Aldeyra Therapeutics Enrolls First Patient in Phase 3 Clinical Trial Designed to Enable Potential Resubmission of New Drug Application of Reproxalap in Dry Eye Disease

May 8, 2024

Clinical Results and Potential New Drug Application Submission Expected in the Second Half of 2024

LEXINGTON, Mass.--(BUSINESS WIRE)--May 8, 2024-- Aldeyra Therapeutics, Inc. (Nasdaq: ALDX) (Aldeyra), a biotechnology company devoted to discovering and developing innovative therapies designed to treat immune-mediated and metabolic diseases, today announced enrollment of the first patient in a Phase 3 dry eye chamber clinical trial designed to enable a potential resubmission of the New Drug Application (NDA) of topical ocular 0.25% reproxalap, an investigational RASP modulator, for the treatment of dry eye disease.

Contingent on positive results from the clinical trial, Aldeyra expects to resubmit the NDA of reproxalap for the treatment of dry eye disease to the U.S. Food and Drug Administration (FDA) in the second half of 2024. Aldeyra intends to include in the potential NDA resubmission a draft label describing chronic and acute improvement in symptoms and ocular redness. To Aldeyra's knowledge, the draft label could represent the first dry eye disease label that incorporates clinical data assessed acutely in a dry eye chamber, and potentially the first dry eye disease label that includes reduction in ocular redness for a chronically administered drug. Per FDA guidance, the planned review period for the potential NDA resubmission is expected to be six months.

In the clinical trial, patients are administered vehicle (the drug product without the active ingredient) before and during exposure to a dry eye chamber. Qualifying patients are subsequently randomized to receive either reproxalap or vehicle before and during exposure to an additional dry eye chamber. Approximately 110 patients are expected to be enrolled to assess the primary endpoint of ocular discomfort. In four previously completed dry eye chamber clinical trials of reproxalap, when analyzed in aggregate with the trial design and statistical plan recently discussed with the FDA, ocular discomfort in the dry eye chamber following treatment with reproxalap was statistically lower than that of vehicle (p=0.0003).

A clinical trial at a different dry eye chamber, in addition to a traditional six-week field clinical trial, are expected to be conducted in parallel as part of a comprehensive strategy designed to account for disease heterogeneity and potential differences in clinical sites and environment. Consistent with previously disclosed guidance and based on the current operating plan, cash, cash equivalents, and marketable securities of $133.0 million as of March 31, 2024 are projected to be sufficient to fund operations to beyond the end of 2026.

About Aldeyra

Aldeyra Therapeutics is a biotechnology company devoted to discovering innovative therapies designed to treat immune-mediated and metabolic diseases. Our approach is to develop pharmaceuticals that modulate protein 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 immune-mediated and metabolic diseases. Our late-stage 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 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 reproxalap; the outcome and expected timing and the results of Aldeyra's planned clinical trials, including planned and ongoing clinical trials for reproxalap; the outcome and timing of the FDA's review, acceptance and/or approval of a NDA resubmission for reproxalap and the adequacy of the data included in the original NDA and the potential NDA resubmission; Aldeyra's expectations regarding the labeling of reproxalap, if approved; and Aldeyra's projected cash runway. 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, issuing a complete response letter, or requiring additional clinical trials or data prior to review or approval of such filings or in connection with resubmissions 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, 2023, and Aldeyra's Quarterly Report on Form 10-Q for the quarter ended March 31, 2024, which are on file with the Securities and Exchange Commission (SEC) and available on the SEC's website at https://www.sec.gov/.

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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