Aileron Therapeutics and Pulmonary Care Experts To Discuss the Potential Implications of LTI-03 for Idiopathic Pulmonary Fibrosis in Virtual Key Opinion Leader Event

February 15, 2024

Topline results from Phase 1b study of LTI-03, Aileron's novel Caveolin-1-related peptide in development for the treatment of idiopathic pulmonary fibrosis, expected in the second quarter of 2024

WALTHAM, Mass., Feb. 15, 2024 (GLOBE NEWSWIRE) -- Aileron Therapeutics, Inc. ("Aileron") (NASDAQ: ALRN), a biopharmaceutical company advancing a novel pipeline of first-in-class medicines to address significant unmet medical needs in orphan pulmonary and fibrosis indications, will host a virtual key opinion leader event today from 4:30 to 5:30 p.m. ET titled "Clinical Perspectives on Treating Idiopathic Pulmonary Fibrosis" featuring pulmonary care experts Fernando J. Martinez, M.D., M.S. from Weill Cornell Medicine; Tejaswini Kulkarni, M.D., M.P.H. from University of Alabama at Birmingham Medicine; and Andreas Günther, M.D. from Agaplesion Evang. Central Hesse Hospital and Justus Liebig University.

The event will include presentations by Aileron management followed by a panel discussion with the key opinion leaders on the treatment landscape for idiopathic pulmonary fibrosis (IPF), including the current challenges and significant unmet needs that remain for patients with the disease and the Company's lead product candidate, LTI-03. A live question-and-answer session will follow.

"As practicing clinicians and experts in pulmonary care medicine, these key opinion leaders bring valuable experience to the discussion of LTI-03 as a potential treatment option for patients with IPF," said Cory Hogaboam, Ph.D., Chief Scientist of Aileron. "While Aileron expects to announce topline data from our Phase 1b study of LTI-03 in the second quarter of this year, we are encouraged by the support of these experts for the work we are doing to address the significant unmet need in this patient population."

IPF is a chronic lung disease characterized by progressive tissue scarring that prevents proper lung function. It is a progressive, fatal, age-associated lung disease affecting approximately 100,000 people in the United States[1]. IPF typically presents in adults 65 or older and is usually fatal within two to five years after diagnosis[2].

Aileron's lead product candidate, LTI-03, is a novel Caveolin-1-related (Cav1) peptide with a dual mechanism targeting both alveolar epithelial cell survival as well as inhibition of profibrotic signaling, whereas approved drugs for the treatment of IPF, such as nintedanib and pirfenidone, have only demonstrated a reduction of profibrotic signaling. Studies conducted by Aileron and third parties have demonstrated that Cav1 is a key protein in the regulation of lung fibrosis that has a decreased expression in IPF patients. LTI-03 completed a Phase 1a clinical trial in healthy volunteers and is currently in a randomized, double-blind, placebo-controlled Phase 1b clinical trial in IPF patients. Aileron expects to announce topline results from this study in the second quarter of 2024.

To access the event, please dial +1 646-876-9923 (domestic) or +44 208-080-6591 (international) and reference webinar ID: 953 9620 1729 and passcode: 554257 when prompted by the operator. A live webcast of the event can be accessed at https://investors.aileronrx.com/events-presentations/investor-events. A replay of the webcast will be available following the completion of the event.

About LTI-03 and Caveolin-1 (Cav1)

LTI-03 is a seven amino acid peptide, the sequence of which is derived from the caveolin scaffolding domain (CSD), an important binding region of the Cav1 protein. Cav1 normally serves a critical function in the prevention of fibrosis by maintaining a balance between pathways that both initiate and arrest lung repair and cell movement. Through the CSD, caveolin interacts with a large number of signaling molecules, all of which possess a caveolin binding sequence region. Cav1 expression is decreased in IPF lung tissues and has been demonstrated to decrease during the fibrotic phase of bleomycin, or BLM, lung injury in mice. Restoring the balance of important biological signals in the lung may not only slow lung function decline but could also restore healthy lung function through the protection of healthy epithelial cells.

About Aileron Therapeutics

Aileron Therapeutics is a biopharmaceutical company advancing a novel pipeline of first-in-class medicines to address significant unmet medical needs in orphan pulmonary and fibrosis indications. Aileron's lead product candidate, LTI-03, is a novel, synthetic peptide with a dual mechanism targeting alveolar epithelial cell survival as well as inhibition of profibrotic signaling. Currently, LTI-03 is being evaluated in a Phase 1b clinical trial for the treatment of idiopathic pulmonary fibrosis, with topline results expected to be reported by the end of 2Q24. Aileron's second product candidate, LTI-01, is a proenzyme that has completed Phase 1b and Phase 2a clinical trials for the treatment of loculated pleural effusions. LTI-01 has received

Orphan Drug Designation in the US and EU and Fast Track Designation in the US.

References

[1] Pergolizzi, Jr., J., LeQuang, J., Varrassi, M., Breve, F., Magnusson, P., Varrassi, G., (2023). What Do We Need to Know About Rising Rates of Idiopathic Pulmonary Fibrosis? A Narrative Review and Update. Springer Nature, Published online 2023 Jan 24. Doi: 10.1007/s12325-022-02395-9.

[2] Nathan et al. “Long-term Course and Prognosis of Idiopathic Pulmonary Fibrosis in the New Millennium”. *Chest Journal* Volume 140, ISSUE 1, P221-229, July 2011.

Forward-Looking Statements

This press release may contain forward-looking statements of Aileron Therapeutics, Inc. (“Aileron”, the “Company”, “we”, “our” or “us”) within the meaning of the Private Securities Litigation Reform Act of 1995, including statements with respect to: the timing and expectation of the results of the Phase 1b study of LTI-03; future expectations, plans and prospects for the Company following the merger transaction between the Company and Lung Therapeutics, Inc. that closed in the fourth quarter of 2023 (the "Merger"); the use of proceeds from the private placement conducted concurrently with the Merger; the sufficiency of the Company’s cash resources; stockholder approval of the conversion of the non-voting preferred stock; the benefits of the Merger; certain milestones of the Company; the projected cash runway of the Company; the status and plans for clinical trials, including the timing of data; future product development; and the potential commercial opportunity of LTI-03 and LTI-01. We use words such as "anticipate," "believe," "estimate," "expect," "hope," "intend," "may," "plan," "predict," "project," "target," "potential," "would," "can," "could," "should," "continue," and other words and terms of similar meaning to help 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 risks and uncertainties related to the ability to recognize the anticipated benefits of the Merger, the ability to maintain the listing of the common stock of the Company on The Nasdaq Stock Market, changes in applicable laws or regulations, the possibility that the Company may be adversely affected by other economic, business, and/or competitive factors, including risks inherent in pharmaceutical research and development, such as: adverse results in the Company’s drug discovery, preclinical and clinical development activities, the risk that the results of preclinical studies and early clinical trials may not be replicated in later clinical trials, the Company’s ability to enroll patients in its clinical trials, and the risk that any of its clinical trials may not commence, continue or be completed on time, or at all; decisions made by the U.S. FDA and other regulatory authorities, investigational review boards at clinical trial sites and publication review bodies with respect to our development candidates; our ability to obtain, maintain and enforce intellectual property rights for our platform and development candidates; our potential dependence on collaboration partners; competition; uncertainties as to the sufficiency of the Company’s cash resources to fund its planned activities for the periods anticipated and the Company’s ability to manage unplanned cash requirements; and general economic and market conditions; as well as the risks and uncertainties discussed in the "Risk Factors" section of the Company’s Annual Report on Form 10-K for the year ended December 31, 2022, which is on file with the United States Securities and Exchange Commission (the “SEC”), the risks and uncertainties discussed under the heading "Risk Factors" of the Company’s Current Report on Form 8-K filed with the SEC on January 25, 2024, and in subsequent filings that the Company files with the SEC. These forward-looking statements should not be relied upon as representing the Company’s view as of any date subsequent to the date of this press release, and we expressly disclaim any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

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