Aldeyra Therapeutics Announces New Drug Application (NDA) Development Plans for Dry Eye Disease

July 7, 2020

- *Top-Line Results from First of Two Planned Clinical Trials Based on Tear RASP Levels Expected by the End of 2020*
- *New Drug Application Submission for Reproxalap in Dry Eye Disease Expected by the End of 2021*
- *Based on Current Operating Plans, Current Cash Expected to Support Operations into 2022, Consistent with Prior Guidance*

LEXINGTON, Mass.--(BUSINESS WIRE)--Jul. 7, 2020-- Aldeyra Therapeutics, Inc. (Nasdaq: ALDX) (Aldeyra), a clinical-stage biotechnology company focused on the development of novel therapies with the potential to improve the lives of patients with immune-mediated diseases, today announced development plans to support a New Drug Application (NDA) for the novel investigational reactive aldehyde species (RASP) inhibitor reproxalap in dry eye disease. Based on U.S. Food and Drug Administration (FDA) meeting minutes, Aldeyra intends to initiate two clinical trials to assess the activity of reproxalap in reducing tear levels of RASP, pro-inflammatory mediators recently accepted by the FDA as an objective sign of dry eye disease.

Top-line results from the first of the RASP trials are expected by the end of 2020, pending potential disruptions due to the COVID-19 pandemic. In addition, a safety trial in dry eye disease patients is expected to be initiated in the fourth quarter of 2020. NDA submission is expected in late 2021.

“Aldeyra’s written meeting minutes with the FDA confirming the use of RASP as an objective sign for the treatment of dry eye disease is a positive step in the regulatory science of novel treatments for ocular surface disease,” stated Gary D. Novack, Ph.D., Professor of Ophthalmology at the School of Medicine at University of California, Davis, President of PharmaLogic Development, Inc., and Chair of the Tear Film and Ocular Surface Society DEWS (Dry Eye Workshop) II Clinical Trial Design Group. “RASP assessment is a measurement of the mechanism of action of reproxalap, and represents a potentially important biomarker-based approach. This announcement comes in a context where we have few biomarkers in pharmacotherapy for ocular diseases, and no regulatory-based biomarkers in the treatment of ocular surface disease.”

Assessment of RASP in the two planned trials is expected after single and multiple doses of drug over two days. Investigational new drug reproxalap covalently binds RASP via a series of reactions that occur rapidly in vitro, and statistically reduced RASP levels in the tears of dry eye patients in a Phase 2a clinical trial.

Aldeyra also reiterated financial guidance that, based on current operating plans, cash, cash equivalents, and marketable securities are sufficient to support operations into 2022, including completion of the two planned RASP trials and the company’s second Phase 3 clinical trial in allergic conjunctivitis, the INVIGORATE Trial.

“With only one drug approved in the United States for the treatment of the symptoms and signs of dry eye disease, the need for therapeutic options with new mechanisms of action is substantial,” stated Todd C. Brady, M.D., Ph.D., President and Chief Executive Officer of Aldeyra. “Reproxalap is a first-in-class investigational RASP inhibitor that, in the Phase 3 RENEW-1 Trial, demonstrated potential rapid and broad symptom control we believe is an important commercial differentiator.”

About RASP

RASP (reactive aldehyde species) are pre-cytokine pro-inflammatory mediators that are elevated in the tears of patients with dry eye disease,[1] and correlate with dry eye disease symptoms and signs.[2] RASP covalently bind to cellular biomolecules, altering molecular function and activating numerous pro-inflammatory pathways implicated in human disease.

About Reproxalap

Reproxalap is a novel investigational small-molecule immune-modulating covalent inhibitor of RASP in development as a topically administered ophthalmic solution for dry eye disease and allergic conjunctivitis. The mechanism of action of reproxalap has been validated with the demonstration of statistically significant and clinically relevant activity in multiple late-phase clinical trials.

About Aldeyra Therapeutics

Aldeyra Therapeutics is a clinical-stage biotechnology company focused on the development of novel therapies with the potential to improve the lives of patients with immune-mediated diseases. Two of the company’s lead compounds, reproxalap and ADX-629, target reactive aldehyde species (RASP), which are elevated in ocular and systemic inflammatory disease, leading to elevated levels of cytokine release via activation of a broad array of inflammatory factors, including NF-κB, inflammasomes, and Scavenger Receptor A. 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, a dihydrofolate reductase inhibitor in Phase 3 testing for proliferative vitreoretinopathy, and ADX-1612, a chaperome inhibitor in Phase 2 testing for COVID-19 and ovarian cancer. 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 statements

regarding Aldeyra's strategy, future operations, prospects, and development plans to support a New Drug Application for reproxalap in dry eye disease and expectations regarding FDA acceptance and review of such NDA and the sign and symptom requirements. 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. As a result of the COVID-19 pandemic, clinical site availability, staffing, and patient recruitment have been negatively affected and the timelines to complete our clinical trials may be delayed. 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 trials involving Aldeyra's product candidates; 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 our business, results of operations and financial position; 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 recent COVID-19 outbreak and subsequent 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, 2019 and Aldeyra's Quarterly Report on Form 10-Q for the quarter ended March 31, 2020, which are on file with the Securities and Exchange Commission (SEC) and available on the SEC's website at www.sec.gov. Additional factors may be set forth in those sections of Aldeyra's Quarterly Report on Form 10-Q for the quarter ended June 30, 2020, expected to be filed with the SEC in the third quarter of 2020.

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] Augustin et al., "Oxidative reactions in the tear fluid of patients suffering from dry eyes," Graefe's Archive for Clinical and Experimental Ophthalmology, 233(11):694-698 (1995).

[2] Choi W., et al. 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, 41(9):1143-9; Reproxalap preclinical and Phase 2a in dry eye disease clinical trial results on file.

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