Aldeyra Therapeutics Submits New Drug Application to the U.S. Food and Drug Administration for Reproxalap for the Treatment of Signs and Symptoms of Dry Eye Disease

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LEXINGTON, Mass.--(BUSINESS WIRE)--Nov. 29, 2022-- Aldeyra Therapeutics, Inc. (Nasdaq: ALDX) (Aldeyra) today announced the submission of a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for topical ocular reproxalap, an investigational new drug candidate, for the treatment of signs and symptoms of dry eye disease.

The NDA submission is supported by safety and efficacy data from five adequate and well-controlled clinical trials encompassing data for ocular dryness symptom score, ocular redness, Schirmer test, and Schirmer test ≥10 mm responder analysis. The regulatory package includes activity ranging from within minutes of drug administration to up to 12 weeks of treatment, crossover and parallel-group clinical trial designs, and assessment in dry eye chamber challenge and natural environment settings. Topical ocular reproxalap has been studied in more than 2,000 patients with no observed clinically significant safety concerns; mild and transient instillation site irritation is the most commonly reported adverse event in clinical trials.

“The NDA submission for reproxalap is, to our knowledge, the most comprehensive regulatory package ever for a dry eye disease drug candidate,” stated Todd C. Brady, M.D., Ph.D., Aldeyra’s President and Chief Executive Officer. “With data suggesting activity within minutes of administration, reproxalap could provide an important treatment option for the millions of dry eye patients who generally regard currently available therapies as inadequate.”

If approved, reproxalap would be the first marketed RASP (reactive aldehyde species) modulator, representing a novel, systems-based pharmacology involving a family of small molecule targets that affect a broad array of protein mediators. Reproxalap is the lead product candidate in Aldeyra’s RASP modulator platform, which includes systemic disease pipeline candidates ADX-629 and related analogs. ADX-629, which successfully completed proof-of-concept trials in psoriasis, asthma, and COVID-19, is currently in Phase 2 clinical trials for chronic cough, alcoholic hepatitis, minimal change disease, and Sjögren-Larsson Syndrome. Top-line results in alcoholic hepatitis are expected by the end of 2022.

In addition to dry eye disease, reproxalap is in late-stage development for allergic conjunctivitis, a condition that is commonly associated with dry eye disease. Results of the Phase 3 INVIGORATE-2 Trial are expected in 2023.

About Reproxalap

Reproxalap, an investigational new drug candidate, 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.

About Dry Eye Disease

Dry eye disease is a common inflammatory disease estimated to affect 39 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, RASP may contribute to ocular inflammation, diminished tear production, ocular redness, and changes in tear lipid composition.[2] By diminishing RASP levels, Aldeyra’s lead RASP modulator reproxalap represents a novel and differentiated approach for the treatment of the symptoms and signs of dry eye disease.

About Aldeyra

Aldeyra Therapeutics is a clinical-stage biotechnology company developing innovative therapies designed to treat immune-mediated diseases. Our approach is to discover 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 pre-commercial product candidates are reproxalap, a potential treatment for dry eye disease and allergic conjunctivitis, and ADX-2191, a potential treatment for primary vitreoretinal lymphoma, proliferative vitreoretinopathy, and other rare sight-threatening retinal diseases. In addition, we are developing other product candidates, including ADX-629 and chemically related molecules, for the potential treatment of systemic and retinal immune-mediated 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 Aldeyra's future expectations, plans and prospects, including without limitation statements regarding Aldeyra’s belief in the adequacy of the data it submitted in the NDA for reproxalap; the potential for FDA acceptance of an NDA for reproxalap; the potential for regulatory approval and commencement of commercialization of reproxalap and Aldeyra’s goals as to timing; the potential profile and benefit of reproxalap in dry eye disease; and the expected timing of results of the Phase 3 INVIGORATE-2 Trial in allergic conjunctivitis and ADX-629 in alcoholic hepatitis. 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,” “on schedule,” “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, 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; updated or refined data based on Aldeyra's continuing or post-hoc review and quality control analysis of clinical data, Aldeyra's ability to design clinical trials with protocols, data analysis methodologies, 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 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) 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 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 subsequent 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, and Aldeyra's Quarterly Report on Form 10-Q for the quarter ended September 30, 2022, 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] Company estimates and Paulsen AJ, Cruickshanks KJ, Fischer ME, et al. Dry eye in the beaver dam offspring study: prevalence, risk factors, and health-related quality of life. Am J Ophthalmol. 2014;157(4):799-806.

[2] Choi W, Lian C, Ying L, Kim GE, You IC, Park SH, Yoon KC. Expression of Lipid Peroxidation Markers in the Tear Film and Ocular Surface of Patients with Non-Sjogren Syndrome: Potential Biomarkers for Dry Eye Disease. Curr Eye Res. 2016 Sep;41(9):1143-9. doi: 10.3109/02713683.2015.1098707. Epub 2016 Jan 5. PMID: 26731289.

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