ZEAL (GSK)

Placebo-controlled Study Comparing Niraparib Plus Pembolizumab Versus Placebo Plus Pembrolizumab as Maintance Therapy in Participants with Advanced/Metastatic Non-small Cell Lung Cancer. This is the trial summary as assessed on clinicaltrials.gov on 01/09/2021.

Minor changes in the protocol may occur. You can check this on this direct link: https://clinicaltrials.gov/ct2/show/NCT04475939.

Trial Design:

Arm	Intervention
Experimental	Niraparib Pembrolizumab
Placebo	Placebo Pembrolizumab

Inclusion criteria:

- Participant must be >=18 years of age.
- Has a histologically or cytologically confirmed diagnosis of NSCLC without known targetable driver alteration (either non-squamous or squamous histology; mixed histology is allowed).
- Has advanced (Stage IIIB not amenable to definitive chemoradiotherapy or Stage IIIC) or metastatic (Stage IV) NSCLC.
- Has completed at least 4 but no more than 6 cycles of standard of care first-line platinum-based induction chemotherapy with pembrolizumab.
- Has SD, PR, or CR of the NSCLC per Investigator's assessment after completion of 4 to 6 cycles of standard of care first-line platinum-based induction chemotherapy with pembrolizumab.
- Has an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1.
- Has a life expectancy of at least 12 weeks.
- Has adequate organ and bone marrow function.
- Must submit tumor specimens.
- Must be able to swallow and retain orally administered study treatment.
- A female is eligible to participate if she is not pregnant or breastfeeding, and must follow contraceptive guidance during the treatment period and 180 days afterwards.
- A male is eligible to participate if he agrees to contraceptive guidance and refrains from sperm donation during the intervention period and for at least 180 days after the last dose of study treatment.

- Is able to understand the study procedures and agrees to participate in the study by providing written informed consent. Participants must be informed that their participation is voluntary. Participants will be required to sign a statement of informed consent to participate in the study.

Exclusion criteria:

- Has mixed small cell lung cancer or sarcomatoid variant NSCLC.
- Has received prior Poly (adenosine diphosphate-ribose) polymerase (PARP) inhibitor(s) in prior lines of treatment.
- Has systolic blood pressure (BP) >140 millimeters of mercury (mmHg) or diastolic BP >90 mmHg.
- Has any clinically significant gastrointestinal abnormalities that may alter absorption such as malabsorption syndrome or major resection of the stomach and/or bowels.
- Has leptomeningeal disease, carcinomatous meningitis, symptomatic brain metastases, or radiographic signs of CNS hemorrhage.
- Has received colony-stimulating factors (granulocyte macrophage colony-stimulating factor or recombinant erythropoietin) within 4 weeks prior to the first dose of study treatment.
- Has an active or previously documented autoimmune or inflammatory disorder.
- Is receiving chronic systemic steroids (prednisone >20 mg per day) other than intermittent use of bronchodilators, inhaled steroids, or local steroid.
- Has other active concomitant malignancy that warrants systemic, biologic, or hormonal therapy.
- Is pregnant, breastfeeding, or expecting to conceive children while receiving study treatment and/or for up to 180 days after the last dose of study treatment.
- Has a known history of Myelodysplastic syndrome (MDS) or Acute myeloid leukemia (AML).
- Has a known history of active tuberculosis.
- Has current active pneumonitis within 90 days of planned start of the study or a known history of interstitial lung disease, drug-related pneumonitis, or radiation pneumonitis requiring steroid treatment.