Aileron Therapeutics Announces First Patients Treated in Phase 1b Trial of ALRN-6924 in Patients with p53-Mutated Neoadjuvant Breast Cancer

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- Aileron is developing ALRN-6924 to protect patients with p53 mutated cancers against chemotherapy-induced bone marrow toxicities and other toxicities
- Trial is evaluating ALRN-6924 as a treatment to prevent chemotherapy-induced neutropenia, other bone marrow toxicities, and toxicities outside of the bone marrow in patients with p53-mutated breast cancer being treated with doxorubicin plus cyclophosphamide and docetaxel (AC+D)
- AC+D is a highly toxic chemotherapy regimen, causing severe neutropenia in up to 75% of patients and alopecia in approximately 90% of patients
- Initial interim results anticipated in 4Q2022
- Aileron to host a virtual KOL investor event today at 4:00 pm ET

BOSTON, May 19, 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 announced it has treated the first patients in its Phase 1b randomized, controlled clinical trial evaluating ALRN-6924 to protect against chemotherapy-induced neutropenia and other bone marrow toxicities, as well as toxicities outside of the bone marrow in patients with p53-mutated breast cancer who are being treated with doxorubicin plus cyclophosphamide and docetaxel (AC+D).

Nearly 1 million patients each year are diagnosed with a p53-mutated cancer in the US. Aileron is pioneering a precision medicine-based approach that is designed to enable the selective chemoprotection of healthy, normal cells in patients with p53-mutated cancers who are receiving chemotherapy without protecting their cancer cells from chemotherapy.

“Dosing of the first patients in our Phase 1b trial in patients with p53-mutated neoadjuvant breast cancer is an important step in advancing our vision to bring chemoprotection to all patients with p53-mutated cancer regardless of the type of cancer or chemotherapy,” said Manuel Aivado, M.D., Ph.D., President and Chief Executive Officer at Aileron Therapeutics. “The severe toxicity profile of AC+D will enable us to evaluate ALRN-6924’s protective effect against multiple chemotherapy-induced toxicities. Moreover, this breast cancer trial may potentially open an additional regulatory opportunity with established precedents for supportive care drug approvals.”

AC+D, a standard of care for patients with neoadjuvant breast cancer, is a highly effective but also highly toxic chemotherapy regimen. It causes severe neutropenia in up to 75% of patients and alopecia in approximately 90% of patients.

Aileron has previously presented non-clinical proof of mechanism data demonstrating ALRN-6924's ability to arrest cell cycling and protect against chemotherapy-induced toxicities in bone marrow stem cells (*in vitro*), epithelial gut mucosa cells (*in vivo*), and hair follicles and their stem cells (*ex vivo*). The company has also presented proof of mechanism data for cell cycle arrest in bone marrow stem cells and hair follicle cells in healthy human volunteers, and proof of concept data for reduced multilineage bone marrow toxicities in patients with small cell lung cancer (SCLC) treated with topotecan.

About the ALRN-6924 Breast Cancer Trial Design

The Phase 1b clinical trial will evaluate the safety, tolerability and protective effect of ALRN-6924 against hematologic toxicities and other toxicities in patients with neoadjuvant breast cancer. Anticipated to enroll 30 patients, the trial involves a parallel group design with a dose expansion cohort. Patients will receive doxorubicin plus cyclophosphamide (AC) on Day 1 of each 3-week cycle for 4 cycles, and then docetaxel (D) on Day 1 of each 3-week cycle for 4 cycles. In part 1 (Dose Evaluation), a control group of 8 patients with p53-wild type breast cancer (i.e., non-p53-mutated) will receive AC+D without ALRN-6924. Patients with p53-mutated breast cancer on the same AC+D regimen will be randomized to concurrently receive ALRN-6924 at 0.3 mg/kg ALRN-6924 (n=6) or at 0.6 mg/kg ALRN-6924 (n=6). ALRN-6924 is given as IV infusion on study days 0, 1 (day of chemotherapy) and 2. In Part 2 (Dose Expansion), 10 patients will receive the same AC+D regimen and the ALRN-6924 dose selected in Part 1.

Upcoming ALRN-6924 Data Readouts

In 4Q2022, Aileron anticipates reporting initial interim results from patients treated with AC in Part 1 of the breast cancer trial. In addition, the company anticipates reporting interim results from its ongoing Phase 1b randomized, double-blind, placebo-controlled clinical trial of ALRN-6924 in patients with non-small cell lung cancer undergoing treatment with first-line carboplatin plus pemetrexed with or without immune checkpoint inhibitors in June 2022 and topline results from that trial in 4Q2022.

Virtual KOL Event Today

Aileron will host a KOL investor event today, May 19, 2022, at 4 pm ET to highlight ALRN-6924's revolutionary potential as the first precision medicine-based supportive care drug, the landscape and unmet need of chemotherapy-induced toxicities, and the company's clinical development program and planned data readouts in 2022. For more details and to register, visit https://investors.aileronrx.com.

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 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; whether preclinical or clinical results will be indicative of results obtained in future clinical trials, including trials in different indications or with different chemotherapies; 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.

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