Immunotherapy After Surgery for People Who Have No Remaining Cancer Cells After Standard Treatment for Early-Stage Non-Small Cell Lung Cancer, INSIGHT Trial

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* Participants must have histologically or cytological confirmed diagnosis of clinical stage II-IIIB (excluding clinical N3 disease) non-small cell lung cancer (NSCLC) * Participants must have had a complete (R0) resection of NSCLC (with appropriate lymph node sampling as defined by the National Comprehensive Cancer Network \[NCCN\] guidelines) within 84 days (12 weeks) prior to randomization. Acceptable types of surgical resection are: lobectomy, sleeve resection, bi-lobectomy, or pneumonectomy. Wedge resection is not allowed. * Note the NCCN guidelines: N1 and N2 node resection and mapping is a routine component of lung cancer resections. It is recommended at a minimum one N1 and three N2 stations is sampled or complete lymph node dissection. Formal ipsilateral mediastinal lymph node dissection is indicated for participants undergoing resection for N2 disease * Participants must have a pathologic complete response (pCR) (no viable tumor in the resected specimen or lymph nodes), as determined by local pathology review * Participants must have a PD-L1 status result (e.g. \[\< 1% versus \>= 1% or unknown\]) * Participants must not have known EGFR mutations, or ALK gene fusion * Participants must have received at least two cycles of neoadjuvant platinum-based chemotherapy and anti-PD-1 or anti-PD-L1 therapy. The neoadjuvant treatment must be Food and Drug Administration (FDA) approved and standard of care as listed in NCCN guidelines * Participants must not be planning to receive any concurrent non-protocol directed chemotherapy, immunotherapy, biologic or hormonal therapy for NSCLC treatment while receiving treatment on this study * Participants must not have received any prior systemic therapy (systemic chemotherapy, immunotherapy or investigational drug) within 28 days prior to randomization * Participants must not have medical contraindications or severe adverse events to receiving anti-PD-1 or anti-PD-L1 therapy * Participants must not have received post-operative radiation therapy (PORT) for NSCLC * Participants must not have any unresolved toxicity National Cancer Institute (NCI) CTCAE grade ≥ 2 from previous anticancer therapy with the exception of alopecia, and vitiligo. Note, participants with grade ≥2 neuropathy may be included at the discretion of the treating investigator. Note, participants with irreversible toxicity not reasonably expected to be exacerbated by treatment with durvalumab may be included at the discretion of the treating investigator * Participant must be ≥ 18 years old at time of study entry * Participants must have body weight \> 30 kg * Participant must have Zubrod performance status of 0-2 * Participant must have a complete medical history and physical exam within 28 days prior to randomization * Hemoglobin \> 9.0 g/dL (within 28 days prior to randomization) * Absolute neutrophil count ≥ 1.5 x 10\^3/uL (within 28 days prior to randomization) * Platelets ≥ 100 x 10\^3/uL (within 28 days prior to randomization) * Total bilirubin ≤ 1 x institutional upper limit of normal (ULN) unless history of Gilbert's disease. Participants with history of Gilbert's disease must have total bilirubin ≤ 5 x institutional ULN (within 28 days prior to randomization) * Aspartate transaminase (AST)/alanine transaminase (ALT) ≤ 3 × institutional ULN (within 28 days prior to randomization) * Participants must have a calculated creatinine clearance ≥ 40 mL/min using the following Cockcroft-Gault formula. This specimen must have been drawn and processed within 28 days prior to randomization. For creatinine clearance formula see the tools on the Clinical Research Associate (CRA) Workbench https://txwb.crab.org/TXWB/Tools.aspx * Participants must have fully recovered from the effects of prior surgery in the opinion of the treating investigator * Participants with a known history of human immunodeficiency virus (HIV)-infection must be on effective anti-retroviral therapy at registration and have undetectable viral load test on the most recent test results obtained within 6 months prior to randomization * Participants with a known history of chronic hepatitis B virus (HBV) infection must have undetectable HBV viral load while on suppressive therapy on the most recent test results obtained within 6 months prior to randomization, if indicated * Participants with a known history of hepatitis C virus (HCV) infection must have been treated and cured. Participants currently being treated for HCV infection must have undetectable HCV viral load test on the most recent test results obtained within 6 months prior to randomization, if indicated * Participants must not have had an organ transplant * Participants must not have a prior or concurrent malignancy whose natural history or treatment (in the opinion of the treating physician) has the potential to interfere with the safety or efficacy assessment of the investigational regimen * Participant must not have medical contraindications to receiving immunotherapy, including history of non-infectious pneumonitis that required steroids or active autoimmune disease that has required systemic treatment with disease modifying agents, corticosteroids or immunosuppressive drugs in the past two years. Replacement therapy (e.g. thyroxine for pre-existing hypothyroidism, insulin for type I diabetes mellitus, or physiologic corticosteroid replacement therapy for adrenal or pituitary insufficiency, etc.) is not considered a form of systemic treatment. Intra-articular steroid injections are allowed * Participants must not be pregnant or nursing (nursing includes breast milk fed to an infant by any means, including from the breast, milk expressed by hand, or pumped). Individuals who are of reproductive potential must have agreed to use an effective contraceptive method during protocol therapy and for 6 months following completion of protocol therapy with details provided as a part of the consent process. A person who has had menses at any time in the preceding 12 consecutive months or who has semen likely to contain sperm is considered to be of "reproductive potential." In addition to routine contraceptive methods, "effective contraception" also includes refraining from sexual activity that might result in pregnancy and surgery intended to prevent pregnancy (or with a side-effect of pregnancy prevention) including hysterectomy, bilateral oophorectomy, bilateral tubal ligation/occlusion, and vasectomy with testing showing no sperm in the semen. Participants should not breastfeed during protocol therapy and for 6 months following completion of protocol therapy * Participants must not have received a live or live attenuated vaccine within 28 days prior randomization. Examples of live vaccines include, but are not limited to, the following: measles, mumps, rubella, varicella/zoster, yellow fever rabies, Bacillus Calmette-Guerin (BCG) and typhoid vaccine. Seasonal influenza vaccines and coronavirus disease 19 (COVID-19) vaccines are allowed, however, intranasal influenza vaccines (e.g. Flu-Mist) are live attenuated, and are not allowed * Participants must be offered the opportunity to participate in specimen banking * Participants who can complete FACT-L, FACT-BRM, and PRO-CTCAE questionnaires forms in English, or Spanish must agree to participate in the patient-reported outcome study * NOTE: As a part of the Oncology Patient Enrollment Network (OPEN) registration process the treating institution's identity is provided in order to ensure that the current (within 365 days) date of institutional review board approval for this study has been entered in the system * Participants must be informed of the investigational nature of this study and must sign and give informed consent in accordance with institutional and federal guidelines * For participants with impaired decision-making capabilities, legally authorized representatives may sign and give informed consent on behalf of study participants in accordance with applicable federal, local, and Central Institutional Review Board (CIRB) regulations

Conditions & Interventions

Interventions:

PROCEDURE: Biospecimen Collection, PROCEDURE: Computed Tomography, BIOLOGICAL: Durvalumab, OTHER: Patient Observation, OTHER: Questionnaire Administration

Conditions:

Lung Non-Small Cell Carcinoma, Stage II Lung Cancer AJCC v8, Stage IIIA Lung Cancer AJCC v8, Stage IIIB Lung Cancer AJCC v8

More Information

Contact(s): ctrrecruit@vcu.edu

Principal Investigator:

IRB

Number:
System ID: NCT06498635

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