Aldeyra Therapeutics Announces Completion of Enrollment in Phase 3 TRANQUILITY-2 Trial in Patients with Dry Eye Disease

April 5, 2022

Top-Line Results from TRANQUILITY-2 Expected in the Second Quarter of 2022

LEXINGTON, Mass.--(BUSINESS WIRE)--Apr. 5, 2022-- Aldeyra Therapeutics, Inc. (Nasdaq: ALDX) (Aldeyra), a biotechnology company discovering and developing innovative therapies for the treatment of immune-mediated diseases, today announced completion of enrollment in the Phase 3 TRANQUILITY-2 Trial of 0.25% reproxalap ophthalmic solution (reproxalap) in patients with dry eye disease.

The multi-center, double-masked, parallel-group TRANQUILITY-2 Trial enrolled 361 patients randomized to receive either reproxalap or vehicle over two days. On the first day, patients received four doses, and Schirmer testing (a measure of tear volume) was performed before and after the fourth dose. On the second day, doses were administered just prior to and at the mid-point of a 90-minute dry eye chamber with minimal humidity, high airflow, and forced visual tasking. The primary endpoints of the TRANQUILITY-2 Trial are Schirmer test on the first day of dosing and ocular redness on the second day of dosing during the dry eye chamber. Top-line results from the trial are expected to be announced this quarter.

Based on the results of the previously completed Phase 2 and TRANQUILITY clinical trials, TRANQUILITY-2 is at least 90% powered to detect a statistically significant difference in Schirmer test or ocular redness endpoints. If successful in meeting one of the primary endpoints, TRANQUILITY-2 could complete New Drug Application (NDA) submission requirements for demonstration of improvement in an objective sign of dry eye disease.

Per draft U.S. Food and Drug Administration (FDA) guidance, to be considered for regulatory approval in the United States, a product candidate for the treatment of dry eye disease must demonstrate efficacy in an objective sign in at least two clinical trials and efficacy in a subjective symptom in at least two clinical trials. To satisfy the symptom efficacy requirements, Aldeyra intends to submit two previously completed 12-week adequate and well-controlled symptom trials that pre-specified patient-reported ocular dryness score as a primary endpoint, the Phase 3 RENEW-Part 1 Trial and the Formulation Phase 2 clinical trial.

Aldeyra's previously announced Phase 2 clinical trial achieved the primary endpoint of ocular redness, an approvable sign of dry eye disease. Pending discussion with the FDA and the results of TRANQUILITY-2, Aldeyra may submit two pivotal trials for either ocular redness (Phase 2 and TRANQUILITY-2) or Schirmer test (TRANQUILITY and TRANQUILITY-2), or two trials for both signs (Phase 2, TRANQUILITY, and TRANQUILITY-2) if ocular redness and Schirmer test are achieved in TRANQUILITY-2. Either Phase 2 or Phase 3 clinical trials can be submitted as pivotal, provided that the trials are adequate and well-controlled.

Pending enrollment of the ongoing 12-month safety trial of reproxalap in dry eye disease patients and the outcome of TRANQUILITY-2, Aldeyra's dry eye disease NDA submission is expected to occur mid-2022.

More information on TRANQUILITY-2 can be found on www.clinicaltrials.gov (NCT05062330).

About Reproxalap

Reproxalap, an investigational new drug, is a first-in-class small-molecule modulator of RASP (reactive aldehyde species), which are elevated in ocular and systemic inflammatory disease. Reproxalap's mechanism of action has been supported by the demonstration of statistically significant and clinically relevant activity in multiple physiologically distinct late-phase clinical indications. Reproxalap is currently in Phase 3 clinical development as a 0.25% ophthalmic solution for the treatment of dry eye disease and allergic conjunctivitis, two of the largest markets in ophthalmology.

About Aldeyra

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 development plans and expectations for its product candidates, including plans and expectations relating to current or future clinical development and regulatory progress of reproxalap in dry eye disease. 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.

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