Aileron Therapeutics Provides Business Update and Outlines 2022 Strategic Priorities to Deliver Key Milestones

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- Plans to initiate Phase 1b clinical trial of ALRN-6924 in neoadjuvant breast cancer in 1H22; interim results expected in 4Q22
- Planned readouts for ongoing randomized, double-blind, placebo-controlled non-small cell lung cancer (NSCLC) trial on track for interim results in 2Q22 and topline results in 4Q22
    - Dosed first 10 patients in NSCLC trial; on track to conduct blinded safety evaluation on these patients after one cycle in 1Q22
- In 2021, Aileron was issued 7 new international patents, including new patent protection for ALRN-6924 in China, and 4 U.S. patents, adding to its strong intellectual property portfolio comprising over 170 U.S. and foreign patents and exclusive worldwide rights to ALRN-6924

BOSTON, Jan. 05, 2022 (GLOBE NEWSWIRE) -- Aileron Therapeutics (NASDAQ:ALRN), a chemoprotection oncology company that aspires to develop medicines to make chemotherapy safer and thereby more effective to save more patients' lives, today provided a business update and outlined the company's strategic priorities for 2022.

"All cancer patients undergoing chemotherapy – still the standard of care for most patients – experience chemotherapeutic side effects to varying degrees, from unpleasant to fatal. Utilizing a biomarker strategy, we are developing ALRN-6924 as a selective chemoprotective agent to shift the paradigm from accepting these side effects to preventing them for patients with p53-mutated cancer regardless of type of cancer or chemotherapy," said Manuel Aivado, M.D., Ph.D., President and Chief Executive Officer at Aileron. "In 2022, we expect several key milestones may propel us toward this vision, including our planned initiation of a clinical trial in breast cancer patients receiving neoadjuvant chemotherapy in the first half of the year with interim results in the fourth quarter, as well as planned interim and topline data readouts for our ongoing NSCLC trial in the second and fourth quarters, respectively."

Aileron is developing ALRN-6924 to selectively protect healthy cells in patients with p53-mutated cancers to reduce or eliminate chemotherapy-induced side effects. Nearly 1 million patients each year are diagnosed with a p53-mutated cancer in the US alone, and Aileron employs a precision medicine approach to exclusively treat those patients with p53-mutated cancers who are receiving chemotherapy. ALRN-6924 is designed to selectively protect these patients' healthy cells from chemotherapy without protecting cancer cells. This novel concept is known as selective chemoprotection. The reduction or elimination of multiple chemotherapy-induced side effects is expected to enhance tolerability of chemotherapy, which is expected to result in fewer dose reductions and delays of chemotherapy, and that is expected to improve efficacy of chemotherapy.

2022 Strategic Priorities and Business Update

- **Initiate clinical trial in neoadjuvant (pre-operative) breast cancer in 1H22, with interim results in 4Q22.** Aileron plans to initiate a new clinical trial in 1H22 to evaluate ALRN-6924 to protect against chemotherapy-induced bone marrow and other toxicities in ER+/HER2- breast cancer patients treated with a doxorubicin + cyclophosphamide and docetaxel chemotherapy regimen, also known as 'AC-D'. The Phase 1b trial will enroll up to 30 patients in a parallel group design trial with a dose expansion cohort. Aileron will provide more details on the planned neoadjuvant breast cancer trial design at the time of trial initiation.
- **Advance ongoing NSCLC trial to interim (20-patient) and topline (60-patient) readouts, in 2Q22 and 4Q22, respectively.** Aileron is currently enrolling patients in the US and EU with advanced p53-mutated NSCLC undergoing treatment with first-line carboplatin plus pemetrexed with or without immune checkpoint inhibitors. As previously guided, Aileron anticipates reporting interim results on 20 patients in 2Q22, and topline results on 60 patients in 4Q22. Aileron has dosed the first 10 patients in the trial and plans to conduct a blinded safety evaluation on these patients after one cycle in

1Q22, as previously guided.

- **Continue to progress ongoing Healthy Volunteer Study.** Aileron is continuing to progress its ongoing Phase 1 pharmacology study which is evaluating ALRN-6924's induction of p21-induced cell cycle arrest in healthy, normal bone marrow cells and other cell types in healthy volunteers receiving ALRN-6924. The company presented initial data from the study in 2021, confirming the drug's novel p53 biomarker-driven mechanism of action, as well as its pharmacodynamic effects, including time to onset, magnitude and duration. The aim of the study is to develop a universal dosing regimen for ALRN-6924 for use as a chemoprotection agent across a range of chemotherapies and p53-mutated cancers. Aileron anticipates reporting additional findings from the study this year.

- **Expanded patent portfolio in 2021 with issuance of 11 new foreign and U.S. patents.** Aileron was issued 7 new international patents and 4 U.S. patents over the past 12 months, including new patent protection for ALRN-6924 in China. These newly issued patents add to Aileron's robust intellectual property portfolio, which includes over 170 U.S. and foreign patents, with another 47 applications in prosecution. These patents and applications include ALRN-6924 methods of manufacture, methods of use, drug product formulations, and compositions of matter (COM). The COM patent in the US expires in 2033 with up to 5 additional years subject to patent term extensions. Of note, Aileron maintains exclusive rights to its proprietary peptide drug technology and ALRN-6924 worldwide.

About Aileron Therapeutics

Aileron is a clinical stage chemoprotection oncology company focused on developing medicines 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 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-Q for the quarter ended September 30, 2021, filed on November 12, 2021, 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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