Aileron Therapeutics Announces Initiation of Expansion Cohort and First Patient Enrolled into Expansion Cohort of Phase 1b/2 Study of ALRN-6924 as a Chemoprotection Agent

May 27, 2020

WATERTOWN, Mass., May 27, 2020 (GLOBE NEWSWIRE) -- Aileron Therapeutics (NASDAQ:ALRN) announced today the expansion of one of the dose levels in the dose optimization part of its Phase 1b/2 clinical trial evaluating ALRN-6924 as an agent to protect patients with small cell lung cancer (SCLC) against chemotherapy-induced toxicity, a concept known as chemoprotection (or myelopreservation). The first patient has been enrolled into the expansion cohort, which was triggered by results from the ongoing trial that met protocol-specified criteria for expansion. The Company expects to enroll approximately 8 patients into this dose optimization expansion cohort to further evaluate the selected dose for chemoprotection from topotecan-induced bone marrow toxicities.

"We recently reported completion of enrollment in the third and final dose level of the dose optimization part of the trial. Results emerging from the third dose level support the data observed with the previous two cohorts, where we observed a protective effect of ALRN-6924 for severe anemia and severe thrombocytopenia when compared to historical rates of those toxicities in SCLC patients treated with topotecan," said Dr. Manuel Aivado, President and CEO of Aileron Therapeutics. "We are very excited about the prospects of being able to develop a treatment that could turn toxic chemotherapy into a form of well-tolerated, targeted therapy."

The Phase 1b study is designed to identify a dose and a schedule of ALRN-6924 administration to reduce chemotherapy toxicities such as severe anemia and thrombocytopenia, and other toxicities resulting from topotecan. ALRN-6924 is administered 24 hours (in the dose optimization part) or six hours (in the schedule optimization part) before each dose of topotecan, which is administered daily on days 1 through 5 of every 21-day treatment cycle.

Aileron currently plans to report interim results for the dose optimization part of the trial in June 2020. The Company plans to report the top-line final data for the dose optimization part of the trial, including this expansion cohort, and data for the schedule optimization part of the trial in the fourth quarter of 2020. The Company expects that these results will determine a recommended ALRN-6924 dose and schedule for subsequent trials.

The Company continues to enroll patients into its chemoprotection trial while carefully monitoring the effect of the coronavirus pandemic on its clinical trial sites and the healthcare system, which may impact the timing of these planned data announcements.

About ALRN-6924
ALRN-6924 is a first-in-class dual MDM2/MDMX inhibitor that is currently being evaluated in a Phase 1b/2 clinical trial to evaluate ALRN-6924 as a chemoprotective 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 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 preliminary or interim results from a clinical trial will be indicative of the final results of the trial; 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 coronavirus pandemic will have an impact on the timing of our clinical development and our operations; and other factors discussed in the "Risk Factors" section of Aileron's quarterly report on Form 10-Q for the period ended March 31, 2020, filed on May 11, 2020, 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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