Adjuvant Pembrolizumab vs Observation Following Curative Resection for Stage I Non-small Cell Lung Cancer (NSCLC) With Primary Tumors Between 1-4 cm

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* The participant (or legally acceptable representative if applicable) must provide written informed consent for the study. The participant may also provide consent for future unspecified research samples. However, the participant may participate in the study without participating in the future unspecified research sample collection. NOTE: Initial informed consent will remain valid throughout the 12-week period between surgical resection and study registration unless, in the opinion of the treating investigator, the participant experiences a significant change in medical or mental status. * Males and females age ≥ 18 years at the time of consent. * ECOG Performance Status of 0-1 within 28 days prior to registration. * Patients must have undergone complete surgical resection of their stage I NSCLC between 4-12 weeks prior to registration and have negative surgical margins (R0). * NOTE: Both squamous and non-squamous histologies are allowed into the study. Cancers with a histology of "adenosquamous" are considered a type of adenocarcinoma and thus "non-squamous histology". * NOTE: Staging will be according to the AJCC 8th edition. * Pathological tumor size must be 1.0

•4.0 cm in greatest dimension. NOTE: According to AJCC 8th edition, subjects with lepidic predominant adenocarcinoma should be staged based on their invasive tumor size and not their total tumor size (i.e., subjects with lepidic predominant tumors whose invasive tumor size is less than 1 cm are not eligible, even if their total tumor size is 1.0 cm or greater). * Surgery for this lung cancer must be completed at least 28 days prior to registration. * Must have either previous NGS and PD-L1 results available using the Dako 22C3 antibody or have archival tissue of surgical specimen from current diagnosis available to perform analyses. PD-L1 results via the Dako 22C3 antibody will be performed per standard of care from a CLIA-accredited laboratory and are required for stratification. If NGS results are not available, subjects must be able to provide at least 10 x 10µm unstained and 1 x 4µm H\&E slides from current diagnosis for future NGS and/or other genetic analyses. * Demonstrate adequate organ function as defined in the protocol; all screening labs to be obtained within 28 days prior to registration. * Females of childbearing potential must have a negative urine or serum pregnancy test within 72 hours prior to registration. If the urine test is positive or cannot be confirmed as negative, a serum pregnancy test will be required. For subjects randomized to the pembrolizumab arm: If there is \> 72 hours between the screening test and C1D1, another pregnancy test (urine or serum) must be performed and must be negative before the subject may start C1D1. * NOTE: Females are considered of childbearing potential unless: they are postmenopausal; are surgically sterile; or they have a congenital or acquired condition that prevents childbearing. See Section 5.1.4 for definitions. * NOTE: Abstinence is acceptable if this is the usual lifestyle and preferred contraception for the subject. * A female participant is eligible to participate if she is not pregnant, not breastfeeding, and at least one of the following conditions applies: * Not a woman of childbearing potential (WOCBP) OR * A WOCBP who is using a highly effective contraceptive method (failure rate of \ <1% per year), or is abstinent from heterosexual intercourse as their preferred and usual lifestyle (abstinent on a long term and persistent basis) during the intervention period and for at least 120 days after the last dose of study drug. The investigator should evaluate the potential for contraceptive method failure (i.e., noncompliance, recently initiated) in relationship to the first dose of study drug. See contraceptive guidance in Section 5.1.4 of the protocol. * Participants who are HBsAg positive are eligible if they have received HBV anti-viral therapy for at least 4 weeks and have undetectable HBV viral load prior to randomization. Note: Participants should remain on anti-viral therapy throughout study intervention and follow local guidelines for HBV anti-viral therapy after completion of study intervention. Hepatitis B screening tests are not required unless: * Known history of HBV infection * As mandated by local health authority * Participants with a history of HCV infection are eligible if HCV viral load is undetectable at screening. Note: Participants must have completed curative anti-viral therapy at least 4 weeks prior to randomization. Hepatitis C screening tests are not required unless: * Known history of HCV infection * As mandated by local health authority * HIV-infected participants are eligible but must have well-controlled HIV on anti-retroviral therapy (ART), defined as: * Participants on ART must have a CD4+ T-cell count ≥350 cells/mm3 at screening. * Participants on ART must have achieved and maintained virologic suppression defined as confirmed HIV RNA level below 50 or the LLOQ (below the limit of detection) using the locally available assay at the time of screening and for at least 12 weeks before screening. * It is advised that participants must not have had any AIDS-defining opportunistic infections within the past 12 months before study entry (Day 1/randomization). * Participants on ART must have been on a stable regimen, without changes in drugs or dose modification, for at least 4 weeks before study entry (Day 1/randomization) and agree to continue ART throughout the study. * Note: HIV screening testing is not required unless mandated by local health authority. * As determined by the enrolling physician or protocol designee, ability of the subject to understand and comply with study procedures for the entire length of the study

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Exclusion Criteria:

* Current lung cancer is \<1 cm or \> 4 cm in size or is stage II, III, or IV. * Patients with tumors that are known to harbor actionable EGFR mutations. * Prior chemotherapy, radiation therapy, or immunotherapy for the treatment of this lung cancer. * Has a known active additional malignancy that is progressing or has required active treatment within the past 2 years. NOTE: Participants with basal cell carcinoma of the skin, squamous cell carcinoma of the skin, or carcinoma in situ (e.g., breast carcinoma in situ, cervical cancer in situ) that have undergone potentially curative therapy are not excluded. Participants with low-risk early-stage prostate cancer (T1-T2a, Gleason score ≤6, and PSA \<10 ng/mL) either treated with definitive intent or untreated in active surveillance with stable disease are not excluded. * Prior therapy with an anti-PD-1, anti-PD-L1, or anti-PD-L2 agent or with an agent directed to another stimulatory or co-inhibitory T-cell receptor (eg, CTLA-4, OX-40, CD137). * Has received a live or live-attenuated vaccine within 30 days prior to the first dose of study drug. Administration of killed vaccines is allowed. * Is currently participating in or has participated in a study of an investigational agent or has used an investigational device within 4 weeks prior to the first dose of study treatment. * Note: Participants who have entered the follow-up phase of an investigational study may participate as long as it has been 4 weeks after the last dose of the previous investigational agent. * Has a diagnosis of immunodeficiency or is receiving chronic systemic steroid therapy (in dosing exceeding 10 mg daily of prednisone equivalent) or any other form of immunosuppressive therapy within 7 days prior to randomization. * Has had an allogenic tissue/solid organ transplant. * Has severe hypersensitivity (≥Grade 3) to pembrolizumab and/or any of its excipients. * Has active autoimmune disease that has required systemic treatment in the past 2 years (i.e. with use of disease modifying agents, corticosteroids or immunosuppressive drugs). Replacement therapy (eg., thyroxine, insulin, or physiologic corticosteroid replacement therapy for adrenal or pituitary insufficiency, etc.) is not considered a form of systemic treatment. * Has a history of (non-infectious) pneumonitis/interstitial lung disease that required steroids or has current pneumonitis/interstitial lung disease. * Has an active infection requiring systemic therapy. * Has active TB (Bacillus Tuberculosis) infection. * HIV-infected participants with a history of Kaposi's sarcoma and/or Multicentric Castleman's Disease. * Has a history or current evidence of any condition, therapy, or laboratory abnormality that might confound the results of the study, interfere with the subject's participation for the full duration of the study, or is not in the best interest of the subject to participate, in the opinion of the treating investigator. * Has known psychiatric or substance abuse disorders that would interfere with cooperation with the requirements of the trial. * Is pregnant or breastfeeding, or expecting to conceive or father children within the projected duration of the study, starting with the screening visit through 120 days after the last dose of trial treatment.

Conditions & Interventions

Interventions:

Interventions:
DRUG: Pembrolizumab
Conditions:
NSCLC, Stage I

More Information

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