

A Study to Learn About the Study Medicine Called PF-08046054/SGN-PDL1V Versus Docetaxel in Adult Participants With Previously-Treated Programmed Cell Death Ligand 1 (PD-L1) Positive Non-Small-Cell Lung Cancer (NSCLC)

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria * Histologically or cytologically confirmed diagnosis of NSCLC with locally advanced, unresectable Stage IIIB or IIIC not eligible for definitive chemoradiotherapy or metastatic (Stage IV: M1a, M1b, or M1c) disease per the American Joint Committee on Cancer (AJCC) Staging Manual, Version 8.0, and the Union for International Cancer Control (UICC) Staging System. Note: Participants with a neuroendocrine component or histology are not eligible. * PD-L1 expression on $\geq 1\%$ of tumor cells based on local immunohistochemistry (IHC) testing with an assay utilizing the anti-PD-L1 monoclonal antibody clones 22C3 or SP263. * Participants who have NSCLC with known AGAs are permitted. * Able to provide any of the following tumor tissues for biomarker analysis: * Archival specimen (preferably collected within 12 months after the last anticancer therapy) (see laboratory manual for details); or * De novo biopsy from a tumor lesion, if medically feasible. * Participants must have received the following therapies and progressed during or relapsed after receiving their most recent prior therapy, or have been intolerant to their most recent therapy: Participants with no known AGAs must fulfill 1 of the following conditions: * Received a platinum-based combination therapy for the treatment of metastatic or recurrent disease, and unless contraindicated, a PD-(L)1 monoclonal antibody (concurrently or sequentially with platinum-based chemotherapy). * Experienced disease progression within 6 months of the last dose of platinum-based chemotherapy in the adjuvant, neoadjuvant, or chemoradiotherapy setting and received a PD-(L)1 monoclonal antibody at any time during the course of treatment. Participants with known AGAs (eg, EGFR mutations, ALK translocations, or other relevant actionable mutations) must fulfill the following conditions: * Must have received at least 1 relevant AGA-targeted therapy if locally available and, in the opinion of the investigator, additional AGA-targeted therapy is not in the best interest of the participant * Received a platinum-based combination therapy for the treatment of metastatic or recurrent disease, or experienced disease progression within 6 months of the last dose of platinum-based chemotherapy in the adjuvant, neoadjuvant, or chemoradiotherapy setting. * May have received PD-(L)1 monoclonal antibody (concurrently or sequentially with platinum-based chemotherapy). **Exclusion Criteria** * History of another malignancy within 3 years before the first dose of PF-08046054, or any evidence of residual disease from a previously diagnosed malignancy. Exceptions are malignancies with a negligible risk of metastasis or death (eg, 5-year overall survival $\geq 90\%$), such as adequately treated carcinoma in situ of the cervix, non-melanoma skin carcinoma, localized prostate cancer, ductal carcinoma in situ, or Stage I uterine cancer. * Any central nervous system (CNS) lesions, unless definitively treated with CNS-directed local therapy (surgery and/or radiotherapy). Participants with definitively treated brain metastases are eligible if they meet the following criteria: * The participant is on a stable dose of ≤ 10 mg/day of prednisone or equivalent for at least > 14 days prior to randomization (if requiring steroid treatment). * No clinical or radiographic progression in the CNS following CNS-directed definitive radiotherapy and/or surgery. * Time since CNS-directed treatment is ≥ 28 days prior to randomization. * Participants with a history of leptomeningeal metastasis are excluded. * Prior treatment with an anti-PD-L1 agent (where indicated per protocol) within 5 half-lives. * Previous receipt of an MMAE-containing agent or prior docetaxel. There are additional inclusion and exclusion criteria. The study center will determine if criteria for participations are met.

Conditions & Interventions

Interventions:

DRUG: PF-08046054, DRUG: Docetaxel monotherapy

Conditions:

Non-small Cell Carcinoma, Non-Small Cell Lung Cancer Metastatic, Non-Small Cell Lung Carcinoma

Keywords:

Non-small cell lung cancer NSCLC, NSCLC

More Information

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IRB

Number:

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