April 20, 2017

Aldeyra Therapeutics, Inc. Receives Orphan Drug Designation from the U.S. Food and Drug Administration for ADX-102 in Sjögren-Larsson Syndrome

LEXINGTON, MA -- (Marketwired) -- 04/20/17 -- Aldeyra Therapeutics, Inc. (NASDAQ: ALDX) (Aldeyra), a clinical-stage biotech company devoted to treating diseases thought to be related to endogenous aldehydes, a naturally occurring class of pro-inflammatory and toxic molecules, today announced that the United States Food and Drug Administration (FDA) has granted Aldeyra's novel compound ADX-102 orphan drug designation for the treatment of congenital ichthyosis, a severe skin disease characteristic of Sjögren-Larsson Syndrome (SLS). There are no FDA-approved therapies specifically indicated for the treatment of SLS, and ADX-102 is believed to be the only potential SLS therapy in clinical development.

"The skin disease associated with SLS is physically and emotionally debilitating, leading to considerable social stigma and requiring significant daily care and medical resources," said Todd C. Brady, M.D., Ph.D., President and CEO of Aldeyra. "Receipt of orphan drug designation by the FDA is great step forward for both Aldeyra and patients suffering from this rare and difficult-to-treat disease."

SLS is caused by genetic mutations that lead to high levels of toxic aldehydes. By sequestering and facilitating the degradation of aldehydes, ADX-102 represents a novel, mechanistically directed potential therapy for SLS. In August of 2016, Aldeyra announced that ADX-102 improved ichthyosis in SLS patients in a randomized, double-blind, vehicle-controlled Phase 2 clinical trial in which ADX-102 was administered to skin for two months. Improvement from baseline was clinically and statistically significant, and the magnitude of improvement was statistically superior to that of vehicle treatment. A global, double-blind, pivotal Phase 3 study is expected to begin later this year. Future clinical trials of ADX-102 or other novel aldehyde traps may involve oral administration as a potential treatment for the neurological aspects of the disease.

The FDA Office of Orphan Products Development designates orphan status to drugs intended to treat, diagnose, or prevent rare diseases that affect fewer than 200,000 people in the United States. Receiving Orphan Drug Designation provides Aldeyra with multiple benefits, including waiver of the Prescription Drug User Fee, post-approval marketing exclusivity for seven years, research tax credits, and assistance during the marketing registration process.

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 Sjögren-Larsson Syndrome
Sjögren-Larsson Syndrome is a rare inborn error of aldehyde metabolism caused by mutations in fatty acid aldehyde dehydrogenase, leading to elevated toxic fatty aldehyde levels that are thought to contribute to severe ichthyosis (scaly, thickened, dry skin), neurological disorders, and retinal disease. There is no therapy for SLS that has been approved by the U.S. Food and Drug Administration.

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 Innoviva'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.

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Source: Aldeyra Therapeutics