Alumis and Kaken Pharmaceutical Announce Collaboration and Licensing Agreement for ESK-001 in Dermatology in Japan

March 25, 2025

- Alumis to receive $40 million in upfront and near-term co-development payments, with potential for approximately $140 million in additional milestone and field option payments, plus tiered royalties on future sales

-Deal underscores the commercial potential of Alumis' ESK-001 and leverages Kaken's regional capabilities and expertise in novel dermatology treatments

-Kaken has the option to license ESK-001 for further clinical development and commercialization in rheumatological and gastrointestinal diseases

SOUTH SAN FRANCISCO, Calif. and BUNKYO-KU, Tokyo, March 25, 2025 (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, and Kaken Pharmaceutical Co., Ltd. (Tokyo Stock Exchange: 4521) today announced that the companies have entered into a collaboration and licensing agreement to develop, manufacture and commercialize ESK-001, a highly selective, next-generation oral tyrosine kinase 2 (TYK2) inhibitor, for dermatology indications in Japan, with the option to expand the license to include rheumatological and gastrointestinal diseases.

Under the terms of the agreement, Alumis will receive $40 million in upfront and near-term co-development payments in 2025 to 2026, with the potential to earn up to approximately $140 million in additional payments based on the achievement of milestones, and field option payments. Alumis is also eligible to receive tiered royalties ranging from the low double-digits into the twenties on aggregate net sales of ESK-001 in Japan. Kaken will be responsible for the clinical development, regulatory approvals and commercialization of ESK-001 in Japan, and Alumis will retain rights to ESK-001 in all other geographies. Kaken will also contribute to a portion of the global development costs of ESK-001.

"We are thrilled to announce this agreement with Kaken, a dermatology leader with significant reach and expertise in the Japanese market," said Martin Babler, President and Chief Executive Officer of Alumis. "This partnership builds on the positive Phase 2 clinical data of ESK-001, our next-generation oral TYK2 inhibitor, supporting our objectives to unlock its full therapeutic potential and ensure ESK-001 is widely accessible to people with immune-mediated disorders around the world."

"We are delighted to enter into an agreement with Alumis to develop ESK-001 for the Japanese market," said Hiroyuki Horiuchi, President and Representative Director of Kaken. "We strongly believe in the potential of ESK-001 to address a range of medical needs in the dermatology space

and potentially rheumatological and gastrointestinal diseases in the future. ESK-001 will be an important addition to the Kaken portfolio of novel therapeutics for dermatology conditions."

About ESK-001

Alumis' lead clinical candidate, ESK-001, is a highly selective, next-generation oral TYK2 inhibitor that is designed to correct immune dysregulation across a spectrum of diseases driven by proinflammatory mediators, including IL-23, IL-17, and type 1 interferon (IFN). ESK-001's selective targeting is designed to deliver maximal inhibition while minimizing off-target binding and effects.

ESK-001 is currently being evaluated in the Phase 3 ONWARD clinical program, which consists of two parallel global Phase 3, multi-center, randomized, double-blind placebo-controlled 24-week clinical trials, ONWARD1 and ONWARD2, including trial sites in Japan, designed to evaluate the efficacy and safety of ESK-001 in adult patients with moderate-to-severe plaque psoriasis. 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. The Phase 3 clinical program is supported by positive data from the Phase 2 STRIDE clinical trial and the ongoing long-term OLE extension showing that ESK-001 treatment led to robust long-term clinical responses and was well tolerated through 52 weeks. In parallel with the Phase 3 clinical program, Alumis is developing a once-daily modified release oral formulation of ESK-001 designed to replace the current immediate release oral formulation that is dosed twice daily.

ESK-001 is also being evaluated in LUMUS, a Phase 2b clinical trial for the treatment of patients with systemic lupus erythematosus. In addition, Alumis continues to leverage its precision data analytics platform to explore ESK-001's potential application in other immune-mediated conditions.

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 TYK2 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 clinical-stage, 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 www.alumis.com.

About Kaken Pharmaceutical

Kaken Pharmaceutical is a specialty pharmaceutical company in Japan with strong experience in developing and commercializing novel pharmaceuticals in the fields of orthopedics and dermatology.

Kaken concentrates its R&D resources in areas such as immune system, nervous system, infectious diseases and rare diseases with unmet medical needs. Kaken, in its philosophy, strives to improve the quality of life of patients through the development and distribution of superior pharmaceuticals.

For further information, visit www.kaken.co.jp/english.

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 including development and commercialization of its pipeline, the potential for ESK-001 to be a best-in-class oral treatment for moderate-to-severe plaque psoriasis, any expectations regarding the safety, efficacy or tolerability of ESK-001 and the potential of ESK-001 to treat moderate-to-severe plaque psoriasis and systemic lupus erythematosus and the collaboration with Kaken and the intended and potential benefits thereof, including the receipt of potential co-development, milestone and royalty payments. 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 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.

Alumis Contact Information Teri Dahlman Red House Communications teri@redhousecomms.com
Kaken Contact Information Corporate Communications Department Contact
https://www.kaken.co.jp/english/contact/