



Aileron to Present Nonclinical Myelopreservation Data for ALRN-6924 at the 2019 AACR-NCI-EORTC Conference on October 29th

October 21, 2019

Nonclinical research showed that ALRN-6924 prevented the toxic side effects of chemotherapy in normal cells without inhibiting the anti-cancer activity of chemotherapy.

ALRN-6924 could enable a precision-medicine strategy to prevent the toxic side effects of chemotherapy in patients with p53-mutated cancer, representing approximately 50% of all patients with cancer.

WATERTOWN, Mass., Oct. 21, 2019 (GLOBE NEWSWIRE) -- Aileron Therapeutics (NASDAQ:ALRN), the clinical-stage leader in the field of stabilized, cell-permeating peptides, is scheduled to present new nonclinical data demonstrating that in *in vivo* studies ALRN-6924, a dual inhibitor of MDM2 and MDMX, prevented chemotherapy-related toxicities without limiting anti-cancer efficacy at the 2019 AACR-NCI-EORTC Conference, which is being held in Boston, MA, from October 26 - 30, 2019. The poster presentation (abstract #: C064), titled "The Investigational Peptide Drug ALRN-6924, a Dual Inhibitor of MDMX and MDM2, is an Effective Myelopreservation Agent," is scheduled to be presented on Tuesday, October 29th.

"Chemotherapy remains the single most important weapon against cancer, but it often takes a terrible toll on normal, healthy cells," said Dr. Manuel Aivado, President and CEO of Aileron Therapeutics. "Cell-cycle arrest has been shown to protect normal, healthy cells from chemotherapy. Developing an agent that selectively induces cell cycle arrest in normal, healthy cells without inducing cell-cycle arrest in cancer cells has long been a challenge for drug developers. We believe that by using p53 mutation as a biomarker, Aileron Therapeutics may have found a way to address this challenge."

"About half of all cancer patients have mutations in their cancer cells in the p53 tumor suppressor gene, which is considered the 'Guardian of the Genome.' Our nonclinical data showed that low doses of ALRN-6924 could activate normal p53 signaling in healthy tissues and trigger temporary cell-cycle arrest. Once arrested, the toxic effects of chemotherapy were reduced in normal cells and tissues, including bone marrow, without inhibiting – but potentially enhancing – the activity of chemotherapy against p53-mutant tumors," stated Allen Annis, Aileron's Senior Vice President of Research. "These findings may give hope to the millions of cancer patients with p53-mutant malignancies who suffer the severe and often life-threatening side effects of chemotherapy."

The Company believes that the absence of ALRN-6924 activity in p53-mutant cancer cells, plus the hematological safety profile of ALRN-6924, which was more favorable in first-in-human trials in solid tumor patients than the hematological safety profiles of other MDM2-inhibitors, could enable a precision-medicine strategy to prevent chemotherapy-related toxicities.

Millions of cancer patients across the US and the EU receive chemotherapy each year. Based on published literature, the Company estimates that p53 mutations are found in about 50% of those cancer patients.

ALRN-6924 is currently being evaluated in the dose-optimization phase 1b portion of a Phase 1b/2 myelopreservation trial designed to identify a recommended phase 2 dose for ALRN-6924 and to evaluate the safety and efficacy of ALRN-6924 in preventing or limiting toxicities caused by treatment with topotecan in small cell lung cancer (SCLC) patients. Based on this nonclinical data the Company plans to expand its clinical program in myelopreservation to include an additional Phase 1b cohort in non-small cell lung cancer patients treated with docetaxel, and a randomized expansion cohort of the Phase 1b SCLC trial to treat patients with alternating cycles of chemotherapy with and without ALRN-6924 (the "on/off" cohort) where each patient will serve as his/her own control. The Company expects to present key findings of the first Phase 1b SCLC portion of the myelopreservation trial in the second quarter of 2020.

In future trials, the Company plans to investigate ALRN-6924 across additional cancer indications and chemotherapy regimens to evaluate ALRN-6924 as a tumor type-agnostic and chemotherapy-agnostic myelopreservation drug.

Poster Presentation Details:

Conference: 2019 AACR-NCI-EORTC Conference on Molecular Targets and Cancer Therapeutics

Poster Title: "The Investigational Peptide Drug ALRN-6924, a Dual Inhibitor of MDMX and MDM2, is an Effective Myelopreservation Agent."

Abstract Number: C064

Date: Tuesday, October 29

Time: 12:30-4:00 PM

Location: Hall D, Hynes Convention Center, Boston, Massachusetts

The Aileron abstract can be accessed via the following link:

http://share.aileronrx.com/abstracts/Aileron_AACR-NCI-EORTC_Carvajal_Abstract_Final.pdf

About ALRN-6924

ALRN-6924 is a first-in-class dual MDM2/MDMX inhibitor that is currently being evaluated as an anti-cancer agent in a Phase 2a clinical trial in combination with Pfizer's palbociclib (Ibrance®) for the treatment of MDM2-amplified advanced solid tumors, and in a Phase 1b/2 clinical trial to evaluate ALRN-6924 as a myelopreservative agent to protect against chemotherapy-related toxicities.

About Aileron

Aileron is a clinical-stage biopharmaceutical company advancing a proprietary platform of cell-permeating alpha-helical peptides. The stabilized helical structure of our peptides allows the design of cell-permeating therapeutic agents with large molecular surfaces for optimal target binding properties, resulting in drug candidates like ALRN-6924. Our current focus is to improve the standard of care for patients with cancer by developing safe and effective therapies and cancer supportive care treatments that leverage our proprietary peptide platform. For more information, visit www.aileronrx.com, and for more information about our clinical trials please visit www.clinicaltrials.gov.

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; and other factors discussed in the "Risk Factors" section of Aileron's quarterly report on Form 10-Q for the period ended June 30, 2019, filed on August 6, 2019, 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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