Alumis Presents Data Highlighting ESK-001's Potential as a High-efficacy Oral Treatment for Systemic Lupus Erythematosus (SLE) at ACR Convergence 2024

November 14, 2024

SOUTH SAN FRANCISCO, Calif., Nov. 14, 2024 (GLOBE NEWSWIRE) -- Alumis Inc. (Nasdaq: ALMS), a clinical stage biopharmaceutical company developing oral therapies using a precision approach to optimize clinical outcomes and significantly improve the lives of patients with immune-mediated diseases, today announced the company will give two data presentations at ACR Convergence 2024, the annual meeting of the American College of Rheumatology (ACR), being held November 14–19, 2024, in Washington, D.C.

Data to be presented at ACR show that treatment with ESK-001, a highly selective allosteric oral tyrosine kinase 2 (TYK2) inhibitor, suppresses both a novel disease biomarker as well as Type 1 interferons, known key drivers of SLE. Additionally, leveraging its proprietary data analytics platform, Alumis identified novel pathways implicated in SLE that can be suppressed through TYK2 inhibition.

"The ACR data show that treatment with ESK-001 downregulates key cytokines and disease biomarkers of SLE," said Dr. Jörn Drappa, Alumis' Chief Medical Officer. "These data, along with ESK-001's demonstrated ability to achieve maximal TYK2 inhibition in psoriasis, suggest that ESK-001 could potentially become a high efficacy oral treatment option for patients with SLE. Our team continues to advance the Phase 2b LUMUS study in SLE, and we look forward to reporting top-line data in 2026."

Details regarding the presentations are as follows:

POSTER PRESENTATION:
Title: *Novel Role of TYK2 mechanism in SLE Pathogenesis via T Cell and B Cell Pathways*
Session Title: Genetics, Genomics & Proteomics Poster
Session Type: Poster Session B
Date and Time: Sunday, November 17, 2024, 10:30 a.m. – 12:30 p.m. EST
Abstract Number: 0902

POSTER PRESENTATION:
Title: *ESK-001, an Allosteric TYK2 Inhibitor, Maximally Suppresses Type 1 Interferon, a Therapeutic Pathway Central to SLE and CLE*
Session Title: SLE – Treatment Poster III
Session Type: Poster Session C
Date and Time: Monday, November 18, 2024, 10:30 a.m. – 12:30 p.m. EST
Abstract Number: 2434

The presentations will be available under the Publications section of the Alumis website on November 18, 2024.

About SLE (Lupus)
Systemic lupus erythematosus (SLE) is a chronic autoimmune disease and is the most common type of lupus. Lupus occurs when the immune system attacks its own tissues, causing inflammation, and in some cases permanent tissue damage, which can be widespread – affecting many parts of the body like the skin, joints, heart, lung, kidneys, circulating blood cells, and brain. Current treatments aim to alleviate symptoms of lupus or reduce inflammation to minimize organ damage; there is no cure for lupus.

About ESK-001
Alumis' lead clinical candidate, ESK-001, is a potent, highly selective allosteric tyrosine kinase 2 (TYK2) inhibitor that reduces signaling through several cytokine receptors including receptors for interleukin (IL)-12, IL-23, and interferon-a.

ESK-001 is currently being evaluated in the Phase 2 LUMUS clinical trial, a global, multicenter, randomized, double-blind, placebo-controlled trial that is designed to evaluate the efficacy, safety and pharmacokinetics of multiple doses of ESK-001 in adult patients with moderately to severely active, autoantibody-positive SLE. The trial is expected to enroll 388 patients across multiple doses of ESK-001 or placebo for a treatment period of 48 weeks. Following the trial, eligible patients may enroll in an open-label extension study or participate in a four-week safety follow up period. The primary endpoint of the trial will compare the proportion of patients with improvement in BICLA at Week 48 relative to baseline across doses of ESK-001 and placebo. British-Isles Lupus Assessment Group (BILAG)-based Combined Lupus Assessment (BICLA) is an accepted composite measure of overall SLE disease activity. Secondary endpoints include safety and tolerability, as well as various measures of effect on disease activity. For more information, visit clinicaltrials.gov.

ESK-001 is also currently being evaluated as a potential treatment for adult patients with moderate-to-severe plaque psoriasis in the Phase 3 ONWARD clinical program which consists of two identical global Phase 3, multi-center, randomized, double-blind placebo-controlled 24-week clinical trials, ONWARD1 and ONWARD2, designed to evaluate the efficacy and safety of the 40 mg twice-daily dose of ESK-001. Patients completing Week 24 will have the opportunity to participate in a long-term extension (LTE) trial, ONWARD3, that will evaluate durability and maintenance of response and long-term safety. In parallel with the Phase 3 clinical program, Alumis is developing a once-daily modified release oral formulation of ESK-001 that can replace the current immediate release oral formulation that is dosed twice daily.

The Phase 3 clinical program in moderate-to-severe plaque psoriasis is supported by positive data from the Phase 2 STRIDE clinical trial in which 228 patients were randomized to one of five ESK-001 dose cohorts or placebo. The trial met its primary endpoint, the proportion of patients achieving a PASI 75 at week 12 compared to placebo, and key secondary efficacy endpoints at all clinically relevant doses tested. Clear dose-dependent responses were observed with maximal efficacy and TYK2 inhibition achieved at the highest dose of 40 mg twice daily. ESK-001 was found to be generally well tolerated at all dose levels.

In addition, Alumis continues to leverage its precision data analytics platform to explore ESK-001's potential application in other autoimmune indications.

About Alumis

Alumis is a clinical-stage biopharmaceutical company developing oral therapies using a precision approach to optimize clinical outcomes and significantly improve the lives of patients with immune-mediated diseases. Leveraging its proprietary precision data analytics platform, Alumis is building a pipeline of molecules with the potential to address a broad range of immune-mediated diseases as monotherapy or combination therapies. Alumis' most advanced product candidate, ESK-001, is an oral, highly selective, small molecule, allosteric inhibitor of tyrosine kinase 2 that is currently being evaluated for the treatment of patients with moderate-to-severe plaque psoriasis and systemic lupus erythematosus. Alumis is also developing A-005, a CNS-penetrant, allosteric TYK2 inhibitor for the treatment of neuroinflammatory and neurodegenerative diseases. Beyond TYK2, Alumis' proprietary precision data analytics platform and drug discovery expertise have led to the identification of additional preclinical programs that exemplify its precision approach. Incubated by Foresite Labs and led by a team of industry veterans experienced in small-molecule compound drug development for immune-mediated diseases, Alumis is pioneering a precision approach to drug development to potentially produce the next generation of treatment to address immune dysfunction. For more information, visit https://www.alumis.com.

Forward-Looking Statements

This press release contains forward-looking statements, including statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These statements may be identified by words such as "aims," "anticipates," "believes," "could," "estimates," "expects," "forecasts," "goal," "intends," "may," "plans," "possible," "potential," "seeks," "will" and variations of these words or similar expressions that are intended to identify forward-looking statements. Any such statements in this press release that are not statements of historical fact may be deemed to be forward-looking statements. These forward-looking statements include, without limitation, statements regarding Alumis' future plans and prospects, the potential for ESK-001 to be a high-efficacy oral treatment in systemic lupus erythematosus, any further expectations regarding the safety, efficacy or tolerability of ESK-001, and the expected timing of clinical data, including data from Alumis' ongoing Phase 2b trial in SLE. Any forward-looking statements in this press release are based on Alumis' current expectations, estimates and projections only as of the date of this release and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. Readers are cautioned that actual results, levels of activity, safety, efficacy, performance or events and circumstances could differ materially from those expressed or implied in Alumis' forward-looking statements due to a variety of risks and uncertainties, which include, without limitation, risks and uncertainties related to Alumis' ability to advance ESK-001 and its other clinical candidates and to obtain regulatory approval of and ultimately commercialize Alumis' clinical candidates, the timing and results of preclinical and clinical trials, Alumis' ability to fund development activities and achieve development goals, Alumis' ability to protect its intellectual property and other risks and uncertainties described in Alumis' filings with the Securities and Exchange Commission (SEC), including any future reports Alumis may file with the SEC from time to time. Alumis explicitly disclaims any obligation to update any forward-looking statements except to the extent required by law.

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