



May 17, 2017

Aldeyra Therapeutics Presents Noninfectious Anterior Uveitis Phase 2 Clinical Trial Data at the Association for Research in Vision and Ophthalmology 2017 Annual Meeting

Data Demonstrate ADX-102 Activity Comparable to Topical Ocular Corticosteroids But Without Known Corticosteroid Side Effects

LEXINGTON, MA -- (Marketwired) -- 05/17/17 -- Aldeyra Therapeutics, Inc. (NASDAQ: ALDX) (Aldeyra), a clinical-stage biotechnology company devoted to treating inflammation, inborn errors of metabolism, and other diseases related to aldehydes, presented the results of a randomized, multi-center, investigator-masked, comparator-controlled, parallel-group Phase 2 clinical trial of topical ocular ADX-102, a first-in-class aldehyde trap, as an Emerging Treatments paper at the Association for Research in Vision and Ophthalmology (ARVO) 2017 Annual Meeting. Data from the trial demonstrated ADX-102 activity comparable to standard-of-care topical ocular corticosteroids in reducing anterior chamber cell count in patients with active noninfectious anterior uveitis (NAU). Unlike corticosteroid therapy, ADX-102 did not increase intraocular pressure, a major corticosteroid side effect that can lead to glaucoma, a potentially blinding chronic condition. Dr. John Sheppard, an internationally recognized expert in ocular inflammation, gave the presentation which is available on the investor relations page of the Aldeyra Therapeutics corporate website at ir.aldeyra.com.

"The need to reduce exposure to the deleterious side effects of corticosteroids are well known within the ophthalmology community," commented Dr. John Sheppard. "The results of this important clinical trial suggest the potential therapeutic applicability of topical ocular ADX-102 as a novel and safe approach for the treatment of inflammation."

Forty-five subjects were randomized equally to receive 0.5% ADX-102 four times daily, Pred Forte® (a corticosteroid) four times daily (tapered), or 0.5% ADX-102 four times daily and Pred Forte® twice daily (tapered). There were no statistical differences among all groups for the clinical endpoints, including anterior chamber cell count and ocular flare. ADX-102 was generally well tolerated and there were no serious adverse events, consistent with previous Phase 1 and Phase 2 clinical trials.

ADX-102 produced clinically meaningful effects on anterior chamber cell counts (ACC) comparable to corticosteroid. After four weeks of therapy, 53% of ADX-102-treated patients achieved ACC Grade 0 (zero or one cells) versus 38% for that of corticosteroid-treated patients. Rescue medication was required in 20% of ADX-102-treated patients versus 38% of corticosteroid-treated patients. In the safety population, clinically significant elevations of intraocular pressure were observed in corticosteroid-treated patients but not in ADX-102-treated patients. Mean intraocular pressure increased in the corticosteroid group, but decreased slightly in the ADX-102 group.

In April 2017, Aldeyra announced the initiation of a Phase 3 clinical trial of topical ADX-102 in NAU. The Phase 3 trial is expected to enroll up to 100 patients with active disease, randomized equally to receive either 0.5% topical ocular ADX-102 or vehicle for four weeks. Consistent with prior trials used for marketing registration, the primary endpoint will be the resolution of inflammation. Results of the trial are expected to be announced in the second half of 2018.

Aldehyde mediators are thought to broadly induce inflammation, including allergic disease such as allergic conjunctivitis and autoimmune disease such as NAU. Thus, ADX-102 and other aldehyde sequestering agents represent a novel anti-inflammatory approach. In February 2016, Aldeyra reported positive Phase 2 data with topical ocular ADX-102 in allergic conjunctivitis. The Phase 2 results in NAU released in May 2016 and presented at ARVO suggest that ADX-102 is also active in autoimmune disease.

"In both autoimmune and allergic ocular inflammation, we have demonstrated in our first series of controlled Phase 2 clinical trials that ADX-102's novel aldehyde trapping mechanism produces clinically relevant effects comparable to existing therapies, along with evidence of a safety profile that could become an important option for clinicians treating patients with inflammatory disease," commented David Clark, M.D., Chief Medical Officer of Aldeyra. "We look forward to the results from our Phase 2b clinical trial in allergic conjunctivitis in June of this year, and in addition, the results from our Phase 2a Dry Eye Syndrome clinical trial, expected in the third quarter of this 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 for ocular inflammation, as well as for Sjögren-Larsson Syndrome and Succinic Semi-Aldehyde Dehydrogenase Deficiency, two inborn errors of aldehyde metabolism. ADX-102 has not been approved for sale in the U.S. or elsewhere.

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 Allergic Conjunctivitis

Allergic conjunctivitis is a common allergic disease that 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.

About Dry Eye Syndrome

Dry Eye Syndrome is a common inflammatory disease characterized by insufficient moisture and lubrication over the anterior surface of the eye. Symptoms may include ocular irritation, burning, stinging, visual fluctuations, blurring, and, in severe cases, corneal ulceration. In patients with Dry Eye Syndrome, aldehydes may contribute to ocular inflammation as well as the impairment of lipids (fats) that lubricate the ocular surface.

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 and Quarterly Report on Form 10-Q for the quarter ended March 31, 2017, which are on file with the Securities and Exchange Commission (SEC) and available on the SEC's website at www.sec.gov. 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](#)

Source: Aldeyra Therapeutics

News Provided by Acquire Media