Aldeyra Therapeutics Announces Positive Mesothelioma Investigator-Sponsored Clinical Trial Results Presented at The International Association for The Study of Lung Cancer 19th World Conference on Lung Cancer

September 25, 2018

61% Partial Response Rate of ADX-1612 in Combination with Platinum Therapy

LEXINGTON, Mass., Sept. 25, 2018 /PRNewswire/ -- Aldeyra Therapeutics, Inc. (Aldeyra) (NASDAQ: ALDX), a biotechnology company devoted to development of next-generation medicines to improve the lives of patients with immune-mediated diseases, today announced positive top-line results from the MESO-2 investigator-sponsored Phase 1/2 clinical trial of ADX-1612 (ganetespib) in patients with pleural malignant mesothelioma. ADX-1612, when combined with standard pemetrexed and platinum therapy, resulted in partial response rates that exceeded historical standard of care. ADX-1612 is a selective inhibitor of heat shock protein 90 (Hsp90), a molecular chaperone that controls the folding and activation of client proteins involved in DNA repair and cell division. Results will be announced at a presentation at the International Association for the Study of Lung Cancer (ASLC) 19thWorld Conference on Lung Cancer (Abstract #11921) on September 25, 2018.

"The MESO-2 results are highly encouraging. Addition of ADX-1612 to pemetrexed and either cisplatin or carboplatin achieved an overall response rate of 61%, the highest seen to date for addition of a novel agent to front-line chemotherapy" said Professor Dean Fennell MD PhD, Chief Investigator of the Cancer Research UK MESO-2 clinical trial. "Hsp90 inhibition could represent a new advance for the treatment of mesothelioma."

The MESO-2 investigator-sponsored dose escalation clinical trial was designed to assess the safety, tolerability, and efficacy of ADX-1612 in combination with standard pemetrexed and platinum therapy, using either cisplatin or carboplatin. Twenty-seven patients with pleural malignant mesothelioma were enrolled at a single site in the UK and divided into one of three cohorts receiving 100, 150, or 200mg/m^2 of ADX-1612 on days 1 and 15 every 21 days. Of 23 evaluable patients, 22 patients (96%) manifested stable disease or clinical response, and one patient (4%) with non-epithelial histology progressed, as measured by via RECIST (Response Evaluation Criteria in Solid Tumors) criteria. The overall response rate was 61%, relative to historical standard of care response rates of 20 to 40%. The response rate in patients with epithelial histology was 76%. In seven patients, reduction of tumor burden was greater than 50%. One patient remained progression-free after 37 months. ADX-1612 was observed to be well-tolerated, and dose-limiting toxicity was observed in three patients, all of whom were enrolled in the highest dose group.

"Malignant mesothelioma has no known cure, a poor prognosis, and a treatment landscape that has not changed in over a decade," stated Todd C. Brady, M.D., Ph.D., President and CEO of Aldeyra. "Based on the strength of the MESO-2 investigator-sponsored trial results relative to the unmet medical need in mesothelioma, we look forward to meeting with regulatory authorities to discuss these results."

About ADX-1612

ADX-1612 (ganetespib) is a selective inhibitor of heat shock protein 90 (Hsp90), a molecular chaperone that controls the folding and activation of client proteins involved in DNA repair and cell division. Aldeyra is developing ADX-1612 for the treatment of lymphoproliferative immune diseases and cancers in combination with DNA-damaging agents.

About Mesothelioma

Malignant pleural mesothelioma is a rare, aggressive cancer that develops in the pleura, a thin layer of tissue surrounding the lungs. Approximately 3,000 people are diagnosed each year in the United States. Response rates to chemotherapy are generally less than 40%, and five-year survival rates are less than 20%.

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 disease, post-transplant lymphoproliferative disease, retinal inflammation, metabolic disease, and cancer. None of Aldeyra's product candidates have been approved for sale in the U.S. or elsewhere.

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 strategy, future operations, future, prospects, plans, and objectives and Aldeyra's plans and expectations for ADX-1612, including plans to initiate further clinical testing. 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. 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. 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 of 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 and pricing for Aldeyra's product candidates and the ability to serve those markets; Aldeyra's expectations regarding Aldeyra's expenses and revenue, the sufficiency or use 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 June 30, 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.

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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