Aldeyra Receives Study May Proceed Letter from FDA to Initiate Clinical Trial of ADX-629 in COVID-19 Patients

September 9, 2020

LEXINGTON, Mass.--(BUSINESS WIRE)--Sep. 9, 2020-- Aldeyra Therapeutics, Inc. (Nasdaq: ALDX) (Aldeyra) today announced that it has received a Study May Proceed letter from the U.S. Food and Drug Administration (FDA) to begin a Phase 2 clinical trial evaluating ADX-629, a novel orally available reactive aldehyde species (RASP) inhibitor, for the treatment of adult patients hospitalized for COVID-19.

“The FDA’s clearance of our Investigational New Drug application for Phase 2 testing in patients with COVID-19 is an important milestone for ADX-629, which represents a new paradigm in the treatment of immune-mediated diseases,” stated Todd C. Brady, M.D., Ph.D., President and CEO of Aldeyra. “The COVID-19 clinical trial is part of a broad systemic disease strategy designed to demonstrate ADX-629 proof of concept in serious inflammatory diseases with critical medical need.”

The planned Phase 2 clinical trial is expected to enroll approximately 30 patients with COVID-19. Patients will be enrolled upon hospitalization for COVID-19 and treated with orally administered ADX-629 or placebo twice-daily for up to 28 days. Key endpoints will include the National Institute of Allergy and Infectious Diseases COVID-19 scale and levels of cytokines and RASP.

Additional proof of concept Phase 2a clinical trials of ADX-629 in psoriasis and atopic asthma are expected to initiate in the fourth quarter of 2020. The timing of trial initiations depends, in part, on restrictions related to COVID-19, the availability of clinical research facilities and staffing, the ability to recruit patients, and regulatory feedback.

About ADX-629

ADX-629 is a novel orally administered RASP inhibitor in Phase 2 clinical development for the treatment of immune-mediated diseases. RASP inhibitors have the potential to represent upstream immunological switches that modulate immune systems from pro-inflammatory states to anti-inflammatory states. ADX-629 is a member of the same chemical class as reproxalap, a RASP inhibitor in Phase 3 clinical trials for dry eye disease and allergic conjunctivitis, two common ocular inflammatory diseases.

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, and result in 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, and ADX-629 is in Phase 2 clinical development for the treatment of systemic inflammatory diseases. 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 development 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, plans, and objectives and Aldeyra's plans and expectations for ADX-629 and its other product candidates. 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 June 30, 2020, which are on file with the Securities and Exchange Commission (SEC) and available on the SEC's website at 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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Source: Aldeyra Therapeutics, Inc.