Aldeyra Therapeutics Announces Achievement of Primary Endpoint of Ocular Redness in Randomized, Double-Masked, Vehicle-Controlled Phase 2 Clinical Trial in Dry Eye Disease

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LEXINGTON, Mass.--(BUSINESS WIRE)--Nov. 2, 2021-- Aldeyra Therapeutics, Inc. (Nasdaq: ALDX) (Aldeyra) today announced achievement of the primary endpoint of ocular redness in a randomized, double-masked, vehicle-controlled Phase 2 clinical trial in patients with dry eye disease.

The clinical trial enrolled 158 patients: 80 patients were randomized to receive 0.25% reproxalap ophthalmic solution, and 78 patients were randomized to receive vehicle ophthalmic solution. Patients received four doses one day prior to and two doses during exposure to a 90-minute dry eye chamber with minimal humidity, high airflow, and forced visual tasking.

Based on final enrollment and data from the run-in cohort of TRANQUILITY, Aldeyra's ongoing Phase 3 trial in dry eye disease, the Phase 2 trial exceeded 90% power to detect statistical significance in the primary endpoint of ocular redness over all time points in aggregate in the dry eye chamber. Ocular redness scores in the reproxalap group were observed to be statistically lower than those of vehicle ($p = 0.016$). Additionally, Schirmer's test scores assessed after the first dose were directionally in favor of reproxalap over vehicle and approached statistical significance ($p = 0.068$). Mean visual analog scale ocular dryness and ocular discomfort scores were lower in reproxalap-treated subjects than in vehicle-treated subjects at all of the 18 time points when symptoms were assessed in the dry eye chamber, including the first time point in the chamber, although differences did not reach statistical significance. Tear RASP level results from the trial are expected to be available later this quarter. Consistent with the clinical experience of reproxalap in more than 1,300 patients, there were no observed safety or tolerability concerns in the trial; the most common adverse event was mild and transient instillation site discomfort lasting less than one minute and similar to many prescribed topical ophthalmic medications for anterior segment inflammation.

"Complementing our rapid and durable symptom control evidenced in three 12-week clinical trials, we are excited to announce achievement of statistical significance of an objective sign of dry eye disease in a well-controlled clinical trial," stated Todd C. Brady, M.D., Ph.D., President and Chief Executive Officer of Aldeyra. "Ocular redness may be the only dry eye disease sign that is of importance to patients, and the reduction in redness observed in this trial following reproxalap treatment potentially represents a major advance for the chronic treatment of dry eye disease."

Two Phase 3 clinical trials of reproxalap in patients with dry eye disease, TRANQUILITY and TRANQUILITY-2, are ongoing. For each trial, the planned enrollment is 300 patients, and the primary endpoint is ocular redness. Pending confirmation of statistical powering and other analyses of the Phase 2 clinical trial results announced today, results from the TRANQUILITY trials are expected to be released by the end of the year.

About Reproxalap

Reproxalap, an investigational new drug, is a novel small-molecule immune-modulating covalent inhibitor of RASP (reactive aldehyde species), which are elevated in ocular and systemic inflammatory disease. Reproxalap's mechanism of action has been validated with 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 ocular inflammatory diseases that often occur together.

About Dry Eye Disease

Dry eye disease is a common inflammatory disease estimated to affect 34 million or more adults in the United States.[1] The disease is characterized by insufficient moisture and lubrication in the anterior surface of the eye, leading to dryness, inflammation, pain, discomfort, irritation, diminished quality of life, and in severe cases, permanent vision impairment. Among many physicians and patients, existing therapy for dry eye disease is generally regarded as inadequate and often requires weeks or months to demonstrate activity. In patients with dry eye disease, pro-inflammatory RASP may contribute to ocular inflammation and changes in tear lipid composition. By diminishing RASP levels, Aldeyra's lead RASP inhibitor reproxalap represents a novel and differentiated approach for the treatment of the symptoms and signs of dry eye disease.

About Aldeyra Therapeutics

Aldeyra Therapeutics is a biotechnology company developing novel immune-modulating therapies to treat ocular and systemic diseases. Two of the company's lead product candidates, reproxalap and ADX-629, target RASP, which are pre-cytokine, systems-based mediators of inflammation. Reproxalap is being evaluated in Phase 3 clinical trials in patients with dry eye disease and allergic conjunctivitis. The company's clinical pipeline also includes ADX-2191 (methotrexate for intravitreal injection), a drug candidate in Phase 3 testing for the prevention of proliferative vitreoretinopathy. 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 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, 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 smaller clinical trials or portions of clinical trials may not accurately predict results of larger scale 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, 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, 2020 and Quarterly Report on Form 10-Q for the quarter ended September 30, 2021, 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.

[1] Paulsen AJ, Cruickshanks KJ, Fischer ME, Huang GH, Klein BE, Klein R, Dalton DS. Dry eye in the beaver dam offspring study: prevalence, risk factors, and health-related quality of life. Am J Ophthalmol. 2014 Apr;157(4):799-806. doi: 10.1016/j.ajo.2013.12.023. Epub 2014 Jan 2. PMID: 24388838; PMCID: PMC3995164.

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