Adlai Nortye Announces First Patient Enrolled in Global Phase 1 Trial of Pan-RAS (ON) Inhibitor AN9025 for Solid Tumors Harboring RAS Mutations

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SINGAPORE and NORTH BRUNSWICK, N.J. and HANGZHOU, China, Feb. 12, 2026 (GLOBE NEWSWIRE) -- Adlai Nortye Ltd. (NASDAQ: ANL) (the "Company" or "Adlai Nortye"), a clinical-stage biotechnology company focused on the development of innovative cancer therapies, today announced that the first patient has been dosed in the United States in early February in its ongoing Phase 1 clinical trial of AN9025, a pan-RAS (ON) inhibitor.

The Phase 1 study is a first-in-human, multicenter, open-label trial designed to evaluate the safety, tolerability, pharmacokinetics and anti-tumor activity of AN9025 in patients with advanced or metastatic solid tumors harboring RAS mutations. This trial is being conducted by Adlai Nortye in collaboration with Jiangsu Aosaikang Pharmaceutical Co. Ltd. ("ASK Pharm") as a multi-regional clinical trial ("MRCT") pursuant to a license agreement, under which Adlai Nortye retains ex-China rights to AN9025, while ASK Pharm holds rights in mainland China, Hong Kong and Macao.

"Dosing the first U.S. patient with AN9025, our wholly in-house discovered, oral pan-RAS(ON) inhibitor with best-in-class potential, is a significant milestone," said Dr. Archie Tse, Head of Research and Development at Adlai Nortye. "This achievement advances our clinical strategy to evaluate AN9025 across multiple RAS-mutant solid tumors. We look forward to efficiently progressing its global clinical development and generating meaningful data to support its future advancement."

About AN9025

AN9025 is an oral small molecule pan-RAS(ON) inhibitor with best-in-class potential, designed to target a broad spectrum of RAS mutations across various tumor types. Preclinical studies have demonstrated that AN9025 effectively inhibits RAS-mutant cancers with potent and durable efficacy, including pancreatic, lung, and colorectal adenocarcinomas, and shows comparable or superior results relative to a benchmark agent of the same class.

About Adlai Nortye

Adlai Nortye (NASDAQ: ANL) is a global clinical-stage company at the forefront of discovering and developing innovative cancer therapies. Leveraging our dual R&D presence in the U.S. and China, we are building a robust pipeline of drug candidates focused on two key areas where we believe we can make a significant difference. (1) Next-generation cancer immunotherapies: our candidates, AN8025 (a tri-functional fusion protein of αPD-L1 x CD86 variant x LAG3 variant), a T-cell and antigen-presenting cell modulator, and AN4005 (a first-in-class oral small-molecule PD-L1 inhibitor), are designed to activate cancer immunity in novel ways. (2) RAS-targeting therapies: we are tackling RAS-driven cancers with AN9025, an oral pan-RAS(ON) inhibitor, and AN4035, a CEACAM5-targeting ADC delivering a potent pan-RAS(ON) inhibitor directly to tumors.

Forward-Looking Statement

This announcement contains forward-looking statements. These statements are made under the "safe harbor" provisions of the U.S. Private Securities Litigation Reform Act of 1995. These forward-looking statements can be identified by terminology such as "will," "expects," "anticipates," "future," "intends," "plans," "believes," "estimates," "potential," "continue," "ongoing," "targets" and similar statements. Among other things, statements that are not historical facts, including statements about the Company's beliefs and expectations, the business outlook and quotations from management in this announcement, as well as the Company's strategic and operational plans, are or contain forward-looking statements.

The Company may also make written or oral forward-looking statements in its periodic reports to the U.S. Securities and Exchange Commission (the "SEC"), in press releases and other written materials and in oral statements made by its officers, directors or employees to third parties. Forward-looking statements involve inherent risks and uncertainties. Factors that could cause the Company's actual results to differ materially from those expressed or implied in such forward-looking statements include, but are not limited to: the initiation, timing, progress and results of the Company's preclinical studies, clinical trials and other therapeutic candidate development efforts; the Company's ability to advance its therapeutic candidates into clinical trials or to successfully complete its preclinical studies or clinical trials; whether the clinical trial results will be predictive of real-world results; the Company's receipt of regulatory approvals for its therapeutic candidates, and the timing of other regulatory filings and approvals; the clinical development, commercialization and market acceptance of the Company's therapeutic candidates; the Company's ability to establish, manage, and maintain corporate collaborations, as well as the ability of its collaborators to execute on their development and commercialization plans; the implementation of the Company's business model and strategic plans for its business and therapeutic candidates; the scope of protection the Company is able to establish and maintain for intellectual property rights covering its therapeutic candidates and its ability to operate its business without infringing the intellectual property rights of others; estimates of the Company's expenses, future revenues, capital requirements and its needs for and ability to access sufficient additional financing; risks related to changes in healthcare laws, rules and regulations in the PRC and United States or elsewhere. Further information regarding these and other risks is included in the Company's filings with the SEC. All information provided in this announcement and in the attachments is as of the date of this announcement, and the Company does not undertake any obligation to update any forward-looking statement, except as required under applicable law.

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