Aldeyra Therapeutics to Announce Top-Line Data for Systemic RASP Modulator ADX-629 at 2022 Research & Development Day

March 29, 2022

- *Signs of Pharmacodynamic and Clinical Activity Generated Across Three Phase 2 Proof-of-Concept Clinical Trials in Patients with Immune-Mediated Disease; No Safety or Tolerability Issues Observed*
- *ADX-629 to Be Advanced to New Development Indications: Ethanol Toxicity, Chronic Cough, Minimal Change Disease, and Sjögren-Larsson Syndrome*
- *Novel RASP Modulators for Systemic and Retinal Disease Expected to Initiate Clinical Testing in 2023*
- *Live Audio Webcast of R&D Day Scheduled to Begin at 10:00 a.m. ET Today*

LEXINGTON, Mass.--(BUSINESS WIRE)--Mar. 29, 2022-- Aldeyra Therapeutics, Inc. (Nasdaq: ALDX) (Aldeyra), a biotechnology company discovering and developing innovative therapies for the treatment of immune-mediated diseases, today will announce at its 2022 Research & Development Day that three clinical trials of ADX-629, a first-in-class orally administered RASP modulator, generated signs of pharmacodynamic and clinical activity consistent with broad-based reduction in pathologic inflammation.

“The promising results exhibited by ADX-629 represent the first clinical data supportive of RASP modulation as a novel pharmacology for the potential treatment of systemic disease,” stated Todd C. Brady, M.D., Ph.D., President and CEO of Aldeyra. “Accordingly, we plan to advance our proprietary RASP modulator platform, which includes ADX-629 and other novel molecules, into new indications mediated by RASP, effecting a new milestone for Aldeyra as we continue to expand our focus to systemic and retinal diseases.”

Top-Line Data from Phase 2 Proof-of-Concept Trials of ADX-629

Autoimmune Disease: Psoriasis

Following treatment of ten moderate psoriasis patients with ADX-629 for 12 weeks, psoriasis area and severity index (PASI) scores were statistically significantly decreased (p=0.0008 vs. baseline at Week 12), and peak PASI 50% and PASI 75% responder percentages were 57% (p=0.001) and 25% (p=0.051), respectively. Investigator global assessment scores decreased over the duration of treatment (p=0.01 vs. baseline at Week 12). Lesional pan-gene expression analysis suggested a trend toward normalization of global gene expression patterns; by Week 12 no gene expression pathways in lesional tissue were dysregulated compared to non-lesional skin. Plasma levels of the commonly described pro-inflammatory RASP malondialdehyde were reduced relative to baseline as soon as four weeks after initiation of treatment (p=0.02).

Allergic Inflammation: Asthma

In a placebo-controlled crossover trial of eight mild asthma patients treated for 7 days, asthma symptom scores and sputum eosinophil cell counts were numerically reduced following treatment with ADX-629 relative to treatment with placebo. Compared to placebo treatment, treatment with ADX-629 led to statistically significant reductions in plasma levels of the pro-inflammatory cytokines IL-5 (p=0.02) and TNFα (p<0.0001), and numerical reductions in plasma levels of malondialdehyde.

Infectious Disease: COVID-19

Following treatment of 11 mild to moderate COVID-19 patients with ADX-629 or placebo for four weeks, change from baseline in the National Institute of Allergy and Infectious Diseases Score (1=death, 8=no activity limitation) was numerically higher in ADX-629-treated patients (n=7) than in placebo-treated patients (n=4) over all days assessed. Consistent with the clinical findings, relative to placebo-treated patients, reductions in plasma levels of the cytokines CXCL9 (p=0.0008), IFNγ (p=0.02), and TNFα (p=0.07) were observed in patients treated with ADX-629.

Across all three clinical trials, in patients treated with ADX-629, no safety concerns were evident from adverse events and there were no serious adverse events observed.

ADX-629 Advanced to New Indications

Today’s R&D Day will include a presentation from Geoffrey M. Thiele, Ph.D., Umbach Professor of Rheumatology in the Department of Internal Medicine at the University of Nebraska Medical Center, who will discuss new results from preclinical studies indicating consistent activity of ADX-629 in reducing hepatic inflammation, lowering RASP, and improving lipid profiles in animals and in human liver tissue exposed to ethanol.

Aldeyra also will announce the advancement of ADX-629 to new clinical development indications: ethanol toxicity; chronic cough; minimal change disease, a rare renal disease that commonly afflicts children; and Sjögren-Larsson Syndrome, a rare inborn error of aldehyde metabolism. Results from the ethanol toxicity trial are expected in the second half of 2022 and results from the chronic cough, minimal change disease, and Sjögren-Larsson Syndrome trials are expected in 2023.

Webcast Details

The R&D Day presentations are scheduled to begin at 10:00 a.m. (ET) today, March 29, 2022, in New York, NY. A live audio webcast of the presentation and a slide deck will be available via the company's Investor Relations website at https://ir.aldeyra.com/. Following the live webcast, an

archived version will be available on the website for 90 days.

About Aldeyra Therapeutics

Aldeyra Therapeutics discovers and develops innovative therapies designed to treat immune-mediated diseases. Our approach is to develop therapies 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. Two of our lead product candidates, reproxalap and ADX-629, target pre-cytokine, systems-based mediators of inflammation known as RASP (reactive aldehyde species). Reproxalap is in Phase 3 clinical trials in patients with dry eye disease and allergic conjunctivitis. ADX-629, an orally administered RASP modulator, is in Phase 2 clinical testing. Our pipeline also includes ADX-2191 (intravitreal methotrexate 0.8%), in development for the prevention of proliferative vitreoretinopathy and the treatment of retinitis pigmentosa and primary vitreoretinal lymphoma. 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 plans and expectations for ADX-629 and its proprietary RASP modulation platform, the anticipated timing of commencement of clinical trials and announcement of clinical trial results. 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," "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 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 review and quality control analysis of clinical data, including P values, Aldeyra's ability to design clinical trials with protocols 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 or smaller preclinical or 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) 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 related 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, which is 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 March 31, 2022, expected to be filed with the SEC in the second quarter of 2022.

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.

View source version on businesswire.com: https://www.businesswire.com/news/home/20220328005825/en/

Corporate Contact:
Joshua Reed
Aldeyra Therapeutics, Inc.
Tel: 781-761-4904 ext. 218
jreed@aldeyra.com

Investor & Media Contact:
Scott Solomon
Sharon Merrill Associates, Inc.
Tel: 857-383-2409
ALDX@investorrelations.com

Source: Aldeyra Therapeutics, Inc.