Testing the Addition of AZD6738 (Ceralasertib) to Immunotherapy to Increase Time Without Cancer for Patients With Non-Small Cell Lung Cancer

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* STEP 0: Patient must be \>= 18 years of age * STEP 0: Patient must have stage II to select stage IIIB (N2 but excluding N3) non-small cell lung cancer (NSCLC) of any histology using International Association for the Study of Lung Cancer (IASLC) 8th edition. Stage is assessed at time of initiating pre-operative chemo-immunotherapy * STEP 0: Patient must fall into one of the following categories: * Planning to undergo, be currently undergoing, or recently completed any standard of care neoadjuvant chemo-immunotherapy with plans to undergo surgical resection * Recently completed any standard of care neoadjuvant chemo-immunotherapy AND completed surgical resection and are awaiting pCR status. * Recently completed any standard of care neoadjuvant chemo-immunotherapy AND completed surgical resection with confirmed non-path complete response (CR) status. NOTES: * Patient must have completed at least 3 cycles of neoadjuvant chemo-immunotherapy before surgery in order to be eligible for Step 1 randomization. * Patients who have completed their surgical resection prior to enrollment in step 0 registration must have their surgery date within a window that will allow initiation of EA5231 treatment (cycle 1 day 1) to commence within 4-12 weeks following surgery * STEP 1: EA5231 CLEAR randomization for patients without a pCR post-surgery. Patient's with pCR after surgery will be offered to enroll in the SWOG study S2414 INSIGHT instead * STEP 1: Patient must have completed R0 resection after standard of care neoadjuvant chemo-immunotherapy (minimum three cycles completed) for stage II to select stage IIIB (N2 but excluding N3) non-small cell lung cancer (NSCLC) of any histology using IASLC 8th Edition * STEP 1: Patient must have non-pathological CR status post-surgery. The pathological CR/non-pathological CR status will be determined by local pathology using IASLC criteria and using the surgical sample tissue * STEP 1: Patient must have an Eastern Cooperative Oncology Group (ECOG) performance status of 0

•≤ 2 (or Karnofsky ≥ 60%) * STEP 1: Patient must not have any known EGFR or ALK genetic alterations. Mutation negative status will be determined per local institutional practices and consistent with National Comprehensive Cancer Network (NCCN) guidelines * STEP 1: Patient must have undergone a chest CT after surgery and within 28 days prior to step 1 randomization * STEP 1: Patient must have recovered from clinically significant adverse events of their most recent therapy/intervention prior to step 1 randomization * STEP 1: Patient must not have experienced a toxicity that led to the permanent discontinuation of prior immunotherapy * STEP 1: Patient must not be receiving ongoing steroids at a dose of prednisone 10 mg or higher (or equivalent) at the time of step 1 randomization. Steroids as premedication for hypersensitivity reactions (e.g., CT scan premedication) are allowed. Intranasal, inhaled, topical steroids, or local steroid injections (e.g., intra articular injection) are allowed * STEP 1: Patient must not have received or have a plan to receive post-operative radiation therapy (PORT) * STEP 1: Patient must not have a history of treatment-related pneumonitis requiring ongoing steroids or supplemental oxygen use * STEP 1: Patient must not have a history of interstitial lung disease (ILD) * STEP 1: Patient must not have diagnosis of ataxia telangiectasia * STEP 1: Patient must not have history of active primary immunodeficiency * STEP 1: Patient must not have history of allogenic organ transplantation * STEP 1: Patient must have body weight \> 30 kg * STEP 1: Patient must not be pregnant or breast-feeding due to the potential harm to an unborn fetus and possible risk for adverse events in nursing infants with the treatment regimens being used. All patients of childbearing potential must have a blood test or urine study within 14 days prior to Step 1 randomization to rule out pregnancy. A patient of childbearing potential is defined as anyone, regardless of whether they have undergone tubal ligation, who meets the following criteria: * Has achieved menarche at some point * Has not undergone a hysterectomy or bilateral oophorectomy * Has not been naturally postmenopausal (amenorrhea following cancer therapy does not rule out childbearing potential) for at least 24 consecutive months (i.e., has had menses at any time in the preceding 24 consecutive months) * STEP 1: Patient must not expect to conceive or father children by using highly accepted and effective method(s) of contraception or by abstaining from sexual intercourse for the duration of their participation in the study. Patients of childbearing potential must use at least 1 highly effective method of contraception in addition to a condom and continue to use it throughout their time on protocol treatment. Male patients must use a condom plus spermicide throughout their time on while on protocol treatment. In addition, all patients must continue contraception use for at least 6 months after the last dose of protocol treatment. Patients must also not breastfeed while on protocol treatment and for at least 6 months after the last dose of protocol treatment. Patients must not donate sperm while on protocol treatment and for 6 months after the last dose of protocol treatment * STEP 1: Patient must not donate blood while on protocol treatment * STEP 1: Patient must have the ability to understand and the willingness to sign a written informed consent document. Patients with impaired decision-making capacity (IDMC) who have a legally authorized representative (LAR) or caregiver and/or family member available will also be considered eligible * STEP 1: Leukocytes ≥ 3,000/mcL (these labs must be obtained ≤ 28 days prior to step 1 randomization) * STEP 1: Hemoglobin ≥ 9.0 g/dL (these labs must be obtained ≤ 28 days prior to step 1 randomization) * STEP 1: Absolute neutrophil count (ANC) ≥ 1,500/mcL (these labs must be obtained ≤ 28 days prior to step 1 randomization) * STEP 1: Platelets ≥ 100,000/mcL (these labs must be obtained ≤ 28 days prior to step 1 randomization) * STEP 1: Total bilirubin ≤ institutional upper limit of normal (ULN) (these labs must be obtained ≤ 28 days prior to step 1 randomization) * STEP 1: Aspartate aminotransferase (AST) (serum glutamic oxaloacetic transaminase \[SGOT\]) and alanine aminotransferase (ALT) (serum glutamic pyruvic transaminase \[SGPT\]) ≤ 3.0 × institutional ULN (these labs must be obtained ≤ 28 days prior to step 1 randomization) * STEP 1: Creatinine clearance ≥ 50 mL/min (estimated using Cockcroft-Gault method or measured) (these labs must be obtained ≤ 28 days prior to step 1 randomization) * STEP 1: Human immunodeficiency virus (HIV)-infected patients on effective anti-retroviral therapy with undetectable viral load within 6 months of step 1 randomization are eligible for this trial * STEP 1: For patients with known chronic hepatitis B virus (HBV) infection, the HBV viral load must be undetectable on suppressive therapy, if indicated * STEP 1: Patients with a history of hepatitis C virus (HCV) infection must have been treated and cured. For patients with HCV infection who are currently on treatment, they are eligible if they have an undetectable HCV viral load * STEP 1: Patients with a prior or concurrent malignancy whose natural history or treatment does not have the potential to interfere with the safety or efficacy assessment of the investigational regimen are eligible for this trial * STEP 1: Patients with known history or current symptoms of cardiac disease, or history of treatment with cardiotoxic agents, should have a clinical risk assessment of cardiac function using the New York Heart Association Functional Classification. To be eligible for this trial, patients should be class 2B or better * STEP 1: Patient must not have received live attenuated vaccine within 30 days prior to the step 1 randomization, while on protocol treatment and within 30 days after the last dose of durvalumab

Conditions & Interventions

Interventions:

PROCEDURE: Biospecimen Collection, DRUG: Ceralasertib, PROCEDURE: Computed Tomography, BIOLOGICAL: Durvalumab, PROCEDURE: Echocardiography Test

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

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IRB Number:
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