Aldeyra to Screen Clinical-Stage Compounds for Activity in COVID-19 Infection

March 24, 2020

LEXINGTON, Mass.--(BUSINESS WIRE)--Mar. 24, 2020-- Aldeyra Therapeutics, Inc. (Nasdaq: ALDX) (Aldeyra) today announced that it will begin screening its library of novel reactive aldehyde species (RASP) inhibitors, including ADX-629 and reproxalap, for potential anti-inflammatory and antiviral activity in the treatment of COVID-19 infection.

ADX-629 and reproxalap are structurally related to chloroquine and hydroxychloroquine, drugs currently in clinical testing for the treatment of COVID-19 infection.

“We are committing scientific expertise and development resources associated with our RASP platform to help reduce the impact of the COVID-19 global healthcare crisis,” stated Todd C. Brady, M.D., Ph.D., President and CEO of Aldeyra. “Given the strong association between RASP and acute respiratory distress syndrome (ARDS), as well as the structural similarity of reproxalap and ADX-629 to chloroquines, we are researching the potential of our novel RASP inhibitors to mitigate the clinical severity of COVID-19 infection.”

Reproxalap[1] and ADX-629[2] have been shown to diminish inflammation in animal models of cytokine storm. Reproxalap has also demonstrated preliminary activity in a preclinical model of ARDS[3].

Aldeyra also announced that, in response to a recent U.S. Department of Health and Human Services solicitation, Aldeyra has submitted a proposal to the Biomedical Advanced Research and Development Authority (BARDA) for the development of ADX-629 for the treatment of COVID-19 infection. ADX-629 has completed a single and multiple ascending dose Phase 1 clinical trial. Initiation of a Phase 2 clinical trial of ADX-629 in patients with immune-mediated disease is planned for the second half of 2020.

Aldeyra is also seeking healthcare industry partners that may be interested in testing ADX-629 pursuant to the U.S. Food and Drug Administration’s Emergency Use Authorization guidelines. Physicians wishing to use ADX-629 under a single patient Investigational New Drug (IND) application for Compassionate or Emergency Use should email Dr. James Gow, Senior Vice President of Clinical Development, at james.gow@aldeyra.com.

“We believe that ADX-629 could potentially be an important tool for physicians treating patients who are experiencing ARDS associated with COVID-19, either as a single agent or as an adjunct to other therapies,” Dr. Brady stated.

About ADX-629

ADX-629 is an orally administered RASP inhibitor with potential antiviral and anti-inflammatory activity. The compound has completed a single-ascending and multiple-ascending dose Phase 1 clinical trial in 85 subjects with no drug-related adverse events observed. ADX-629 is a member of the same chemical class as reproxalap, a RASP inhibitor in Phase 3 clinical testing for ocular inflammation.

About Reproxalap

Reproxalap is a novel, small-molecule immune-modulating covalent inhibitor of RASP (reactive aldehyde species), which are elevated in ocular and systemic inflammatory disease, and lead to activation of intracellular inflammatory factors, including NF-kB, inflammasomes, and Scavenger Receptor A. The mechanism of action of reproxalap has been validated with the demonstration of statistically significant and clinically relevant activity in multiple physiologically distinct late-phase clinical indications.

About Aldeyra Therapeutics

Aldeyra Therapeutics is a biotechnology company devoted to developing and commercializing next-generation medicines to improve the lives of patients with immune-mediated diseases. Aldeyra's lead investigational drug product candidates are potential first-in-class treatments in development for dry eye disease, allergic conjunctivitis, and proliferative vitreoretinopathy. The company is also developing other product candidates for retinal and systemic inflammatory diseases.

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 its product candidates, including expectations regarding the potential of its RASP inhibitors, including ADX-629 and reproxalap, for potential anti-inflammatory and antiviral activity in the treatment of COVID-19. 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; 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 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, which is 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.

[1] Cullen V, Mechanic J, Welihinda A, Young S, Amento E, Brady T. The small molecule aldehyde trap NS2 exhibits potent anti-inflammatory activity in 3 murine models of inflammation. Poster session presented at: American Academy of Allergy Asthma & Immunology 2015 Annual Meeting; 2015 Feb 20-24; Houston, TX.

[2] Data on file.

[3] Macdonald SG, Cullen V, Brady T, Beal D, Andreotta PW, Young SL. The Novel Aldehyde Trap, ADX-102, Reduces Inflammation-Mediated Lung Infiltrate in a Mouse Model of LPS-Induced Acute Lung Injury. Poster session presented at: World Congress on Inflammation 2017 Meeting; 2017 Jul 8-12; London, United Kingdom.

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