Aileron Therapeutics to Present New Clinical Data at ESMO Virtual Congress 2021 Supporting Novel, Selective Chemoprotective Agent ALRN-6924

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- Preliminary findings from ongoing Phase 1 healthy volunteer study will include data relating to mechanism of action; optimal dose; and time to onset, duration and magnitude of pharmacodynamic effects
- Final data from completed Phase 1b study in patients with small cell lung cancer (SCLC) receiving topotecan supporting best-in-class potential of ALRN-6924

BOSTON, Sept. 10, 2021 (GLOBE NEWSWIRE) -- Aileron Therapeutics (Nasdaq: ALRN), a chemoprotection oncology company focused on fundamentally transforming the experience of chemotherapy for cancer patients, today announced two upcoming poster presentations at the European Society of Medical Oncology (ESMO) Virtual Congress 2021, which is being held September 16-21, 2021. In these posters, Aileron will present preliminary data from its ongoing Phase 1 study of ALRN-6924 in healthy volunteers and final data from its completed Phase 1b study of ALRN-6924 in patients with small cell lung cancer (SCLC) receiving second-line topotecan treatment. Aileron is developing ALRN-6924 to selectively protect healthy cells in patients with cancers that harbor p53 mutations to reduce or eliminate chemotherapy-induced side effects while preserving chemotherapy's attack on cancer cells, an emerging concept known as chemoprotection. ALRN-6924, a 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.

"We are excited to share preliminary findings from our ongoing study of ALRN-6924 in healthy volunteers as well as final results from our completed Phase 1b study of ALRN-6924 in patients with small cell lung cancer at the upcoming ESMO Congress," said Manuel Aivado, M.D., Ph.D., President and CEO of Aileron. "These findings support the design of our ongoing randomized, double-blind, placebo-controlled study of ALRN-6924 in patients with non-small cell lung cancer and are helping us plan for future clinical studies of ALRN-6924 in multiple p53-mutated cancers and types of chemotherapy."

Aileron ESMO Poster Presentations

Title: A Phase 1b Study of the Dual MDMX/MDM2 Inhibitor, ALRN-6924, for the Prevention of Chemotherapy-induced Myelosuppression
Abstract/Poster #: 1654P

Title: A Phase 1 Study of the Dual MDMX/MDM2 Inhibitor, ALRN 6924, in Healthy Volunteers
Abstract/Poster #: 1791P

Archived versions of Aileron's ESMO poster presentations will be available under the Scientific Publications section of Aileron's website at https://www.aileronrx.com/science/scientific-publications/.

About the Phase 1 Study in Health Volunteers

Aileron is conducting a multi-part Phase 1 pharmacology study in healthy volunteers to evaluate the pharmacokinetics (PK) and pharmacodynamics (PD) of ALRN-6924. Aileron will present the findings from Parts 1 and 2 of the study at ESMO. The objectives of these first two parts are to determine a dose of ALRN-6924 that initiates p53-mediated transcriptional regulation and yields transient cell cycle arrest via p21 induction in human bone marrow with minimal signal for apoptosis (Part 1), and to determine the time to onset, magnitude, and duration of bone marrow PD effects (Part 2). The study is ongoing, and Aileron anticipates presenting additional findings at a later date.

About the Phase 1b Study in Patients with p53-Mutated SCLC

In October 2020, Aileron presented positive clinical data from the Phase 1b trial in SCLC demonstrating clinical proof-of-concept that treatment with ALRN-6924 resulted in a protective effect against severe neutropenia, anemia and thrombocytopenia in patients with p53-mutated SCLC treated with second-line topotecan. The final data set from this trial, which Aileron will present at ESMO, includes results from 13 additional patients, including two new cohorts of seven patients receiving 0.3 mg/kg ALRN-6924 given six hours before topotecan; four patients receiving 0.2 mg/kg ALRN-6924 given 24 hours before topotecan; and two new patients receiving 0.3 mg/kg ALRN-6924 given 24 hours before topotecan. These data are in line with the proof-of-concept data previously presented and with Aileron's expectation that administering ALRN-6924 at 0.3 mg/kg and 24 hours before topotecan is the optimal dose and schedule in this patient population.

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.

Investor Contacts:
Richard Wanstall, SVP Chief Financial Officer
Aileron Therapeutics
617-995-0900
rwanstall@aileronrx.com

Hans C. Vitzthum
LifeSci Advisors, LLC.
617-430-7578
hans@lifesciadvisors.com

Media Contact:
Liz Melone
617-256-6622
lmelone@aileronrx.com