Aileron Enters Clinical Trial Collaboration with Pfizer to Evaluate ALRN-6924 in Combination with IBRANCE® (palbociclib) in MDM2-Amplified Cancers

November 27, 2018

WATERTOWN, Mass., Nov. 27, 2018 (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 it has entered into a clinical trial collaboration with Pfizer to evaluate the combination of Aileron's ALRN-6924 and Pfizer's palbociclib, also known as IBRANCE®, in MDM2-amplified cancers. Overexpression of MDM2 in cancer is typically a driver of tumor proliferation. Aileron expects this Phase 1B trial to start enrolling patients with solid tumors in the first quarter of 2019. Pfizer will provide drug supply in support of the trial.

ALRN-6924 is a first-in-class, stabilized cell-permeating peptide that mimics the p53 tumor suppressor protein to disrupt the interaction with both its endogenous 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 one-another, with CDK4 very frequently co-amplified in the MDM2-amplification-positive patients to be enrolled in this trial. This co-amplification further suggests a potential patient benefit from combining the MDM2/MDMX-inhibitor ALRN-6924 with the CDK4/6-inhibitor palbociclib[1].

"We are excited about this combination trial with Pfizer's palbociclib," stated Manuel Aivado, MD, PhD, President and Chief Executive Officer of Aileron. "The combination of ALRN-6924 and palbociclib demonstrated enhanced antitumor activity and meaningfully delayed tumor growth in animal models over single agents alone. We believe the combination of these two drugs represents a complementary attack on the proliferation of cancer cells that may benefit patients with a variety of different cancers."

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

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 this collaboration will be successful and 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 Therapeutics
Don Dougherty, CFO
617-995-0900
ddougherty@aileronrx.com

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

Source: Aileron Therapeutics, Inc.