Adding the Immunotherapy Drug Cemiplimab to Usual Treatment for People With Advanced Non-Small Cell Lung Cancer Who Had Previous Treatment With Platinum Chemotherapy and Immunotherapy (An Expanded Lung-MAP Treatment Trial)

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* Participants must have been assigned to S1800E by the Southwest Oncology Group (SWOG) Statistics and Data Management Center (SDMC). Assignment to S1800E is determined by the LUNGMAP protocol * Participants must have measurable or non-measurable disease documented by CT or MRI. The CT from a combined positron emission tomography (PET)/CT may be used to document only non-measurable disease unless it is of diagnostic quality. Measurable disease must be assessed within 28 days prior to randomization. Pleural effusions, ascites and laboratory parameters are not acceptable as the only evidence of disease. Non-measurable disease must be assessed within 42 days prior to randomization. All disease must be assessed and documented on the Baseline Tumor Assessment Form. Participants whose only measurable disease is within a previous radiation therapy port must demonstrate clearly progressive disease (in the opinion of the treating investigator) prior to registration * Participants must have a CT or MRI scan of the brain to evaluate for central nervous system (CNS) disease within 42 days prior to randomization * Participants must have received exactly one anti-PD-1 or anti-PD-L1 therapy for advanced disease (stage IV or recurrent disease, or stage I-III disease in certain circumstances outlined below). Anti-PD-1 or anti-PD-L1 therapy may have been given alone or in combination with other therapy. For participants who received neoadjuvant, adjuvant, and/or consolidation anti-PD-1 or anti-PD-L1 therapy for stage I-III disease: * If they experienced disease progression within (≤) 365 days from initiation (cycle 1 day 1) or anti-PD-1 or anti-PD-L1 therapy, this counts as the single allowed anti-PD-1 or anti-PD-L1 therapy for advanced disease * If they experienced disease progression more than (\>) 365 days from initiation (cycle 1 day 1) or anti-PD-1 or anti-PD-L1 therapy, this is not considered anti-PD-1 or anti-PD-L1 therapy for advance disease. These participants must have received anti-PD-1 or anti-PD-L1 therapy for stage IV or recurrent disease * Participants must have experienced disease progression (in the opinion of the treating investigator) more than (\>) 84 days following initiation (cycle 1 day 1) of their most recent anti-PD-1 or anti-PD-L1 therapy * Participants who received anti-PD-1 or anti-PD-L1 therapy for stage IV or recurrent disease must have had a best response of stable disease, partial response or complete response (in the opinion of the treating investigator) on the anti-PD-1 or anti-PD-L1 therapy for stage IV or recurrent disease * Participants must have received platinum-based chemotherapy and experienced disease progression (in the opinion of the treating investigator) during or after this regimen * Participants with a known sensitizing molecular alteration for which a Food and Drug Administration (FDA)-approved targeted therapy for NSCLC exists (e.g., EGFR, ALK, ROS1, BRAF, RET, NTRK, KRAS, HER2, and MET sensitizing mutations), must have previously received at least one of the approved therapy(s). Prior targeted therapy for participants with targetable alterations is allowed if all other eligibility criteria are also met * Participants must have recovered (≤ grade 1) from any side effects from the most recent anti-cancer treatment prior to randomization * Participants must not have received prior therapy with docetaxel for this disease * Participants must not have received any palliative radiation therapy within 14 days (or palliative bone radiation therapy within 7 days) prior to randomization * Participants must not be planning to receive any concurrent chemotherapy, immunotherapy, or biologic therapy for cancer treatment while receiving treatment on this study * Participants must not have undergone major surgery within 28 days prior to randomization, or subcutaneous venous access device placement within 7 days prior to randomization. Participants must not have postoperative bleeding complications or wound complications from a surgical procedure performed within 2 months prior to randomization. The participant must not have elective or planned major surgery to be performed during the course of this study * Absolute neutrophil count ≥ 1.5 x 10\^3/uL (within 28 days prior to randomization) * Hemoglobin ≥ 9.0 g/dL (within 28 days prior to randomization) * Platelets ≥ 100 x 10\^3/uL (within 28 days prior to randomization) * Total bilirubin ≤ 1.5 x institutional upper limit of normal (ULN) (within 28 days prior to randomization) unless history of Gilbert's disease. Participants with history of Gilbert's disease must have total bilirubin ≤ 5 x institutional ULN * Aspartate aminotransferase (AST) and alanine aminotransferase (ALT) ≤ 3 x institutional ULN (within 28 days prior to randomization). Participants with history of liver metastasis must have AST and ALT ≤ 5 x ULN * Participants must have a creatinine ≤ the institutional (I)ULN or calculated creatinine clearance ≥ 50 mL/min using the following Cockcroft-Gault formula. This specimen must have been drawn and processed within 28 days prior to randomization * Participants must have a urinary protein test performed within 28 days prior to randomization * Participants' most recent Zubrod/Eastern Cooperative Oncology Group (ECOG) performance status must be 0-1 and be documented within 28 days prior to randomization * Participants must have a completed medical history and physical exam within 28 days prior to randomization * Participants with evidence 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 by the treating investigator * Participants with a 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 by the treating investigator * Participants with known human immunodeficiency virus (HIV) infection are eligible, provided they are on effective anti-retroviral therapy and have undetectable viral load at their most recent viral load test and within 6 months prior to randomization * Participants must not have a prior or concurrent malignancy whose natural history or treatment has the potential to interfere with the safety or efficacy assessment of the investigational regimen * Participants must not have an active autoimmune disease that has required systemic treatment within 730 days prior to randomization (i.e., with use of disease modifying agents, corticosteroids or immunosuppressive drugs). Replacement therapy (e.g., thyroxine, insulin, or physiologic corticosteroid replacement therapy for adrenal or pituitary insufficiency) is not considered a form of systemic treatment and is allowed * Participants must not have any history of primary immunodeficiency * Participants must be able to safely receive study therapy and must not have experienced the following: * Any grade 3 or worse immune-mediated adverse event. Exception: asymptomatic nonbullous/nonexfoliative rash * Any unresolved grade 2 immune-mediated adverse event * Any toxicity that led to permanent discontinuation of prior anti-PD-1/PD-L1 immunotherapy * Exception to the above: Toxicities of any grade that requires replacement therapy and has stabilized on therapy (e.g., thyroxine, insulin, or physiologic corticosteroid replacement therapy for adrenal or pituitary insufficiency) are allowed * Participants must not have any history of organ transplant that requires use of immunosuppressives * Participants must not have received a live or live attenuated vaccine within 28 days prior to 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 COVID-19 vaccines are allowed, however, intranasal influenza vaccines (e.g. Flu-Mist) are live attenuated and are not allowed * Participants must not have clinical signs or symptoms of active tuberculosis infection * Participants must not have a history of (non-infectious) pneumonitis that required steroids or current pneumonitis/interstitial lung disease * Participants must not have had a serious or nonhealing wound, ulcer, or bone fracture within 28 days prior to randomization * Participants must not have a history of gastrointestinal perforation or fistula within 6 months prior to randomization * Participants must not have grade 3-4 gastrointestinal bleeding (defined by National Cancer Institute \[NCI\] Common Terminology Criteria for Adverse Events \[CTCAE\] version \[v\]5) within 3 months prior to randomization. No history of gastrointestinal (GI) bleed within 3 months prior to randomization * Participants must not have any grade III/IV cardiac disease as defined by the New York Heart Association criteria (i.e., participants with cardiac disease resulting in marked limitation of physical activity or resulting in inability to carry on any physical activity without discomfort), unstable angina pectoris, and myocardial infarction within 6 months prior to randomization, or serious uncontrolled cardiac arrhythmia * Participants must not have experienced any arterial thromboembolic events, including but not limited to myocardial infarction, transient ischemic attack, cerebrovascular accident, or unstable angina, within 6 months prior to randomization * Participants must not have gross hemoptysis within two months prior to randomization (defined as bright red blood or ≥ 1/2 teaspoon) or with radiographic evidence of intratumor cavitation or has radiologically documented evidence of major blood vessel invasion or encasement by cancer * Participants must not have been diagnosed with venous thrombosis within

radiologically documented evidence of major blood vessel invasion or encasement by cancer * Participants must not have been diagnosed with venous thrombosis within 3 months prior to randomization. Participants with venous thrombosis diagnosed more than 3 months prior to randomization must be on stable doses of anticoagulants * Participants must not have cirrhosis at a level of Child-Pugh B (or worse) AND a history of hepatic encephalopathy or clinically meaningful ascites resulting from cirrhosis, OR any degree of cirrhosis * Participants must not be pregnant or breastfeeding (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 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 must agree to have blood specimens submitted for circulating tumor DNA (ctDNA) * Participants must be offered participation in specimen banking. With participant consent, specimens must be collected and submitted via the SWOG specimen tracking system * 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. NOTE: 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, BIOLOGICAL: Cemiplimab, PROCEDURE: Computed Tomography, DRUG: Dexamethasone, DRUG: Docetaxel, PROCEDURE: Magnetic Resonance Imaging, BIOLOGICAL: Ramucirumab
Conditions:
Recurrent Lung Non-Small Cell Carcinoma, Stage IV Lung Cancer AJCC v8

More Information

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