

Aldeyra Therapeutics Expands Retinal Disease Pipeline with Acquisition of Helio Vision

January 29, 2019

Addition of Phase 3-Ready Clinical Program

Orphan Drug Designation for Proliferative Vitreoretinopathy, A Potentially Blinding Disease with No Approved Treatment Initial Clinical Trial Results Expected in 2020

LEXINGTON, Mass., Jan. 29, 2019 /PRNewswire/ -- 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 that it has acquired Helio Vision, Inc. (Helio Vision), a privately held biotechnology company. The acquisition adds to Aldeyra's pipeline a Phase 3-ready product candidate (ADX-2191, intravitreal methotrexate) for the treatment of proliferative vitreoretinopathy (PVR), a serious sight-threatening condition with no approved treatment. ADX-2191 has received Orphan Drug Designation from the U.S. Food and Drug Administration.

PVR, a serious inflammatory condition that can cause permanent vision loss, affects up to 10% of patients undergoing surgery for retinal detachment, and 50% or more of patients undergoing retina surgery following open globe injury. ADX-2191 is an innovative therapeutic option discovered by Dr. Dean Eliott, the Stelios Evangelos Gragoudas Associate Professor of Ophthalmology at Harvard Medical School and the Director of the Retina Service at Massachusetts Eye and Ear Infirmary (MEEI). ADX-2191 was co-developed by Dr. Eliott and Dr. Tomasz Stryjewski, also a retinal surgeon at MEEI.

"The acquisition of Helio Vision is highly complementary to Aldeyra's focus on novel therapeutic approaches for immune-mediated diseases and broadens our late-stage pipeline," stated Todd C. Brady, M.D., Ph.D., President and CEO of Aldeyra. "Helio Vision's unique approach is at the cross-hairs of our areas of expertise, leveraging an immunological mechanism that diminishes inflammation and cell proliferation, an orphan indication addressing a significant unmet medical need, the potential applicability to a variety of other diseases, and a Phase 3-ready retinal program that represents another important catalyst in our development pipeline."

"We are thrilled to be working with Aldeyra to develop a novel treatment approach for PVR, a debilitating disease for which there is no approved therapy," stated Josef H. von Rickenbach, co-founder, President and CEO of Helio Vision. "Aldeyra's proven track record of development success across a number of clinical programs bodes well for the advancement of ADX-2191."

Under the terms of the agreement, Aldeyra has acquired Helio Vision for an upfront payment of approximately \$10 million in common stock, subject to a six-month lock-up period, and an additional \$2.5 million payment in common stock two years from the date of closing, subject to certain terms and conditions of the agreement. Helio Vision shareholders will also be eligible to receive up to an additional \$12.5 million in Aldeyra stock upon achievement of certain regulatory milestones. Dr. Eliott and the other co-founders of Helio Vision will continue to work with Aldeyra on ADX-2191 as consultants under the terms of the acquisition.

The acquisition of Helio Vision and the near-term development of ADX-2191 has no impact on Aldeyra's previous financial guidance. An adaptive Phase 3 clinical program for ADX-2191 in PVR is expected to initiate in 2019, with results expected in 2020.

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. Over 50% of PVR cases result in severe uncorrectable vision loss, 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 product candidate, reproxalap, is a first-in-class treatment in late-stage development for dry eye disease, allergic conjunctivitis, noninfectious anterior uveitis, and Sjögren-Larsson Syndrome. The company is also developing other product candidates for autoimmune disease, post-transplant lymphoproliferative disease, retinal disease, metabolic disease, and cancer. None of Aldeyra's product candidates have been approved for sale in the U.S. or elsewhere.

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, prospects, plans, and objectives and Aldeyra's plans and expectations for its product candidates, including plans to initiate further clinical testing, the timing of results from clinical programs, the expected synergies of the acquisition of Helio Vision and the advancement of ADX-2191 into clinical trials. 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 "may," "might," "will," "objective," "intend," "should," "could," "can," "would," "expect," "believe," "anticipate," "project," "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 revi

costs of developing and commercializing Aldeyra's product candidates; 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 ability to establish and maintain development partnerships; 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, 2017 and Aldeyra's Quarterly Report on Form 10-Q for the quarter ended September 30, 2018, both of which are on file with the Securities and Exchange Commission (SEC) and available on the SEC's website at www.sec.gov. Additional factors may be set forth in those sections of Aldeyra's Annual Report on Form 10-K for the year ended December 31, 2018, to be filed with the SEC in the first quarter of 2019.

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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