Aileron Therapeutics Commences Enrollment in a Phase 2a Expansion Cohort for ALRN-6924 in Combination with Pfizer's IBRANCE® (palbociclib) in Patients with MDM2-Amplified Cancers

January 16, 2019

WATERTOWN, Mass., Jan. 16, 2019 (GLOBE NEWSWIRE) -- Aileron Therapeutics (NASDAQ:ALRN), the clinical-stage leader in the field of stabilized, cell-permeating peptides to treat cancer and other diseases, today announced that the first patient has been enrolled in a Phase 2a expansion cohort intended to assess preliminary activity and safety of ALRN-6924 in combination with Pfizer's palbociclib, also known as IBRANCE®, in cancer patients with MDM2-amplified solid tumors.

"We are excited to launch this Phase 2a expansion cohort, expanding on our ALRN-6924 clinical trial combination program," said Vojo Vukovic, MD, PhD, and Chief Medical Officer of Aileron. "ALRN-6924 and palbociclib address the MDM2 (p53) and CDK4 (Rb) pathways, which have interdependent roles in cancer biology, and preclinical results recently presented by Aileron show synergistic activity for ALRN-6924 and palbociclib in cancer cells and animal models[1]. Furthermore, the MDM2 and CDK4 genes are co-amplified in many cancers. We are using this biomarker-driven approach to select cancer patients with tumors exhibiting this genetic profile. We are hopeful that a dual MDM2 and CDK4 inhibition strategy will benefit these patients."

About the Phase 2a MDM2-amplified Expansion Cohort
This Phase 2a expansion cohort is intended to assess the preliminary activity and safety of ALRN-6924 in combination with palbociclib. The trial is expected to enroll up to 25 MDM2-amplified cancer patients with advanced solid tumors that test positive for the presence of wild-type p53. The objectives of the trial include determining the overall response rate and other parameters of efficacy, as well as evaluating the safety and tolerability of the combination. Aileron expects to present preliminary data in the second half of 2019 at a medical conference.

ALRN-6924 is a first-in-class, stabilized cell-permeating peptide that mimics the p53 tumor suppressor protein to disrupt the interaction with both p53-inhibitors, MDMX and MDM2. For p53 wild-type tumors, ALRN-6924 can restore p53-dependent tumor suppression. Palbociclib is an oral inhibitor of cell cycle check-point regulators CDK4/6. The MDM2 and CDK4 genes are located on chromosome 12 in close proximity to each other, with CDK4 very frequently co-amplified in patients with MDM2-amplified cancers who will be enrolled in this trial. This co-amplification provides the mechanistic rationale and suggests a potential patient benefit from combining the MDM2/MDMX-inhibitor, ALRN-6924, with the CDK4/6-inhibitor, palbociclib[2].

1. 2018 San Antonio Breast Cancer Symposium abstract #1129, "The Stapled Peptide ALRN-6924, a Dual Inhibitor of MDMX and MDM2, and the CDK4/6 Inhibitors Palbociclib, Ribociclib, or Abemaciclib Synergistically Enhance Each Other's in vitro and in vivo Anticancer Activity"

2. Laroche-Clary et al. Journal of Hematology & Oncology (2017) 10:123 DOI 10.1186/s13045-017-0482-3

About ALRN-6924
ALRN-6924 is currently being evaluated in multiple clinical trials for the treatment of solid and hematological cancers, including acute myeloid leukemia (AML) and myelodysplastic syndrome (MDS). For information about Aileron's clinical trials, please visit www.clinicaltrials.gov.

About Aileron
Aileron is a clinical-stage biopharmaceutical company advancing a proprietary platform of cell-permeating alpha-helical peptides that address the most important intracellular targets in oncology and other therapeutic areas. 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 unique drugs like ALRN-6924. Our current focus is to improve the standard of care for patients with solid tumors and hematological malignancies by developing safe and effective therapies 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; whether the Company will be able to enter into additional collaborations; and other factors discussed in the "Risk Factors" section of Aileron's quarterly report on Form 10-Q for the period ended September 30, 2018, filed on November 7, 2018, 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 TherapeuticsDon Dougherty, CFO
617-995-0900
ddougherty@aileronrx.comHans C. VitzthumLifeSci Advisors, LLC.
617-535-7743
hans@lifesciadvisors.com

Source: Aileron Therapeutics, Inc.