



Adlai Nortye Receives NMPA Approval for Pelareorep Phase III Clinical Trials

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HANGZHOU, China, -- March 21, 2019 -- Adlai Nortye Ltd. ("Adlai Nortye"), a global clinical-stage biopharmaceutical company today announced that it has received a clearance from the National Medical Products Administration (NMPA) of China for initiating the open-label, randomized, multicenter, global phase III clinical trial for pelareorep (AN1004) in combination with paclitaxel in patients with advanced/ static breast cancer in China.

Pelareorep is a first-in-class intravenously delivered immuno-oncolytic virus for the treatment of solid tumors and hematological malignancies. In the presentation of pelareorep clinical data, additional randomized phase II data in static breast cancer demonstrates doubling (21.8 months vs. 10.8 months) of overall survival in Hormone Receptor Positive (ER+PR+)/HER2- patients. Pelareorep has received Fast Track designation and Special Protocol Assessment Agreement for Phase III Clinical Trial from FDA for the treatment of static breast cancer.

Carsten Lu, Chairman and CEO of Adlai Nortye said: " The incidence of breast cancer ranks No. 1 among female malignant tumors in China. Adlai Nortye focuses on discovering and developing innovative treatments in cancer patients, trying to transform cancer into a chronic disease condition even cure the cancer disease. The NMPA gave detailed and constructive guidance to the pelareorep phase III clinical program. We are very pleased and encouraged by the result. We will launch the clinical trial to join our global partner Oncolytics Biotech Inc. when they initiate their phase III registration study. We will continue to bring more options to cancer patients."

About Pelareorep (AN1004)

Pelareorep is a non-pathogenic, proprietary isolate of the unmodified reovirus: a first-in-class intravenously delivered immuno-oncolytic virus for the treatment of solid tumors and hematological malignancies. The compound induces selective tumor lysis and promotes an inflamed tumor phenotype through innate and adaptive immune responses to treat a variety of cancers and has been demonstrated to be able to escape neutralizing antibodies found in patients.

About Adlai Nortye

Adlai Nortye is a global clinical-stage biopharmaceutical company that is developing differentiated, innovative immuno-oncology medicines. Adlai Nortye focuses on discovering and developing important new treatments for cancer with a mission to improve patient lives by identifying and developing differentiated innovative medicines that help people live better, live longer. Through close collaborations with global partners, Adlai Nortye have successfully positioned itself in the field of immuno-oncology and have several programs ongoing from early pre-clinical to phase III ready. Adlai Nortye got exclusive development and commercialization rights to pelareorep in mainland China, Hong Kong, Macau, Singapore, South Korea and Taiwan from Oncolytics through a Regional Licensing Agreement in Nov. 2017.

About Oncolytics Biotech Inc.

Oncolytics is a biotechnology company developing pelareorep, an intravenously delivered immuno-oncolytic virus. The compound induces selective tumor lysis and promotes an inflamed tumor phenotype - turning "cold" tumors "hot" - through innate and adaptive immune responses to treat a variety of cancers. Pelareorep has demonstrated synergies with immune checkpoint inhibitors and may also be synergistic with other approved immuno-oncology agents. Oncolytics is currently conducting and planning additional studies in combination with checkpoint inhibitors and targeted therapies in solid and hematological malignancies, as it prepares for a phase 3 registration study in static breast cancer.