Adlai Nortye Announces Clinical Trial Notification Submission and HREC Approval for the Phase I Clinical Trial of Pan-RAS(ON) Inhibitor ADC AN4035 in Australia

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First-in-class pan-RAS(ON) ADC is cleared for clinical development

Designed to selectively deliver pan-RAS(ON) inhibition to tumors while minimizing systemic toxicity.

IND submissions to U.S. FDA and China NMPA are in process

SINGAPORE and NORTH BRUNSWICK, N.J., Aug. 03, 2026 (GLOBE NEWSWIRE) -- Adlai Nortye Ltd. (NASDAQ: ANL) (“Adlai Nortye” or the “Company”), a clinical-stage biotechnology company focused on the development of innovative cancer therapies, today announced that it has submitted a Clinical Trial Notification (CTN) to Australia's Therapeutic Goods Administration (TGA) and received approval from the Human Research Ethics Committee (HREC) to commence its phase I clinical trial evaluating AN4035, a CEACAM5-targeting, pan-RAS(ON) inhibitor-based antibody drug conjugate (ADC) for the treatment of CEACAM5-enriched RAS-addicted solid tumors.

“AN4035 is a first-in-class CEACAM5-targeting ADC armed with a pan-RAS(ON) inhibitor payload, and is our first drug candidate to demonstrate proof-of-concept of our RASiCA™ (RAS Inhibitor Conjugated Antibody) platform.” said Dr. Archie Tse, President, Head of Research & Development. “To our knowledge, AN4035 is the first pan-RAS(ON) ADC to enter the clinic globally. We believe that utilizing targeted delivery via an ADC could localize pan-RAS(ON) inhibitor activity to the tumor while minimizing systemic RAS pathway inhibition, which could potentially both widen the therapeutic window and enable rational combinations. We are excited to see this asset advance into clinical development and the potential benefit it may bring to our patients globally.”

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 an antigen that is overexpressed in colorectal, pancreatic, and lung cancers, which frequently harbor RAS mutations. Adlai Nortye is also filing investigational new drug (IND) applications for AN4035 with the U.S. Food and Drug Administration (FDA) and China National Medical Products Administration (NMPA). Patient dosing with AN4035 is expected to begin in the second half of 2026.

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, AN4035 demonstrated nanomolar to picomolar cytotoxicity in CEACAM5-positive / RAS-addicted cancer cell lines, along with a robust bystander killing effect. It also exhibited potent anti-tumor activity with deep regression in CDX/PDX models, favorable developability with desirable pharmacokinetic properties, and enhanced target-mediated tumor retention with improved tumor selectivity over normal tissue -- 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 (NASDAQ: ANL) is a global clinical-stage biopharmaceutical company dedicated to developing innovative cancer therapies. The company is building a rich and 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, and AN4005, a first-in-class oral PD-L1 inhibitor.

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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