Aileron Therapeutics Reports Second Quarter 2018 Financial Results

August 7, 2018

- *Preclinical in-vivo ALRN-6924 combination data with CDK4/6 inhibitors, PD-1/-L1 inhibitors, or paclitaxel (formulated as Abraxane or Taxol) all show promise in breast cancer and other cancer models*
- *Initiation of clinical trials of ALRN-6924 in combination with approved anti-cancer drugs planned over the next six to twelve months*
- *Recent publications in Science Translational Medicine, Nature Communications, and The Hematologist–ASH News and Reports reflect increased scientific recognition of ALRN-6924 and stapled peptides*
- *New clinical and preclinical data to be available for presentation at four major scientific conferences in the fourth quarter 2018*
- *Expansion cohort for MDS patients, testing ALRN-6924 in combination with Ara-C, initiated in the third quarter of 2018*
- *PTCL Phase 2a trial enrolling. Data is expected to be presented at a major medical conference in the fourth quarter of 2018*
- *New Watertown facility nearing completion, move-in expected in the third quarter of 2018*

CAMBRIDGE, Mass., Aug. 07, 2018 (GLOBE NEWSWIRE) -- Aileron Therapeutics (Nasdaq:ALRN), the clinical-stage leader in the field of stapled peptide therapeutics for cancers and other diseases, today reported business highlights and financial results for the second quarter ended June 30, 2018. ALRN-6924 is a first-in-class stapled peptide designed to reactivate wild-type p53 tumor suppression in solid and liquid tumors. “In our clinical and preclinical programs to-date, ALRN-6924 has been shown to act on-target and to have antitumor activity. Further, in the second quarter, we completed a number of preclinical in-vivo studies with ALRN-6924 in combination with CDK4/6 inhibitors, IO drugs, and chemotherapeutic agents in solid and liquid tumors,” said Manuel Aivado, SVP, CSO and CMO of Aileron. “It was gratifying to see impressive complementary activity between ALRN-6924 and a number of cancer therapeutics in these models. These studies are the basis of four preclinical abstracts that we expect to present at scientific meetings in the fourth quarter of this year.” “The results of these preclinical studies increase our confidence in the potential of ALRN-6924 as a combination therapy,” said John Longenecker, Aileron CEO. “In addition to our ongoing clinical programs, and informed by these preclinical studies, we look forward to initiating clinical trials of ALRN-6924 in combination with both generic and proprietary anticancer drugs within the next six to 12 months, subject to the results of our ongoing research, partnering discussions and obtaining additional funding.”

ALRN-6924 Program Updates

- **Enrollment Ongoing in Phase 2a Trial with ALRN-6924 in Peripheral T-Cell Lymphoma**
  Aileron is conducting a Phase 2a open-label, multi-center trial of ALRN-6924 as a monotherapy in patients with relapsed or refractory peripheral T-cell lymphoma (PTCL). The Company is enrolling patients in an expansion cohort to determine if more frequent dose intensity (days 1, 3, and 5 in a 21-day cycle vs. days 1,8, and 15 in a 28-day cycle) can provide an increased benefit to patients. Interim data from our QW (1,8, and 15) dosing schedule have shown response rates that we believe are similar to those of currently prescribed drugs in this indication. Additional interim data from this trial are expected to be presented at a major medical conference in the fourth quarter of 2018.

- **Phase 1 and 1b Studies in AML and MDS**
  Aileron is conducting Phase 1 and 1b open-label, multi-center dose-escalation clinical trials of ALRN-6924 as a monotherapy and in combination with cytosine arabinoside (Ara-C) for the treatment of acute myeloid leukemia (AML) and myelodysplastic syndrome (MDS). In the Phase 1 monotherapy trial, the Company is currently testing patients with ALRN-6924 (starting at 2.7 mg/kg) three times per week for two consecutive weeks, followed by one week off, in a 21-day cycle. In this arm of the trial, after the first cohort of three patients cleared safety review committee oversight at the 2.7 mg/kg dose, three new patients were enrolled at 3.8 mg/kg, the next dose level per protocol. One of those three patients died of tumor lysis syndrome related to treatment with ALRN-6924. The Company has reported the death to the FDA, and

since the death, has dosed an additional three patients at the 2.7 mg/kg dose level as per trial protocol. The Company plans to continue to enroll patients in the trial. The Company also has initiated an expansion cohort of its Phase 1b trial for MDS patients, testing ALRN-6924 in combination with Ara-C, in the third quarter of 2018. The Company plans to report interim data from its AML/MDS trials at a major medical conference in the fourth quarter, including data from the MDS expansion cohort.

- **Pipeline products**
  Aileron has initiated additional preclinical work within and outside of the therapeutic area of oncology and believes its technology to be well-suited to address heretofore undruggable targets. The company is committed to fully exploring the utility of its stapled peptide technology.

Corporate Update

- **Company to Present at Upcoming Scientific and Investor Conferences**
  The Company plans to participate at upcoming investor conferences, including the Canaccord Genuity 38th Annual Growth Conference (Aug. 8-9, Boston). Aileron also expects to present abstracts in the fourth quarter at venues that may include the 60th ASH Annual Meeting in San Diego (12-1 thru 4), the 30th EORTC-NCI-AACR Symposium in Dublin (11-13 thru 16), SITC 2018 in Washington D.C. (ll-7 thru 11), and the San Antonio Breast Cancer Symposium in San Antonio (12-4 thru 8).

- **CEO Search ongoing**
  John P. Longenecker, Ph.D. was named interim Chief Executive Officer on May 15, 2018. Aileron is actively engaged in a process to appoint a new CEO.

- **Moving to New Built-to-Suit Facility**
  Aileron plans to move to a new built-to-suit lab and office facility at 490 Arsenal Way in Watertown, MA in the third quarter of 2018.

Second Quarter 2018 Financial Results

Cash Position and Guidance: Cash, cash equivalents and investments as of June 30, 2018 were $35.8 million, compared to $50.8 million as of December 31, 2017. The Company believes that its cash, cash equivalents and investments as of June 30, 2018 will enable the Company to fund its operating expenses and capital expenditure requirements into the second half of 2019.

R&D Expenses: Research and development (R&D) expenses were $5.3 million for the three months ended June 30, 2018, compared to $3.2 million for the same period in 2017 and $10.2 million for the six months ended June 30, 2018 compared to $6.1 million for the same period in 2017. The increase in R&D expense for both the three and six months ended June 30, 2018 was primarily driven by increased activity in the Company's non-clinical research and increases in clinical personnel expense. The Company expects R&D expenses to continue to increase as it advances its ALRN-6924 and other programs and hires additional R&D personnel.

G&A Expenses: General and administrative (G&A) expenses were $4.3 million in the three months ended June 30, 2018, compared to $1.8 million for the same period in 2017 and $7.3 million for the six months ended June 30, 2018 compared to $3.4 million for the same period in 2017. Approximately $1.1 million of the increased expense during the three and six months ended June 30, 2018 was due to charges in connection with a separation agreement with our former Chief Executive Officer. Of this $1.1 million charge, approximately $0.5 million is a salary continuation charge and $0.6 million resulted from a non-cash charge for stock option modifications. The remaining increase in G&A expenses for both the three and six-month periods ended June 30, 2018 was primarily due to increases in personnel related costs, higher legal fees in connection with our anticipated facility relocation in third quarter 2018, increased insurance costs associated with being a public company, and increased non-cash stock compensation costs. The Company expects G&A expenses to increase slightly in the future as it hires additional personnel to support the Company's anticipated growth in its research and development activities.

Stock-based compensation: Stock-based compensation expense included in research and development expense and general and administrative was $1.3 million for the three months ended June 30, 2018 compared to $0.3 million for the same period in 2017. The increase of $1.0 million is attributable to stock option modification charges of $0.6 million and the effect of stock option grants made over the past twelve months.

Net Loss: The Company reported a net loss attributable to common stockholders of $9.5 million in the three months ended June 30, 2018 compared to $4.9 million for the same period in 2017 and a net loss of $17.1 million and $9.5 million for the six months ended June 30, 2018 and 2017, respectively. Based on the Company's weighted average shares outstanding, the Company reported a net loss attributable to common stockholders of $0.64 per share in the three months ended June 30, 2018, compared to $10.98 per share for the same period in 2017 (prior to the conversion of preferred stock to common), and a net loss of $1.16 per share for the six months ended June 30, 2018 compared to $21.56 per share for the same period in 2017 (prior to the preferred stock conversion to common).

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, 2018, there were 14.7 million shares of common stock outstanding.

About ALRN-6924

ALRN-6924 is a first-in-class product candidate designed to reactivate wild type p53 tumor suppression by disrupting the interactions between the two

primary p53 suppressor proteins, MDMX and MDM2. Aileron believes ALRN-6924 is the first and only product candidate in clinical development that can equipotently bind to and disrupt the interaction of MDMX and MDM2 with p53. ALRN-6924 is currently being evaluated in multiple clinical trials for the treatment of acute myeloid leukemia (AML), advanced myelodysplastic syndrome (MDS) and peripheral T-cell lymphoma (PTCL). In addition, because many approved drugs and drug candidates for cancer require a functioning p53 pathway, the company has expanded and advanced its non-clinical research to test a variety of approved drugs in combination with ALRN-6924, including cyclin-dependent kinase inhibitors, immuno-oncology agents, and traditional chemotherapeutic agents for solid and liquid tumors. For information about its clinical trials, please visit www.clinicaltrials.gov.

About Aileron

Aileron is a clinical-stage biopharmaceutical company advancing stapled peptides, a novel class of therapeutics for cancers and other diseases. Stapled peptides are chemically stabilized alpha-helical peptides that are modified to improve their stability and cell penetrability while maintaining high affinity for large protein surfaces. The company's goal is to use its proprietary stapled peptide drug platform to create first-in-class therapeutics, like ALRN-6924, that may be able to address historically undruggable targets and complex mechanisms that underlie many diseases with high unmet medical need. The company's platform enables it to chemically stabilize and improve the performance and activity of a broad range of alpha-helical peptides that it believes can potentially activate and inhibit key cellular functions that are otherwise difficult to target with existing drug technologies, including small molecules and monoclonal antibodies. For more information, 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, 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 period 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, 2018, filed on August 7, 2018, 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 attributable to common stockholders and non-GAAP weighted-average shares outstanding to calculate non-GAAP net loss per share attributable to common stockholders. This non-GAAP financial measure reflects charges incurred in connection with the separation agreement with our former Chief Executive Officer in 2018, and gives effect to the conversion of all outstanding shares of preferred stock to common stock, as if such conversion had occurred at the beginning of the period in 2017.

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 periods prior to the closing of our initial public offering on July 5, 2017, we give effect to the automatic conversion of all outstanding shares of redeemable convertible preferred stock to common stock, as if such conversion had occurred at the beginning of the period, in our calculations of non-GAAP weighted-average common shares, basic and diluted, and non-GAAP net loss per share attributable to common stockholders, basic and diluted. The inclusion of these shares facilitates the comparison of results and business outlook for future periods with results for prior periods in order to better understand the long-term performance of our business. For the 2018 periods, 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.
Reconciliation of non-GAAP net loss per share, basic and diluted
(in thousands, except per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
GAAP net loss per share attributable to common stockholders—basic and diluted	$ (0.64)	$ (10.98)	$ (1.16)	$ (21.56)
Numerator:				
GAAP net loss	$ (9,491)	$ (4,923)	$ (17,079)	$ (9,480)

Stock based compensation charge related to CEO separation agreement	612	-	612	-
Salary continuation charge related to CEO separation agreement	564	-	564	-
Accretion of redeemable convertible preferred stock to redemption value	-	(21)	-	(41)
Non-GAAP net loss attributable to common stockholders	$ (8,315)	$ (4,944)	$ (15,903)	$ (9,521)
Denominator:				
GAAP weighted average common shares outstanding — basic and diluted	14,737,236	450,495	14,734,775	441,661
Assumed conversion of redeemable convertible preferred stock to common stock[1]	-	10,509,774	-	10,495,988
Non-GAAP weighted average common shares outstanding - basic and diluted	14,737,236	10,960,269	14,734,775	10,937,649
Non-GAAP net loss per share attributable to common stockholders—basic and diluted	$ (0.56)	$ (0.45)	$ (1.08)	$ (0.87)

(1) All redeemable convertible preferred stock converted to common stock upon the settlement of the IPO on July 5th, 2017. Conversion of preferred stock into common stock is presumed to have occurred at the beginning of each of the periods presented.

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