Aldeyra Therapeutics Announces Confirmation of Antiviral Activity of ADX-1612

December 22, 2020

- Nanomolar Antiviral Potency of ADX-1612 Against SARS-CoV-2 Confirmed in Preclinical Studies
- Novel Anti-Inflammatory Activity of ADX-1612 Demonstrated in SARS-CoV-2-Infected Human Cells
- International Collaboration Established with the Laboratory of Dr. Markus Landthaler at the Max Delbrück Center for Molecular Medicine in Berlin, Germany for Assessment of ADX-1612 in Cell and Animal COVID-19 Models
- Additional Third-Party Publications of ADX-1612 Activity in COVID-19-Related Experiments Released

LEXINGTON, Mass.--(BUSINESS WIRE)--Dec. 22, 2020-- Aldeyra Therapeutics, Inc. (Nasdaq: ALDX) (Aldeyra) today announced confirmation of SARS-CoV-2 antiviral activity of ADX-1612, in addition to novel anti-inflammatory activity in SARS-CoV-2-infected primary human cells in preclinical studies. The results are derived from an international collaboration with the Max Delbrück Center for Molecular Medicine in the Helmholtz Association (MDC) in Berlin, Germany, which plans additional studies with colleagues at the Charité – Universitätsmedizin Berlin University Hospital in cell and animal COVID-19 models.

“The antiviral and anti-inflammatory activity of ADX-1612 demonstrated in COVID-19 models may be applicable to viral diseases generally,” stated Emanuel Wyler, Ph.D., Research Scientist at MDC.

“We look forward to continuing our collaboration with Aldeyra as we advance ADX-1612 to additional cell and animal models to further characterize the activity of ADX-1612 in COVID-19 and other viral infections,” added Markus Landthaler, Ph.D., Group Leader of the Coronavirus Task Force and the Laboratory for RNA Biology and Post-transcriptional Regulation at MDC.

In May 2020, Dr. Wyler and colleagues identified HSP90 as a key antiviral target against SARS-CoV-2[1] and have confirmed the antiviral activity of ADX-1612, a potent HSP90 inhibitor, reported by Aldeyra earlier this year. Additional reports of the activity of ADX-1612, also known as ganetespib, and other HSP90 inhibitors have been subsequently published by independent laboratories.[2]

The anti-inflammatory activity of ADX-1612, as assessed by cytokine transcription in SARS-CoV-2-infected primary human cells, included down-regulation of TNF-α, IFN-1β, IL-6, and a variety of other cytokines and pro-inflammatory mediators.

“We are thrilled to work with the MDC as we continue to characterize the activity of ADX-1612 as a potential antiviral and immune-modulating approach for the treatment of serious viral infections,” stated Todd C. Brady, M.D., Ph.D., President and Chief Executive Officer of Aldeyra.

About ADX-1612

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.[3] 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 and other viral infections. Importantly, via comprehensive expression profiling of human cell lines infected with SARS-CoV-2, HSP90 was identified as a key pharmaceutical target for viral inhibition.[1] More recently, the anti-inflammatory activity of ADX-1612 has been demonstrated in SARS-CoV-2-infected human cells.

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 RASP (reactive aldehyde species), 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. 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 the antiviral and anti-inflammatory activity of ADX-1612 and plans for additional preclinical testing. 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 and Aldeyra's Quarterly Report on Form 10-Q for the quarter ended September 30, 2020, which are on file with the Securities and Exchange Commission (SEC) and available on the SEC's website at https://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] 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.

[2] Global analysis of protein-RNA interactions in SARS-CoV-2 infected cells reveals key regulators of infection, https://doi.org/10.1101/2020.11.25.398008; SARS-CoV-2 infection remodels the host protein thermal stability landscape, https://doi.org/10.21203/rs.3.rs-105193/v1.

[3] HSP90: a promising broad-spectrum antiviral drug target. Arch Virol. 2017; 162(11): 3269-3282, https://doi.org/10.1007/s00705-017-3511-1; Could targeting the heat shock protein 90 revolutionize antiviral therapy? Future Virology 2018; 13(2): 119-127, https://doi.org/10.2217/fvl-2017-0111.

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