UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): May 20, 2020

ALDEYRA THERAPEUTICS, INC.
(Exact name of Registrant as specified in its charter)

Delaware	**001-36332**	**20-1968197**
(State or other jurisdiction of incorporation)	**(Commission File No.)**	**(IRS Employer Identification No.)**

131 Hartwell Avenue, Suite 320
Lexington, MA 02421
(Address of principal executive offices and zip code)

Registrant's telephone number, including area code: (781) 761-4904

Not Applicable
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.001 par value per share	**ALDX**	**The Nasdaq Stock Market, LLC**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01. Regulation FD Disclosure.

As reported under Item 8.01 of this Current Report on Form 8-K, on May 20, 2020, Aldeyra Therapeutics, Inc. (the "Company") issued a press release (the "Press Release") providing an update on its COVID-19 development plans. The Company is holding a conference call on May 20, 2020. A copy of the supplemental presentation which will be referenced during this conference call and posted on the Company's website is furnished herewith as Exhibit 99.1 and is incorporated by reference herein.

This information in this Item 7.01 of this Current Report on Form 8-K shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that Section, or incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in any such filing.

Item 8.01. Other Events.

On May 20, 2020, the Company provided an update on its COVID-19 development plans. The Press Release is filed as Exhibit 99.2 to this Current Report on Form 8-K and is incorporated by reference herein.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Aldeyra Therapeutics, Inc. Presentation dated May 20, 2020.
99.2	Aldeyra Therapeutics, Inc. Press Release dated May 20, 2020.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: May 20, 2020

ALDEYRA THERAPEUTICS, INC.

By: /s/ Joshua Reed
Name: Joshua Reed
Title: Chief Financial Officer

May 20, 2020

Systems-Based Approaches for Immunological Disease

COVID-19 Development Update

Nasdaq: ALDX

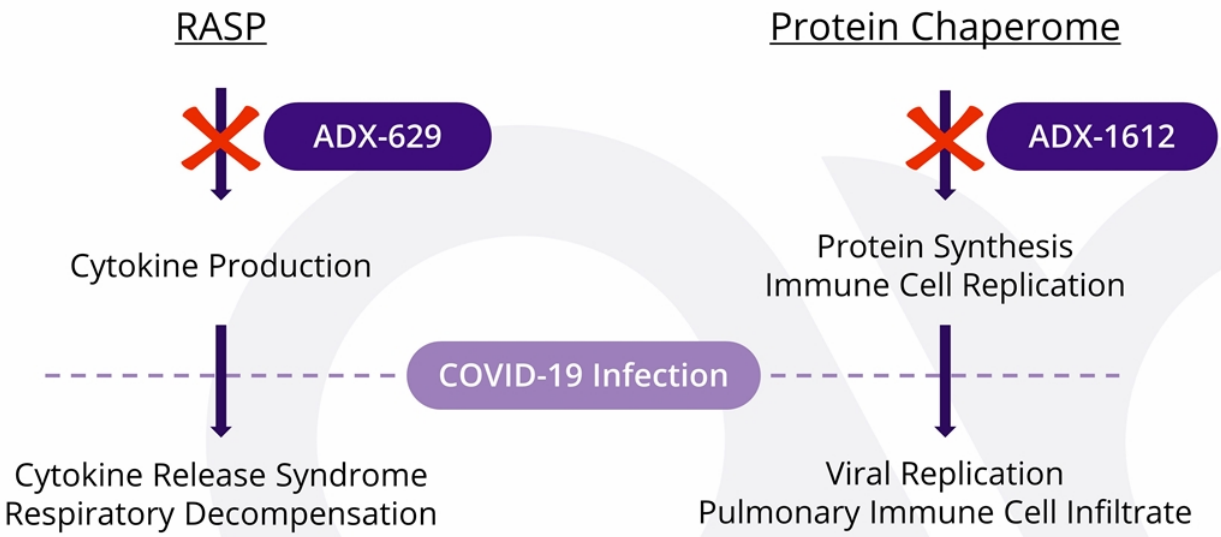
Disclaimers and Forward-Looking Statements

This presentation and various remarks which may be made during this presentation contain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and Section 21E of the Securities Exchange Act of 1934, as amended, including statements regarding Aldeyra's possible or assumed future results of operations, expenses and financing needs, business strategies and plans, research and development plans or expectations, political, economic, legal, social and health risks, including the recent COVID-19 outbreak and subsequent public health measures and other responses to it, that may affect Aldeyra's business or the global economy, the structure, timing and success of Aldeyra's planned or pending clinical trials, expected milestones, market sizing, pricing and reimbursement, competitive position, regulatory matters, industry environment and potential growth opportunities, among other things. The results of earlier preclinical or clinical trials may not be predictive of future results. As a result of the COVID-19 pandemic, clinical site availability, staffing, and patient recruitment have been negatively affected and the timelines to complete Aldeyra's clinical trials may be delayed. Forward-looking statements include all statements that are not historical facts and, in some cases, can be identified by terms such as "may," "might," "will," "objective," "intend," "should," "could," "can," "would," "expect," "believe," "anticipate," "project," "target," "design," "estimate," "predict," "potential," "plan" or similar expressions and the negatives of those terms.

Forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause Aldeyra's actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. These statements reflect Aldeyra's current views with respect to future events and are based on assumptions and subject to risks and uncertainties, including the development, clinical and regulatory plans or expectations for Aldeyra's product candidates and systems-based approaches and Aldeyra's continuing review and quality control analysis of clinical data. Important factors that could cause actual results to differ materially from those reflected in Aldeyra's forward-looking statements are described in Aldeyra's most recent Annual Report on Form 10-K and Quarterly Report on Form 10-Q, as well as Aldeyra's subsequent filings with the Securities and Exchange Commission. All of Aldeyra's development plans and timelines may be subject to adjustment depending on funding, recruitment rate, regulatory review, preclinical and clinical results, and other factors any of which could result in changes to Aldeyra's development plans and programs or delay the initiation, completion, or reporting of clinical trials.

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 presentation is provided only **as of May 20, 2020**, and Aldeyra undertakes no obligation to update any forward-looking statements contained in this presentation on account of new information, future events, or otherwise, except as required by law.

For the Treatment of COVID-19, Aldeyra Is Developing Two Systems-Based Approaches That Potentially Modulate Numerous Targets



Aldeyra Therapeutics is developing ADX-629 and ADX-1612 as investigational new drugs for the treatment of immune mediated diseases, including cancer. Aldeyra has initiated communication with the Food and Drug Administration (FDA) about the potential use of ADX-629 for the treatment of COVID-19 related cytokine release syndrome. Aldeyra has not yet communicated with the FDA about the potential use of ADX-1612 to treat COVID-19 related conditions.

RASP = Reactive Aldehyde Species

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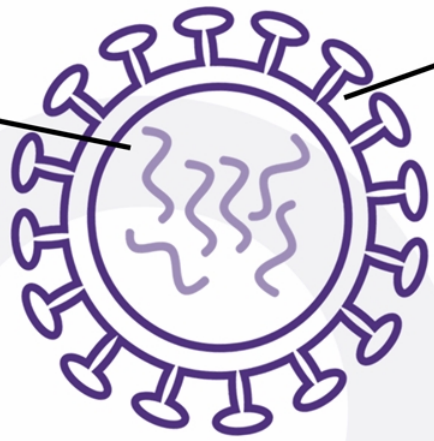
May 2020

COVID-19 DEVELOPMENT UPDATE

ADX-1612: A Potential COVID-19 Antiviral with Nanomolar Potency

Nasdaq: ALDX

ADX-1612 Represents a Potentially Synergistic Treatment with Antivirals that Target Viral Nucleic Acids



RNA

Remdesivir

Virus Neutralization Assay:
EC50 = 750 nM

Folded Protein Complexes

ADX-1612

Virus Neutralization Assay:
Virus-induced cell death blocked at 80-160 nM

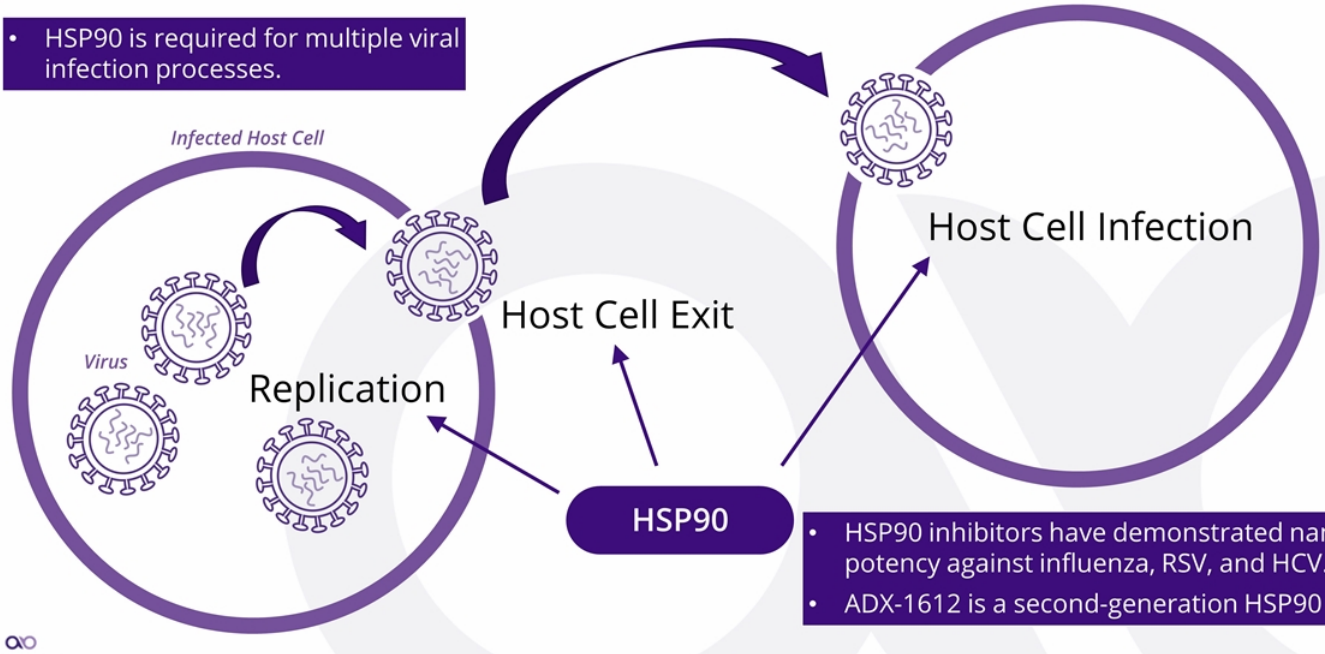
SARS-CoV-2 Virus

Remdesivir in vitro antiviral activity at 48 hours post-treatment from the Emergency Use Authorization Fact Sheet;
ADX-1612 in vitro antiviral activity based on Aldeyra Therapeutics internal data on file.

EC50 = Half maximal effective concentration

ADX-1612 Inhibits HSP90, Which is Required for Multiple Processes Associated with Viral Infection

- HSP90 is required for multiple viral infection processes.



- HSP90 inhibitors have demonstrated nanomolar potency against influenza, RSV, and HCV.
- ADX-1612 is a second-generation HSP90 inhibitor.

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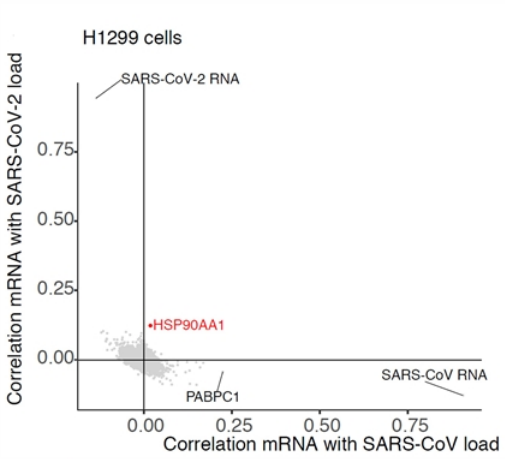
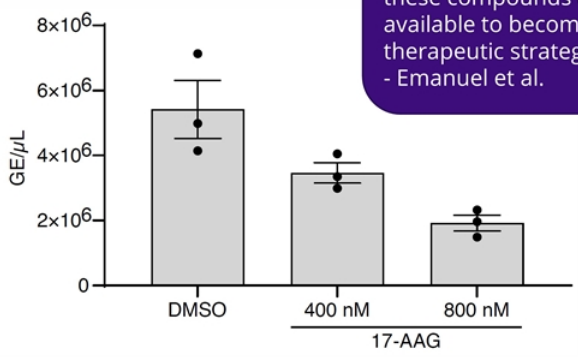
Wang et al. *HSP90: a promising broad-spectrum antiviral drug target*. Arch Virol, August 5, 2017; DOI 10.1007/s00705-017-3511-1

HSP90 Recently Identified as a Potential Therapeutic Target of SARS-CoV-2





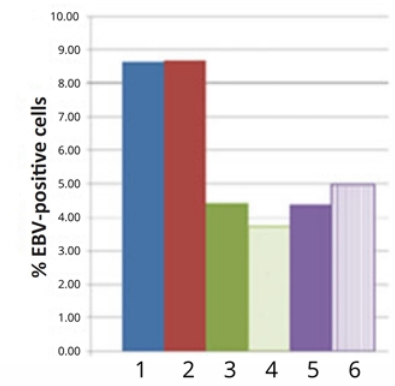
"Since several inhibitors of HSP90 with higher affinities have been in clinical development … some of these compounds could be readily available to become part of a therapeutic strategy for COVID-19." - Emanuel et al.

Elevated HSP90 RNA found in SARS-CoV-2, and a low-potency HSP90 inhibitor reduced viral load in cell culture

Emanuel et al. *Bulk and single-cell gene expression profiling of SARS-CoV-2 infected human cell lines identifies molecular targets for therapeutic intervention*, bioRxiv preprint, May 5, 2020. DOI:10.1101/2020.05.05.079194. Not certified by peer review.

17-AAG = a low-potency HSP90 inhibitor; GE = genetic equivalent; DMSO = solvent.

ADX-1612 Has Been Tested in Over 1600 Cancer Patients to Date, and Has Clinically Demonstrated Antiviral Activity in a Viral-Induced Cancer

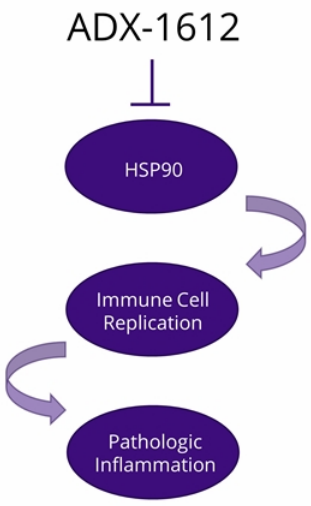


1 = Pre-treatment
2 = Pre-treatment
3 = 1 week post dose 1 (120 mg/m^2)
4 = 1 day post dose 2 (120 mg/m^2)
5 = 2 weeks post dose 2 (120 mg/m^2)
6 = 2 days post dose 1 (150 mg/m^2)

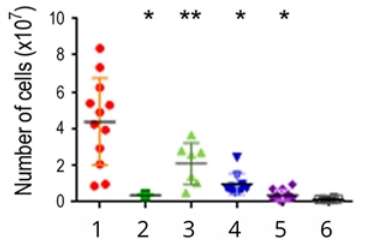
In an EBV-infected patient, ADX-1612 reduced the percentage of circulating EBV-positive cells.

Shatzer et al. *Ganetespib, an HSP90 inhibitor, kills Epstein–Barr virus (EBV)-infected B and T cells and reduces the percentage of EBV-infected cells in the blood*, Leukemia & Lymphoma, 2016, DOI: 10.1080/10428194.2016.1213823

In Addition to Antiviral Activity, ADX-1612 Has Demonstrated Potential Suppression of Pathologic Inflammation

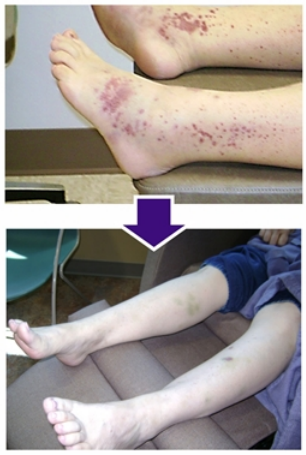


Immune cell count reduction in animal model of lupus[1]



1 = Vehicle
2 = Cyclophosphamide
3 = Cyclophosphamide/2
4 = ADX-1612
5 = ADX-1612 + cyclophosphamide
6 = Normal animal

Clinical response in patient with chronic vasculitis after a single dose



[1]Liu et al. *The HSP90 Inhibitor Ganetespib Alleviates Disease Progression and Augments Intermittent Cyclophosphamide Therapy in the MRL/lpr Mouse Model of Systemic Lupus Erythematosus*, PLoS One, May 14, 2015. DOI:10.1371/journal.pone.0127361

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ADX-1612 Planned Phase 2 COVID-19 Clinical Trial Synopsis*

- **Patient Population:**
  Adults and children hospitalized for COVID-19 with an oxygen saturation (SpO2) ≤ 94% on room air, or requiring supplemental oxygen, mechanical ventilation, or extracorporeal membrane oxygenation
- **Size:**
  Up to 30 subjects, randomized 2:1 drug:placebo
- **Treatment Period:**
  Two doses 72 hours apart
- **Endpoints:**
  Time to discharge, days in intensive care unit, days in hospital, global clinical score

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*Contingent on FDA review of information submitted via the Coronavirus Treatment Acceleration Program (CTAP), funding, and other factors. The timing of clinical trial initiation depends, in part, on restrictions related to COVID-19, the availability of clinical research facilities and staffing, and the ability to recruit patients.

Expected ADX-1612 Development Milestones and Clinical Plans*

- Coronavirus Treatment Acceleration Program application **May 2020**
- COVID-19 IND submission **Q3 2020**
- Initiation of clinical testing for COVID-19 **Q3 2020**
- Completion of enrollment for ovarian cancer (the Phase 2 EUDARIO Trial) **June 2020**

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*The timing of clinical trial initiation depends, in part, on restrictions related to COVID-19, the availability of clinical research facilities and staffing, and the ability to recruit patients. Contingent on funding, regulatory review, and other factors.

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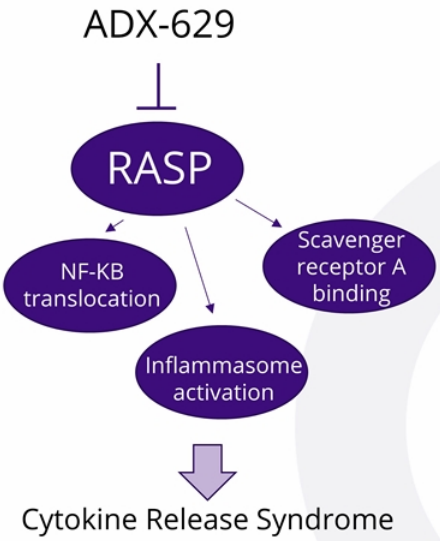
May 2020

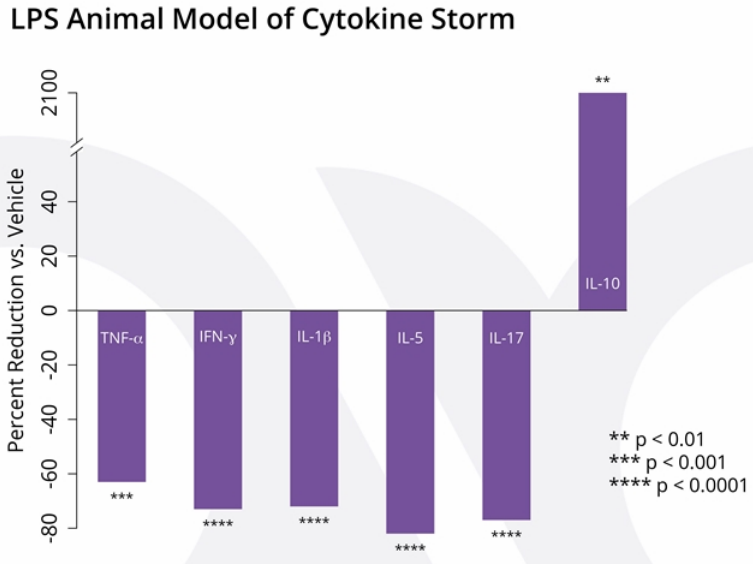
COVID-19 DEVELOPMENT UPDATE

ADX-629 For The Potential Treatment of Cytokine Release Syndrome

Nasdaq: ALDX

ADX-629 is a Pre-Cytokine, Systems-Based Approach with the Potential to Mitigate Cytokine Responses in COVID-19





RASP = Reactive Aldehyde Species; Cytokine data on file; LPS = lipopolysaccharide

ADX-629 Planned Phase 2 COVID-19 Clinical Trial Synopsis*

- **Patient Population:**
  COVID-19 patients recently admitted to hospital for respiratory compromise
- **Dosing:**
  600mg oral twice daily
- **Size:**
  Up to 30 subjects, randomized 2:1 drug:placebo
- **Treatment Period:**
  Up to 28 days
- **Endpoints:**
  Proportion on mechanical ventilation, time to discharge, cytokine profile

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*Contingent on FDA review of information submitted via the Coronavirus Treatment Acceleration Program (CTAP), funding, and other factors. The timing of clinical trial initiation depends, in part, on restrictions related to COVID-19, the availability of clinical research facilities and staffing, and the ability to recruit patients.

Expected ADX-629 Development Milestones and Clinical Plans*

- ✓ Coronavirus Treatment Acceleration Program (CTAP) application **March 2020**
- ✓ BARDA CoronaWatch application **May 2020**
- ✓ BARDA CoronaWatch meeting accepted (to be scheduled)
- ✓ Pre-IND FDA discussion (Pulmonary Division)
- ○ COVID-19 IND submission **June 2020**
- ○ COVID-19 clinical trial initiation **Q3 2020**
- ○ Psoriasis and atopic asthma clinical trial initiations **H2 2020**

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*The timing of clinical trial initiation depends, in part, on restrictions related to COVID-19, the availability of clinical research facilities and staffing, and the ability to recruit patients. Contingent on funding, regulatory review, and other factors.

Systems-Based Approaches for Immunological Disease

Nasdaq: ALDX

Exhibit 99.2

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

- 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., 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.”

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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.

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.

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