Aileron Therapeutics Presents Initial Findings from Ongoing Healthy Volunteer Study of ALRN-6924 at ISEH 50th Annual Scientific Meeting

August 27, 2021

- Initial findings from an ongoing study demonstrated that a 0.3 mg/kg dose of ALRN-6924 has been very well tolerated and resulted in p53-mediated induction of the cell cycle inhibitor p21 in normal bone marrow cells in healthy volunteers
- Aileron is currently conducting a Phase 1b randomized, double-blind, placebo-controlled trial of ALRN-6924 0.3 mg/kg as a chemoprotective agent in patients with advanced p53-mutated non-small cell lung cancer (NSCLC)
- ALRN-6924 is designed to activate normal p53 in healthy cells, thereby upregulating p21, which selectively pauses cell cycle in normal cells but not in cancer cells with mutant p53
- Nearly 1 million patients in the U.S., across all cancer types, are diagnosed annually with p53-mutated cancer

BOSTON, Aug. 27, 2021 (GLOBE NEWSWIRE) -- Aileron Therapeutics (Nasdaq: ALRN), a chemoprotection oncology company focused on fundamentally transforming the experience of chemotherapy for cancer patients, today announced a poster presentation showcasing initial findings from its ongoing study of ALRN-6924 in healthy volunteers at the International Society for Experimental Hematology (ISEH) 50th Annual Scientific Meeting, which is currently underway. The initial findings demonstrated that a 0.3 mg/kg dose of ALRN-6924 has been very well tolerated and resulted in p53-mediated induction of the cell cycle inhibitor p21 in healthy, normal bone marrow cells without concurrent induction of apoptosis. The poster can be viewed on Aileron's website here.

"We're pleased to present our first human data demonstrating ALRN-6924's mechanism of action, namely, p53-mediated induction of p21 in healthy, normal cells without concurrently inducing apoptosis," said Manuel Aivado, M.D., Ph.D., President and Chief Executive Officer of Aileron. "We believe these data validate our previously presented preclinical mechanism of action results for ALRN-6924 and also support the robust chemoprotective effect ALRN-6924 demonstrated against multiple chemotherapy-induced bone marrow toxicities in our Phase 1b trial in patients with p53-mutated small-cell lung cancer (SCLC). We look forward to presenting additional data from the ongoing healthy volunteer study in the future and evaluating clinical translation of these findings in our ongoing randomized, double-blind, placebo-controlled trial of ALRN-6924 in patients with p53-mutated NSCLC."

The healthy volunteer study is designed to characterize the time to onset, magnitude and duration of p21-induced cell cycle arrest in human bone marrow relative to ALRN-6924 administration. The ultimate aim of the study is to develop a universal dosing regimen for ALRN-6924 for use as a selective chemoprotective agent across a range of chemotherapies and p53-mutant tumor indications.

Aileron is currently evaluating ALRN-6924 in a Phase 1b randomized, double-blind, placebo-controlled trial of ALRN-6924 in patients with advanced p53-mutated NSCLC undergoing treatment with first-line carboplatin plus pemetrexed with or without immune checkpoint inhibitors.

In October 2020, Aileron presented data from its now completed Phase 1b clinical trial of ALRN-6924 in SCLC, demonstrating clinical proof-of-concept that treatment with ALRN-6924 resulted in a protective effect against neutropenia, thrombocytopenia and anemia in patients with p53-mutated SCLC treated with topotecan. Aileron will present final data from the Phase 1b SCLC trial and additional data from the healthy volunteer study at the upcoming European Society for Medical Oncology (ESMO) Congress, being held September 16-21, 2021.

About Aileron Therapeutics

Aileron is a clinical stage chemoprotection oncology company focused on fundamentally transforming the experience of chemotherapy for cancer patients. 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 while ensuring we do not protect 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.

Nearly 1 million patients in the U.S., across all cancer types, are diagnosed annually with p53-mutated cancer. Our vision is to bring selective

chemoprotection to patients with p53-mutated cancers 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 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 findings or 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; whether, if ALRN-6924 obtains approval, it will be successfully distributed and marketed; uncertainties as to the 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 June 30, 2021, filed on August 11, 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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