EA5163/S1709 INSIGNA: A Randomized, Phase III Study of Firstline Immunotherapy alone or in Combination with Chemotherapy in Induction/Maintenance or Postprogression in Advanced Nonsquamous Non Small Cell Lung Cancer (NSCLC) with Immunobiomarker SIGNature driven Analysis

Status: Recruiting

Eligibility Criteria

Sex: Male or Female
Age Group: 18 years and over
This study is NOT accepting healthy volunteers

Inclusion Criteria:

- confirmed stage IV non-squamous non-small cell lung cancer (NSCLC) - PD-L1 expression Tumor Proportion Score (TPS) >= 1% in tumor cells -

Exclusion Criteria:

- Prior systemic chemotherapy or immunotherapy for advanced metastatic NSCLC - EGFR mutations (except exon 20 insertion), BRAF mutations (V600) or ALK or ROS1 translocations - significant gastrointestinal disorders with diarrhea as a major symptom - history of auto-immune condition (including Guillain-Barre Syndrome or Multiple Sclerosis) requiring ongoing or intermittent systemic treatment in the past 2 years - pregnant or breast-feeding

Conditions & Interventions

Interventions:
Procedure: Biospecimen Collection, Drug: Carboplatin, Procedure: Computed Tomography, Procedure: Magnetic Resonance Imaging, Biological: Pembrolizumab, Drug: Pemetrexed, Procedure: Positron Emission Tomography
Conditions:
Cancer
Keywords:
Lung Cancer, Lung Cancer, Immunotherapy, Nonsquamous Non-Small Cell Lung Cancer (NSCLC)

More Information

Description: We are studying the use of pembrolizumab to treat people who have stage IV non-squamous, non-small cell lung cancer. Pembrolizumab may help the body's own immune system attack cancer so tumor cells cannot grow and spread. We are looking at when it is most effective to give the pembrolizumab and when to combine it with other anticancer drugs, pemetrexed and carboplatin.
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Phase: PHASE3
IRB Number: MMCORC012

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