



Aldeyra Therapeutics Announces Initiation of Phase 2 Clinical Trials of ADX-629, a First-in-Class Orally Administered RASP Inhibitor, for the Treatment of COVID-19, Atopic Asthma, and Psoriasis

December 17, 2020

LEXINGTON, Mass.--(BUSINESS WIRE)--Dec. 17, 2020-- [Aldeyra Therapeutics, Inc.](#) (Nasdaq: ALDX) (Aldeyra) today announced the initiation of Phase 2 clinical trials of ADX-629, a first-in-class orally administered reactive aldehyde species (RASP) inhibitor, for the treatment of COVID-19, atopic asthma, and psoriasis as part of a systematic strategy to assess activity across different types of immunological diseases. The Phase 2 clinical trials follow a successful Phase 1 clinical trial of ADX-629, which demonstrated no treatment-related adverse events at any dose tested, as well as target engagement evidenced by statistically lower RASP levels in drug-treated subjects relative to controls.

"The initiation of Phase 2 clinical testing of ADX-629, a first-in-class orally administered RASP inhibitor, is an exciting milestone for Aldeyra as we broaden the focus of our RASP platform from ocular indications to systemic disease," stated Todd C. Brady, M.D., Ph.D., President and CEO of Aldeyra. "The Phase 2 clinical trials announced today underscore our mission to develop new therapies that improve patient outcomes by fine-tuning the body's immune response. Unlike traditional immunologic drugs, ADX-629 is designed to modulate the immune system rather than shut down singular molecular targets, an approach that may lead to toxicity."

COVID-19 – A Clinical Model of Cytokine Release Syndrome

The multi-center, double-blind, placebo-controlled, parallel-group Phase 2 clinical trial in COVID-19 will evaluate the safety, tolerability, efficacy, and pharmacodynamics of ADX-629 in adult patients. Approximately 30 patients will be randomized to receive either 300 mg of 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 plasma levels of cytokines and RASP. Enrollment is expected to begin by year-end.

Atopic Asthma – A Clinical Model of Allergic Inflammation

The single-center, double-masked, placebo-controlled, crossover Phase 2 clinical trial will assess the safety and efficacy of ADX-629 in adult patients with mild asthma induced by bronchial asthma challenge. Twelve patients with cat or house dust mite allergen-induced asthma will be randomized to receive either 600 mg of ADX-629 or placebo twice daily for approximately one week. Outcomes will include pulmonary function testing following allergen and methacholine challenge, sputum eosinophil counts, and plasma levels of cytokines and RASP. Enrollment is expected to begin in the first quarter of 2021.

Psoriasis – A Clinical Model of Autoimmune Disease

The multi-center, open-label, single-group Phase 2 clinical trial will assess the safety and efficacy of ADX-629 in adult patients with mild to moderate plaque psoriasis. Ten adult patients will receive 250 mg of ADX-629 twice daily for up to 90 days. Outcomes will include psoriasis area and severity index, skin cytokine transcription profiles, plasma leukocyte cytokine release following endotoxin-challenge, and plasma levels of cytokines and RASP. Enrollment is expected to begin in the first half of next year.

"We believe that ADX-629 has broad applicability to systemic immune-mediated diseases," Dr. Brady said. "We look forward to characterizing more fully the immune modulating activity of ADX-629 in multiple types of severe inflammation."

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 potentially 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 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- κ B, 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 chaperone 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 initiation and enrollment of Phase 2 clinical trials of ADX-629 in COVID-19, atopic asthma, and psoriasis. 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.

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Source: Aldeyra Therapeutics, Inc.