Aldeyra Therapeutics Announces Statistically and Clinically Significant Improvement from Baseline in Phase 2 Clinical Trial of ADX-629 in Patients with Atopic Dermatitis

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- Statistically significant improvement from baseline observed in investigator-assessed Eczema Area and Severity Index (EASI, p=0.0006) and Investigator Global Assessment (IGA, p<0.0001)
- EASI 75% improvement (EASI-75) threshold observed in three patients (38%), and affected body surface area was completely cleared in one patient (13%)
- Patient-reported itching eliminated in two patients (25%) and clinically relevant threshold achieved in patient-reported eczema score (POEM) in six patients (75%)
- Statistically significant improvement from baseline observed in Hamilton Rating Scale for Depression (HAM-D, p=0.02)
- Results supportive of advancing ADX-246, an analog investigational drug of ADX-629, to Phase 1/2 placebo-controlled clinical trial in healthy volunteers and atopic dermatitis patients
- Company to present top-line results in conference call and webcast at 8:00 a.m. ET today

LEXINGTON, Mass.--(BUSINESS WIRE)--Dec. 19, 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 a Phase 2 clinical trial of ADX-629, an investigational RASP modulator, in patients with atopic dermatitis. Relative to baseline, the clinical trial demonstrated statistically significant and clinically relevant improvement in investigator-assessed and patient-reported outcomes across a number of different physiological and psychosocial assessments, including complete resolution of affected body surface area observed in one patient and elimination of itching reported by two patients.

“The demand for safe, tolerable, and orally administered atopic dermatitis therapies, particularly for mild to moderate patients, is substantial,” stated Dr. Matthew Zirwas, founder of the Bexley Dermatology Research clinic and Board-certified dermatologist who served as Principal Investigator of the clinical trial. “The data announced today offer a glimpse into what may be possible for many patients who today are not adequately treated.”

An open-label, single-center Phase 2 clinical trial of ADX-629 was conducted in eight mild to moderate atopic dermatitis patients. Over three months of treatment, patients received 250mg ADX-629, administered orally twice daily. The primary endpoint of the clinical trial was safety and tolerability. Secondary endpoints included Eczema Area and Severity Index (EASI), Investigator Global Assessment (IGA), Patient-Oriented Eczema Measure (POEM), Peak Pruritus Numerical Rating Scale, time to flare, Hamilton Depression Rating Scale (HAM-D), and Beck Anxiety Inventory (BAI).

Relative to baseline, over three months of treatment, improvement was observed in all patients. Statistical significance was achieved for improvement in EASI (p=0.0006). EASI thresholds for 50% improvement (EASI-50), 75% improvement (EASI-75), and 90% improvement (EASI-90) were met in four patients (50%), three patients (38%), and one patient (13%), respectively. Statistical significance was achieved for improvement in affected body surface area (p<0.0001); one patient (13%) achieved complete clearance of affected body surface area. Statistical significance was achieved for improvement in IGA (p<0.0001). The IGA threshold score of 0 (clear) or 1 (almost clear) was met in one (13%) patient. Statistical significance was achieved for improvement in patient-reported itching (p=0.0002); the clinically relevant threshold of improvement by 4 or more points was met in three patients (38%), and two patients (25%) reported elimination of itching. Statistical significance was achieved for improvement in patient-reported eczema severity (POEM, p<0.0001); the clinically relevant threshold of improvement by 4 or more points was met in six patients (75%). Statistical significance was achieved for improvement in depression (HAM-D, p=0.02) and numerical improvement was observed for improvement in anxiety (BAI, p=0.1).

All enrolled patients completed the trial per protocol. No patients experienced flare requiring rescue therapy. Only two adverse events deemed to be at least possibly related to ADX-629 were reported, and both events were mild. There were no observed serious adverse events or discontinuations due to adverse events.

“The results from the clinical trial of ADX-629 in atopic dermatitis are consistent with activity demonstrated in previously disclosed clinical trials of ADX-629, including Phase 2 clinical trials in psoriasis, asthma, and chronic cough, adding to a growing body of evidence that we believe is supportive of the activity of RASP modulators in systemic diseases associated with inflammation,” stated Todd C. Brady, M.D., Ph.D., President and Chief Executive Officer of Aldeyra. “Based on the signal-finding activity of ADX-629, we enthusiastically plan to advance our next-generation investigational RASP modulator ADX-246 to Phase 1/2 clinical testing in healthy volunteers and patients with atopic dermatitis.”

Aldeyra expects to initiate a multicenter, randomized, placebo-controlled Phase 1/2 clinical trial of ADX-246 in healthy volunteers and patients with atopic dermatitis in the first half of 2024. Topline results from the trial are expected in the second half of 2024.

Conference Call & Webcast Information

Aldeyra will host a conference call at 8:00 a.m. ET today, December 19, 2023, to discuss the top-line results of the Phase 2 clinical trial of ADX-629 in atopic dermatitis. 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 audio webcast of the conference call also will be accessible from the “Investors & Media” section of Aldeyra's website at ir.aldeyra.com. 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 and allergic conjunctivitis, and ADX-2191, a novel formulation of intravitreal methotrexate for the potential treatment of proliferative vitreoretinopathy and retinitis pigmentosa.

About ADX-629 and ADX-246

ADX-629 is an orally administered RASP modulator currently in development as a signal-finding molecule for the treatment of mass-market immune-mediated diseases. ADX-629 has demonstrated potential activity in clinical trials of patients with psoriasis, asthma, COVID, ethanol toxicity, chronic cough, and atopic dermatitis. In more than 100 healthy volunteers and patients, no consistent adverse events associated with ADX-629 have been identified. An analog of ADX-629, ADX-246 is an orally administered next-generation RASP modulator expected to initiate clinical testing in the first half of 2024 in a Phase 1/2 clinical trial in healthy volunteers and patients with atopic dermatitis. Top-line results from the Phase 1/2 clinical trial are expected in the second half of 2024.

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 ADX-246, and anticipated clinical or regulatory milestones for ADX-629 and ADX-246. 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, or 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; 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, 2022, and Aldeyra's Quarterly Report on Form 10-Q for the quarter ended September 30, 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 Annual Report on Form 10-K for the year ended December 31, 2023, expected to be filed with the SEC in the first quarter of 2024, and Aldeyra's other filings with the SEC.

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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