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Aldeyra Therapeutics Announces First Patient Enrolled in Noninfectious Anterior Uveitis Phase 3 Clinical Trial

LEXINGTON, MA -- (Marketwired) -- 04/27/17 -- Aldeyra Therapeutics, Inc. (NASDAQ: ALDX) (Aldeyra), a biotechnology company focused primarily on the development of new products for inflammation, inborn errors of metabolism, and other diseases that are thought to be related to endogenously generated toxic and pro-inflammatory chemical species known as aldehydes, today announced that it has enrolled the first patient in a Phase 3 clinical trial of topical ocular ADX-102 for the treatment of noninfectious anterior uveitis (NAU).

"Based on positive results from our Phase 2 clinical trial announced last year, we are excited to commence Phase 3 clinical testing of our novel aldehyde trap, ADX-102, in noninfectious anterior uveitis," commented Todd C. Brady, M.D., Ph.D., President and CEO of Aldeyra. "NAU is a rare and potentially blinding ocular disorder that affects an estimated 150,000 patients in the United States. In contrast to corticosteroids, which are often used to treat NAU, ADX-102 does not appear to cause increases in intraocular pressure -- a precursor to glaucoma -- and thus may represent a safer therapeutic option than the current standard of care."

ADX-102 and other product candidates generated from Aldeyra's aldehyde trap platform sequester and facilitate the degradation of aldehydes, a class of endogenously generated pro-inflammatory mediators. In a Phase 2 clinical trial in NAU, 0.5% topical ocular ADX-102 led to the resolution of inflammation to the same degree as corticosteroid therapy, but without the increases in intraocular pressure observed in corticosteroid-treated patients.

The Phase 3 clinical trial is expected to enroll up to 100 NAU patients with active disease, randomized equally to receive either 0.5% topical ocular ADX-102 or vehicle for four weeks. Consistent with the Phase 2 trial, the primary endpoint will be the resolution of inflammation. Results of the Phase 3 trial are expected in the second half of 2018.

A clinical trial synopsis will be available on www.clinicaltrials.gov (NCT03131154).

About Noninfectious Anterior Uveitis

Noninfectious anterior uveitis is a rare, potentially blinding disease that may be mediated in part by pro-inflammatory aldehydes, and is characterized by inflammation in the front of the eye, pain, impaired vision, and photophobia.

About Aldeyra Therapeutics

Aldeyra Therapeutics, Inc. is a biotechnology company devoted to improving lives by inventing, developing and commercializing products that treat diseases thought to be related to endogenous aldehydes, a naturally occurring class of pro-inflammatory and toxic molecules. Aldeyra's lead product candidate, ADX-102, is an aldehyde trap in development for ocular inflammation, as well as for Sjögren-Larsson Syndrome and Succinic Semi-Aldehyde Dehydrogenase Deficiency, two inborn errors of aldehyde metabolism. Aldeyra's product candidates have not 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 plans for its product candidates. 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. 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; the ability to obtain and maintain regulatory approval to conduct clinical trials and to commercialize Aldeyra's product candidates, and the labeling for any approved products; the scope, progress, expansion, and costs of developing and commercializing Aldeyra's product candidates; the size and growth of the potential markets for Aldeyra's product candidates and the ability to serve those

markets; Aldeyra's expectations regarding Aldeyra's expenses and revenue, the sufficiency 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, 2016, which is on file with the Securities and Exchange Commission (SEC) and available on the SEC's website at www.sec.gov. Additional factors may be described in those sections of Aldeyra's Quarterly Report on Form 10-Q for the quarter ended March 31, 2017, to be filed with the SEC in the second quarter of 2017. 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.

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.

Corporate Contact:

Stephen Tulipano
Aldeyra Therapeutics, Inc.
Tel: +1 781-761-4904 ext. 205
[Email Contact](#)

Investor Contact:

Chris Brinzey
Westwicke Partners
Tel: 339-970-2843
[Email Contact](#)

Media Contact:

Cammy Duong
MacDougall Biomedical Communications
781-591-3443
[Email Contact](#)

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