Adlai Nortye Announces Completion of Patient Enrollment in Global Phase III Clinical Trial of Buparlisib (AN2025) in Combination with Paclitaxel for the Treatment of Recurrent or Metastatic HNSCC

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SINGAPORE and NORTH BRUNSWICK, N.J. and HANGZHOU, China, Nov. 17, 2023 (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 the Completion of Patient Enrollment in Global Phase III Clinical Trial (BURAN) of Buparlisib (AN2025) in Combination with Paclitaxel for the Treatment of Recurrent or Metastatic HNSCC in more than 180 sites around the world, spanning over 18 markets in North America, Europe, Asia, and South America.

This clinical study evaluates buparlisib (AN2025), an oral pan-PI3K inhibitor, in combination with paclitaxel for the treatment of recurrent or metastatic head and neck squamous cell carcinoma (HNSCC). This represents the first global multicenter phase III trial for HNSCC in the class of PI3K inhibitors.

"There is a high unmet medical need for patients with recurrent or metastatic HNSCC after anti-PD-1/anti-PD-L1 therapy. As the trial is now fully enrolled, we eagerly look forward to the results which may change the paradigm of second-line treatment for HNSCC and provide a new treatment option for patients worldwide," said Lars Birgerson, President and Chief Medical Officer of Adlai Nortye Ltd.

About BURAN study
The BURAN study is a randomized, open-label, multicenter phase III study to assess the treatment effect of once-daily buparlisib in combination with weekly paclitaxel compared to weekly paclitaxel alone in patients with recurrent or metastatic head and neck squamous cell carcinoma (HNSCC) that have progressed after prior anti–PD–1/anti–PD–L1 monotherapy; prior anti–PD–1/anti–PD–L1 therapy in combination with platinum-based therapy; or after sequential treatment of anti–PD–1/anti–PD–L1 therapy, either prior to or post, platinum-based therapy.

About AN2025 (buparlisib)
AN2025 (buparlisib) is an oral pan-PI3K inhibitor that targets all class I PI3K isoforms and is active in both hematologic malignancies and solid tumors. In the global randomized Phase II clinical trial for the treatment of recurrent or metastatic HNSCC with buparlisib in combination with paclitaxel, the median overall survival was as high as 10.4 months (vs. 6.5 months in paclitaxel only group). Buparlisib was granted Fast-Track designation for this indication from the FDA. The ongoing study is the first global Phase III clinical trial conducted by Adlai Nortye.

About Adlai Nortye
Adlai Nortye (NASDAQ: ANL) is a global clinical-stage biotechnology company focused on the discovery and development of innovative cancer therapies for patients across the spectrum of tumor types, with global R&D centers established in New Jersey and Hangzhou. With a strategic emphasis on oncology. The Company has identified and developed a robust pipeline of six drug candidates.

Adlai Nortye has assembled a management team and a scientific advisory board with industry leaders and influential scientists, who provide international and strategic guidance to its R&D, business development, and operational teams. In addition to building its own R&D capabilities, the Company continues to seek and secure partnerships with leading multi-national pharmaceutical companies such as Eisai and Novartis, to fully realize the potential of its pipeline programs. The Company strives to become a global leader in the next wave of immuno-oncology therapies employing a combination therapy strategy. Its ultimate goal is to transform deadly cancer into a chronic and eventually curable disease.

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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