A Study of Pembrolizumab (MK-3475) With or Without Intismeran Autogene (V940) in Participants With Non-small Cell Lung Cancer (V940-009/INTerpath-009)

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

The main inclusion criteria include but are not limited to the following: * Has histologically/cytologically confirmed diagnosis of previously untreated and pathologically confirmed resectable Stage II, IIIA, or IIIB (N2) non-small cell lung cancer (NSCLC) \[American Joint Committee on Cancer (AJCC) 8th Edition\] * Has an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1 within 7 days before the first dose of study intervention * Participants who have not achieved a pathological complete response (pCR) following completion of neoadjuvant chemotherapy and pembrolizumab followed by surgery will be eligible * Confirmation that epidermal growth factor receptor (EGFR)-directed therapy is not indicated as primary therapy (documentation of absence of tumor-activating EGFR mutations \[eg, DEL19 or L858R\]) * Human immunodeficiency virus (HIV)-infected participants must have well controlled HIV on anti-retroviral therapy (ART) * Participants who are hepatitis B surface antigen (HBsAg) positive are eligible if they have received hepatitis B virus (HBV) antiviral therapy for at least 4 weeks and have undetectable HBV viral load prior to randomization * Participants with history of hepatitis C virus (HCV) infection are eligible if HCV viral load is undetectable at screening

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Exclusion Criteria:

The main exclusion criteria include but are not limited to the following: * Diagnosis of SCLC or, for mixed tumors, presence of small cell elements, or has a neuroendocrine tumor with large-cell components, or a sarcomatoid carcinoma, or a pancoast tumor * Documentation by local test report indicating presence of anaplastic lymphoma kinase (ALK) gene rearrangements * Received prior neoadjuvant therapy for their current NSCLC diagnosis * Received prior therapy with an anti-programmed cell death 1 (PD-1), anti-programmed cell death ligand 1 (PD-L1), or anti-programmed cell-death ligand 2 (PD-L2) agent, or with an agent directed to another stimulatory or coinhibitory T-cell receptor (eg, cytotoxic T-lymphocyte-associated protein \[CTLA-4\], OX-40, CD137) * Received prior systemic anticancer therapy including investigational agents other than what is specified in this protocol * Received prior treatment with a cancer vaccine * Received prior radiotherapy within 2 weeks of start of study intervention, or has radiation-related toxicities, requiring corticosteroids * Received a live or live-attenuated vaccine within 30 days before the first dose of study intervention

Conditions & Interventions

Interventions:
BIOLOGICAL: Pembrolizumab, DRUG: Cisplatin, DRUG: Carboplatin, DRUG: Pemetrexed, DRUG: Gemcitabine, DRUG: Paclitaxel, BIOLOGICAL: Intismeran autogene, OTHER: Placebo

Conditions:
Carcinoma, Non-Small-Cell Lung

Keywords:
Programmed Cell Death-1 (PD1, PD-1), Programmed Cell Death 1 Ligand 1 (PDL1, PD-L1), Programmed Cell Death 1 Ligand 2 (PDL2, PD-L2), Individualized neoantigen therapy (INT)

More Information

Contact(s): Toll Free Number - Trialsites@msd.com
Principal Investigator:
IRB
Number:
System ID: NCT06623422
