Adlai Nortye Announces Global License-out Agreement with Biotime for Several Products Including PD-L1 Inhibitor (AN4005) and Anti-hTNFR2 Antibody (AN3025)

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NEW JERSEY and HANGZHOU, China, recently -- Adlai Nortye Ltd. ("Adlai Nortye"), a clinical-stage biopharmaceutical company focused on the development of innovative cancer therapies, announced that it has entered into a Global License Agreement with Xiamen Biotime Biotechnology Co., Ltd. ("Biotime") for several compounds. This includes the rights and interests of Adlai Nortye in the development, manufacturing and commercialization of AN4005 and AN3025 in Greater China, and AN1005, AN6015 and AN9015 worldwide. According to the terms of the agreement, the total amount of this cooperation will reach hundreds of millions of yuan, including the upfront payments, progress-dependent milestone payments and tiered royalties on sales.

According to Jianping Yu, the chairman secretary of Biotime, "Based on independent innovation, Biotime has started involving in innovative drug business, increased R&D investment, actively integrated into the global innovation network and focused on creating an innovation engine for high-quality development. The cooperation with Adlai Nortye, a leading brand of innovative drugs, will be a win-win attempt."

Dr. Nanhai He, the head of drug discovery of Adlai Nortye, said, "We are very happy to reach this agreement with Biotime, who has strong technical capabilities and scientific and technological strength, and puts a high value on product R&D and technological innovation. This cooperation will pave the way for the development and commercialization of several products, including AN4005 and AN3025, on a global scale, and benefit patients all over the world. We firmly believe that the partnership with Biotime will greatly accelerate the R&D and commercialization of these drugs."

About AN4005

AN4005 is an orally available, small-molecule PD-L1 inhibitor that demonstrates anti-tumor activity by the blockade of PD-1/PD-L1 interaction. In preclinical studies, AN4005 has demonstrated significant pharmacological activity, target affinity and acceptable safety profiles, which support the clinical development as a potential therapy for advanced malignancies. In pharmacology studies, AN4005 was shown to overcome the inhibition derived from PD-1/L1 interaction in hPBMC-based functional assays. Small molecule PD-L1 inhibitors are expected to provide several benefits over mAbs, such as, allowing for oral administration, lower production costs, improved tumor penetration, and lack of immunogenicity.

About AN3025

AN3025 is a novel humanized IgG1 (variant) anti-hTNFR2 antibody that is currently under preclinical study. This antibody binds to the extracellular domain of human TNFR2 with sub-nanomolar affinity and occludes its ligand TNFa from accessing TNFR2. Since TNFR2 is highly expressed on a subset of immunosuppressive cells, including regulatory T cells (Tregs) and MDSCs, within the tumor microenvironment, AN3025 is expected to amplify the antitumor immune response to aid in immunotherapy.

About Biotime

Established in April 2008, Xiamen Biotime Biotechnology Co., Ltd. is a hi-tech enterprise specializing in R&D, production, and sales of point-of-care testing ("POCT") in vitro diagnostic devices and reagents. Biotime has successfully established mature medical marketing channels during the past years. With the leading technologies, Biotime aims to develop superior in vitro diagnosis ("IVD") products that provide better solutions for health care and benefit people all over the world. For more information, please visit: www.biotime.cn.

About Adlai Nortye

Adlai Nortye is a global clinical-stage biopharmaceutical 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 more than 10 drug candidates in development. Currently, four of them are being investigated in multiple clinical trials, including (i) Buparlisib(AN2025) which received the FDA Fast-Track designation and was in a global Phase III clinical trial; (ii) Pelareorep (AN1004), an intravenously administered oncolytic virus which received the FDA Fast-Track designation and have completed a phase II clinical trial; (iii) 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® in patients with multiple solid tumors; and (iv) AN4005, an oral small molecule PD-L1 drug which was currently in Phase I trial that was shown to functionally overcome the inhibition derived from PD-1/L1 interaction in reporter- and human PBMC (hPBMC)-based cellular assays. In addition, Adlai Nortye also completed the first patient dosing for its Phase I clinical trial in collaboration with Roche to evaluate the triple combination of AN2025, AN0025 and Tecentriq® (PD-L1 inhibitor) for a variety of PIK3CA mutant solid tumors in September 2021 in the U.S.

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 deadly cancer into a chronic and eventually a curable disease. For more information, please visit: www.adlainortye.com.