# Aldeyra Therapeutics Reports Full-Year 2019 Financial Results and Provides Updates on Anticipated Clinical Milestones

March 12, 2020

- INVIGORATE Phase 3 Trial of Reproxalap in Allergic Conjunctivitis Expected to be Completed in Second Half of 2020
- Based on Achievement of Symptom Endpoint in Two Clinical Trials, Subsequent Development Plans for Reproxalap in Dry Eye Disease Pending FDA Feedback, Expected in the Second Half of 2020
- GUARD Phase 3 Trial of ADX-2191 in Proliferative Vitreoretinopathy Initiated
- Strategic Prioritization of Late-Stage Ocular Pipeline Expected to Extend Company's Cash Runway Through the End of 2021
- Management to Host Conference Call at 8:00 a.m. ET Today

LEXINGTON, Mass.--(BUSINESS WIRE)-- Aldeyra Therapeutics, Inc. (Nasdaq: ALDX) (Aldeyra), a biotechnology company devoted to developing and commercializing next-generation medicines to improve the lives of patients with immune-mediated diseases, today reported financial results for the year ended December 31, 2019 and provided an update on anticipated clinical milestones.

"2019 was a year of continued momentum for our lead programs, as we reported statistically significant and clinical relevant data that underscored the potential of reproxalap as a first-line therapy in allergic conjunctivitis and dry eye disease, conditions that in the aggregate affect more than one billion people worldwide," stated Todd C. Brady, M.D., President and CEO of Aldeyra. "Reproxalap potentially represents a highly differentiated mechanism of action compared with existing therapies. We are excited about the market opportunities for reproxalap as we continue to advance towards the completion of clinical development."

**Recent Highlights and Upcoming Milestones**

- **Allergic Conjunctivitis:** Aldeyra expects to complete the INVIGORATE Phase 3 clinical trial of topical ocular reproxalap in the second half of 2020. In 2019, Aldeyra announced achievement of the primary endpoint of the Phase 3 ALLEVIATE Trial in allergic conjunctivitis, as well as statistically significant reductions in ocular itching and redness in an allergen chamber clinical trial.
- **Dry Eye Disease:** Based on the achievement of symptom endpoints in two well-controlled clinical trials, Aldeyra plans to meet with the U.S. Food and Drug Administration (FDA) prior to initiating Part 2 of the RENEW Trial, and plans to provide an update on future development in dry eye disease following FDA feedback, expected in the second half of 2020.
- **Proliferative Vitreoretinopathy (PVR):** Aldeyra is currently enrolling patients in the GUARD Phase 3 Trial of ADX-2191, a novel anti-inflammatory and anti-proliferative agent for the prevention of PVR, a rare sight-threatening condition with no approved treatment. The GUARD Trial is a two-part, multi-center, randomized, controlled, adaptive clinical trial evaluating the efficacy of intravitreal injections of ADX-2191 versus standard-of-care for the prevention of PVR. The trial will compare recurrent retinal detachment rates over a 24-week period following surgical repair of retinal detachment due to PVR or open globe injury. Enrollment is currently expected to be completed in 2021.
- **Systemic Autoimmune Disease:** A single and multiple ascending dose Phase 1 clinical trial has been completed for ADX-629, a novel orally administered RASP inhibitor in development for the treatment of systemic autoimmune disease and potentially other serious medical conditions. Top-line results are expected in the second quarter of this year. Initiation of Phase 2 clinical testing is planned for the second half of 2020.

**Strategic Prioritization of Late-Stage Programs in Ocular Disease**
In a separate news release issued earlier today, Aldeyra announced strategic prioritization of late-stage ocular disease programs in allergic conjunctivitis, dry eye disease, and proliferative vitreoretinopathy. In conjunction with the strategic prioritization, Aldeyra appointed ophthalmology drug development expert James A. Gow, M.D., as Senior Vice President of Clinical Development.

Aldeyra has elected to place on hold its clinical development of topical dermal reproxalap for the treatment of ichthyosis associated with Sjogren-Larsson Syndrome and ADX-1612 for the treatment of post-transplant lymphoproliferative disorder. The initiatives to prioritize the portfolio are expected to extend the company's cash runway through the end of 2021.

**Year Ended December 31, 2019 Financial Review**
Aldeyra reported a net loss of $60.8 million for the year ended December 31, 2019, compared with a net loss of $38.9 million in 2018. Basic net loss per share was $2.24 for the year ended December 31, 2019, compared with $1.79 per share in 2018. Losses have resulted from the costs of Aldeyra's clinical trials and research and development programs, as well as from general and administrative expenses.

Research and development expenses were approximately $44.4 million for the year ended December 31, 2019, compared with approximately $29.8 million for the year ended December 31, 2018. The increase of $14.6 million is primarily related to the increase in clinical and preclinical development

and manufacturing costs; an increase in personnel costs; and non-cash compensation costs related to a portion of upfront acquisition consideration that is subject to vesting based on continued service.

Acquired in-process research and development expenses were $6.6 million for the year ended December 31, 2019. Aldeyra did not have acquired in-process research and development expenses for the year ended December 31, 2018. The $6.6 million increase is related to the in-process research and development expenses associated with the January 2019 acquisition of Helio Vision.

General and administrative expenses were approximately $12.2 million for the year ended December 31, 2019, compared with $9.9 million for the year ended December 31, 2018. The increase of $2.3 million is primarily related to an increase in personnel costs and public company costs related to compliance with the Sarbanes-Oxley Act of 2002.

Total operating expenses were approximately $63.1 million for the year ended December 31, 2019, compared with total operating expenses of approximately $39.7 million for the year ended December 31, 2018.

Cash, cash equivalents, and marketable securities were $73.4 million as of December 31, 2019.

**Conference Call & Webcast Information**
Aldeyra will host a conference call today at 8:00 a.m. ET to discuss its full-year 2019 financial results and provide a corporate update. The dial-in numbers are (866) 211-4098 for domestic callers and (647) 689-6613 for international callers. The Conference ID number is 9984588.

A live webcast of the conference call will also be available on the Investors Relations section of the Aldeyra Therapeutics website at https://ir.aldeyra.com. After the live webcast, the event will remain archived on the Aldeyra Therapeutics website for 90 days.

***About Reproxalap***
Reproxalap is a novel, small-molecule immune-modulating covalent inhibitor of RASP (reactive aldehyde species), which are elevated in ocular and systemic inflammatory disease, and lead to activation of intracellular inflammatory factors, including NF-kB, inflammasomes, and Scavenger Receptor A. Reproxalap’s mechanism of action has been validated with the demonstration of statistically significant and clinically relevant activity in multiple physiologically distinct late-phase clinical indications. Topical ocular reproxalap has now been studied in more than 1,100 patients with no observed safety concerns reported; mild instillation site irritation is the most commonly reported adverse event in clinical trials.

***About ADX-2191***
ADX-2191, an intravitreal formulation of methotrexate, has received orphan drug and fast track designations from the FDA for the prevention of PVR. The observed clinical activity of ADX-2191 in patients with PVR is believed to be the result of down-regulation of aberrant retinal cell proliferation and activity, thereby leading to reduced retinal scarring that is characteristic of PVR. Aldeyra retains an exclusive license to certain patents related to the use of ADX-2191 for the prevention of PVR.

***About Aldeyra Therapeutics***
Aldeyra Therapeutics is a biotechnology company devoted to developing and commercializing next-generation medicines to improve the lives of patients with immune-mediated diseases. Aldeyra's lead investigational drug product candidates are potential first-in-class treatments in development for dry eye disease, allergic conjunctivitis, and proliferative vitreoretinopathy. The company is also developing other product candidates for retinal and systemic inflammatory diseases.

***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 financial position and cash runway, projected costs and expenses, prospects, plans, and objectives and Aldeyra's plans and expectations for its product candidates, including plans relating to current or future clinical development and its strategic prioritization. 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, but not limited to, "may," "might," "will," "objective," "intend," "should," "could," "can," "would," "expect," "believe," "anticipate," "project," "on track," "scheduled," "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; delay in or failure to obtain regulatory approval of Aldeyra's product candidates; the ability to maintain regulatory approval of Aldeyra's product candidates, and the labeling for any approved products; the risk that prior results, such as signals of safety, activity or durability of effect, observed from preclinical or clinical trials, will not be replicated or will not continue in ongoing or future studies or clinical trials involving Aldeyra's product candidates; the scope, progress, expansion, and costs of developing and commercializing Aldeyra's product candidates; uncertainty as to Aldeyra’s ability to commercialize (alone or with others) Aldeyra's product candidates following regulatory approval, if any; 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; political, economic, legal, and social risks that may affect Aldeyra’s business or the global economy; 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 limited sales and marketing infrastructure; Aldeyra's ability to establish and maintain development partnerships; Aldeyra’s ability to successfully integrate acquisitions into its business; 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, 2018 and Aldeyra's Quarterly Report on Form 10-Q for the quarter ended September 30, 2019, which are on file with the Securities and Exchange Commission (SEC) and available on the SEC's website at www.sec.gov. Additional factors are expected to be described in those sections of Aldeyra's Annual Report on Form

10-K for the year ended December 31, 2019, expected to be filed in the first quarter of 2020.

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.

**ALDEYRA THERAPEUTICS, INC.**

**CONSOLIDATED BALANCE SHEETS**

| | December 31, 2019 | December 31, 2018 |
|---|---|---|
| **ASSETS** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 16,425,830 | $ 3,357,472 |
| Cash equivalent- reverse repurchase agreements | 28,000,000 | 44,000,000 |
| Marketable securities | 28,938,545 | 46,242,220 |
| Prepaid expenses and other current assets | 1,804,450 | 1,169,594 |
| Total current assets | 75,168,825 | 94,769,286 |
| Deferred offering costs | — | 86,644 |
| Property and equipment, net | 148,449 | 235,225 |
| Right-of-use assets | 201,007 | — |
| Total assets | $ 75,518,281 | $ 95,091,155 |
| **LIABILITIES AND STOCKHOLDERS' EQUITY** | | |
| Current liabilities: | | |
| Accounts payable | $ 808,302 | $ 3,051,678 |
| Accrued expenses | 11,873,122 | 5,421,498 |
| Current portion of operating lease liabilities | 226,328 | — |
| Total current liabilities | 12,907,752 | 8,473,176 |
| Long-term debt | 14,528,212 | — |
| Total liabilities | 27,435,964 | 8,473,176 |
| Commitments and contingencies | | |
| Stockholders' equity: | | |
| Preferred stock, $0.001 par value, 15,000,000 shares authorized, none issued and outstanding | — | — |
| Common stock, voting, $0.001 par value; 150,000,000 authorized and 28,656,832 | | |

| | | |
|---|---|---|
| and 26,244,435 shares issued and outstanding, respectively | 28,657 | 26,244 |
| Additional paid-in capital | 247,409,793 | 225,136,127 |
| Accumulated other comprehensive income (loss) | 5,866 | (9,224) |
| Accumulated deficit | (199,361,999) | (138,535,168) |
| Total stockholders' equity | 48,082,317 | 86,617,979 |
| Total liabilities and stockholders' equity | $ 75,518,281 | $ 95,091,155 |

**ALDEYRA THERAPEUTICS, INC.**
**CONSOLIDATED STATEMENT OF OPERATIONS**

| | Years ended December 31, | |
|---|---|---|
| | **2019** | **2018** |
| Operating expenses: | | |
| Research and development | $ 44,351,851 | $ 29,823,007 |
| Acquired in-process research and development | 6,567,754 | — |
| General and administrative | 12,154,702 | 9,876,144 |
| Loss from operations | (63,074,307) | (39,699,151) |
| Other income (expense): | | |
| Interest income | 1,541,349 | 952,698 |
| Interest expense | (603,846) | (146,792) |
| Total other income (expense), net | 937,503 | 805,906 |
| Loss before income taxes | (62,136,804) | (38,893,245) |
| Income tax benefit | 1,309,973 | — |
| Net loss | $ (60,826,831) | $ (38,893,245) |
| Net loss per share - basic and diluted | $ (2.24) | $ (1.79) |
| Weighted average common shares outstanding - basic and diluted | 27,111,840 | 21,685,642 |

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