Adlai Nortye Announces First Patient Dosed in Randomized Phase II Clinical Trial of Palupiprant (AN0025) for the Treatment of Locally Advanced Rectal Cancer with Radiation Therapy

2024-05-22

SINGAPORE and NORTH BRUNSWICK, N.J. and HANGZHOU, China, May 22, 2024 (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, recently announced that the first patient was dosed in the Phase II clinical trial known as ARTEMIS (Augmenting RadioTherapy in REctal Cancer to Minimise Invasive Surgery). This clinical study evaluates palupiprant (AN0025), a small molecule prostaglandin E receptor 4 ("EP4") antagonist, with chemoradiotherapy and radiotherapy (total neoadjuvant therapy: 'TNT') ("CRT") for the treatment of rectal cancer. The study has been developed and is being led by the Cancer Research ("CRUK") Clinical Trials Unit ("CTU") at the University of Leeds, with clinical leadership teams from consultant oncologists Prof Simon Gollins and Prof Mark Saunders.

Building upon the encouraging Phase Ib results of the immune modulator AN0025 in combination with chemoradiation in rectal cancer, ARTEMIS is a randomized, Phase II, multi-center, open-label study that compares TNT with or without AN0025 in patients with moderate to high-risk rectal cancer. One hundred and forty patients (70 per arm) will receive either long-course chemoradiation ("LCCRT") or short-course radiotherapy ("SCRT") (physician choice) followed by chemotherapy, or a combination of AN0025 and LCCRT/SCRT followed by chemotherapy. The primary endpoint of this study is clinical complete response (cCR) rate at six months post the start of radiotherapy.

"This study aims to contribute to a transformation currently taking place in rectal cancer treatment. For locally advanced rectal cancer, traditionally chemoradiation followed by radical surgery has been the standard of care, despite the significant morbidity associated with surgery. Following the promising published phase 1b data, the current study assesses whether AN0025 increases the likelihood of achieving a cCR, when added to TNT in the treatment of locally advanced rectal cancer. We are very excited to explore the potential of AN0025 to improve efficacy, minimize invasive surgery, and offer patients a viable alternative," said Prof Simon Gollins, the consultant in clinical oncology at Shrewsbury and Telford Hospital NHS Trust.

About Palupiprant (AN0025)
AN0025 is a small molecule prostaglandin E receptor 4 (EP4) antagonist, discovered by Eisai Co., Ltd. (Eisai), designed to modulate the tumor microenvironment. Adlai Nortye has been granted exclusive rights concerning the research, development, manufacture and marketing in all regions outside of Japan and part of Asia (excluding China) by Eisai. It is currently under development for the treatment of locally advanced rectal cancer with radiation therapy in the ongoing global Phase II ARTEMIS study. We presented Phase 1b results for this indication at the European Society for Medical Oncology ("ESMO") in October 2019, where combination therapy with AN0025 and RT/CRT was safe and enabled 36% of patients to achieve either a cCR or pathologic complete response (pCR).

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, US, and Hangzhou, China. With a strategic emphasis on oncology, the company has identified and developed a robust pipeline of six drug candidates.

Adlai Nortye has assembled a global management team and a scientific advisory board with industry leaders and influential scientists to provide important strategic guidance to its R&D, business development, and operational organizations. 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 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.

Contacts:
Investor Relations:
Charles Zhou
Amanda Kong

Adlai Nortye Ltd.
ir@adlainortye.com