Aldeyra Therapeutics Announces Next-Generation RASP-Modulator Drug Candidates Expected to Begin Clinical Trials for Systemic Immune-Mediated Diseases and Geographic Atrophy

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ADX-246 for Systemic Immune-Mediated Diseases and ADX-248 for Geographic Atrophy Build on Aldeyra's Drug Discovery and Development Engine Targeting RASP Modulation

New Product Candidates Highlight Aldeyra's Clinical Indication Expansion to Systemic and Retinal Diseases Characterized by Inflammation

LEXINGTON, Mass.--(BUSINESS WIRE)--Feb. 23, 2023-- Aldeyra Therapeutics, Inc. (Nasdaq: ALDX) (Aldeyra) today announced the advancement of two investigational new drug candidates, ADX-246 and ADX-248, to clinical testing, pending completion of U.S. Food and Drug Administration Investigational New Drug (IND) requirements. ADX-246 and ADX-248 represent the most recent group of product candidates generated from Aldeyra's systems-based drug discovery and development engine focused on novel RASP modulators designed to decrease immune responses that lead to disease. Pending completion of the IND requirements, a Phase 1 clinical trial of orally administered ADX-246 for the treatment of systemic immune-mediated diseases, and a Phase 1/2 clinical trial of intravitreally injected ADX-248 for the treatment of geographic atrophy, a sight-threatening retinal disease, are expected to initiate in the second half of 2023 or early 2024.

"Highlighting Aldeyra's expansion to treatment of diseases that affect the retina and other areas of the body, ADX-246 and ADX-248 further support Aldeyra's position as a leader in RASP modulation, a novel pharmacology that potentially addresses a broad array of diseases characterized by inflammation," stated Todd C. Brady, M.D., Ph.D., President and Chief Executive Officer of Aldeyra. "Few safe, broadly active, orally administered therapeutic options are available for the treatment of systemic immune-mediated diseases, and only a single drug is approved for the treatment of geographic atrophy."

ADX-246 is designed to treat immune-mediated systemic diseases thought to be caused or exacerbated by pro-inflammatory RASP. ADX-246 is one of the most potent RASP modulators developed by Aldeyra and has demonstrated activity following systemic administration in animal models of sepsis, hepatitis, and atopic dermatitis.

ADX-248 is designed to reduce the inflammation and macromolecular aggregate formation associated with geographic atrophy, a severe form of macular degeneration. Pro-inflammatory RASP are associated with inflammation in geographic atrophy and potentially contribute to visual impairment in low-light settings early in the course of the disease. Further, retinaldehyde, a well-described RASP associated with retinal disease, leads to the formation of macromolecular aggregates that comprise, in part, retinal inclusions characteristic of geographic atrophy and related diseases, including Stargardt disease and the dry form of age-related macular degeneration.

In aggregate, more than 100 million individuals in the United States may be impacted by diseases associated with systemic inflammation.[1] Geographic atrophy, a leading cause of blindness, affects more than 1 million people in the United States.[2]

About Aldeyra

Aldeyra Therapeutics is a clinical-stage biotechnology company developing innovative therapies designed to treat immune-mediated diseases. Our approach is to discover and develop pharmaceuticals that modulate immunological 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 diseases. Our pre-commercial product candidates are reproxalap, a RASP modulator for the potential treatment of dry eye disease (under U.S. Food and Drug Administration New Drug Application review) and allergic conjunctivitis, and ADX-2191, a novel formulation of intravitreal methotrexate for the potential treatment of primary vitreoretinal lymphoma (under U.S. Food and Drug Administration New Drug Application review), proliferative vitreoretinopathy, and other rare sight-threatening retinal diseases. For more information, visit https://www.aldeyra.com/ and follow us on LinkedIn, Facebook, and Twitter.

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 expected timing of initiating clinical trials of ADX-246 for systemic immune-mediated diseases and ADX-248 for geographic atrophy. 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," "on schedule," "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, 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; updated or refined data based on Aldeyra's continuing or post-hoc review and quality control analysis of clinical data, Aldeyra's ability to design clinical trials with protocols, data analysis methodologies, and endpoints acceptable to applicable regulatory authorities; 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 clinical trials involving Aldeyra's product candidates in clinical trials focused on the same or on different indications; the risk that the results from earlier clinical trials, portions of clinical trials, or pooled clinical data may not accurately predict results of subsequent trials or the remainder of a clinical trial; 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 revenue, the sufficiency or use of Aldeyra's cash resources and needs for additional financing; political, economic, legal, social, and health risks, including the COVID-19 pandemic and subsequent public health measures, and war or other military actions, that may affect Aldeyra's business or the global economy; 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, 2021, and Aldeyra's Quarterly Report on Form 10-Q for the quarter ended September 30, 2022, which are 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 Annual Report on Form 10-K for the year ended December 31, 2022, expected to be filed with the SEC in the first quarter of 2023.

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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[1] https://www.ncbi.nlm.nih.gov/books/NBK493173/; updated August 8, 2022.

[2] Lancet Global Health. 2(2):e106-16, 2014.

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