Aldeyra Therapeutics Announces Statistically Significant Reduction in Cough Frequency in Phase 2 Clinical Trial of ADX-629 in Patients With Chronic Cough

June 27, 2023

- **Relative to Placebo, Statistical Significance Achieved for Reduction in Awake Cough Frequency (P=0.01), 24-Hour Cough Frequency (P=0.001), Awake Cough Count (P=0.001), and 24-Hour Cough Count (P=0.001)**
- **ADX-629 Was Well Tolerated and No Safety Concerns Were Identified**
- **Company to Discuss Results in Conference Call and Webcast at 8:00 a.m. ET Today**

LEXINGTON, Mass.--(BUSINESS WIRE)--Jun. 27, 2023-- Aldeyra Therapeutics, Inc. (Nasdaq: ALDX) (Aldeyra), a biotechnology company devoted to discovering and developing innovative therapies designed to treat immune-mediated diseases, today announced positive top-line results from the Phase 2 clinical trial of orally administered ADX-629, an investigational new drug, in patients with chronic cough. The clinical trial demonstrated statistically significant reduction in cough frequency following administration of ADX-629 relative to placebo.

“Consistent with previously demonstrated activity in clinical trials of patients with psoriasis, asthma, and COVID-19, the reduction in cough frequency observed in the Phase 2 clinical trial in chronic cough supports the potentially broad-based activity of ADX-629 as a novel, immune-modulating therapeutic approach,” stated Todd C. Brady, M.D., Ph.D., President and CEO of Aldeyra. “We look forward to discussing the results with regulatory authorities as we consider the expansion of clinical testing to include patients with co-morbid conditions of frequent coughing and active inflammation.”

The multicenter, randomized, double-blind, placebo-controlled, two-period Phase 2 crossover trial enrolled 51 patients with refractory or unexplained chronic cough, which is often defined as a cough that persists for more than eight weeks and is unresponsive to treatment. Patients were randomized to receive ADX-629 or placebo twice daily for 14 days, followed by a 14-day washout period prior to crossing over to 14 days of treatment with ADX-629 or placebo, whichever was not received in the first period. The primary endpoint of the clinical trial was safety. Secondary endpoints included awake cough frequency (the key secondary endpoint), 24-hour cough frequency, quality of life, and clinical impression scales.

Fifty-one patients were enrolled, and all patients completed both treatment periods. Relative to placebo, statistical significance was achieved for the key secondary endpoint of reduction in awake cough frequency (P=0.01), the secondary endpoint of 24-hour cough frequency (P=0.001), and the related post-hoc analyses of awake cough count (P=0.001) and 24-hour cough count (P=0.001). Quality of life and clinical impression scales did not consistently change between treatment groups over the two-week treatment periods. ADX-629 was well tolerated, and no safety concerns were identified following administration of either ADX-629 or placebo. No serious adverse events were reported, adverse event frequencies were similar across treatment groups, and no patients discontinued due to adverse events.

“Frequent coughing, which is characteristic of a number of inflammatory pulmonary diseases, represents a persistently disturbing condition for patients,” stated Gary N. Gross, MD., Clinical Professor of Internal Medicine at Southwestern Medical School and a Board-certified allergist and immunologist with the Dallas Allergy & Asthma Center. “The difficulty in treating chronic coughing highlights the medical need for new therapies.”

Consistent with a Phase 1 clinical trial and the Phase 2 clinical trial in psoriasis, improvement in LDL and HDL levels was observed following treatment with ADX-629 relative to treatment with placebo. 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. ADX-629 is also currently in development for atopic dermatitis, idiopathic nephrotic syndrome, and Sjögren-Larsson Syndrome. Initial results from each trial are expected in the second half of 2023. A Phase 2 clinical trial of ADX-629 in moderate alcohol-associated hepatitis is expected to initiate in the second half of 2023.

Conference Call & Webcast Information

Aldeyra will host a conference call at 8:00 a.m. ET today to discuss top-line results of the Phase 2 clinical trial of ADX-629 in chronic cough. The dial-in numbers are (888) 415-4305 for domestic callers and (646) 960-0336 for international callers. The access code is 5858366. 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 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 proliferative vitreoretinopathy 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 ADX-629 and anticipated clinical or regulatory milestones for ADX-629. 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," "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 may 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, requiring additional clinical trials or data prior to review or approval 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; the current and potential future impact of the COVID-19 pandemic on Aldeyra's business, results of operations, and financial position; 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, 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; 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, 2022, and Aldeyra's Quarterly Report on Form 10-Q for the quarter ended March 31, 2023, 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 Quarterly Report on Form 10-Q for the quarter ended June 30, 2023, expected to be filed with the SEC in the third 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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