Aileron Therapeutics Reports First Quarter 2022 Financial Results and Business Highlights

May 5, 2022

- On track to report interim results from Phase 1b clinical trial of ALRN-6924 in patients with advanced p53-mutated non-small cell lung cancer (NSCLC) in June 2022; topline results anticipated in 4Q 2022
- On track to initiate Phase 1b clinical trial of ALRN-6924 in patients with p53-mutated ER+/HER2- neoadjuvant breast cancer in 2Q 2022; initial interim results anticipated in 4Q 2022
- Company to host a virtual investor event on May 19th to discuss ALRN-6924's revolutionary potential as the first precision medicine-based supportive care drug, the landscape of chemotherapy-induced toxicities, and the company's planned 2022 data readouts
- Cash, cash equivalents, and investments as of March 31, 2022, expected to fund operations into the fourth quarter of 2023

BOSTON, May 05, 2022 (GLOBE NEWSWIRE) -- Aileron Therapeutics (Nasdaq: ALRN), a chemoprotection oncology company that aspires to make chemotherapy safer and thereby more effective to save more patients' lives today, reported financial results and business highlights for the first quarter ended March 31, 2022.

"Building on our positive proof-of-concept trial last year in patients with small cell lung cancer treated with topotecan, we view 2022 as a year of validation and execution for Aileron as we seek to bring selective chemoprotection to all patients with p53-mutated cancers regardless of the type of cancer or chemotherapy. Our ongoing NSCLC clinical trial and upcoming breast cancer clinical trial are designed to help us further understand ALRN-6924's chemoprotective effect against chemotherapy-induced hematologic toxicities as well as other toxicities," said Manuel Aivado, M.D., Ph.D., President and Chief Executive Officer of Aileron. "We believe that evaluating ALRN-6924 across these two major cancer types treated with different chemotherapies that carry distinct toxicity profiles may provide us with an expanded regulatory opportunity based on established precedent for other supportive care drug approvals."

Nearly 1 million patients are diagnosed with a p53-mutated cancer in the US each year. Aileron is pioneering a precision medicine-based approach known as selective chemoprotection to exclusively treat patients with p53-mutated cancers receiving chemotherapy. ALRN-6924 is designed to selectively protect these patients' healthy cells from chemotherapy without interfering with chemotherapy's effects on cancer cells. Aileron's vision is to bring chemoprotection to all patients with p53-mutated cancers regardless of the type of cancer or chemotherapy.

First Quarter 2022 Highlights and Recent Updates

- **On track to report interim results from ongoing randomized, double-blind, placebo-controlled Phase 1b clinical trial of ALRN-6924 in advanced p53-mutated NSCLC in June 2022.** Aileron plans to enroll 60 patients with advanced p53-mutated NSCLC undergoing treatment with first-line carboplatin plus pemetrexed with or without immune checkpoint inhibitors. Patients are randomized 1:1 to receive carboplatin/pemetrexed plus 0.3 mg/kg ALRN-6924 or placebo for four 21-day treatment cycles.

  The company anticipates reporting interim results on the first 20 patients enrolled in June 2022 and topline results on 60 patients in 4Q 2022. The interim readout will include an initial evaluation of the trial's composite endpoint, composed of the proportion of treatment cycles free of severe toxicities, blood transfusions, and the use of growth factors, as well as dose reductions or dose delays, in patients treated with ALRN-6924 versus placebo.

- **Completed blinded safety evaluation of NSCLC clinical trial.** In 1Q 2022, Aileron conducted a blinded safety evaluation of the first ten patients enrolled in the NSCLC clinical trial who completed the first cycle of treatment with ALRN-6924 and carboplatin plus pemetrexed. The evaluation did not identify any safety concerns, consistent with ALRN-6924's previously demonstrated safety and tolerability profile.

- **On track to initiate Phase 1b randomized trial of ALRN-6924 in patients with p53-mutated ER+/HER2- neoadjuvant breast cancer in 2Q 2022.** The planned breast cancer trial will evaluate ALRN-6924's protection against chemotherapy-induced bone marrow toxicities, as well as other toxicities, including alopecia, in patients with p53-mutated ER+/HER2- breast cancer treated with a doxorubicin + cyclophosphamide and docetaxel chemotherapy regimen. The Phase 1b trial is anticipated to enroll up to 30 patients in a parallel group design trial with a dose expansion cohort.

- **Announced management team updates.** In April 2022, Aileron announced the appointment of Christopher Zergebel as Vice President, Program Management and Clinical Operations. Mr. Zergebel previously served as Vice President, R&D Services at Taiho Oncology, Inc., overseeing clinical project management, clinical operations, data management, medical writing, and clinical supplies through all phases of clinical development and through regulatory approvals. Aileron also recently announced the pending departure of Richard Wanstall, Chief Financial Officer. Mr. Wanstall joined Aileron in July 2018 and has been instrumental in Aileron's successful evolution to a chemoprotection oncology company and helped expand Aileron's finance, operations, and human resources infrastructure. Prior to joining Aileron, Mr. Wanstall served for four years as Vice President, Finance at Moderna. Aileron has launched a formal search process to identify Mr. Wanstall's successor.

- **Upcoming virtual investor event on Thursday, May 19th.** Aileron's management team, joined by guest speakers, will host an investor event to discuss ALRN-6924's revolutionary potential as the first precision medicine-based supportive care drug, the landscape of chemotherapy-induced toxicities, and the company's clinical trials and planned 2022 data readouts. To register, visit https://investors.aileronrx.com.

First Quarter 2022 Financial Results

- **Cash Position:** Cash, cash equivalents, and investments on March 31, 2022, were $38.1 million, compared to $45.9 million on December 31, 2021. Based on its current operating plan, the company expects its existing cash, cash equivalents, and investments will fund operations into the fourth quarter of 2023.

- **Research and Development (R&D) Expenses:** R&D expenses for the quarter ended March 31, 2022, were $5.9 million, compared to $4.3 million for the quarter ended March 31, 2021. The $1.6 million increase in R&D spending primarily resulted from $0.4 million of increased spending for clinical development of ALRN-6924 related to the Phase 1b clinical trial in patients with advanced p-53 mutated NSCLC and startup activities related to the Phase 1b randomized trial of ALRN-6924 in patients with p53-mutated ER+/HER2- neoadjuvant breast cancer, partially offset by lower spending for the ongoing Phase 1 trial in healthy human volunteers and the completion of the Phase 1b trial in small cell lung cancer in 2021. R&D expenses also increased in the first quarter of 2022 compared to the first quarter of 2021 resulting from increased ALRN-6924 manufacturing activities.

- **General and Administrative (G&A) Expenses:** G&A expenses for the quarter ended March 31, 2022, were $2.5 million compared to $2.7 million for the quarter ended March 31, 2021. The decrease in general and administrative expenses was the result of lower professional services fees during the first quarter of 2022 as compared to the first quarter of 2021.

- **Net Loss:** Net loss for the quarter ended March 31, 2022, was $8.4 million, compared to $7.0 million for the corresponding quarter in 2021. The basic and diluted net loss per share for the first quarter of 2022 was $0.09 compared to $0.08 for the first quarter of 2021.

About Aileron Therapeutics

Aileron is a clinical stage chemoprotection oncology company that aspires to make chemotherapy safer and thereby more effective to save more patients' lives. ALRN-6924, our first-in-class MDM2/MDMX dual inhibitor, is designed to activate p53, which in turn upregulates p21, a known inhibitor of the cell replication cycle. ALRN-6924 is the only reported chemoprotective agent in clinical development to employ a biomarker strategy, in which we exclusively focus on treating patients with p53-mutated cancers. Our targeted strategy is designed to selectively protect multiple healthy cell types throughout the body from chemotherapy without protecting cancer cells. As a result, healthy cells are spared from chemotherapeutic destruction while chemotherapy continues to kill cancer cells. By reducing or eliminating multiple chemotherapy-induced side effects, ALRN-6924 may improve patients' quality of life and help them better tolerate chemotherapy. Enhanced tolerability may result in fewer dose reductions or delays of chemotherapy and the potential for improved efficacy.

Our vision is to bring chemoprotection to all patients with p53-mutated cancers, which represent approximately 50% of cancer patients, regardless of type of cancer or chemotherapy. Visit us at aileronrx.com to learn more.

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 potential of ALRN-6924 as a chemoprotective agent, the Company's strategy and clinical development plans and the Company's cash runway. 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 anticipated or with respect to the matters anticipated; whether initial results of clinical trials will be indicative of final results of those trials or results obtained in future clinical trials, including trials in different indications; whether ALRN-6924 will advance through the clinical trial process on a timely basis, or at all; whether the results of such trials will be accepted by and warrant submission for approval from the United States Food and Drug Administration or equivalent foreign regulatory agencies; whether ALRN-6924 will receive approval from regulatory agencies on a timely basis or at all or in which territories or indications ALRN-6924 may receive approval; whether, if ALRN-6924 obtains approval, it will be successfully distributed and marketed; what impact the coronavirus pandemic may have on the timing of our clinical development, clinical supply and our operations; and other factors discussed in the "Risk Factors" section of Aileron's annual report on Form 10-K for the year ended December 31, 2021, filed on March 28, 2022, 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.

Investor Contact:
Stern Investor Relations
Alexander Lobo
alex.lobo@sternir.com

Media Contact:
Liz Melone
lmelone@aileronrx.com

Aileron Therapeutics, Inc.
Balance Sheet Data
(In thousands)

	March 31, 2022	December 31, 2021
Cash, cash equivalents, and investments	$ 38,075	$ 45,933
Working capital	35,847	43,669
Total assets	40,255	48,481
Accumulated deficit	(253,878)	(245,456)
Total stockholders' equity	$ 36,109	$ 43,904

Aileron Therapeutics, Inc.
Condensed Statement of Operations
(In thousands, except share and per share data)

	Three Months Ended March 31,	
	2022	2021
Revenue	$ -	$ -
Operating expenses:		
Research and development	5,893	4,316
General and administrative	2,528	2,673
Total operating expenses	8,421	6,989
Loss from operations	(8,421)	(6,989)
Interest and other income	(1)	14
Net loss	(8,422)	(6,975)
Net loss per share — basic and diluted	$ (0.09)	$ (0.08)
Weighted average common shares outstanding—basic and diluted	90,673,597	83,384,371