Protocol Title: EA5161: Randomized Phase II Clinical Trial of Cisplatin/Carboplatin and Etoposide (CE) Alone or in Combination with Nivolumab as Frontline Therapy for Extensive Stage Small Cell Lung Cancer (ED-SCLC)

Target Population: Extensive Stage Small Cell Lung Carcinoma

Summary: This randomized phase II clinical trial studies how well Cisplatin, Carboplatin, and Etoposide work when given together with Nivolumab in treating patients with Extensive Stage Lung Cancer.

Key Eligibility Criteria:
- Must have histologically or cytologically confirmed Extensive Stage Small Cell Lung Cancer and must be a candidate for systemic therapy
- Must have measurable disease based on RECIST 1.1
- ECOG Performance Status 0 or 1
- Adequate bone marrow, renal, and liver function
- Patients are eligible if CNS metastases are adequately treated and neurological symptoms have returned to baseline or are controlled for at least 2 Weeks prior to enrollment
- Cannot have had prior chemotherapy or biologic therapy for Small Cell Lung Cancer for front line treatment
  - Patients receiving prior whole brain radiation cannot register within 7 Days after completion of radiation, and must have resolved adverse events attributed to radiation to ≤ grade 1
- Patients who have received prior chemoradiation for limited-stage SCLC must have been treated with curative intent at least 6 Months since last treatment from diagnosis of extensive-stage SCLC
- Must not have history of allergic reactions attributed to compounds of similar chemical or biologic composition to Nivolumab or other agents used in the study
- Women must not be pregnant or breast-feeding
- No prior or current invasive malignancy (except non-melanomatous skin cancer, localized bladder and prostate cancer) unless disease free for a minimum of 2 Years
  - For example, carcinoma in situ of the breast, oral cavity, or cervix are all permissible
- No prior systemic 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 co-stimulation or immune checkpoint pathways
- Must not have leptomeningeal disease
- No active, known or suspected autoimmune disease and neuromuscular paraneoplastic syndromes, type I diabetes mellitus, hypothyroidism only requiring hormone replacement, skin disorders not requiring systemic treatment, or conditions not expected to recur in absence of an external trigger
- No interstitial lung disease that is symptomatic or may interfere with the detection or management of suspected drug-related pulmonary toxicity
- Must NOT have uncontrolled intercurrent illness or psychiatric illness/social situations that would limit compliance with study requirements
- HIV-positive patients on combination antiretroviral therapy are ineligible
- Any patients positive for Hepatitis B or Hepatitis C Virus indicating acute or chronic infection are excluded
- Ineligible if administration of a live, attenuated vaccine within 4 Weeks before randomization
- No history of severe hypersensitivity reaction to any monoclonal antibody or allergy to study drug components

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For additional information: https://clinicaltrials.gov/ct2/show/NCT03382561