Aileron Therapeutics Reports First Quarter 2020 Financial Results and Provides Corporate Update

May 11, 2020

Enrollment completed in the dose optimization part of the ongoing Phase 1b/2 clinical trial of ALRN-6924 as a chemoprotection agent in cancer patients

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Scheduled to report interim results from the dose optimization part of the Phase 1b/2 trial 2nd Quarter 2020, and planning final data readout in the fourth quarter of 2020

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Company implemented measures to reduce operating expenses to extend its cash runway to first quarter 2021

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WATERTOWN, Mass., May 11, 2020 (GLOBE NEWSWIRE) -- Aileron Therapeutics (NASDAQ:ALRN) today reported business highlights and financial results for the first quarter ended March 31, 2020.

“We continue to advance ALRN-6924 as a chemoprotection agent for cancer patients, even as the world continues to face the ongoing coronavirus pandemic. We are extremely grateful to our clinical trial sites, and our investigators and their teams for enabling this progress under such difficult circumstances. We have completed enrollment in the third and final cohort of the dose optimization part of our Phase 1b/2 clinical trial in which we are treating small cell lung cancer patients with ALRN-6924 twenty-four hours before topotecan, a standard of care chemotherapy, to study the impact of ALRN-6924 on chemotherapy toxicities,” said Dr. Manuel Aivado, President and CEO of Aileron Therapeutics. “We look forward to announcing interim data from the dose optimization part of the study in the 2nd quarter of this year.”

ALRN-6924 as a chemoprotection agent

The Company recently completed enrollment in the dose optimization part of its Phase 1b/2 clinical trial evaluating ALRN-6924 as an agent to protect patients with small cell lung cancer (SCLC) against chemotherapy-induced toxicity, a concept known as chemoprotection (or myelopreservation). The Phase 1b part of the study is designed to identify a dose and a schedule of ALRN-6924 administration to reduce chemotherapy toxicities such as severe anemia and thrombocytopenia resulting from topotecan. In this part of the trial, topotecan is administered daily on days 1 through 5 of every 21-day treatment cycle and ALRN-6924 is administered 24 hours before each dose of topotecan (on days 0 through 4 every 21 days). The dose optimization part of the study includes three patient cohorts, one for each dose level, and enrolled a total of 17 patients.

As previously reported, the Company was encouraged by the interim results of a data cutoff on January 22, 2020. In the first eleven patients across the first 2 dose levels tested, a protective effect of ALRN-6924 was observed for severe anemia and thrombocytopenia. Based on the preliminary data from the Phase 1b trial, and historical rates of these toxicities in SCLC patients treated with topotecan, Aileron believes that ALRN-6924, when dosed before chemotherapy may have a chemoprotective effect on toxicities such as severe anemia and thrombocytopenia.

Aileron has now completed enrollment of its final patient cohort of ALRN-6924 at a third dose level in the dose optimization part of the trial. The Company is encouraged with the initial data that is emerging from this cohort as it supports the trends observed with the previous two cohorts.

The Company plans to commence the schedule optimization part of the Phase 1b trial in June 2020. In this part of the trial, ALRN-6924 will be evaluated at up to two dose levels, potentially with an expansion cohort, in approximately up to 20 patients, and ALRN-6924 will be administered six hours before each dose of topotecan (on days 1 through 5 of every 21-day treatment cycle). The objective of the second dosing schedule is to determine if ALRN-6924 given six hours before topotecan has the potential to enhance the chemoprotection effects while also improving patient convenience by reducing the total number of days for infusion of ALRN-6924 and topotecan from six infusion days for the -24 hour schedule to five infusion days for the -6 hour schedule.

Aileron currently plans to report interim results for the three dose levels of the dose optimization part of the trial in the 2nd quarter of 2020. The Company currently plans to report top-line final data for the dose optimization part of the trial and data for the schedule optimization part of the trial in the fourth quarter of 2020. The Company expects that these results will determine a recommended ALRN-6924 dose and schedule for subsequent trials.

The Company is monitoring carefully the effect of the coronavirus pandemic on the healthcare system and its clinical sites, which may impact the timing of these planned data announcements.

First Quarter 2020 Financial Results

Cash Position: Cash, cash equivalents and investments as of March 31, 2020 were $12.7 million. In light of the Company's cash resources and the uncertainties associated with the coronavirus pandemic, the Company has determined to focus its efforts on the development of ALRN-6924 as a chemoprotective agent, and does not plan to advance development of ALRN-6924 for any other program at this time. The Company believes that its cash, cash equivalents and investments as of March 31, 2020 will be sufficient to fund its operations and capital expenditure requirements into the first quarter of 2021.

R&D Expenses: Research and development expenses for the three months ended March 31, 2020 were $4.1 million, compared to $4.2 million for the three months ended March 31, 2019. The decrease of $0.1 million is primarily attributed to a decrease of $0.6 million in the Company's employee and other development expenses due to a decrease in the number of research and development employees from 15 in 2019 to seven in 2020, as well as a decrease of $0.2 million in other early-stage development programs due to the Company's determination not to conduct further research activities. These decreases are partially offset by an increase of $0.7 million in costs that were incurred in the period related to the manufacture and clinical development of ALRN-6924. In March 2020, the Company implemented cost savings initiatives including the elimination of previously planned research studies. Accordingly, the Company expects that its quarterly expenditures on research and development will be lower for the remainder of 2020 as compared to the first quarter of 2020.

G&A Expenses: General and administrative expenses were $2.8 million for the three months ended March 31, 2020, compared to $3.1 million for three months ended March 31, 2019. The decrease primarily reflects costs saved due to lower administrative support-related costs. The Company anticipates that cost savings initiatives implemented in March 2020 will result in lower quarterly general and administrative expenses for the remainder of 2020 as compared to the first quarter of 2020.

Net Loss: Net loss was $6.7 million for the three months ended March 31, 2020, compared to $7.2 million for the same period in 2019.

Shares Outstanding: As of March 31, 2020, there were 27.8 million shares of common stock outstanding. Pursuant to its Capital on Demand Sales Agreement, between April 1, 2020 and May 4, 2020, the Company issued and sold an aggregate of 1.3 million shares of common stock for gross proceeds of $0.7 million.

About ALRN-6924

ALRN-6924 is a first-in-class dual MDM2/MDMX inhibitor that is currently being evaluated in a Phase 1b/2 clinical trial to evaluate ALRN-6924 as a chemoprotective agent to protect against chemotherapy-related toxicities.

About Aileron

Aileron is a clinical-stage biopharmaceutical company advancing a proprietary platform of cell-permeating alpha-helical peptides. The stabilized helical structure of the Company's peptides allows the design of cell-permeating therapeutic agents with large molecular surfaces for optimal target binding properties, such as the Company's lead product candidate ALRN-6924. The Company's focus is to improve the standard of care for patients with cancer by developing safe and effective therapies that leverage the Company's proprietary peptide platform. For more information, visit www.aileronrx.com, and for more information about our clinical trials please visit www.clinicaltrials.gov.

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 strategy and clinical development plans. 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 the Company's clinical trials will be conducted on the timelines anticipated; whether results obtained in preclinical and nonclinical studies and clinical trials will be indicative of results obtained in future clinical trials; whether preliminary or interim results from a clinical trial will be indicative of the final results of the trial; 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; whether the coronavirus pandemic will have an impact on the timing of the Company's clinical development and operations; and other factors discussed in the "Risk Factors" section of Aileron's quarterly report on Form 10-Q for the period ended March 31, 2020, filed on May 11, 2020, 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.

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