEC) and available on the SEC website at https://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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