Aldeyra Therapeutics Announces First Patient Enrolled in Sjögren-Larsson Syndrome Pivotal Phase 3 Clinical Trial

July 24, 2018

LEXINGTON, Mass., July 24, 2018 /PRNewswire/ -- Aldeyra Therapeutics, Inc. (NASDAQ: ALDX) (Aldeyra), a biotechnology company devoted to development of next-generation medicines to improve the lives of patients with immune-mediated diseases, today announced that the first patient has enrolled in a pivotal Phase 3 clinical trial of topical dermal reproxalap for the treatment of ichthyosis (scaly, thickened, dry skin) associated with Sjögren-Larsson Syndrome (SLS).

"There is currently no FDA-approved therapy for the patients suffering from SLS, a rare inborn error of metabolism that leads to severe skin and neurological disease," commented Todd C. Brady, M.D., Ph.D., President and CEO of Aldeyra. "Based on the positive results from our Phase 2 clinical trial, which demonstrated consistent improvement in the dermatologic manifestations of SLS, we are pleased to enroll our first subject in the Phase 3 clinical trial as part of our ongoing commitment to develop a targeted therapy for SLS patients and their caregivers."

In August 2016, Aldeyra announced that the results of a randomized, parallel-group, double-blind, vehicle-controlled clinical trial in SLS demonstrated clinically relevant activity in diminishing the severity of ichthyosis. As assessed by central review, five of six drug-treated subjects (83%) achieved a rating of "almost clear" or "mild" on global assessment. Six of six (100%) drug-treated subjects improved over the course of therapy as assessed by central review ($p < 0.05$), and the improvement was greater than that observed in vehicle-treated patients ($p < 0.05$). For drug-treated subjects, mean reductions in ichthyosis severity were greater after eight weeks of therapy than after four weeks of therapy, suggesting disease modifying activity.

The randomized, double-blind, multi-center, parallel-group Phase 3 clinical trial is expected to be performed in two parts: the first part of the trial will assess six months of treatment in select areas of ichthyosis over increasing proportions of body surface area; the second part of the trial is expected to assess six months of treatment in all areas of ichthyosis. Data generated from the first part of the trial will be used to confirm statistical power for the second part of the trial. The primary endpoint for the second part of the trial will be improvement in ichthyosis in drug-treated patients over six months of therapy.

A clinical trial synopsis can be found on clinicaltrials.gov (#NCT03445650).

About Aldeyra Therapeutics
Aldeyra Therapeutics is developing next-generation medicines to improve the lives of patients with immune-mediated diseases. Aldeyra's lead product candidate, reproxalap, is a first-in-class treatment in late-stage development for dry eye disease and other forms of ocular inflammation. The company is also developing other product candidates for autoimmune and metabolic diseases. None of Aldeyra's product candidates have been approved for sale in the U.S. or elsewhere.

About Sjögren-Larsson Syndrome
Sjögren-Larsson Syndrome is a rare inborn error of metabolism caused by mutations in fatty acid aldehyde dehydrogenase, leading to ichthyosis (scaly, thickened, dry skin), neurological disorders, and retinal disease. No therapy for SLS has been approved by the U.S. Food and Drug Administration. Aldeyra's RASP (reactive aldehyde species that are pro-inflammatory) inhibitor platform sequesters aldehydes, and thus represents a novel, mechanistically directed therapeutic approach in SLS.

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 reproxalap and its other product candidates; and the potential of reproxalap as an agent for the treatment of SLS. 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, completion and reporting 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, 2017 and Aldeyra's Quarterly Report on Form 10-Q for the quarter ended March 31, 2018, both of 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 Quartly Report on Form 10-Q for the quarter ended June 30, 2018, expected to be filed with the SEC in the third quarter of 2018. 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, completion or reporting 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:
David McMullin
Aldeyra Therapeutics, Inc.
Tel: 781-761-4904 ext. 218
dmcmullin@aldeyra.com

Investor Contact:
Chris Brinzey
Westwicke Partners
Tel: 339-970-2843
Chris.brinzey@westwicke.com

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

View original content:http://www.prnewswire.com/news-releases/aldeyra-therapeutics-announces-first-patient-enrolled-in-sjogren-larsson-syndrome-pivotal-phase-3-clinical-trial-300685365.html

SOURCE Aldeyra Therapeutics, Inc.