Aileron Therapeutics Reports Second Quarter 2022 Financial Results and Business Highlights

August 15, 2022

- Company continues to advance ALRN-6924 as a selective chemoprotective agent for all patients with p53-mutated cancer, with immediate focus on breast cancer clinical trial
- Extended cash runway expected to support operations through end of 1Q 2024
- Presented new data at the Society for Investigational Dermatology 2022 Annual Meeting suggesting ALRN-6924's potential to protect against chemotherapy-induced alopecia
- Reported new data from healthy volunteer study demonstrating ALRN-6924-induced cell cycle arrest in hair follicles and suggesting that higher levels of ALRN-6924 may generally prolong cell cycle arrest
- Strengthened management team with appointment of Susan L. Drexler as interim Chief Financial Officer (CFO)

BOSTON, Aug. 15, 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 second quarter ended June 30, 2022.

"As we announced earlier this month, we are pleased that we have extended our cash runway, which is now expected to fund our operations through the end of 1Q 2024. We expect that our cash resources will support key planned data readouts from our ongoing breast cancer trial, including initial data in 4Q 2022, an interim readout in 2Q 2023, and topline results in 3Q 2023, in addition to pivotal trial readiness activities, subject to the breast cancer trial data and discussions with the FDA," said Manuel Aivado, M.D., Ph.D., President and Chief Executive Officer at Aileron.

Dr. Aivado continued, "Supportive care continues to be a severely underserved medical need. Available pharmacologic therapies, like G-CSF for severe neutropenia and EPO for anemia, have limited efficacy and are associated with severe toxicities of their own. For several other toxicities, like alopecia, there are no approved pharmacologic therapies. Chemotherapy-induced toxicities frequently can lead to dose reductions and delays, significant adverse impact on quality of life, and premature treatment discontinuations. By delivering a chemoprotective agent that can effectively protect multiple tissue types simultaneously, we have the potential to usher in a new era in supportive care where 'whole patient care' becomes the accepted and expected standard."

Second Quarter 2022 and Recent Highlights

- **Preparing to re-initiate enrollment of Phase 1b breast cancer clinical trial.** As recently announced, Aileron anticipates reinitiating enrollment in the breast cancer trial under the amended protocol in the coming weeks. The Phase 1b open-label, single-arm, multicenter trial is designed to evaluate the chemoprotective effect of 1.2 mg/kg dose of ALRN-6924 against severe neutropenia, as well as chemotherapy-induced alopecia, and other hematologic and non-hematologic toxicities in breast cancer patients with p53-mutant tumors who are undergoing either neoadjuvant or adjuvant treatment with docetaxel, doxorubicin and cyclophosphamide, also known as TAC. Previous data has shown that up to 75% of patients receiving TAC experience severe neutropenia in cycle 1 despite prophylactic use of G-CSF[1], and up to 98% of patients experience alopecia[2].

- **Presented new non-clinical data demonstrating ALRN-6924 protected human hair follicles and their stem cells from paclitaxel-induced toxicity and irreversible stem cell damage.** The new *ex vivo* data – developed in collaboration with Professor Ralf Paus, M.D., DSc, FRSB and his colleagues at the Dr. Phillip Frost Department of Dermatology & Cutaneous Surgery at the University of Miami Miller School of Medicine – were highlighted in a late-breaking oral presentation at the Society of Clinical Dermatology Annual Meeting. The data demonstrated proof of principle that ALRN-6924 can temporarily arrest the cell cycle in human scalp hair follicles and their stem cells as well as protect hair follicles from paclitaxel-induced toxicity and irreversible stem cell damage.

- **Reported new pharmacodynamic (PD) effect and mechanism of action data from the recently completed Phase 1 pharmacology study of ALRN-6924 in healthy human volunteers.** Previous PD data demonstrated that serum levels of MIC-1 were correlated with bone marrow p21, which is a marker for cell cycle arrest. The most recent PD data demonstrated that higher doses of ALRN-6924 prolonged the elevation of serum MIC-1 in a dose-dependent fashion. Based on these findings, Aileron believes that prolonged elevation of serum levels of MIC-1 at higher ALRN-6924 dose levels should indicate prolonged cell cycle arrest in bone marrow and other tissues, and thereby prolonged chemoprotection. Aileron has submitted these and other results from the healthy volunteer study for presentation at a scientific congress in 2H 2022.

- **Strengthened intellectual property (IP) portfolio with additional composition of matter patent for ALRN-6924 in China.** The China National Intellectual Property Administration granted Aileron patent No. ZL 2020114599292, providing exclusivity over the composition of matter of ALRN-6924. Aileron's strong IP portfolio comprises over 160 U.S. and foreign patents, including ALRN-6924 compositions of matter, drug product formulations, methods of manufacture, and methods of use. Aileron maintains exclusive worldwide rights to its proprietary peptide drug technology and ALRN-6924.

- **Appointed Susan L. Drexler, MBA, CPA, as Interim CFO.** Ms. Drexler is an accomplished executive with over 25 years of experience with development- and commercial-stage life science companies in financial management, M&A and licensing deals, financial planning & analysis, and business analytics. Ms. Drexler was most recently CFO with Harmony Biosciences Holdings, Inc., where she oversaw finance, accounting, and IT operations.

Second Quarter 2022 Financial Results

- **Cash Position:** Cash, cash equivalents, and investments on June 30, 2022, were $32.4 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 through the end of first quarter of 2024.

- **Research and Development (R&D) Expenses:** R&D expenses for the quarter ended June 30, 2022, were $5.4 million, compared to $3.9 million for the quarter ended June 30, 2021. R&D expenses increased by $1.6 million which was primarily due to $1.0 million of spending for our Phase 1b clinical trial in breast cancer, $0.2 million of increased spending for our Phase 1b clinical trial in non-small cell lung cancer, and $0.3 million of increased manufacturing costs for ALRN-6924 to support our clinical trials and research studies.

- **General and Administrative (G&A) Expenses:** G&A expenses for the quarter ended June 30, 2022, were $2.6 million compared to $2.2 million for the quarter ended June 30, 2021. G&A expenses increased by $0.5 million, which was primarily due to an increase in professional services fees during the second quarter of 2022 as compared to the same period in 2021.

- **Net Loss:** Net loss for the quarter ended June 30, 2022, was $8.0 million, compared to $5.7 million for the corresponding quarter in 2021. The basic and diluted net loss per share for the second quarter of 2022 was $0.09 compared to $0.06 for the second 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 quarterly report on Form 10-Q for the quarter ended June 30, 2022, filed on August 15, 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.

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[1] U.S. Food & Drug Administration (FDA) Statistical Review of FULPHILA®

[2] Martin et al., N Engl J Med 2005;352:2302-13.

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

	June 30, 2022	December 31, 2021
Cash, cash equivalents and investments	$ 32,382	$ 45,933
Working capital	28,399	43,669
Total assets	33,770	48,481
Accumulated deficit	(261,870)	(245,456)
Total stockholders' equity	28,619	43,904

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

	Three Months Ended June 30,	
	2022	2021
Revenue	$ -	$ -
Operating expenses:		
Research and development	5,433	3,853
General and administrative	2,608	2,156
Total Operating expenses	8,041	6,009
Loss from operations	(8,041)	(6,009)
Interest and other income, net	49	323
Net loss	(7,992)	(5,686)
Net loss per share — basic and diluted	$ (0.09)	$ (0.06)
Weighted average common shares outstanding—basic and diluted	90,823,597	90,458,550