Adlai Nortye Announces Topline Results of Phase III BURAN Trial Evaluating Buparlisib (AN2025) in Combination with Paclitaxel for Recurrent or Metastatic HNSCC

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SINGAPORE and NORTH BRUNSWICK, N.J. and HANGZHOU, China, May 30, 2025 -- Adlai Nortye Ltd. (NASDAQ: ANL) (the "Company" or "Adlai Nortye"), a global clinical-stage biotechnology company focused on the development of innovative targeted and immune-modulating cancer therapies, today announced topline results from its Phase III BURAN trial evaluating buparlisib (AN2025), a PI3K inhibitor, in combination with paclitaxel for the treatment of patients with recurrent or metastatic head and neck squamous cell carcinoma (HNSCC).

The study did not meet the primary endpoint of improving overall survival compared to paclitaxel alone. The safety profile of buparlisib was consistent with previous findings, with no new safety signals observed. Detailed results will be presented at an upcoming medical conference.

"We are disappointed with the outcome of the phase III BURAN study," said Carsten Lu, CEO and Chairman of Adlai Nortye. "While the outcome is not what we hoped for, we are deeply grateful to the patients, investigators, and research teams whose commitment and contributions made this global trial possible. Based on these results, we have decided to discontinue further development of buparlisib. We will, however, continue to analyze the data to better understand the findings and to inform future drug development in HNSCC."

"The Company expects to make near-term changes to its business operations and to reduce its workforce in order to preserve cash, including but not limited to: optimizing workforce structure and compensation, pursuing strategic business development opportunities, and expanding our financing options," Carsten Lu added. "We will refocus our resources and efforts on advancing AN8025 and AN9025, together with our emerging candidates, which we believe have strong potential to address unmet needs across multiple tumor types, and deliver transformative therapies to patients worldwide."

About Phase III BURAN Trial

The BURAN study is a randomized (2:1), open-label Phase III study to assess the treatment effect of buparlisib in combination with paclitaxel compared to weekly paclitaxel alone in patients with recurrent and metastatic HNSCC that have progressed after anti-PD-(L)1-based treatment. A total of 487 patients were enrolled globally. The primary endpoint of the trial was overall survival (OS), with secondary endpoints including progression-free survival (PFS), objective response rate (ORR), and duration of response (DoR). This Phase III trial builds on positive Phase II data, where the buparlisib-paclitaxel combination demonstrated improvements in ORR, PFS, and OS compared to paclitaxel alone. Notably, these Phase II findings preceded the establishment of anti-PD-(L)1 therapies as the cornerstone treatment for recurrent/metastatic HNSCC.

About AN8025

AN8025 is a next-generation tri-specific antibody fusion protein in particular PD-1-based immunotherapy, derived from an approved αPD-L1 antibody and fused with functionally optimized CD86 and LAG3 variants. Designed to modulate T cell and antigen-presenting cell (APC) functions, preclinical studies have demonstrated that AN8025 enhances both the quantity and quality of APCs while also inducing robust PD-L1-dependent T cell activation and anti-tumor efficacy in vivo. The Company plans to submit the IND application in mid-2025.

About AN9025

AN9025 is an in-house developed 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. The company plans to submit an IND application in the second half of 2025.

About AN4005

AN4005 is an orally available, small-molecule PD-L1 inhibitor that demonstrates antitumor activity by the blockade of PD-1/PD-L1 interaction. Preliminary results from the Dose-Escalation Phase, presented at SITC 2024, demonstrated that AN4005 exhibits favorable safety and tolerability in patients with advanced tumors. Encouraging preliminary efficacy was observed in a tumor type known to respond to anti-PD-(L)1 therapy. The trial has now advanced to the Expansion Phase, evaluating two doses of AN4005 in checkpoint inhibitor-naïve patients. Proof-of-concept data from the Expansion Phase is expected by the end of 2025.

About Adlai Nortye

Adlai Nortye (NASDAQ: ANL) is a global clinical-stage company focused on the development of innovative cancer therapies, with global R&D centers in the U.S. and China, the Company is advancing a robust oncology pipeline. We are advancing multiple drug candidates including AN8025, a multifunctional fusion protein acting as a T cell and antigen-presenting cell ("APC") modulator, AN9025, an oral small molecule pan-RAS(ON) inhibitor and AN4005, an oral small molecule PD-L1 inhibitor.

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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