



Adlai Nortye Ltd. in collaboration with Nucleai, to Present "Utilizing H&E Images and Digital Pathology to Predict Response to Buparlisib in SCCHN" at ESMO 2023

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SINGAPORE and NORTH BRUNSWICK, N.J. and HANGZHOU, China, October 16, 2023 -- Adlai Nortye Ltd. (NASDAQ: ANL) (the "Company" or "Adlai Nortye"), a global clinical-stage biotechnology company focused on innovative oncology drugs, and Nucleai, a pathology-based AI-powered biomarker discovery and diagnostics company, today announced the presentation of the study "Utilizing H&E Images and Digital Pathology to Predict Response to Buparlisib in SCCHN". The study assessed a novel methodology for identifying recurrent or metastatic squamous cell carcinoma of the head and neck (SCCHN) patients that are likely to benefit from combination Buparlisib + paclitaxel treatment. The focus is to examine AI-based structuring and analysis of H&E images to identify spatial features associated with clinical outcomes.

"Identifying potential candidates for Buparlisib + paclitaxel therapy among metastatic SCCHN patients is an important step to provide safer, more effective treatments, in order to realize positive health related outcomes, in a timely manner and to ultimately save lives," said Dr. Lars Birgerson, President & CMO of Adlai Nortye.

"We are excited to bring novel spatial biomarkers to the forefront of drug research and development, and look forward to further validating these findings in partnership with Adlai Nortye" said Oscar Puig, VP Translational Medicine and Diagnostics at Nucleai.

The poster, #869P, is scheduled to be presented at the Head and Neck Cancers poster session on Sunday, 22 October 2023.

About Buparlisib (AN2025)

Buparlisib (AN2025) is an oral pan-PI3K inhibitor that targets all class I PI3K isoforms and is active in both hematologic malignancies and solid tumors. It is currently under development for metastatic SCCHN in the ongoing global Phase III BURAN study (NCT04338399).

About the 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 static 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-d therapy; or after sequential treatment of anti-PD-1/anti-PD-L1 therapy, either prior to or post, platinum-based therapy.

About Adlai Nortye (ANL)

Adlai Nortye is a global clinical-stage biotechnology company focused on innovative oncology drugs, with its R&D and global clinical operation centers in both China and the U.S. With a strategic emphasis on oncology, the Company has built a global pipeline through collaborations and internal discovery with six drug candidates in development. Currently, three of them are being investigated in multiple clinical trials, including (i) Buparlisib (AN2025) which received the FDA Fast-Track designation and is in a global Phase III clinical trial; (ii) Palupiprant (AN0025), an oral EP4 antagonist which has completed Phase Ib trial in a neoadjuvant setting in locally advanced rectal cancer and is undergoing Phase 1b trial in combination with Keytruda or pembrolizumab in patients with multiple solid tumors; and (iii) AN4005, an oral small molecule PD-L1 drug which is currently in Phase I trial that was shown to functionally overcome the inhibition derived from PD-1/L1 interaction in reporter- and human PBMC-based cellular assays. In addition, a Phase I clinical trial has been initiated for a combination therapy consisting of AN2025, AN0025, and Tecentriq or atezolizumab targeting a variety of PIK3CA mutant solid tumors.

Adlai Nortye has assembled an experienced management team, built its unique immuno-oncology platforms and partnered with multiple top pharmaceutical companies to promote innovation. Adlai Nortye is committed to becoming an innovative biopharmaceutical company with global vision and strives to benefit patients worldwide. The ultimate goal of the Company is to transform life-threatening cancer into a chronic and eventually a curable disease. For more information, please visit: www.adlainortye.com.

About Nucleai

Nucleai is an AI-driven biomarker and diagnostics company powered by digital pathology and spatial biology. Leveraging all modalities of digital pathology, Nucleai provides pharmaceutical companies, contract research organizations, and diagnostics laboratories with a state-of-the-art AI platform to improve clinical trials and facilitate development/deployment of AI-powered diagnostics. For more information, visit www.nucleai.ai.

Forward-Looking and Cautionary Statements

This press release 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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