



Aileron Therapeutics Announces Proof-of-Concept Data for ALRN-6924 to be Featured in Late-Breaking Presentation at EORTC-NCI-AACR Annual Symposium

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- Aileron aims to create new paradigm of proactive prevention of chemotherapy-induced side effects to address significant unmet need among cancer patients
- ALRN-6924 is first and only chemoprotective therapy in clinical development to utilize a biomarker strategy by treating patients with p53-mutated cancers
- Novel mechanism of action activates wild-type p53 to selectively shield healthy cells from chemotherapy without interrupting chemotherapy's targeting of cancer cells
- Company to hold investor call on Monday, October 26, 2020 to discuss the new data and outline strategy to advance chemoprotection across multiple cancers and chemotherapies

WATERTOWN, Mass., Oct. 12, 2020 (GLOBE NEWSWIRE) -- Aileron Therapeutics (Nasdaq: ALRN) today announced that proof-of-concept data from the company's Phase 1b study of ALRN-6924 will be featured in a late-breaking poster presentation during the 32nd EORTC-NCI-AACR Annual (ENA 2020) Symposium on Molecular Targets and Cancer Therapeutics, being held virtually October 24 – 25, 2020.

The abstract entitled, "Prevention of Chemotherapy-induced Myelosuppression in SCLC patients treated with the Dual MDM2/MDMX inhibitor ALRN-6924," (LBA96) will be presented starting Saturday, October 24, on the ENA 2020 [website](#).

The data to be presented is from Aileron's Phase 1b study, which is evaluating ALRN-6924 as a therapeutic agent administered ahead of chemotherapy to prevent chemotherapy-induced toxicities, such as severe anemia, neutropenia and thrombocytopenia, in patients with p53-mutated small cell lung cancer (SCLC) who are being treated with the chemotherapy topotecan. In June 2020, Aileron [announced](#) positive interim data from this study.

"Chemotherapy, which remains the backbone of treatment for millions of cancer patients, is associated with toxicities and side effects – ranging from unpleasant to life-threatening, and sometimes fatal. Current supportive care drugs try to manage these side effects, but often unsuccessfully and with associated toxicities of their own. Aileron has the potential to bring much-needed innovation to this area of cancer care, improving patients' quality of life as well as their tolerance for chemotherapy," said Manuel Aivado, M.D., Ph.D., President and Chief Executive Officer at Aileron Therapeutics.

Dr. Aivado continued, "ALRN-6924 is the first and only chemoprotective agent to utilize a biomarker strategy by treating patients with p53-mutated cancers. In these patients, ALRN-6924 is designed to selectively shield healthy non-p53-mutated cells while chemotherapy can continue targeting p53-mutated cancer cells. We believe that our novel mechanism of action has the potential to introduce a transformative paradigm of proactive prevention of hematological and non-hematological chemotherapy-induced side effects. Importantly, our approach is designed to give oncologists access to a chemoprotective agent that will not reduce the efficacy of chemotherapy."

Aileron's long-term vision is to bring chemoprotection to all patients with p53-mutated cancers, which represent at least 50% of cancer patients, regardless of cancer type or chemotherapy.

Aileron Investor Call

Aileron will host a virtual investor call and webcast to discuss the new data as well as the company's clinical development strategy to expand chemoprotection to patients with p53-mutated cancers. The event will take place on Monday, October 26 at 8:30 a.m. ET. Details will be provided closer to the event at <https://investors.aileronrx.com/events-presentations/investor-events>.

How ALRN-6924 Works to Protect Healthy Cells from Chemotherapy

ALRN-6924 is being developed by Aileron as a novel chemoprotective medicine to selectively protect healthy cells in patients with cancers that harbor p53-mutations to reduce or eliminate chemotherapy-induced side effects.

Chemotherapy preferentially acts on cells that are cycling, or undergoing the process of cell division. In cancer cells, the cell cycle is unchecked, which

leads to uncontrolled cell proliferation, a hallmark of cancer. Certain types of healthy cells also naturally need to cycle, such as bone marrow cells, hair follicle cells, skin cells, and cells lining the oral cavity and the gastrointestinal tract. As a result, chemotherapy targets and kills both cycling healthy cells and cycling cancer cells. This, in turn, leads to a spectrum of chemotherapy-induced side effects, from unpleasant to life-threatening and fatal.

ALRN-6924, an investigational first-in-class MDM2/MDMX dual inhibitor, is administered prior to chemotherapy to patients with p53-mutant cancers. ALRN-6924 is designed to activate normal p53 protein in patients' healthy cells, temporarily and reversibly pausing cell cycling to selectively shield the patients' healthy cells from chemotherapy. The protection is limited to healthy cells, as ALRN-6924 cannot work in p53-mutated cancer cells given that p53 has lost its function in those cells. Therefore, cancer cells continue to cycle uninterrupted and remain fully susceptible to destruction by chemotherapy.

About Aileron Therapeutics

At Aileron, we are focused on transforming the experience of chemotherapy for cancer patients, enabling them to fight cancer without the fear or burden of chemotherapy-induced side effects. ALRN-6924, our first-in-class MDM2/MDMX dual inhibitor activating p53, is the only therapeutic agent in development to employ a biomarker strategy to elicit selective chemoprotection for cancer patients. With this unique, targeted strategy, ALRN-6924 is designed to protect multiple healthy cell types throughout the body from chemotherapy while ensuring chemotherapy continues to destroy cancer cells.

In addition to potentially reducing or eliminating multiple side effects, ALRN-6924 may also improve patients' quality of life and help them better tolerate chemotherapy, potentially allowing patients to complete their treatment without dose reductions or delays. Our long-term vision is to bring chemoprotection to patients with p53-mutated cancers – approximately 50% of cancer patients – regardless of cancer type 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 and/or trials anticipated; whether results obtained in preclinical and nonclinical studies and clinical trials will be indicative of results obtained in future clinical trials; whether Aileron's product candidates will advance through the clinical trial process on a timely basis, or at all; whether the results of such trials will warrant submission for approval from the United States Food and Drug Administration or equivalent foreign regulatory agencies; whether Aileron's product candidates will receive approval from regulatory agencies on a timely basis or at all; whether, if product candidates obtain approval, they 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 quarterly report on Form 10-Q for the period ended June 30, 2020, filed on August 5, 2020, 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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