



Aldeyra Therapeutics Announces First Patient Enrolled in the Phase 3 GUARD Trial for Prevention of Proliferative Vitreoretinopathy

December 19, 2019

LEXINGTON, Mass.--(BUSINESS WIRE)--Dec. 19, 2019-- Aldeyra Therapeutics, Inc. (Nasdaq: ALDX) (Aldeyra), a biotechnology company devoted to developing and commercializing next-generation medicines to improve the lives of patients with immune-mediated diseases, today announced enrollment of the first patient into the Phase 3 GUARD Trial of ADX-2191 for the prevention of proliferative vitreoretinopathy (PVR). PVR is a serious, sight-threatening retinal disease with no approved treatment.

"Initiation of patient enrollment in the GUARD Trial marks an important step toward our goal of improving clinical outcomes for the thousands of patients with this rare but devastating condition," said Todd C. Brady, M.D., Ph.D., President and CEO of Aldeyra. "Today, the only option for patients who develop PVR is surgery, which fails in a significant number of cases. ADX-2191 is a new therapeutic approach with the potential to prevent vision loss from recurrent retinal detachments."

The GUARD Trial is a two-part, multi-center, randomized, controlled, adaptive Phase 3 clinical trial evaluating the efficacy of intravitreal injections of ADX-2191 versus standard-of-care for the prevention of PVR. GUARD will compare recurrent retinal detachment rates over a 24-week period following surgical repair of retinal detachment due to PVR or open globe injury.

In September 2019, the U.S. Food and Drug Administration (FDA) granted fast track designation to ADX-2191 for the prevention of PVR. ADX-2191 has also received orphan drug designation from the FDA for the prevention of PVR.

More information about the GUARD Trial is available on www.clinicaltrials.gov (NCT 04136366).

About Proliferative Vitreoretinopathy

Proliferative vitreoretinopathy (PVR) is a rare inflammatory fibroproliferative disorder that leads to severe retinal scarring and blindness, and is the leading cause of failure of retinal reattachment surgery. Approximately 40% to 50% of PVR cases result in severe uncorrectable vision loss (visual acuity of 20/320 or worse), and 76% of PVR patients suffer from at least moderate uncorrectable vision loss. PVR complicates up to 10% of surgeries for retinal detachment and 50% or more of surgeries for open globe injury. There is currently no approved therapy for the treatment of PVR.

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, proliferative vitreoretinopathy, and Sjögren-Larsson Syndrome. 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, future financial position, projected costs and expenses, prospects, plans, and objectives and Aldeyra's plans and expectations for its product candidates, including plans relating to current or future clinical development of ADX-2191. 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; 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, 2018 and

Aldeyra's Quarterly Report on Form 10-Q for the quarter ended September 30, 2019, 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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