UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): December 19, 2023

ALDEYRA THERAPEUTICS, INC.
(Exact name of Registrant as specified in its charter)

Delaware	**001-36332**	**20-1968197**
(State or other jurisdiction of incorporation)	**(Commission File No.)**	**(IRS Employer Identification No.)**

131 Hartwell Avenue, Suite 320
Lexington, MA 02421
(Address of principal executive offices and zip code)

Registrant's telephone number, including area code: (781) 761-4904

Not Applicable
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, $0.001 par value per share	**ALDX**	**The Nasdaq Stock Market LLC**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01. **Regulation FD Disclosure.**

As reported under Item 8.01 of this Current Report on Form 8-K, on December 19, 2023, Aldeyra Therapeutics, Inc. (the "Company") issued a press release (the "Press Release") announcing positive top-line results from the Phase 2 clinical trial of ADX-629 in patients with atopic dermatitis, and development plans for ADX-246, an analog investigational drug of ADX-629. The Company is holding a conference call regarding the announcement on December 19, 2023. A copy of the supplemental presentation which will be referenced during the conference call and posted on the Company's website is furnished herewith as Exhibit 99.1 and is incorporated by reference herein.

This information in this Item 7.01 of this Current Report on Form 8-K shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that Section, or incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in any such filing.

Item 8.01. **Other Events.**

The Press Release is filed as Exhibit 99.2 to this Current Report on Form 8-K and is incorporated by reference herein.

Item 9.01. **Financial Statements and Exhibits.**

(d) Exhibits

Exhibit No.	Description
99.1	Aldeyra Therapeutics, Inc. Presentation dated December 19, 2023
99.2	Aldeyra Therapeutics, Inc. Press Release dated December 19, 2023
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

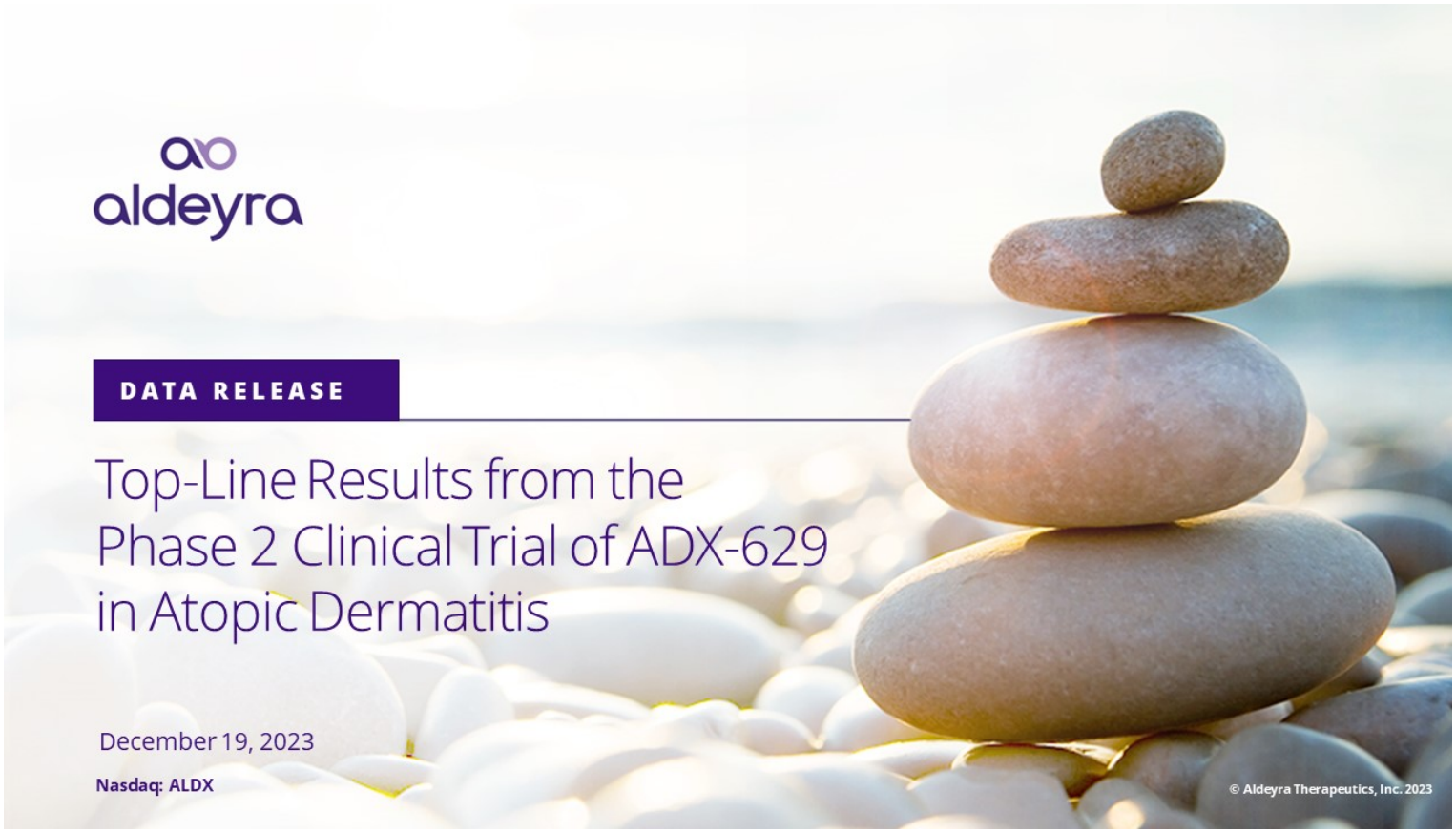
SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

ALDEYRA THERAPEUTICS, INC.

By: /s/ Todd C. Brady
Name: Todd C. Brady, M.D., Ph.D.
Title: Chief Executive Officer

Dated December 19, 2023


aldeyra
DATA RELEASE
Top-Line Results from the Phase 2 Clinical Trial of ADX-629 in Atopic Dermatitis
December 19, 2023
Nasdaq: ALDX
© Aldeyra Therapeutics, Inc. 2023

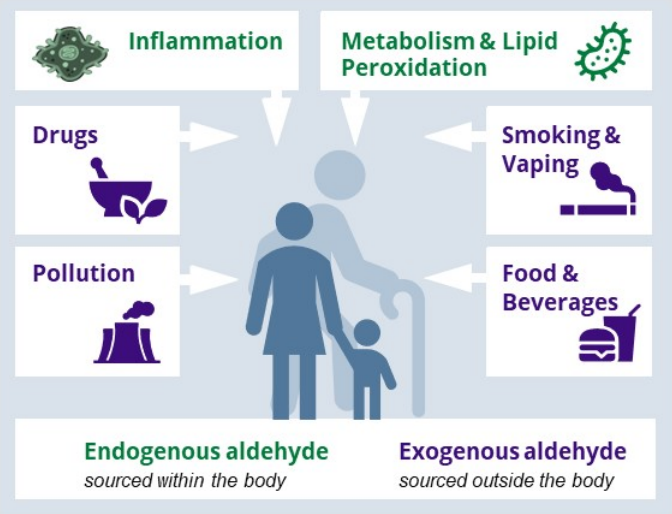
Disclaimers and Forward-Looking Statements

This presentation and various remarks which may be made during this presentation contain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and Section 21E of the Securities Exchange Act of 1934, as amended, including statements regarding Aldeyra's future expectations, plans and prospects, including, without limitation, statements regarding: the outcome and expected timing and results of clinical trials; the adequacy of the data from clinical trials for potential submissions to the FDA; the potential profile and benefit of its product candidates in the indications for which they are developed, including atopic dermatitis; the goals, opportunity and potential for its product candidates, anticipated clinical or regulatory milestones for ADX-2191, ADX-246, ADX-248, and ADX-629 including expectations regarding the results of scheduled FDA meetings, clinical trial initiations and completions and submissions to the FDA; Aldeyra's business, research, development and regulatory plans or expectations; political, economic, legal, social and health risks that may affect Aldeyra's business or the global economy; the structure, timing and success of Aldeyra's planned or pending clinical trials; and expected milestones, market sizing, pricing and reimbursement, competitive position, regulatory matters, industry environment and potential growth opportunities, among other things. The results of earlier preclinical or clinical trials may not be predictive of future results. Forward-looking statements include all statements that are not historical facts and, in some cases, can be identified by terms such as "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.

Forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause Aldeyra's actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. These statements reflect Aldeyra's current views with respect to future events and are based on assumptions and subject to risks and uncertainties, including the development of, and clinical and regulatory plans or expectations for Aldeyra's investigational new drugs (including reproxalap, ADX-2191, ADX-246, ADX-248, and ADX-629), and systems-based approaches, later developments with the FDA that may be inconsistent with Aldeyra's expectations and beliefs, including 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 for the same or different indications, inconsistent expectations regarding FDA acceptance and review of the company's filings and submitted data sets, and Aldeyra's continuing or post-hoc review and quality control analysis of clinical data. Important factors that could cause actual results to differ materially from those reflected in Aldeyra's forward-looking statements are described in Aldeyra's most recent Annual Report on Form 10-K and Quarterly Report on Form 10-Q, as well as Aldeyra's subsequent filings with the Securities and Exchange Commission. All of Aldeyra's development plans and timelines may be subject to adjustment depending on funding, recruitment rate, regulatory review, which regulatory review timeline may be flexible and subject to change based on the regulator's workload and other potential review issues, preclinical and clinical results, and other factors any of which could result in changes to Aldeyra's development plans and programs or delay the initiation, enrolment, completion, or reporting of clinical trials.

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 presentation is provided only as of December 19, 2023, and Aldeyra undertakes no obligation to update any forward-looking statements contained in this presentation on account of new information, future events, or otherwise, except as required by law.

RASP are Toxic, and Represent a Novel, Potentially Broadly Applicable Pharmaceutical Target



RASP affect large classes of proteins, especially those associated with the immune cascade.

RASP = reactive aldehyde species

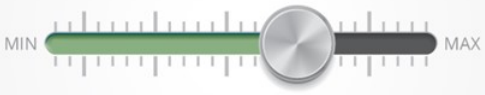
RASP Modulation Represents a Novel Pharmacology

Traditional pharmacology targets specific proteins and is generally limited to two actions: on or off.

Activating or inhibiting specific proteins on a sustained basis, which rarely occurs in nature, may lead to toxicity and could limit activity.

Vs.

RASP modulation may allow for control of protein *systems*, without turning any single protein on or off.

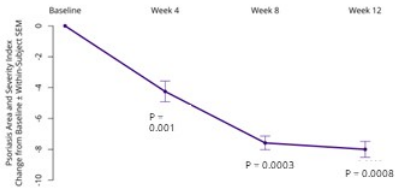


Systems-based pharmacology could potentially lead to broader-based activity with less toxicity associated with activation or inhibition of specific proteins.

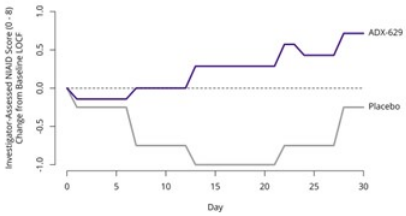
RASP = reactive aldehyde species

ADX-629, a First-in-Class Orally Administered RASP Modulator, Has Demonstrated Activity in Phase 2 Clinical Trials

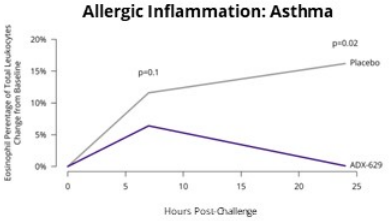
Autoimmune Disease: Psoriasis



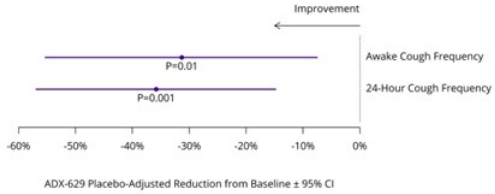
Infectious Disease: COVID-19



Allergic Inflammation: Asthma



Idiopathic Inflammation: Chronic Cough



Signal-finding results of ADX-629 are potentially supportive of the RASP platform for the treatment of systemic immune-mediated diseases.

ADX-629 is an investigational drug candidate. CI = confidence interval. LOCF = last observation carried forward. NIAID = National Institute of Allergy and Infectious Diseases. RASP = reactive aldehyde species. SEM = standard error of measurement. Sources: previously disclosed data on file.

aldeyra

ADX-629 Data Suggest Potential for Next-Generation Investigational RASP Modulators ADX-246 and ADX-248

ADX-246

Oral Administration

... designed to treat immune-mediated systemic diseases thought to be caused or exacerbated by pro-inflammatory RASP.

Pre-clinical studies of ADX-246 demonstrated high affinity for RASP and activity following systemic administration in animal models of sepsis, hepatitis, and atopic dermatitis.

ADX-248

Intravitreal Injection

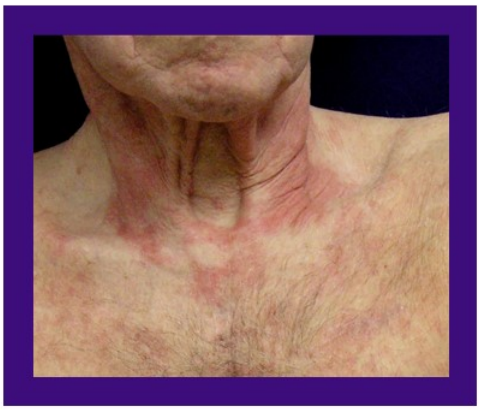
... designed to reduce inflammation and toxic metabolite formation associated with geographic atrophy, a severe form of macular degeneration.

Preclinical studies of ADX-248 demonstrated high affinity for binding retinaldehyde, a key RASP involved in retinal inflammation and the formation of toxic metabolites that accumulate in the retina.

ADX-629 is an investigational drug candidate.

Current Treatment Options for Patients with Mild to Moderate Atopic Dermatitis are Often Sub-Optimal

- Atopic dermatitis is a common skin disease associated with itching and dermal lesions, occurring in children and adults.
- The etiology of atopic dermatitis is generally thought to be caused by immune dysfunction associated with hyperreactivity to endogenous or exogenous factors.
- Moderate to severe patients are often treated with topical corticosteroids and injections, which may be inconvenient and can be associated with toxicity.
- We believe the demand for a safe, tolerable, and orally administered therapy for the treatment of mild to moderate atopic dermatitis patients is substantial.



ADX-629: Phase 2 Clinical Trial Design in Atopic Dermatitis

Design

Single-center, open-label clinical trial of ADX-629 (250mg administered orally twice daily for 90 days) in adults with atopic dermatitis

Inclusion Highlights

- Mild, moderate, or severe atopic dermatitis, defined as an Investigator Global Assessment (IGA) score of ≥2
- Atopic dermatitis body surface area of ≥2%
- An average score of ≥5 on peak pruritus numerical rating scale
- Inadequate response to standard-of-care treatment(s) defined as a failure to maintain remission or achieve a low disease activity state despite stable use of treatment
- Willingness to use emollient over the duration of the trial
- Stable doses of dupilumab or topical corticosteroid continued through at least two weeks after the start of the trial

Primary Endpoint

Treatment-emergent adverse events and serious adverse events

Secondary Efficacy Endpoints

- Investigator global assessment (IGA)
- Eczema Area and Severity Index (EASI)
- Time to flare (i.e., rescue therapy required)

Investigator-assessed

- Patient-Oriented Eczema Measure (POEM)
- Peak Pruritus Numerical Rating Scale (itching)
- Hamilton Depression Rating Scale
- Beck Anxiety Inventory

Patient-reported

ADX-629 is an investigational drug candidate.

Baseline Characteristics

Enrolled Population (N=8)	Mean (SD)
Age	39.9 (14.7)
Atopic dermatitis history (years)	10.9 (8.7)
IGA	3.0 (0.9)
EASI	6.0 (3.7)
POEM	18.9 (4.1)
Peak itching score	7.1 (1.7)

Baseline characteristics are consistent with a mild to moderate adult atopic dermatitis population.

ADX-629 is an investigational drug candidate. IGA = investigator global assessment. EASI = eczema area and severity index. POEM = patient-oriented eczema measure. SD = standard deviation.

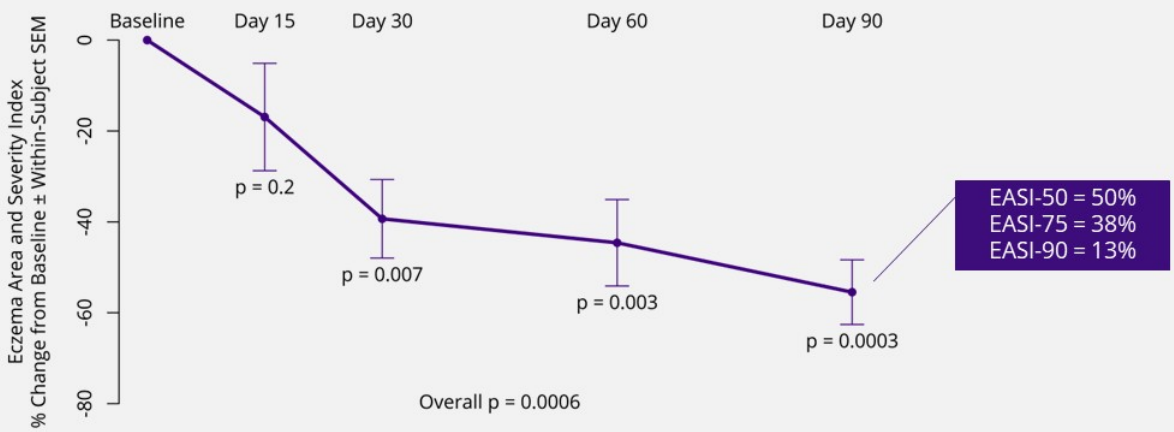
ADX-629 Was Observed to be Well Tolerated and No Safety Signals Were Identified

	Safety Population (N=8)
	Number (%) of Subjects with Treatment-Related Adverse Events
Severe	0
Moderate	0
Mild	2 (25%)

No adverse events led to discontinuation and no rescue therapy was required.

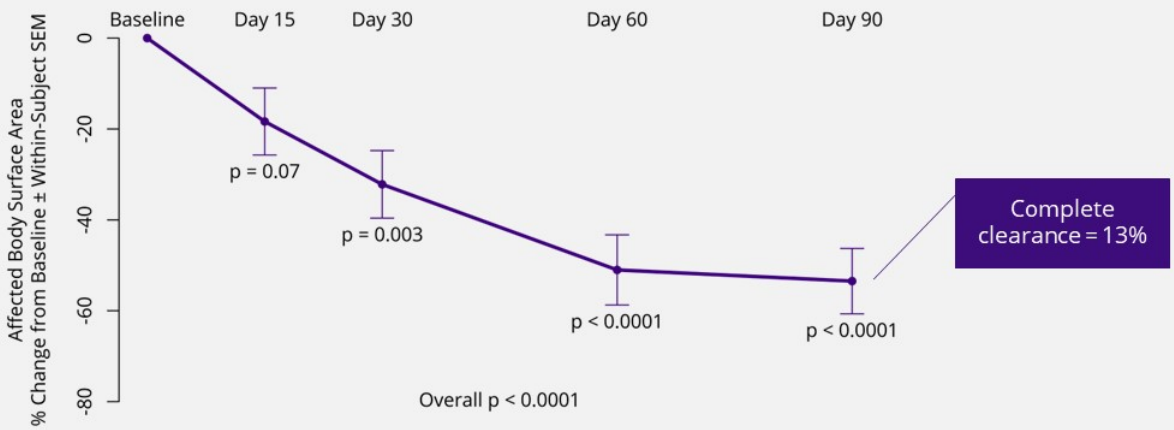
ADX-629 is an investigational drug candidate. Treatment-related adverse events are treatment-emergent adverse events at least possibly related to drug.

Statistically and Clinically Significant Improvement in EASI Score was Observed during Treatment with ADX-629



ADX-629 is an investigational drug candidate. EASI = eczema area and severity index (investigator-assessed). SEM = standard error of measurement.

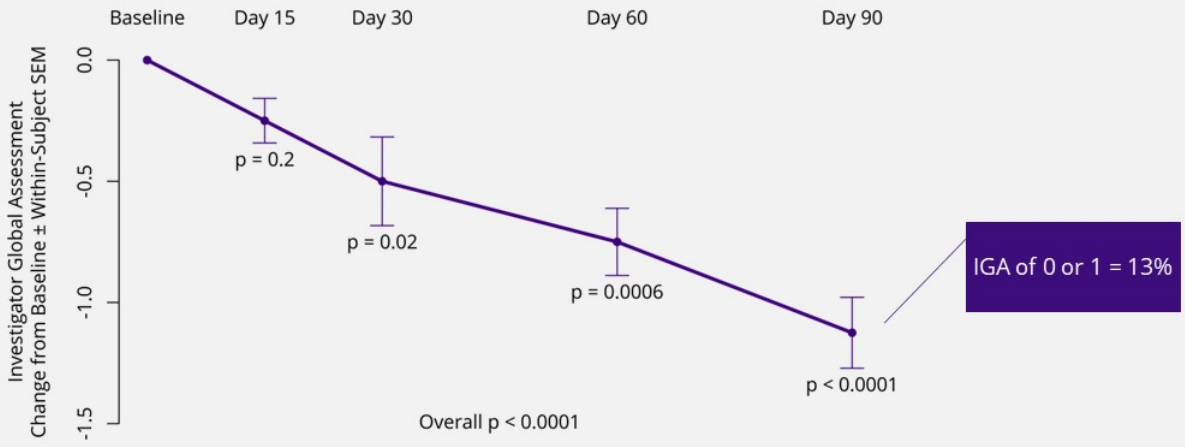
Statistically and Clinically Significant Improvement in Affected Body Surface Area was Observed during Treatment with ADX-629



ADX-629 is an investigational drug candidate. Affected body surface area was investigator-assessed. SEM = standard error of measurement.

aldeyra

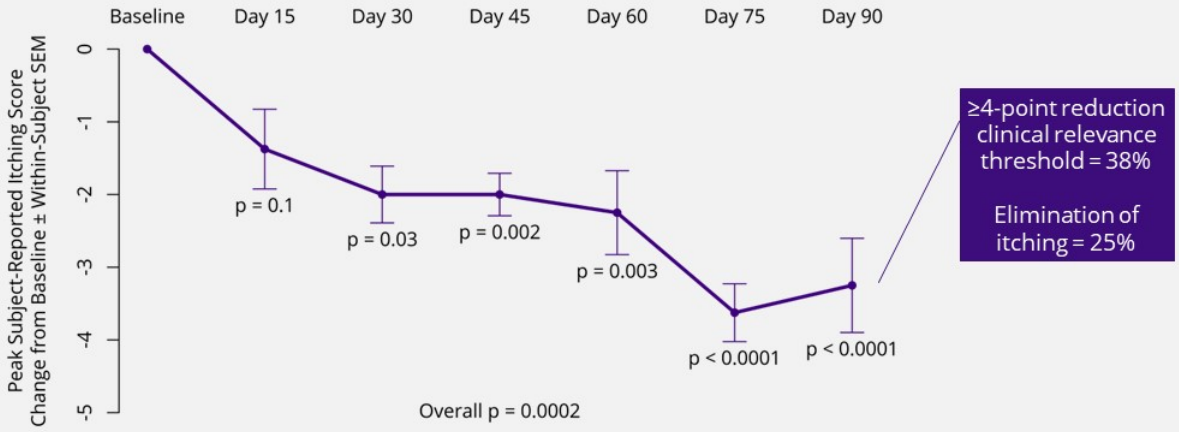
Statistically and Clinically Significant Improvement in IGA was Observed during Treatment with ADX-629



ADX-629 is an investigational drug candidate. IGA = investigator global assessment; IGA of 0 is clear and IGA of 1 is almost clear. SEM = standard error of measurement.

aldeyra

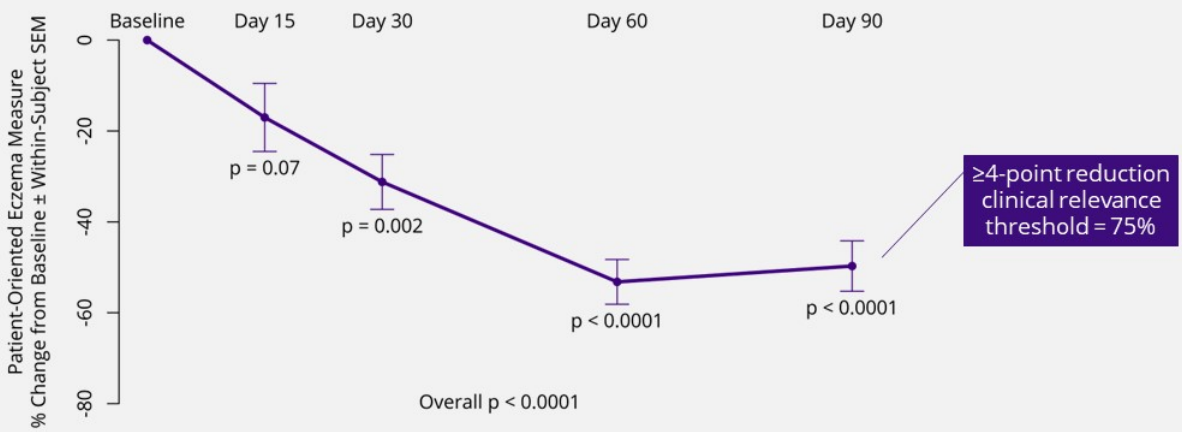
Statistically and Clinically Significant Improvement in Peak Itching Score was Observed during Treatment with ADX-629



ADX-629 is an investigational drug candidate. Patient-reported peak itching score was assessed by the Peak Pruritus Numerical Rating Scale. SEM = standard error of measurement.

aldeyra

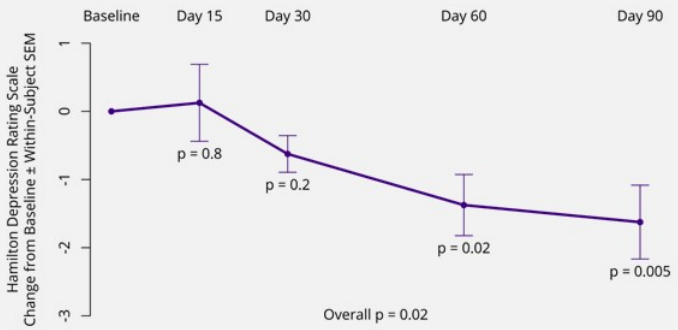
Statistically and Clinically Significant Improvement in POEM was Observed during Treatment with ADX-629

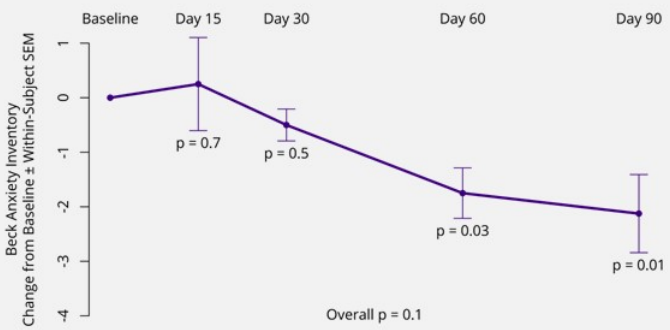


ADX-629 is an investigational drug candidate. POEM = patient-oriented eczema measure (patient-reported). SEM = standard error of measurement.

aldeyra

Improvement in Assessments of Depression and Anxiety was Observed during Treatment with ADX-629



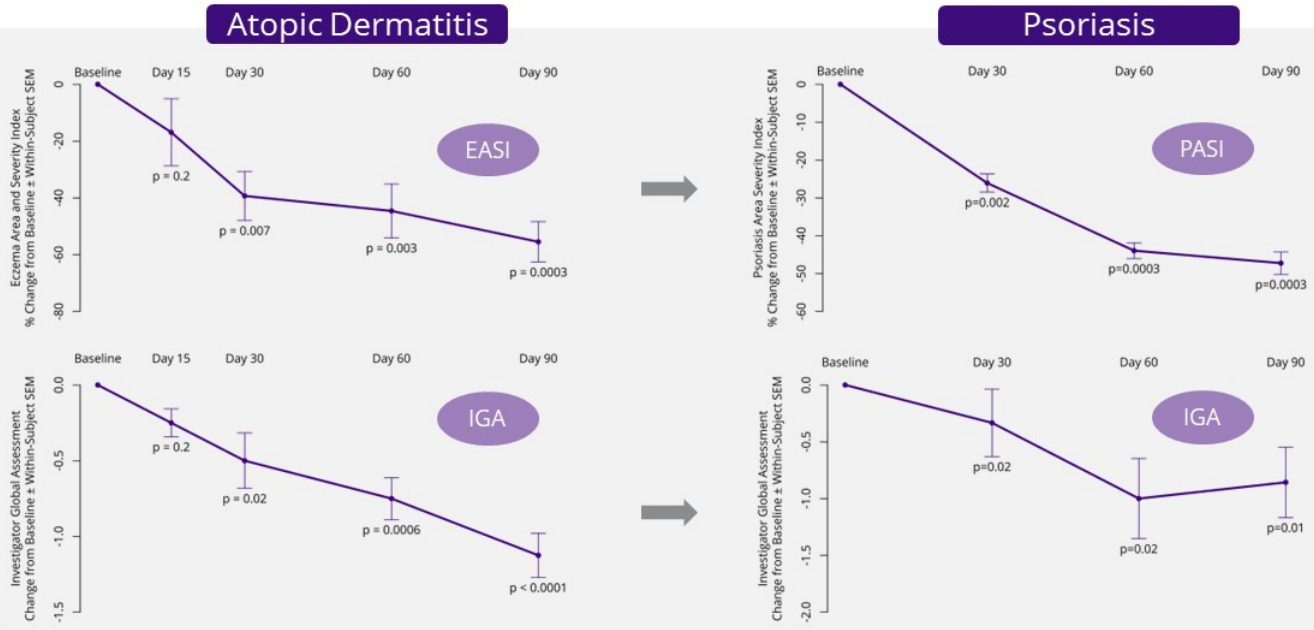


Atopic dermatitis is associated with anxiety, depression, and suicidal ideation.†

ADX-629 is an investigational drug candidate. SEM = standard error of measurement. †Allergy. 73(1): 214-220, 2018.

aldeyra

The Observed Activity of ADX-629 in Atopic Dermatitis is Consistent with the Observed Activity of ADX-629 in Psoriasis



ADX-629 is an investigational drug candidate. SEM = standard error of measurement.

ADX-629 Demonstrated Broad Investigator-Assessed and Patient-Reported Activity in Atopic Dermatitis

- **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 completely cleared 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)
- **ADX-246**, an analog of ADX-629, expected **to be advanced to Phase 1/2**, multicenter, placebo-controlled clinical trial **in healthy volunteers and atopic dermatitis patients**

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.**

ADX-629 is an investigational drug candidate.

Atopic Dermatitis is the First of Aldeyra's RASP Programs to Advance to Formal Development with ADX-246

- Given the positive signal-finding results from ADX-629, **ADX-246**, which we believe is **the most potent RASP modulator ever developed**, is expected to be **advanced to clinical testing in Phase 1/2 clinical trial in** heathy volunteers and **atopic dermatitis** patients.
- The **Phase 2** portion of the clinical trial is expected to randomize 20 patients to ADX-246 and 10 patients to placebo for 90 days of treatment, and is expected **to begin in the first half of 2024.**
- **Results** are expected in the **second half of 2024.**

ADX-246 is an investigational drug candidate. Clinical trial initiations and results are subject to regulatory review, patient recruitment, and other factors.

aldeyra

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

- **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)--December 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.

Contacts

Investor & Media:
David Burke
Tel: (917) 618-2651
investorrelations@aldeyra.com