



Aileron Presents Interim ALRN-6924 Data from PTCL, MDS, and AML Clinical Trials at the 60th Annual American Society of Hematology Meeting

December 4, 2018

Results in relapsed/refractory peripheral T-cell lymphoma (PTCL) demonstrate single-agent clinical proof-of-concept

Combination therapy dose-escalation with low-dose cytarabine (Ara-C) in myelodysplastic syndrome (MDS) patients who failed hypomethylating agents shows promising activity; expansion cohort enrolling

Single agent dose-escalation in relapsed/refractory AML continues

WATERTOWN, Mass., Dec. 04, 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, announced today the presentation of two posters at the 60th Annual American Society of Hematology (ASH) Meeting:

[Preliminary Results of the Stapled Peptide ALRN-6924, a Dual Inhibitor of MDMX and MDM2, in Two Phase IIa Dose Expansion Cohorts in Relapsed/Refractory TP53 Wild-Type Peripheral T-Cell Lymphoma](#)

and

[Phase 1/1b Study of the Stapled Peptide ALRN-6924, a Dual Inhibitor of MDMX and MDM2, As Monotherapy or in Combination with Cytarabine for the Treatment of Relapsed/Refractory AML and Advanced MDS with TP53 Wild-Type](#)

PTCL

Based on the interim data presented from this trial, Aileron has established ALRN-6924 single-agent proof-of-concept in PTCL, showing complete and partial remissions for single-agent therapy along with a favorable safety profile in the once-per-week dosing arm. For strategic reasons, Aileron has decided not to take the PTCL indication forward into a pivotal trial. Instead, based on the favorable ALRN-6924 and low-dose Ara-C combination therapy data, Aileron plans to focus on the potential synergy of ALRN-6924 in combination with other anti-cancer agents. To review the PTCL data presented, the Aileron PTCL poster can be accessed via the following link:

http://share.aileronrx.com/posters/Aileron_ASH_2018_Shustov_Final.pdf

MDS

Aileron reported that in its Phase 1/1b clinical trial, ALRN-6924 in combination with low-dose Ara-C has shown clinical activity in patients with MDS who failed hypomethylating agents. The activity seen includes marrow complete responses (mCRs) and/or hematological improvements in four of six evaluable patients. Due to these data, Aileron has already begun dosing an expansion cohort of MDS patients who have failed hypomethylating agents with this combination and expects to report interim results in the first half of 2019.

AML

Aileron also reported an update on 26 patients with AML or MDS who received ALRN-6924 as single-agent. Two different dosing regimens, once weekly and three-times per week, were tested and no responses were seen when administering ALRN-6924 once weekly. Dose escalation in the three-times per week dosing arm continues. To review the AML and MDS data presented, the Aileron AML/MDS poster can be accessed via the following link: http://share.aileronrx.com/posters/Aileron_ASH_2018_Sallman_Final.pdf

Regarding the data presented at ASH, Manuel Aivado, MD, PhD, and CEO of Aileron Therapeutics commented: "We are pleased to be sharing these clinical ALRN-6924 results with the medical and scientific community. Having shown single-agent proof-of-concept in relapsed/refractory PTCL patients, and responses in combination with low-dose Ara-C in MDS patients who failed hypomethylating agents, where low-dose Ara-C alone shows little to no benefit, we are excited to advance ALRN-6924 into larger and more promising potential combination indications including low-dose Ara-C and ALRN-6924 for MDS as well as combinations with other approved chemotherapies and targeted agents for solid tumor patients."

In addition to our MDS expansion cohort, within the next few months, Aileron plans to initiate combination therapy cohorts in a variety of solid tumors, including a biomarker-guided trial with Pfizer's palbociclib in MDM2-amplified tumors. For more detail on these planned trials, please view our corporate presentation at:

<https://aileronrx.gcs-web.com/static-files/021060f4-1da6-4b23-a16a-d280a8cd06bc>.

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. 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 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.

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Source: Aileron Therapeutics, Inc.