Aldeyra Therapeutics Enrolls First Patient in Phase 2 Clinical Trial of ADX-629 in Atopic Dermatitis

April 6, 2023

Top-Line Results from Part 1 of the Trial Expected in the Second Half of 2023

LEXINGTON, Mass.--(BUSINESS WIRE)--Apr. 6, 2023-- Aldeyra Therapeutics, Inc. (Nasdaq: ALDX) (Aldeyra) today announced enrollment of the first patient in the Phase 2 clinical trial of orally administered RASP modulator ADX-629, an investigational new drug, for the treatment of atopic dermatitis.

The multicenter, adaptive, two-part Phase 2 clinical trial will evaluate the safety and efficacy of ADX-629 alone and in combination with standard of care in adults with mild, moderate, or severe atopic dermatitis. In Part 1, approximately 10 patients will receive open-label ADX-629 twice daily for 90 days. Outcomes will include improvement in Investigator Global Assessment and Eczema Area and Severity Index scores. Top-line results from Part 1 are expected in the second half of 2023. Pending the results of Part 1, Part 2 will randomize patients to either ADX-629 or placebo treatment twice daily for 90 days.

“Atopic dermatitis, a chronic hypersensitivity condition characterized by dry, itchy, and inflamed skin, affects an estimated 16.5 million adults and more than 9.6 million children in the United States,[1]” stated Todd C. Brady, M.D., Ph.D., President and Chief Executive Officer of Aldeyra. “ADX-629, if approved, would be the first RASP modulator and one of the few orally administered therapies indicated for the treatment of atopic dermatitis.”

In patients with atopic dermatitis, the pro-inflammatory RASP malondialdehyde is elevated compared to levels observed in healthy controls.[2,3] By lowering RASP levels, ADX-629 may diminish the inflammation associated with atopic dermatitis. ADX-629 has previously demonstrated immune-modulating activity in clinical trials of patients with psoriasis, asthma, and COVID-19.

In addition to atopic dermatitis, ADX-629 also is being evaluated in Phase 2 clinical trials for the treatment of chronic cough, idiopathic nephrotic syndrome, and Sjögren-Larsson Syndrome. Top-line results from the chronic cough trial are expected in the first half of 2023. Top-line results from Part 1 of the idiopathic nephrotic syndrome and Sjögren-Larsson Syndrome trials 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.

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 primary vitreoretinal lymphoma (under U.S. Food and Drug Administration New Drug Application Priority Review), proliferative vitreoretinopathy, and other rare sight-threatening retinal 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 the expected timing of top-line results of Part 1 of the Phase 2 clinical trial of ADX-629 for the treatment of atopic dermatitis, expected timing of top-line results of the Phase 2 clinical trial of ADX-629 for the treatment of chronic cough, expected timing of top-line results from Part 1 of the idiopathic nephrotic syndrome and Sjögren-Larsson Syndrome trials, expected timing of initiation of the Phase 2 clinical trial of ADX-629 in moderate alcohol-associated hepatitis, and Aldeyra’s plans and expectations for ADX-629, including statements regarding Part 2 of the Phase 2 clinical trial of ADX-629 for the treatment of atopic dermatitis. 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, 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, 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, 2023, expected to be filed with the SEC in the second 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.

[1] https://nationaleczema.org/research/eczema-facts.

[2] Heliyon 28;7(3): e06621, 2021.

[3] J Clin Diagn Res. 7(12): 2683-5, 2013.

View source version on businesswire.com: https://www.businesswire.com/news/home/20230405005610/en/

Investor & Media
Scott Solomon
Sharon Merrill Associates, Inc.
Senior Vice President
(857) 383-2409
ALDX@investorrelations.com

Source: Aldeyra Therapeutics, Inc.