Protocol Title: Feasibility Trial of Neoadjuvant Cisplatin-Pemetrexed with Atezolizumab in Combination and in Maintenance for Resectable Malignant Pleural Mesothelioma

Target Population: Stage I, IA, IB, II, and III Pleural Malignant Mesothelioma with Epithelioid or Biphasic Histology

Summary: This phase I pilot trial studies how well Atezolizumab, Pemetrexed Disodium, Cisplatin, and surgery with or without radiation therapy in treating patients with Stage I-III Pleural Malignant Mesothelioma.

STEP 1: Neoadjuvant Eligibility Criteria:
- Must have Stage I-III Malignant Pleural Mesothelioma that is deemed resectable and must be planning to undergo Pleurectomy Decortication (P/D) or Extrapleural Pneumonectomy (EPP).
- Must have epithelioid or biphasic histology.
- Must have CT with contrast or fludeoxyglucose F-18 (FDG)-PET/CT scan performed within 28 Days prior to step 1 registration.
- Must have measurable disease documented by CT or MRI.
- Must have undergone surgical staging including mediastinoscopy or endobronchial US within 42 Days prior to step 1 registration.
  - At minimum, samples must be obtained from mediastinal stations 4R, 7 (subcarinal), and 4L.
  - Must be T1-3 and N0-N2 (single station).
- Must undergo video-assisted thoracoscopic surgery and diagnostic laparoscopy within 28 Days prior to step 1 registration; must undergo the diagnostic laparoscopy to rule out peritoneal disease spread.
- Must have consultation with a surgeon within 21 Days prior to step 1 registration; surgeon must confirm that the patient’s disease is resectable by P/D or EPP and that the patient is an appropriate candidate for the surgical procedures.
- Must not have had prior immunotherapy or chemotherapy for Malignant Pleural Mesothelioma.
- Must have Zubrod Performance Status 0 or 1 documented within 28 Days prior to step 1 registration.
- No other prior malignancy is allowed except for adequately treated basal cell or squamous cell skin cancer, in situ cervical cancer, adequately treated stage I or II cancer from which the patient is currently in complete remission or any other cancer from which the patient has been disease free for 3 Years.
- Must not have active autoimmune disease that has required systemic treatment in past 2 Years.
- Must not have undergone prior allogeneic bone marrow transplantation or prior solid organ transplantation.
- Must not have active tuberculosis, h/o idiopathic pulmonary fibrosis, pneumonitis, organizing pneumonia, or active pneumonitis.
- Must not have significant cardiovascular disease.
- Must not receive live, attenuated influenza vaccine within 4 Weeks prior to registration or at any time during the study and until 5 Months after the last dose of Atezolizumab.

STEP 2: Surgery Eligibility Criteria:
- Must have a CT with contrast or FDG-PET/CT scan within 28 Days prior to step 2 registration with no evidence of progression.
- Planning to receive EPP must also be evaluated for appropriateness of RT within 14 Days prior to step 2 registration.
- Must have received at least 2 cycles of triplet neoadjuvant therapy (all 3 drugs) during step 1.
- Must be registered to step 2 no less than 21 Days and no more than 90 Days after final cycle of neoadjuvant therapy.

STEP 3: Maintenance Eligibility Criteria:
- Must have received either P/D or EPP and must have recovered from all effects of surgery with adequate wound healing.
  - Patients who received RT must be registered to step 3 within 28 Days after discontinuing RT.
  - Patients who did not receive RT must be registered to step 3 within 56 Days after surgery.
- Must have a CT with contrast or FDG-PET/CT scan within 28 Days prior to step 3 registration with no evidence of progression.
- May have discontinued RT early due to toxicity or other reasons.

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For additional information: https://clinicaltrials.gov/ct2/show/study/NCT03228537

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