Adlai Nortye Reports Unaudited First Half 2024 Financial Results and Highlights Recent Operational Progress

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Company Announces Appointment of Roger Sawhney, M.D. as a New Member of the Board of Directors

SINGAPORE and NORTH BRUNSWICK, N.J. and HANGZHOU, China, Aug. 08, 2024 (GLOBE NEWSWIRE) -- 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 its business highlights, the appointment of Roger Sawhney, M.D. to its Board of Directors and its first half financial results for the period ended June 30, 2024.

"I am pleased with our team's important progress and operational execution across our innovative pipeline of targeted and immune-modulating therapies," said Carsten Lu, CEO and Chairman of Adlai Nortye. "We strengthened our team, by having welcoming Archie Tse, M.D., Ph.D., as the Head of Research and Development who brings critical expertise in oncology drug development, and Roger Sawhney, M.D., our newest member of our board of directors. We also shared encouraging safety and efficacy data, including one complete response for AN4005, our first-in-class oral PD-L1 inhibitor from Phase 1 study, and successfully nominated the development candidate for AN8025, a multifunctional fusion protein that serves as a T cell and APC modulator.

As we look to the second half of 2024 and beyond, we plan to present a clinical update from AN4005 which has the potential to provide a more convenient treatment option for patients as an IV-administered anti-PD-L1 therapy. Importantly, we remain highly focused on the advancement of our lead candidate, buparlisib, for the potential treatment of patients with recurrent or metastatic head and neck squamous cell carcinoma (HNSCC) that has progressed after prior anti-PD(L)1 treatment and remain on track to report the Phase 3 OS data in the first quarter of 2025."

Recent Development and Business Highlights

Corporate

Archie Tse, M.D., Ph.D. appointed as Head of Research and Development. On March 29, the Company announced the appointment of Dr. Archie Tse as Head of Research and Development. Dr. Tse brings a wealth of knowledge and industry expertise in oncology drug development. Prior to joining the Company, Dr. Tse served as the Chief Scientific Officer, Senior Vice President, Head of Research and Early Clinical Development, and Head of CMC at CStone Pharmaceuticals, where he provided strategic leadership and oversight to the research, early clinical development, and CMC aspects of the entire CStone's pipeline. Before joining CStone, Dr. Tse held leadership positions in multinational companies, including Merck (known as MSD outside of US and Canada) and Daiichi-Sankyo where he managed the advancement of innovative oncology drugs across all stages of development, encompassing various modalities, including small molecule targeted therapies, mono- and multi-specific antibodies, ADCs, and cancer vaccines. Prior to his career in the industry, Dr. Tse served as a faculty member at the Memorial Sloan Kettering Cancer Center in New York. Dr. Tse holds Doctor of Medicine and Doctor of Biochemistry and Molecular Biology degrees from the University of Southern California.

The Company appointed Roger Sawhney, M. D. as a Director, effective August 8, 2024. Dr. Sawhney has nearly thirty years of financial and strategic expertise across the life sciences industry. Dr. Sawhney currently serves as the Chief Financial Officer of LB Pharmaceuticals, a neuro-psych focused Company, based in New York City. From September 2022 to December 2023, Dr. Sawhney served as the Chief Financial Officer of Garuda Therapeutics, Inc. From March 2020 to May 2022, Dr. Sawhney served as the Chief Financial Officer of Omega Therapeutics, Inc., a pioneer in mRNA-based therapeutics for precision gene modulation, and he served as the Chief Business Officer of Omega from May 2022 to September 2022. From September 2018 to August 2020, Dr. Sawhney served at KKR & Co. Inc., a global investment firm, as Director of its healthcare investment platform in the Americas where his work focused on investments across private and growth equity in the healthcare sector. From July 2009 to August 2012, Dr. Sawhney served as Senior Vice President and Head of Global Corporate Strategy for Novartis AG, as well as Senior Vice President of Corporate Strategy and Business Development for Outcome Health from February 2017 to February 2018. Dr. Sawhney has also served as Partner with Bain & Company from August 2012 to February 2017 and the Boston Consulting Group from 1996 to 2009, where he managed numerous client engagements across the life sciences, med-tech and digital health sectors. Dr. Sawhney holds an M.D. from Harvard Medical School and a B.A. in Economics from Stanford University.

Pipeline updates AN2025 (Buparlisib)

- The Company is conducting BURAN (NCT04338399), a randomized, open-label phase 3 trial 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 HNSCC that has progressed after prior anti-PD(L)1 treatment.
- The Company remains on track to present overall survival (OS) data in the first quarter of 2025.

AN4005

- In an ongoing Phase 1 study (NCT04999384), the Company is investigating the safety of AN4005, its oral small-molecule PD-L1 inhibitor.
- The Company plans to provide a clinical update in the second half of 2024.
- The expansion cohort portion of the trial for IO treatment-naïve patients was initiated in July

2024.

AN8025

- AN8025 is an in-house developed multifunctional fusion protein, which serves as a T cell and APC modulator. The Company anticipates submitting the investigational drug application (IND) in mid-2025.

AN9025

- AN9025 is an in-house developed oral small molecule pan-RAS inhibitor. The Company anticipates submitting the IND in the second half of 2025.

Financial Highlights for the Six Month Period Ended June 30, 2024

The consolidated financial statements of the Company are prepared in accordance with IFRS as issued by the International Accounting Standard Board (IASB). The consolidated financial statements are presented in US dollars, the Company's functional and presentation currency.

As of June 30, 2024, cash and cash equivalents totaled US$98.0 million compared to US$91.5 million on December 31, 2023. Based on our current operating plan, we believe that our current cash and cash equivalents will be sufficient to meet our current and anticipated working capital requirements and capital expenditures for at least the next 12 months.

Net cash used in operating activities for the six months ended June 30, 2024 was US$28.4 million, compared to US$18.3 million for the six months ended June 30, 2023.

Research and development expenses decreased by 4.5% from US$27.2 million for the six months ended June 30, 2023 to US$26.0 million for the six months ended June 30, 2024. The decrease was primarily due to lower expenses associated with the development of the clinical stage programs, a result of a decrease in CRO service fees.

General and administrative expenses decreased by 9.8% from US$5.2 million for the six months ended June 30, 2023 to US$4.7 million for the six months ended June 30, 2024, primarily attributable to a decrease in share-based compensation expenses resulting from the vesting schedule of certain stock options in 2024.

Other income and gains increased by 852.4% from US$0.3 million for the six months ended June 30, 2023 to US$2.6 million for the six months ended June 30, 2024, primarily attributable to additional government grants received in 2024.

Fair value loss on financial liabilities at FVTPL was US$45.9 million for the six months ended June 30, 2023, compared to nil for the six months ended June 30, 2024. Financial liabilities at FVTPL recorded for the six months ended June 30, 2023 were caused by the repurchase rights of shareholders' investments before the company went public. The fair value loss on financial liabilities recorded for the six months ended June 30, 2023 was due to valuation changes before the company's initial public offering ("IPO"). There will no longer be any fair value loss on financial liabilities at FVTPL after the company's IPO, as a result of all financial liabilities at FVTPL have been converted to ordinary shares.

For the reasons described above, the Company's net loss for the period ended June 30, 2024 decreased significantly by 64.8% from US$78.6 million for the six months ended June 30, 2023 to US$27.7 million for the six months ended June 30, 2024.

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. In the global phase II clinical trial for the treatment of head and neck squamous cell carcinoma (HNSCC), the median overall survival was as high as 10.4 months. It has received Fast-Track designation and an approval for initiating the phase III clinical study from FDA. The BURAN study investigating Buparlisib is also the first global phase III clinical trial conducted by Adlai Nortye.

About the BURAN Study

The BURAN study (NCT04338399) 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(L)1 monotherapy; prior anti–PD(L)1 therapy in combination with platinum-based therapy; or after sequential treatment of anti–PD(L)1 therapy, either prior to or post, platinum-based therapy.

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. In nonclinical studies, AN4005 has demonstrated significant pharmacological activity, target engagement and acceptable safety profiles, which support the clinical development as a potential therapy for advanced malignancies. In pharmacology studies, AN4005 was shown to functionally overcome the inhibition derived from PD-1/L1 interaction in reporter- and human PBMC (hPBMC)-based cellular assays. Small molecule PD-L1 inhibitors are expected to provide several benefits over monoclonal antibodies (mAbs), such as, allowing for oral administration, lower production costs, improved tumor penetration, and lack of immunogenicity.

About Adlai Nortye

Adlai Nortye (NASDAQ: ANL) is a global clinical-stage company focused on the development of innovative targeted and immune-modulating cancer therapies, with global R&D centers in the U.S. and China. The Company is advancing a robust oncology pipeline, with our lead candidate Buparlisib (AN2025), a pan-PI3K inhibitor, currently being evaluated in a registrational Phase 3 trial (NCT04338399) in patients with recurrent or metastatic head and neck squamous cell cancer (HNSCC) that has progressed after prior anti-PD(L)1 treatment. Additionally, we are advancing multiple drug candidates including AN4005, an oral small molecule PD-L1 inhibitor, AN8025, a multifunctional fusion protein acting as a T cell and antigen-presenting cell ("APC") modulator, and AN9025, an oral small molecule pan-RAS 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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