Aileron Therapeutics Announces FDA Acceptance of IND for ALRN-6924 as a Myelopreservation Agent in Patients with p53-mutant Cancer Treated with Chemotherapy

June 27, 2019

Phase 1b/2 trial expected to start in September 2019; topline data readout expected in 1Q 2020

WATERTOWN, Mass., June 27, 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 U.S. Food and Drug Administration (FDA) has accepted its Investigational New Drug (IND) application for ALRN-6924 as a myelopreservation agent in patients with p53-mutant cancers treated with chemotherapy.

“We are excited to advance another application for ALRN-6924 into the clinic. In preclinical studies ALRN-6924 has been shown to trigger a transient, dose-dependent cell-cycle arrest in normal bone marrow cells with normal p53. As others have shown, triggering cell-cycle arrest in rapidly dividing normal cells, such as bone marrow cells, can protect them from toxic effects of chemotherapy. In the clinic we plan to use a precision medicine approach to treat patients with cancers harboring p53 mutations (approximately 50% of all cancers). ALRN-6924 does not induce cell-cycle arrest in p53-mutant cancer cells, and leaves them vulnerable to chemotherapy. While our first myelopreservation clinical trial will be in small cell lung cancer patients treated with topotecan, we plan to develop ALRN-6924 as a tumor type-agnostic myelopreservation drug,” stated Dr. Vojislav Vukovic, Chief Medical Officer of Aileron.

“The FDA acceptance of our IND application represents an important milestone for ALRN-6924 and keeps us on schedule to commence our first clinical trial in myelopreservation as planned in September 2019,” said Dr. Manuel Aivado, CEO & President of Aileron. “Chemotherapy remains the standard of care for many cancer patients, yet it damages the bone marrow and other normal cells, causing serious and often life-threatening side effects for patients. With ALRN-6924, we are exploring the potential to protect normal cells and improve the outcome of patients with p53-mutated cancers without diminishing anti-tumor activity, regardless of the type of chemotherapy. We are very excited about the possibility to spare cancer patients from chemotherapy-induced toxicities.”

The Company expects to enroll up to 40 patients in the Phase 1b portion of the planned Phase 1b/2 trial to evaluate the safety, tolerability, and efficacy of ALRN-6924 with topotecan as a 2nd line therapy for small cell lung cancer patients. The study will use existing standard gene tests, such as the ‘Foundation One’ panel, to screen patients for p53-mutation.

About ALRN-6924
ALRN-6924 is a first-in-class, stabilized cell-permeating alpha-helical peptide that mimics the p53 tumor suppressor protein to disrupt its interactions with both its endogenous inhibitors, MDMX and MDM2. ALRN-6924 is currently being evaluated in multiple clinical trials for the treatment of a variety of cancers, including cancers with MDM2-amplified tumors. 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 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; and other factors discussed in the "Risk Factors" section of Aileron's quarterly report on Form 10-Q for the period ended March 31, 2019, filed on May 8, 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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