Aileron Therapeutics Announces Clinical Trial Collaboration with Dana-Farber/Boston Children's Cancer and Blood Disorders Center

November 1, 2018

Investigator-Initiated Phase 1Trial of the Dual MDM2/MDMX Inhibitor ALRN-6924 in Pediatric Cancer

WATERTOWN, Mass., Nov. 01, 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 an agreement with Dana-Farber/Boston Children's Cancer and Blood Disorders Center for an open-label, multi-center, pediatric phase 1 clinical trial of ALRN-6924, Aileron's lead clinical candidate. In this investigator-initiated trial, pediatric patients with solid tumors will receive ALRN-6924 as a single agent, while pediatric patients with acute leukemia will be treated with a combination of ALRN-6924 and cytarabine. In addition to these two dose-escalation cohorts, a third cohort of this trial will be biomarker-enriched with the intent of improving response rates with this precision medicine approach.

Principal Investigator, Steven DuBois, MD, of the Dana-Farber/Boston Children's Cancer and Blood Disorders Center, commented: "Recently published preclinical data by Kimberly Stegmaier, MD, and Loren Walensky, MD, PhD, both from Dana-Farber/Boston Children's Cancer and Blood Disorders Center, revealed that targeting MDM2 and MDMX had a selective cytotoxic effect in a range of pediatric cancers. Together with our collaborators at several world-class pediatric clinical trial sites, we are committed to bringing this agent to the clinic for our pediatric patients with relapsed cancer."

"I am particularly gratified to see the initiation of this trial," said Dr. Walensky. "Dana-Farber and I have deep roots in the discovery and development of this technology. Seeing it deployed now in an effort to treat pediatric patients represents great progress."

"MDMX and MDM2 play a role in many cancers, and our dual inhibitor of MDMX and MDM2, ALRN-6924, has shown in clinical trials that it can achieve responses in cancer patients," said Manuel Aivado, MD, PhD and CEO of Aileron Therapeutics. "We are thankful for the opportunity to provide ALRN-6924 to relapsed and refractory pediatric patients in an effort to improve outcomes for these children."

About ALRN-6924
ALRN-6924 is a first-in-class, stabilized alpha-helical peptide that mimics the p53 tumor suppressor protein to disrupt its interactions with both its endogenous inhibitors, MDMX and MDM2. For p53 wild-type tumors, ALRN-6924 can restore p53-dependent tumor suppression. ALRN-6924 is currently being evaluated in multiple clinical trials for the treatment of solid and hematological cancers, including acute myeloid leukemia (AML), myelodysplastic syndrome (MDS), and peripheral T-cell lymphoma (PTCL). 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 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 June 30, 2018, filed on August 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.

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