# Aldeyra Therapeutics to Advance ADX-1612, an Investigational New HSP90 Inhibitor with Potential Nanomolar Potency Against SARS-CoV-2, to Clinical Testing for COVID-19; ADX-629 Accepted for BARDA CoronaWatch Meeting

May 20, 2020

- ADX-1612 Demonstrates Nanomolar SARS-CoV-2 Antiviral Potency In Vitro
- Pending FDA Feedback, IND Submission for ADX-1612 Expected in Third Quarter 2020
- IND Submission for ADX-629 Expected in June 2020
- Management to Host Conference Call at 8:00 a.m. ET Today

LEXINGTON, Mass.--(BUSINESS WIRE)--May 20, 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 the planned advancement of the investigational new HSP90 inhibitor ADX-1612 to clinical testing for COVID-19, and provided an update on ADX-629, a novel investigational RASP inhibitor in development for COVID-19 and other inflammatory diseases.

ADX-1612, which has been clinically tested in more than 1,600 subjects for the potential treatment of cancer, is an inhibitor of chaperone protein HSP90, a target widely implicated in viral disease.[1] Aldeyra announced that ADX-1612 has demonstrated nanomolar potency similar to or greater than that of remdesivir in an in vitro model. Complementary to the nucleic acid inhibition mechanism of action of remdesivir and related antiviral compounds, ADX-1612 potentially leads to the inhibition of proteins associated with viral replication and infection, and thereby may enhance the activity of other antiviral drugs for the treatment of COVID-19. Importantly, via comprehensive expression profiling of human cell lines infected with SARS-CoV-2, HSP90 was recently identified as a key pharmaceutical target for viral inhibition.[2] Pending FDA feedback, an Investigational New Drug (IND) submission for ADX-1612 is expected in the third quarter of 2020.

Aldeyra also announced that ADX-629, a novel orally administered investigational RASP inhibitor, has been granted a BARDA CoronaWatch meeting. ADX-629 has completed pre-IND discussions with the Pulmonary Division of the U.S. Food & Drug Administration, and Aldeyra expects to submit an IND application in June 2020. Severe COVID-19 is characterized by cytokine release syndrome, which may lead to respiratory compromise, often including the requirement for mechanical ventilation. In a preclinical model of cytokine storm, ADX-629 has demonstrated broad-based reductions across a variety of TH1, TH2, and TH17 inflammatory cytokines, while upregulating the key anti-inflammatory cytokine, IL-10.

“The nanomolar potency of ADX-1612 against SARS-CoV-2 in an in vitro model announced today is consistent with a broad array of mechanistic target validation, in vitro viral inhibition, and preliminary clinical data that support investigation of ADX-1612 for the treatment of COVID-19,” stated Todd C. Brady, M.D., Ph.D., President and Chief Executive Officer of Aldeyra. “In addition, we are pleased to announce that ADX-629, a novel investigational immune-modulating drug, continues to progress toward clinical testing in COVID-19-associated respiratory compromise as part of a systematic approach to identify activity across a variety of different inflammatory diseases.”

Aldeyra announced that, in addition to the planned COVID-19 clinical trial, the current Phase 2 investigator-sponsored trial of ADX-1612 in ovarian cancer (the Phase 2 EUDARIO Trial) is expected to complete enrollment in June 2020. Aldeyra previously announced that Phase 2a clinical trials of ADX-629 in psoriasis and atopic asthma are expected to initiate in the second half of 2020.

***Conference Call***

Aldeyra will host a conference call to discuss this announcement today, Wednesday, May 20, 2020, at 8:00 a.m. ET. The dial-in numbers are (866) 211-4098 for domestic callers and (647) 689-6613 for international callers. The Conference ID is 8170518. A live webcast of the conference call will also be available on the Investor Relations section of the Aldeyra Therapeutics website at https://ir.aldeyra.com. Presentation slides will be available on the investor relations page approximately 30 minutes prior to the start of the conference call and webcast.

After the live webcast, the event will remain archived on the Aldeyra Therapeutics website for 90 days.

***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. In addition, the company is also developing ADX-1612, an HSP90 inhibitor for the treatment of viral and 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 statements regarding Aldeyra's strategy, future operations, prospects, plans, and objectives and Aldeyra's plans and expectations for its product candidates, including ADX-1612 and ADX-629, and other systems-based approaches. 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.

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] HSP90: a promising broad-spectrum antiviral drug target. *Arch Virol*. 2017; 162(11): 3269-3282; Could targeting the heat shock protein 90 revolutionize antiviral therapy? *Future Virology* 2018; 13(2): 119-127.

[2] Bulk and single-cell gene expression profiling of SARS-CoV-2 infected human cell lines identifies molecular targets for therapeutic intervention. *BioRxiv* 2020. https://doi.org/10.1101/2020.05.05.079194.

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**Corporate:**
David McMullin
Aldeyra Therapeutics, Inc.
Tel: 781-761-4904 ext. 218
dmcmullin@aldeyra.com

**Investor & Media:**
Scott Solomon
Sharon Merrill Associates, Inc.
Tel: 617-542-5300
ALDX@investorrelations.com

Source: Aldeyra Therapeutics, Inc.