



Adlai Nortye Announces First Patient Dosed in Australia and U.S. FDA IND Clearance for AN4035, a First-in-Class Pan-RAS(ON) Inhibitor-Based ADC

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First-in-class CEACAM5-targeting ADC armed with a pan-RAS(ON) inhibitor – designed for tumor-selective RAS pathway inhibition

First patient dosed in Australia; global Phase I initiated

U.S. FDA cleared IND with "Study-May-Proceed" letter

SINGAPORE and NORTH BRUNSWICK, N.J., Sept. 08, 2026 (GLOBE NEWSWIRE) -- Adlai Nortye Group Ltd. (NASDAQ: ANL) ("Adlai Nortye" or the "Company"), a clinical-stage biotechnology company focused on the development of innovative cancer therapies, today announced that the first patient has been dosed with AN4035 in Australia, initiating the global Phase I trial in patients with CEACAM5-enriched RAS-addicted solid tumors. The Company also received a "Study-May-Proceed" letter from the U.S. Food and Drug Administration (FDA) on its investigational new drug (IND) application, clearing the path to expand the trial into the United States.

"AN4035 is the first proof-of-concept candidate from our RAS Inhibitor Conjugated Antibody (RASiCA™) platform, specifically engineered to address two pressing challenges in oncology. First, the ADC field urgently needs novel payload classes to overcome cross-resistance, as existing options remain largely confined to just topoisomerase I and microtubule inhibitors. Second, systemic pan-RAS(ON) inhibitors have been hampered by on-target, off-tumor toxicities, particularly in the skin and gastrointestinal tract. By conjugating our potent pan-RAS(ON) payload to a CEACAM5-targeting antibody, AN4035 is designed for tumor-selective delivery while sparing normal tissues," said Dr. Archie Tse, President, Head of Research & Development. "Following regulatory clearance to begin the trial in Australia last month, we have dosed the first patient and secured a "Study-May-Proceed" letter from the U.S. FDA. We look forward to advancing this asset globally and remain on track to report full Phase Ia data in the second half of 2027."

This global phase I trial will evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics, and preliminary efficacy of AN4035 as monotherapy and in combination with cetuximab in patients with CEACAM5-enriched, RAS-addicted solid tumors. CEACAM5 is highly overexpressed in colorectal, pancreatic, and lung cancers – tumor types that frequently harbor RAS mutations. The Company is also filing an IND application for AN4035 with the China National Medical Products Administration (NMPA).

About AN4035

AN4035 is a first-in-class ADC targeting CEACAM5 and armed with a highly potent pan-RAS(ON) inhibitor payload. In preclinical studies, the ADC demonstrates favorable thermal and plasma stability with desirable pharmacokinetic properties. Strong intracellular payload retention drives nanomolar to picomolar cytotoxicity in CEACAM5-positive, RAS-addicted cancer cell lines, coupled with a potent bystander-killing effect. In vivo, AN4035 has shown robust anti-tumor activity with deep tumor regression in CEACAM5-positive CDX and PDX models. Compared with the payload alone, the ADC exhibits enhanced target-mediated tumor retention and significantly improved tumor selectivity over normal tissues, resulting in an overall favorable therapeutic index. Adlai Nortye is evaluating AN4035 in a global phase I trial in patients with CEACAM5-enriched RAS-addicted solid tumors.

About Adlai Nortye

Adlai Nortye is a global clinical-stage biopharmaceutical company dedicated to developing innovative cancer therapies. The global infrastructure supports the efficient execution of our robust pipeline of drug candidates covering two key therapeutic areas:

- 1) Precision RAS pathway targeted therapies: including the oral pan-RAS(ON) inhibitor AN9025, and the CEACAM5-targeting ADC AN4035 engineered from the Company's proprietary RASiCA™ (RAS Inhibitor Conjugated Antibody) platform, which efficiently delivers a potent pan-RAS(ON) inhibitor to the tumor site.
- 2) Next-generation PD-1/L1 pathway modulating immunotherapies: including AN8025, a multi-functional fusion protein that simultaneously modulates T cells and antigen-presenting cells.

Forward-Looking and Cautionary Statements

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

press release and in the attachments is as of the date of this press release, and the Company does not undertake any obligation to update any forward-looking statement, except as required under applicable law.

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