Aileron Therapeutics Reports Second Quarter 2019 Financial Results

August 6, 2019

- *Enrollment in Phase 2a expansion cohort testing ALRN-6924 in combination with Pfizer's IBRANCE® (palbociclib) in MDM2-amplified cancers ongoing and ahead of schedule. Interim data on at least 15 patients to be presented at The European Society for Medical Oncology (ESMO, 9-28-19).*
- *U.S. Food and Drug Administration (FDA) has accepted our Investigational New Drug (IND) application to assess ALRN-6924 as a myelopreservative agent in mutant p53 cancer patients. P1b/2 trial to be initiated in September 2019.*
- *Josef H. von Rickenbach and William T. McKee join Aileron's Board of Directors*

WATERTOWN, Mass., Aug. 06, 2019 (GLOBE NEWSWIRE) -- Aileron Therapeutics (NASDAQ: ALRN), the clinical-stage leader in the field of cell permeating peptide therapeutics for cancers and other diseases, today reported business highlights and financial results for the quarter ended June 30, 2019.

"Aileron continues to make substantial progress in advancing its clinical trial programs," said Dr. Manuel Aivado, President and Chief Executive Officer. "Our execution remains strong, with our clinical programs in MDM2-amplified cancers and myelopreservation on track to reach important milestones by the end of the third quarter of this year including our ESMO presentation on MDM2-amplified cancers on September 28, 2019, and the initiation of our planned Phase 1b/2 myelopreservation trial, also expected in September of this year." Dr. Aivado continued, "We are also very pleased to have strengthened our Board with the additions of Joe von Rickenbach and Bill McKee".

Highlights

- We expect to present interim data on at least 15 patients from our combination trial of ALRN-6924 and palbociclib (Ibrance™), marketed by Pfizer, Inc., for the treatment of MDM2-amplified advanced solid cancers at The European Society for Medical Oncology Annual Congress on September 28, 2019. The majority of patients enrolled to date have been liposarcoma patients due to the high rate of MDM2-amplification in this tumor type, where efficacy is typically measured in months of progression-free survival. Since we expect to fully enroll our targeted 25 patients by the end of September 2019, and since the combination has been well tolerated, we plan to expand enrollment from 25 to 35 patients, focusing on indications outside of liposarcoma to determine the broader applicability of this combination therapy in other MDM2-amplified cancers. We expect to present results from all patients in the second quarter of 2020.
- In June, the U.S. Food and Drug Administration (FDA) accepted our Investigational New Drug (IND) application for ALRN-6924 as a myelopreservation agent in patients with p53-mutant cancers treated with chemotherapy. We expect to enroll approximately 40 patients in this Phase 1b/2 trial beginning in September 2019 and to report proof of concept data from all patients (30-40) from the Phase 1b portion of the trial in the second quarter of 2020.

Corporate Updates

- **Josef H. von Rickenbach joins Aileron's Board of Directors**
  Mr. von Rickenbach has built a long and successful career in the drug development industry. Last year, he retired after 35 years as the Chairman and Chief Executive Officer of PAREXEL, one of the world's largest biopharmaceutical service providers with about 19,000 employees and operations in more than 50 countries. Mr. von Rickenbach co-founded PAREXEL in 1982, led the company through its IPO in late 1995 and made more than 40 mergers and acquisitions during his tenure. Pamplona Capital Management, a private equity firm, took PAREXEL private for approximately $5 billion in September 2017. Mr. von Rickenbach started his career at Schering-Plough, Inc., and held positions at 3M (East), a

division of 3M Company, and ERCO (later ENSECO), Inc. Currently the Managing Director of stet vision LLC, Mr. von Rickenbach recently was co-Founder, President & CEO of Helio Vision, Inc., a Boston-based ophthalmic biopharma company developing a therapy for proliferative vitreoretinopathy (PVR), that merged into Aldeyra, Inc. (NASDAQ: ALDX) in early 2019. Mr. von Rickenbach serves on the Board of Trustees of McLean Hospital and on the Board of Directors of NEHI (Network for Excellence in Health Innovation). Mr. von Rickenbach received a B.A. in Business Economics from Lucerne University in Switzerland and an M.B.A. from Harvard Business School.

- **William T. McKee joins Aileron's Board of Directors**
  Mr. McKee is a seasoned pharmaceutical industry executive and consultant. Currently, Mr. McKee serves as the Chief Executive Officer of MBJC Associates, LLC, a business consulting firm serving the pharmaceutical and biotech industry. Prior to joining MBJC Associates, Mr. McKee served as the Chief Operating Officer and Chief Financial Officer for EKR Therapeutics, Inc. from July 2010 until June 2012, when EKR was sold to Cornerstone Therapeutics Inc. From December 2008 until March 2010, Mr. McKee served as the executive vice president, chief financial officer and treasurer of Barr Pharmaceuticals, LLC, a subsidiary of Teva Pharmaceutical and the successor entity to Barr Pharmaceuticals, Inc., which was acquired by Teva in December 2008. Mr. McKee was also executive vice president and chief financial officer of Barr prior to its acquisition by Teva, after having served in positions of increasing responsibility at Barr from 1995 until its acquisition. Mr. McKee serves as a member of the board of directors and chairman of the audit committee of Assertio Therapeutics, Inc., a specialty pharmaceutical company, and Agile Therapeutics, Inc., a biopharmaceutical company. Mr. McKee received a B.B.A. from the University of Notre Dame.

- We will be presenting at the Canaccord Genuity Growth Conference on August 7, 2019. We will post an updated corporate slide deck and our presentation will be webcast on our website at www.aileronrx.com. Subsequently, the archive of our webcast will be available on our website.

Second Quarter 2019 Financial Results

- **Cash Position and Guidance:** Cash, cash equivalents and investments as of June 30, 2019 were $31.5 million, compared to $20.7 million as of December 31, 2018. The company closed a private placement in second quarter 2019 with net proceeds of $23.8 million. The Company believes that its cash, cash equivalents and investments as of June 30, 2019 will enable the Company to fund its operating expenses and capital expenditure requirements into the fourth quarter of 2020.

- **R&D Expenses:** Research and development (R&D) expenses were $4.3 million for the three months ended June 30, 2019, compared to $5.3 million for the same period in 2018 and $8.5 million for the six months ended June 30, 2019, compared to $10.2 million for the same period in 2018. The decrease in R&D expense in both the three and six months ended June 30, 2019 as compared to the corresponding periods in 2018 primarily reflects costs incurred in 2018 in connection with our ALRN-6924 PTCL trial which we completed, and our AML and MDS trials which we discontinued in early 2019 and is partially offset by the clinical development costs associated with the Phase 2a expansion cohort evaluating the combination of ALRN-6924 and palbociclib (Ibrance) for the treatment of MDM2-amplified advanced solid cancers and costs incurred in preparation for our planned Phase 1b/2 clinical trial to evaluate ALRN-6924 as a myelopreservative agent . The decrease in R&D expense also reflects a decrease of $0.4 million and $0.8 during the three months and six months, respectively, ended June 30, 2019 as compared to the same periods in 2018, in our employee, facility and other development expenses.

- **G&A Expenses:** General and administrative (G&A) expenses were $3.1 million in the three months ended June 30, 2019, compared to $4.3 million for the same period in 2018, and $6.2 million for the six months ended June 30, 2019, compared to $7.3 million for the same period in 2018. The higher expense in the three months and six months ended June 30, 2018 primarily reflects costs under the 2018 separation agreement with our former chief executive officer.

- **Stock-based compensation:** Stock-based compensation expense was $0.5 million or $0.02 per share for the three months ending June 30, 2019 compared to $1.3 million or $0.09 per share for the same period in 2018 and $1.0 million or $0.05 per share for the six months ended June 30, 2019 compared to $2.1 million or $0.14 per share. The decrease of $0.8 million for the three-month period and $1.1 million for the six-month period is attributed to stock option modification charges of $0.6 million in 2018 and the effect of stock option forfeitures over the past twelve months.

- **Net loss:** The Company reported a net loss of $7.2 million or $0.26 per share for the three months ended June 30, 2019 compared to a net loss of $9.5 million or $0.64 per share for the same period in 2018 and it reported a net loss of $14.4 million or $0.68 per share and $17.1 million or $1.16 per share for the six months ended June 30, 2019 and 2018, respectively.

- **Non-GAAP net loss:** The Company reported a Non-GAAP net loss for the three months ended June 30, 2019 of $7.2 million or $0.26 per share compared to a Non-GAAP net loss of $8.3 million or $0.56 per share for the same period in

2018 and it reported Non-GAAP net loss for six months ended June 30, 2019 of $14.4 million or $0.68 per share compared to a Non-GAAP net loss of $15.9 million or $1.08 per share in the same period last year. Non-GAAP net loss per share for the three and six months ended June 30, 2018 excludes costs incurred under the 2018 separation agreement with our former chief executive officer.

A reconciliation of GAAP to non-GAAP financial measures has been provided in the table included below in this press release. An explanation of these measures is also included below under the heading “Non-GAAP Financial Measures.”

- **Shares Outstanding:** As of June 30, 2019, there were 26.7 million shares of common stock outstanding and 1.1 million pre-funded warrants outstanding. In July, these pre-funded warrants were exercised and converted to shares of common stock, increasing the number of shares outstanding to 27.8 million.

About ALRN-6924
ALRN-6924 is a first-in-class, stabilized cell-permeating alpha-helical peptide that mimics the p53 tumor suppressor protein to disrupt its interactions with both its endogenous inhibitors, MDMX and MDM2. ALRN-6924 is currently being evaluated in multiple clinical trials for the treatment of a variety of cancers, including cancers with MDM2-amplified tumors. For information about Aileron’s clinical trials, please visit www.clinicaltrials.gov.

About Aileron
Aileron is a clinical-stage biopharmaceutical company advancing a proprietary platform of cell-permeating alpha-helical peptides that address the most important intracellular targets in oncology and other therapeutic areas. The stabilized helical structure of our peptides allows the design of cell-permeating therapeutic agents with large molecular surfaces for optimal target binding properties, resulting in unique drugs like ALRN-6924. For more information, please visit www.aileronrx.com.

Forward-Looking Statements
Statements in this press release about Aileron's future expectations, plans and prospects, as well as any other statements regarding matters that are not historical facts, including statements about Aileron’s clinical trials, financial prospects, future operations and sufficiency of funds for future operations, may constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. These statements include, but are not limited to, statements about the company’s cash forecast, the sufficiency of the Company’s cash resources and the timing of clinical trial enrollments and data. The words “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “should,” “target,” “would” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including whether Aileron’s cash resources will be sufficient to fund its continuing operations for the periods and/or trials anticipated; whether results obtained in preclinical studies and clinical trials will be indicative of results obtained in future clinical trials; whether Aileron’s product candidates will advance through the clinical trial process on a timely basis, or at all; whether the results of such trials will warrant submission for approval from the United States Food and Drug Administration or equivalent foreign regulatory agencies; whether Aileron's product candidates will receive approval from regulatory agencies on a timely basis or at all; whether, if product candidates obtain approval, they will be successfully distributed and marketed; and other factors discussed in the "Risk Factors" section of Aileron's quarterly report on Form 10-Q for the period ended June 30, 2019, filed on August 6, 2019, and risks described in other filings that Aileron may make with the Securities and Exchange Commission. Any forward-looking statements contained in this press release speak only as of the date hereof, and Aileron specifically disclaims any obligation to update any forward-looking statement, whether because of new information, future events or otherwise.

Non-GAAP Financial Measures
We report all financial information required in accordance with U.S. generally accepted accounting principles (GAAP). To supplement our unaudited condensed financial statements presented in accordance with GAAP, we use certain non-GAAP measures of financial performance. The presentation of these non-GAAP financial measures is not intended to be considered in isolation from, as a substitute for, or superior to, the financial information prepared and presented in accordance with GAAP and may be different from non-GAAP financial measures used by other companies. We use non-GAAP net loss to calculate non-GAAP net loss per share. This non-GAAP financial measure reflects charges incurred in connection with the separation agreement with our former Chief Executive Officer in 2018.

For a reconciliation of non-GAAP financial measures to the most directly comparable GAAP financial measures, please see the accompanying table titled "Reconciliation of Non-GAAP Financial Measures to GAAP Financial Measures."

We believe that these non-GAAP financial measures, when taken together with the corresponding GAAP financial measures, provide meaningful supplemental information regarding our results. Management uses and believes that investors benefit from referring to these non-GAAP financial measures in assessing our operating results, as well as when planning, forecasting and analyzing future periods. For the three and six months ended June 30, 2018, we reduced our net loss by the amount of charges incurred in connection with a separation agreement with our former Chief Executive Officer to calculate our non-GAAP net loss per share. We believe the quantification of these items will enable investors to more clearly understand the nature of our current expenses and increase the comparability of them to prior periods.

Reconciliation of Non-GAAP Financial Measures to GAAP Financial Measures
Aileron Therapeutics, Inc.
(in thousands, except per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018

Numerator:				
GAAP net loss	$ (7,172)	$ (9,491)	$ (14,385)	$ (17,079)
Stock based compensation charge related to CEO separation agreement		612		612
Salary continuation charge related to CEO separation agreement		564		564
Non-GAAP net loss	$ (7,172)	$ (8,315)	$ (14,385)	$ (15,903)
Denominator				
GAAP weighted average common shares outstanding —basic and diluted	27,526,065	14,737,236	21,206,269	14,734,775
GAAP net loss per share —basic and diluted	$ (0.26)	$ (0.64)	$ (0.68)	$ (1.16)
Non-GAAP net loss per share —basic and diluted	$ (0.26)	$ (0.56)	$ (0.68)	$ (1.08)

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Source: Aileron Therapeutics

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