Aileron Therapeutics Announces the Initiation of Patient Treatment in its First Clinical Ph1b/2 Trial of ALRN-6924 as a Myelopreservation Agent

October 16, 2019

Treatment uses 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.

Management plans to expand its ongoing clinical myelopreservation trial to include two additional cohorts: an expansion cohort in small-cell lung cancer patients and a cohort in non-small-cell lung cancer patients.

Company expects to present key findings of the phase 1b portion of this myelopreservation trial in the 2nd quarter of 2020.

WATERTOWN, Mass., Oct. 16, 2019 (GLOBE NEWSWIRE) -- Aileron Therapeutics (NASDAQ:ALRN), the clinical-stage leader in the field of stabilized, cell-permeating peptides, today announced that the first patient has completed the initial cycle of treatment in the Company's first clinical trial evaluating ALRN-6924 as a myelopreservation agent in patients with p53-mutant small-cell lung cancers (SCLC) treated with the chemotherapy topotecan.

"Every year, millions of cancer patients undergo chemotherapy with the hope of prolonging their lives or being cured from a deadly disease. These patients have no choice but to suffer through the severe and life-threatening side effects that chemotherapy inflicts on their normal, healthy cells," said Dr. Manuel Aivado, CEO & President of Aileron. "Based on the preclinical data and the mechanism of action we observed, we believe that ALRN-6924 has the potential to not only diminish or end many side effects of chemotherapy but also to improve its anti-tumor effects."

One basis for the potential anti-tumor effects lies in the fact that cancer cells frequently possess a mutated p53 gene, whereas normal cells, including immune system cells of cancer patients are not mutated, i.e., "p53-wildtype." Importantly, the activation of p53-wildtype has been shown to have effects on the immune system that can enhance anti-tumor efficacy and ALRN-6924 is a first-in-class dual MDM2/MDMX-inhibitor that can activate p53-wildtype.

Aileron's ongoing Phase 1b myelopreservation trial is designed to identify a recommended phase 2 dose for ALRN-6924 and evaluate the safety and efficacy of ALRN-6924 when administered to protect SCLC patients from toxicities caused by treatment with topotecan. The study will enroll up to 40 patients and will use existing standard gene tests to screen patients for p53-mutations as a biomarker-based patient selection strategy unique to ALRN-6924.

Dr. Vojislav Vukovic, Chief Medical Officer of Aileron stated, "In preclinical studies, low doses of ALRN-6924 triggered temporary cell-cycle arrest in normal bone marrow cells, significantly minimizing the toxic effects of chemotherapy. Furthermore, in SCLC models, the combination of ALRN-6924 and topotecan actually led to enhancement of anti-tumor activity. Although this first myelopreservation trial for ALRN-6924 is in SCLC patients treated with topotecan, we plan to develop ALRN-6924 as a tumor type-agnostic and chemotherapy-agnostic myelopreservation drug."

"Improving the tolerability of chemotherapy has the potential to reduce dose delays and dose reductions. Such optimized chemotherapy delivery and the potential stimulation of the immune system represent two independent mechanisms that inform our belief that treatment with ALRN-6924 will enhance the anti-tumor effects of chemotherapy," said Dr. Manuel Aivado, CEO & President of Aileron. "We plan to present the key findings of the Phase 1b dose-optimization trial in the second quarter of 2020."

Encouraged by the strong data from preclinical studies, the Company plans to expand its clinical program for ALRN-6924 in myelopreservation to include an additional Phase 1b cohort in non-small cell lung cancer patients treated with docetaxel. In addition, the company is planning 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). This "on/off" cohort is designed to provide a robust clinical proof of concept to demonstrate the effects of ALRN-6924 as a myelopreservative agent, as each patient will serve as his/her own control. After identifying a recommended phase 2 dose in the ongoing phase 1b trial, patient enrollment into these 2 new cohorts is expected to commence in the second quarter of 2020. The Company currently plans to reallocate resources from early-stage pipeline programs to accommodate the greater investment into the clinical development of ALRN-6924.

There are approximately 1.3 million cancer patients across the US and in the five largest European markets who receive chemotherapy each year. The company estimates that p53 mutations are found in about 50% of those cancer patients; therefore, an opportunity may exist to use ALRN-6924 to prevent or limit chemotherapy-related toxicities in more than 700,000 patients in the US and EU alone.

About ALRN-6924
ALRN-6924 is a first-in-class dual MDM2/MDMX inhibitor that is currently being evaluated 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-induced 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 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.

Investors:
Aileron Therapeutics
Rick Wanstall, VP Finance & Operations
617-995-0900
rwanstall@aileronrx.com

Hans C. Vitzthum
LifeSci Advisors, LLC.
617-535-7743
hans@lifesciadvisors.com

Source: Aileron Therapeutics, Inc.