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Aldeyra Therapeutics Submits IND Filing to FDA for Clinical Testing of NS2 in Patients With Sjogren-Larsson Syndrome

LEXINGTON, Mass., Jan. 5, 2015 (GLOBE NEWSWIRE) -- Aldeyra Therapeutics, Inc. (Nasdaq:ALDX) (Aldeyra), a biotechnology company focused on the development of products to treat diseases related to free aldehydes, today announced that an Investigational New Drug application (IND) to conduct Phase 2 clinical testing of NS2 for the treatment of Sjögren-Larsson Syndrome (SLS) was submitted to the United States Food and Drug Administration (FDA) on December 30, 2014. The filing was the Company's second IND submission during the month of December for the clinical testing of NS2 in orphan indications.

Todd C. Brady, M.D., Ph.D., President and CEO of Aldeyra, commented, "SLS is a rare disease with no approved therapy. Because the disease is caused by genetic mutations in an aldehyde-metabolizing enzyme, we believe that the aldehyde trap NS2 is analogous to enzyme replacement therapy and has the potential to significantly improve the quality of life in patients who suffer from SLS. With this IND submission of NS2 for the treatment of SLS, we have achieved our stated goal of filing two INDs for orphan indications by the end of 2014. We are excited to continue to advance the development of NS2, and remain focused on preparing for the initiation of clinical trials for both SLS and noninfectious anterior uveitis this year."

SLS is a rare disease caused by mutations in fatty acid aldehyde dehydrogenase that lead to severe ichthyosis (scaly, thickened, dry skin), neurological disorders, and retinal disease. There are no FDA-approved therapies for SLS.

About NS2

NS2, a product candidate that is designed to trap free aldehydes, is under development for the treatment of Sjögren-Larsson Syndrome, a rare disease caused by mutations in an enzyme that metabolizes fatty aldehydes, and noninfectious anterior uveitis, a rare disease characterized by severe inflammation and pain in the anterior eye.

About Aldeyra Therapeutics

Aldeyra Therapeutics, Inc., is a biotechnology company focused primarily on the development of products to treat diseases thought to be related to endogenous free aldehydes, a naturally occurring class of toxic molecules. The company has developed NS2, a product candidate designed to trap free aldehydes. Aldeyra plans to initiate Phase II clinical studies of NS2 in Sjögren-Larsson Syndrome and noninfectious anterior uveitis in early 2015. NS2 has not been approved for sale in the U.S. or elsewhere. www.aldeyra.com

Safe Harbor Statement

This release contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, including statements regarding Aldeyra's plans for its product candidates. 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 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; Aldeyra's ability to attract or retain key personnel; 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 Quarterly Report on Form 10-Q for the quarter ended September 30, 2014 which is on file with the Securities and Exchange Commission (SEC) and available on the SEC's website at www.sec.gov.

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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