Aileron Therapeutics Reports Third Quarter 2022 Financial Results and Business Highlights

November 1, 2022

- Activated multiple existing and new sites under amended Phase 1b breast cancer clinical trial protocol; additional site activations anticipated in 4Q 2022 and 1Q 2023
- Presented healthy volunteer study results at EORTC-NCI-AACR International Conference demonstrating potential of ALRN-6924 to prevent chemotherapy-induced neutropenia, thrombocytopenia, and anemia, as well as chemotherapy-induced alopecia
- Presented new *ex vivo* data at European Society for Dermatological Research Annual Meeting showing ALRN-6924 protected hair follicles and their stem cells from cyclophosphamide-induced damage
- Cash runway expected to support operations and key milestones through end of 1Q 2024, including planned breast cancer trial readouts in 2023

BOSTON, Nov. 01, 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 third quarter ended September 30, 2022.

"Several sites in the U.S. and Eastern Europe are now open for enrollment under the amended protocol for our breast cancer trial, and we expect multiple additional sites to open in Western and Eastern Europe in the fourth quarter of 2022 and the first quarter of 2023," said Manuel Aivado, M.D., Ph.D., President and Chief Executive Officer at Aileron. "We're grateful to have enthusiastic investigators who recognize the significant challenges that chemotherapy-induced toxicities present for cancer patients, the drawbacks that are associated with the limited supportive care treatments that are available, and the transformative potential of a single agent like ALRN-6924 that may simultaneously prevent multiple hematologic and non-hematologic toxicities."

Third Quarter 2022 and Recent Highlights

- **Activated multiple existing and new trial sites in the U.S. and Europe under amended Phase 1b breast cancer trial protocol, with planned activation of additional sites in 4Q 2022 and 1Q 2023.** This 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. Aileron plans to report initial data from the breast cancer trial in 4Q 2022, an interim readout in 2Q 2023, and topline results in 3Q 2023.

- **Presented detailed results from Phase 1 study in healthy volunteers at the EORTC-NCI-AACR International Conference on Molecular Targets and Cancer Therapeutics.** The poster presentation in October 2022 included results demonstrating the potential of ALRN-6924 to prevent chemotherapy-induced neutropenia, thrombocytopenia, and anemia, as well as chemotherapy-induced alopecia in patients with p53-mutated cancer. The presentation also included data showing that higher doses of ALRN-6924 prolonged the elevation of serum macrophage inhibitory cytokine-1 (MIC-1), a biomarker of p53 activation, in a dose-dependent fashion. Based on these findings, Aileron believes that the degree and duration of serum MIC-1 elevation at higher ALRN-6924 dose levels indicates more durable cell cycle arrest in bone marrow and other tissues, and thereby prolonged chemoprotection. These healthy volunteer study results, combined with clinical results from a 1.2 mg/kg cohort of topotecan-treated patients in Aileron's previously conducted proof-of-concept study of ALRN-6924 in p53-mutated small cell lung cancer, support the company's selection of a 1.2 mg/kg dose in its breast cancer trial. The EORTC-NCI-AACR presentation also included data showing that safety profiles, pharmacokinetics and pharmacodynamics were similar for both a 3-minute intravenous (IV) bolus and a 1-hour IV infusion of ALRN-6924,

providing rationale for future development of ALRN-6924 bolus IV administration.

- **Presented new non-clinical data demonstrating ALRN-6924 protected human hair follicles and their stem cells from cyclophosphamide-induced toxicity and irreversible stem cell damage.** The *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 an oral presentation at the European Society for Dermatological Research (ESDR) Annual Meeting in September 2022. The ESDR presentation also included *ex vivo* data previously reported by Dr. Paus and his colleagues showing 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.

Third Quarter 2022 Financial Results

- **Cash Position:** Cash, cash equivalents, and investments on September 30, 2022, were $25.5 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 September 30, 2022, were $4.2 million, compared to $4.3 million for the quarter ended September 30, 2021. R&D expenses decreased by less than $0.1 million for the three months ended September 30, 2022, which was primarily due to a decrease in manufacturing costs for ALRN-6924, offset by an increase in spending for the company's Phase 1b breast cancer trial, during the third quarter of 2022 as compared to the same period in 2021.

- **General and Administrative (G&A) Expenses:** G&A expenses for the quarter ended September 30, 2022, were $2.2 million compared to $2.5 million for the quarter ended September 30, 2021. G&A expenses decreased by $0.3 million for the three months ended September 30, 2022, which was primarily due to a decrease in stock compensation expense during the third quarter of 2022 as compared to the same period in 2021.

- **Net Loss:** Net loss for the quarter ended September 30, 2022, was $6.4 million, compared to $6.7 million for the corresponding quarter in 2021. The basic and diluted net loss per share for the third quarter of 2022 was $0.07 compared to $0.07 for the third 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, the Company's planned enrollment and data readouts from its Phase 1b breast cancer trial, 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 the company will enroll patients in, and report data from, its Phase 1b breast cancer trial on a timely basis; 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 September 30, 2022, filed on November 1, 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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Aileron Therapeutics, Inc.
Selected Balance Sheet Data
(In thousands)

	September 30, 2022 (Unaudited)	December 31, 2021 (Audited)
Cash, cash equivalents and investments	$ 25,477	$ 45,933
Working capital	22,518	43,669
Total assets	27,232	48,481
Accumulated deficit	(268,238)	(245,456)
Total stockholders' equity	22,696	43,904

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Revenue	$ -	$ -	$ -	$ -
Operating expenses:				
Research and development	4,239	4,278	15,565	12,447
General and administrative	2,243	2,513	7,379	7,342
Total Operating expenses	6,482	6,791	22,944	19,789
Loss from operations	(6,482)	(6,791)	(22,944)	(19,789)
Interest and other income, net	114	87	162	424
Net loss	(6,368)	(6,704)	(22,782)	(19,365)
Net loss per share — basic and diluted	$ (0.07)	$ (0.07)	$ (0.25)	$ (0.22)
Weighted average common shares outstanding—basic and diluted	90,823,597	90,548,972	90,744,146	88,211,362