



Aldeyra Therapeutics Announces Expansion of RASP Platform to Include Central Nervous System Diseases and Provides Updates on Reproxalap at Research & Development Webcast

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LEXINGTON, Mass.--(BUSINESS WIRE)--Nov. 13, 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 at a research and development webcast the expansion of the RASP platform to include programs in central nervous system diseases associated with inflammation, and provided updated manufacturing information on reproxalap.

- Based on new preclinical results in models of Parkinson's disease and amyotrophic lateral sclerosis, which included improved grip strength, balance, and biomarkers of central nervous system function, potential clinical indications for the orally administered, next-generation RASP modulator ADX-248 were expanded to include neuroinflammatory diseases that affect the central nervous system.
- The U.S. Food and Drug Administration (FDA) completed routine site inspections of reproxalap drug substance and drug product manufacturing facilities in 2025. The inspections resulted in Voluntary Action Indicated (VAI) designations, and the FDA has notified the manufacturers that the inspections are closed, and that no further action was necessary.

"A testament to the growing opportunity for immune-modulating therapeutic approaches, the new results announced today in preclinical models of neurological diseases associated with inflammation highlight the potentially broad applicability of ADX-248 and other next-generation RASP modulators as novel product candidates for the treatment of a number of clinical indications," stated Todd C. Brady, M.D., Ph.D., President and Chief Executive Officer of Aldeyra. "We look forward to providing future updates on ADX-248, reproxalap, and other RASP modulators as we advance our therapeutic pipeline."

Conference Call & Webcast Information

Aldeyra will host a conference call at 8:00 a.m. ET today to discuss new preclinical results from ADX-248 in models of diseases that affect the central nervous system and provide clinical and manufacturing updates on reproxalap. The dial-in numbers are (833) 470-1428 for domestic callers and (646) 844-6383 for international callers. The access code is 663378. 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: the goals, opportunity, and potential for Aldeyra's RASP modulator product candidates and pipeline; the outcome and timing of any clinical trials of Aldeyra's RASP modulator product candidates; anticipated timing of regulatory filings; and the outcome of the New Drug Application of reproxalap 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, 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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