

S14001
Lung-MAP Sub-Study

A Phase II Randomized Study of Nivolumab Plus Ipilimumab vs. Nivolumab for Previously Treated Patients with Stage IV Squamous Cell Lung Cancer and No Matching Biomarker

Treatment Plan	
ARM 1	ARM 2
Nivolumab 3mg/kg IV on Day 1 q 14 days Ipilimumab 1mg/kg IV on Day 1 q 42 days	Nivolumab 3mg/kg IV on Day 1 q 14 days

S1400D:

- Must not have had prior treatment with an anti-PD-1, anti-PD-L1, anti-PD-L2, anti-CTLA-4 antibody, or any other antibody or drug specifically targeting T-cell costimulation or immune checkpoint pathways.
- Must not have an active, known, or suspected autoimmune disease. Patients are permitted to enroll if they have vitiligo, type I diabetes mellitus, hypothyroidism only requiring hormone replacement, psoriasis not requiring systemic treatment, or conditions not expected to recur in the absence of an external trigger.
- Must not have any known allergy or reaction to any component of the nivolumab and ipilimumab formulations.
- Must not have received systemic treatment with corticosteroids (> 10 mg daily prednisone or equivalent) or other immunosuppressive medications within 14 days prior to sub-study registration. Inhaled or topical steroids, and adrenal replacement doses < 10 mg daily prednisone or equivalent are permitted in the absence of active autoimmune disease.
- Must not have a known positive test for hepatitis B virus surface antigen (HBV sAg) or hepatitis C virus ribonucleic acid (HCV antibody) indicating acute or chronic infection. Patients with a positive hepatitis C antibody with a negative viral load are allowed. [This criterion replaces common eligibility criteria]
- Must not have known history of testing positive for human immunodeficiency virus (HIV) or known acquired immunodeficiency syndrome (AIDS).
- Must not have interstitial lung disease that is symptomatic or disease that may interfere with the detection or management of suspected drug-related pulmonary toxicity.
- Must also be offered participation in banking for future use of specimens as described in Section 15.0.