Aileron Therapeutics Announces Termination of Phase 1b Breast Cancer Chemoprotection Trial and Exploration of Strategic Alternatives

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BOSTON, Feb. 21, 2023 (GLOBE NEWSWIRE) -- Aileron Therapeutics (Nasdaq: ALRN) today announced that a review of initial data from its Phase 1b chemoprotection trial of ALRN-6924 in patients with p53-mutated breast cancer showed that patients in the trial experienced severe neutropenia (Grade 4) and alopecia. The primary endpoint of the Phase 1b open-label trial, which was evaluating ALRN-6924 in patients with breast cancer receiving neoadjuvant or adjuvant treatment with docetaxel, doxorubicin, and cyclophosphamide, or "TAC" chemotherapy, was duration and incidence of severe neutropenia in cycle 1. Incidence of chemotherapy-induced alopecia (hair loss) was a secondary endpoint. Based on these findings, Aileron has decided to terminate the Phase 1b breast cancer trial and further development of ALRN-6924.

Aileron also announced that it is exploring a range of strategic alternatives to maximize shareholder value. The company has engaged Ladenburg Thalmann & Co., Inc. to act as a strategic advisor for this process. Strategic alternatives that are being evaluated may include, but are not limited to, an acquisition, a merger, a business combination, a sale of assets or other transactions. There is no set timetable for this process and there can be no assurance that this process will result in Aileron pursuing a transaction or that any transaction, if pursued, will be completed on attractive terms. Aileron does not intend to comment further on this process unless or until its Board of Directors has approved a definitive course of action or it is determined that other disclosure is appropriate.

Aileron has determined to reduce its remaining workforce from 9 to 3 full-time employees in the coming weeks. The company plans to retain the remaining employees to assist in executing the strategic alternatives review process.

"We are very disappointed by these initial findings from our breast cancer trial, given the significant unmet need of cancer patients who must endure a wide range of chemotherapy-induced side effects and given the activity we had observed in our clinical trial in small cell lung cancer patients receiving topotecan chemotherapy. I would like to extend a heartfelt thanks to our patients, investigators and clinical trial staff and scientific advisors, as well as all others who have supported this trial and our efforts to advance ALRN-6924 as a chemoprotective agent. I would also like to thank our talented and truly dedicated Aileron team who have worked so diligently to advance ALRN-6924," said Manuel Aivado, M.D., Ph.D., President and Chief Executive Officer at Aileron Therapeutics. "We certainly hoped for a much different outcome for patients, but it is imperative that we now shift our focus toward conserving our resources as we explore strategic alternatives to maximize shareholder value."

About ALRN-6924

ALRN-6924 is an MDM2/MDMX inhibitor that leverages Aileron's proprietary peptide drug technology. Aileron originally initiated development of ALRN-6924 as an anti-cancer agent to restore p53-dependent tumor suppression in p53 wild-type tumors, evaluating ALRN-6924 as an anti-cancer agent in 196 patients in multiple clinical trials, including a single-agent Phase 1 trial in solid tumor and lymphoma patients [1]; a single-agent Phase 2a trial for the treatment of peripheral T-cell lymphoma (PTCL) [2]; a single-agent and Ara-C-combination Phase 1/1b trial for the treatment of acute myeloid leukemia (AML) and myelodysplastic syndrome (MDS) [3]; and a Phase 2a combination trial of ALRN-6924 and palbociclib in patients with tumors harboring MDM2 amplifications [4]. In these trials, ALRN-6924 was generally well-tolerated, with evidence of single-agent anti-tumor activity including complete and partial responses. Aileron has also conducted three clinical trials of ALRN-6924 as a chemoprotective agent in p53-mutated small cell lung cancer [5], non-small cell lung cancer, and breast cancer.

Aileron has a strong intellectual property portfolio in the U.S. and internationally and maintains exclusive worldwide rights to ALRN-6924 as well as the company's proprietary peptide drug technology.

The company is based in Boston, Mass. Visit aileronrx.com to learn more.

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 potential of ALRN-6924, the Company's future operations, the exploration of strategic alternatives and the outcome of such exploration. 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 period anticipated or with respect to the matters anticipated; whether the Company will identify a strategic transaction to pursue and whether such a transaction may be consummated on favorable terms, on a timely basis or at all; whether results obtained in clinical trials would be indicative of results that could be obtained in future clinical trials; and other factors discussed in the "Risk Factors" section of Aileron's annual report on Form 10-K for the year ended December 31, 2021, filed on March 28, 2022, and quarterly report on Form 10-Q for the quarter ended September 30, 2022, filed on November 1, 2022, 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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