Aileron Presents Positive Interim Phase 2a Data for ALRN-6924 in Combination with Pfizer's Palbociclib at the 2019 Congress of the European Society for Medical Oncology

September 28, 2019

Final data expected in the second quarter of 2020

WATERTOWN, Mass., Sept. 28, 2019 (GLOBE NEWSWIRE) -- Aileron Therapeutics (NASDAQ: ALRN), the clinical-stage leader in the field of stabilized, cell-permeating peptides to treat cancer patients, announced the presentation of interim results from its ongoing Phase 2a clinical trial evaluating the combination of ALRN-6924 and Pfizer's IBRANCE® (palbociclib) for the treatment of patients with tumors harboring wild-type p53 and MDM2 amplification or MDM2/CDK4 co-amplification at the 2019 Congress of the European Society for Medical Oncology (ESMO) (Presentation Number: 475P).

As of the data cutoff date of September 2, 2019, the trial had enrolled 26 patients. "We are pleased with the strong interest from our investigators, which led to significant acceleration in the rate of enrollment in the trial," stated Dr. Vojislav Vukovic, Chief Medical Officer of Aileron. "The vast majority of patients enrolled thus far are sarcoma patients, including 20 with liposarcoma, as MDM2 amplification or MDM2/CDK4 co-amplification is very often found in this tumor type."

The reported safety results show that the combination has been very well-tolerated in the trial, with the most common non-hematological related adverse events grade ≤2 being nausea (46%) and fatigue (23%). Neutropenia was the only grade ≥3 hematological related AE occurring in >5% of patients (27%), while grade ≥3 thrombocytopenia and leukopenia each were observed in only one patient (3.8%).

The preliminary analysis of activity in the 17 evaluable patients with liposarcoma showed a disease control rate of 88% and a median progression-free survival of 4.4 months with 53% censoring. No partial or complete responses have been observed. Patients who have had at least one post-baseline assessment and have MDM2-amplified, TP53-WT tumors were deemed evaluable.

On the basis of these encouraging preliminary safety and efficacy results, the Company expects that the first indication for the combination of ALRN-6924 and palbociclib may be MDM2-amplified sarcoma patients, for whom there exists a substantial unmet need across all lines of treatment for the estimated 15,000 patients worldwide diagnosed each year. In addition, these results have further encouraged the Company to expand enrollment to a total of 35 patients in order to evaluate the combination on the treatment of other MDM2-amplified cancers. Aileron expects to announce a final data readout in the second quarter of 2020.

The Aileron poster containing the trial results can be accessed via the following link:
http://share.aileronrx.com/posters/Aileron_ESMO_2019_Meric-Bernstam_Final.pdf

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 is planned to be evaluated in an upcoming Phase 1b/2 clinical trial to evaluate ALRN-6924 as a myelopreservative agent to protect against chemotherapy-induced toxicities.

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 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 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; 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.

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