Aldeyra Therapeutics' Investigational RASP Modulator ADX-629 Improved Signs of Intoxication in Alcohol Challenge Phase 2 Clinical Trial

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Relative to Placebo, ADX-629 Reduced Dermal Flushing (P=0.0007), Increased Romberg Test Balance Time (P=0.02), and Lowered Levels of Acetaldehyde (P=0.03) Following Exposure to Alcohol

Aldeyra Plans to Support Investigator-Sponsored Phase 2 Clinical Trial of ADX-629 in Moderate Alcoholic Hepatitis, Expected to be Initiated in 2023

LEXINGTON, Mass.--(BUSINESS WIRE)--Dec. 13, 2022-- Aldeyra Therapeutics, Inc. (Nasdaq: ALDX) (Aldeyra) today announced demonstration of target engagement and improvement in the signs of alcohol intoxication in a sequence-randomized, double-masked, placebo-controlled crossover Phase 2 clinical trial of ADX-629, a first-in-class orally administered investigational new drug candidate. Relative to placebo, ADX-629 reduced dermal flushing (P=0.0007), increased Romberg test balance time (P=0.02), and lowered levels of the ethanol RASP metabolite acetaldehyde (P=0.03) following acute exposure to alcohol.

"The evidence of activity of ADX-629 following acute alcohol intoxication is encouraging given the paucity of treatment options for patients with alcohol-associated liver diseases," stated Loretta L. Jophlin, M.D., Ph.D., Assistant Professor of Medicine at the University of Louisville. "For patients with moderate alcohol-associated hepatitis, standard of care is generally observation, and thus there is demand for potential new therapies such as ADX-629 that could prevent disease progression or otherwise improve outcomes."

ADX-629 or placebo was administered twice before exposure to alcohol and once afterwards. Post-baseline assessments occurred when target blood alcohol concentrations were reached and again over the following day. Assessments included proprioception tests, flushing, symptoms, and plasma laboratory markers. Of the 25 subjects who were randomized, 23 subjects were exposed to both ADX-629 and placebo. Both ADX-629 and placebo were well tolerated, and no safety concerns were noted. Most assessments were statistically similar between treatment groups. In addition to statistical superiority of ADX-629 over placebo in Romberg test balance time, flushing, and acetaldehyde, levels of total cholesterol (P=0.02) and LDL (P=0.047) were statistically lower following ADX-629 treatment than following placebo treatment. The full results of the trial are expected to be presented at a medical meeting.

"The observed reduction in acetaldehyde, the key toxic RASP metabolite of ethanol, in addition to improvement in proprioception and reduction in flushing shown in this clinical trial, further support the potential of systemic RASP modulation as an innovative therapeutic approach across a variety of diseases characterized by inflammation," stated Todd C. Brady, M.D., Ph.D., President and Chief Executive Officer of Aldeyra. "With unparalleled expertise in the discovery and development of drug product candidates that target RASP, we remain committed to bringing to market a novel pharmacology to address unmet medical need."

Based on the results of the alcohol challenge clinical trial, Aldeyra plans to support an investigator-sponsored Phase 2 clinical trial of ADX-629 in moderate alcoholic hepatitis. The trial is expected to be initiated in 2023. Results from a Phase 2 clinical trial of ADX-629 in chronic cough are expected in the first half of 2023, and results from Phase 2 clinical trials of ADX-629 in minimal change disease and Sjögren-Larsson Syndrome are expected in 2023.

About ADX-629

ADX-629, an investigational new drug, is a novel, orally administered RASP (reactive aldehyde species) modulator for the potential treatment of systemic immune-mediated diseases. RASP modulators potentially represent upstream immunological switches that shift immune systems from pro-inflammatory states to anti-inflammatory states. ADX-629 is a member of the same chemical class as reproxalap, an investigational new drug in late-stage development for dry eye disease and allergic conjunctivitis, two common ocular inflammatory diseases.

About Aldeyra

Aldeyra Therapeutics is a clinical-stage biotechnology company developing innovative therapies designed to treat immune-mediated diseases. Our approach is to discover 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 pre-commercial product candidates are reproxalap, a potential treatment for dry eye disease and allergic conjunctivitis, and ADX-2191, a potential treatment for primary vitreoretinal lymphoma, proliferative vitreoretinopathy, and other rare sight-threatening retinal diseases. In addition, we are developing other product candidates, including ADX-629 and chemically related molecules, for the potential treatment of systemic and retinal immune-mediated 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 planned initiation of the investigator-sponsored Phase 2 clinical trial of ADX-629 in moderate alcoholic hepatitis; and the expected timing of results from Phase 2 clinical trials of ADX-629 in chronic cough, minimal change disease, and Sjögren-Larsson Syndrome. 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/.

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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