October 10, 2017

Aldeyra Therapeutics Announces New Data at 2017 Research & Development Day

Dry Eye Disease Clinical Activity Correlated with Aldehyde Reduction
Efficacy of ADX-102 in Allergic Conjunctivitis Demonstrated to be Clinically Relevant
ADX-103, a New Aldehyde Trap, Active in Three Preclinical Models of Retinal Disease

LEXINGTON, Mass., Oct. 10, 2017 /PRNewswire/ -- Aldeyra Therapeutics, Inc. (NASDAQ: ALDX) ("Aldeyra" or "the Company"), a clinical-stage biotechnology company devoted to treating inflammation, inborn errors of metabolism, and other diseases related to endogenous aldehyde toxicity, announced new clinical data for ADX-102 from recently completed Phase 2 clinical trials of dry eye disease and allergic conjunctivitis, and the introduction of a retinal disease development program with ADX-103, a novel aldehyde trap.

"These newly released results from our Phase 2 clinical trials in dry eye disease and allergic conjunctivitis strongly support the broad and clinically relevant activity profile of ADX-102 in ocular inflammatory disease," commented Todd C. Brady, M.D., Ph.D., President and Chief Executive Officer of Aldeyra. "In addition, we are pleased to announce the expansion of our ocular franchise with a new development program in retinal disease, featuring our second novel aldehyde trap, ADX-103."

Dry Eye Disease Clinical Activity Correlated with Aldehyde Reduction. Newly announced results from the recent Phase 2a clinical trial in dry eye disease indicated that the statistically significant reduction in levels of a pro-inflammatory aldehyde mediator, malondialdehyde, was correlated with improvement of ocular staining scores and tear osmolarity. To Aldeyra's knowledge, these data represent the first correlation of drug biomarker improvement with dry eye disease clinical activity. Aldeyra plans to commence Phase 2b clinical testing of ADX-102 in dry eye disease in the first half of 2018.

ADX-102 Generated Clinically Important Responses Statistically Superior to Vehicle in Patients with Allergic Conjunctivitis. Newly announced results from the recent Phase 2b clinical trial in allergic conjunctivitis indicated that 0.1% and 0.5% ADX-102 groups were statistically superior to the vehicle group in achieving a clinical response ($p=0.02$ for each group), defined as within-patient one-point improvement in ocular itching score (range 0 to 4) from peak baseline values. Odds ratio analysis indicated that patients treated with each concentration of ADX-102 in the trial were greater than three times more likely to achieve a clinical response than patients treated with vehicle. For the 0.1% and 0.5% ADX-102 groups, time to within-patient one-point clinical response was significantly faster than the vehicle group ($p=0.0006$ and $p=0.008$). In the United States, ocular itching is an approvable endpoint for allergic conjunctivitis, and one-point improvement represents the regulatory precedent for clinical relevance. Allergic conjunctivitis is a persistently disturbing and common ocular disease affecting 20% or more of the worldwide population. Aldeyra plans to commence Phase 3 clinical testing of ADX-102 in allergic conjunctivitis in the first half of 2018.

Introduction of Retinal Disease Development Program with Novel Aldehyde Trap ADX-103. ADX-103, a novel aldehyde trap with a chemical structure distinct from ADX-102, demonstrated activity in pre-clinical retinal disease models of macular degeneration, uveitis, and diabetic macular edema. Retinal disease represents one of the largest markets in ophthalmology and is associated with the generation and accumulation of pro-inflammatory and toxic aldehyde mediators. Additional results are expected to be released at a major scientific meeting in 2018.

Webcast
A live webcast of the presentation and slide deck will be available on the investor relations page of Aldeyra's corporate website at ir.aldeyra.com. After the live webcast, the event will remain archived on Aldeyra's website for one year.

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 as topical eye drops for the treatment of ocular inflammation. ADX-102 has now been tested in over 250 patients in Phase 2 clinical trials in dry eye disease, allergic conjunctivitis, and noninfectious anterior uveitis. A dermatologic form of ADX-102 is in late-stage clinical development for the treatment of ichthyosis due to Sjögren-Larsson Syndrome, an inborn error of aldehyde metabolism. ADX-102 has not been approved for sale in the U.S. or elsewhere.

About Dry Eye Disease
Dry eye disease is a common inflammatory disease estimated to affect approximately 20 million people in the United States, and is characterized by insufficient moisture and lubrication in the anterior surface of the eye, leading to dryness, inflammation, pain, discomfort, irritation, and in severe cases, decreased vision. Among physicians and patients, existing therapy for dry eye disease is generally regarded as inadequate. In patients with dry eye disease, pro-inflammatory aldehyde mediators may contribute to ocular inflammation. By diminishing aldehyde levels, Aldeyra's topical ocular aldehyde trap platform represents a novel and differentiated approach for the treatment of dry eye disease.

About Allergic Conjunctivitis
Allergic conjunctivitis is a common allergic disease that affects 20% or more of the population worldwide. The disease is thought to be mediated in part by pro-inflammatory aldehydes, and is characterized by inflammation of the conjunctiva (a membrane covering part of the front of the eye), resulting in ocular itching, excessive tear production, lid swelling, and redness.

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 and expectations for the development of ADX-102 and ADX-103; and the potential of ADX-102 as an agent for the treatment of dry eye disease and allergic conjunctivitis and ADX-103 as an agent for the treatment of retinal disease. 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; 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, 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 and Quarterly Report on Form 10-Q for the quarter ended June 30, 2017, 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 described in those sections of Aldeyra's Quarterly Report on Form 10-Q for the quarter ended September 30, 2017, to be filed with the SEC in the fourth 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: 781-761-4904 ext. 205
stulipano@aldeyra.com

Investor Contact:
Chris Brinzey
Westwicke Partners

Tel: 339-970-2843
Chris.brinzey@westwicke.com

Media Contact:
Cammy Duong
MacDougall Biomedical Communications
Tel: 781-591-3443
cduong@macbiocom.com

View original content:http://www.prnewswire.com/news-releases/aldeyra-therapeutics-announces-new-data-at-2017-research--development-day-300533624.html

SOURCE Aldeyra Therapeutics, Inc.