PANCREATIC NEUROENDOCRINE

Clinical Trial Name: SWOG-S201 Randomized Phase II/III Trial of First Line Platinum/Etoposide with or without Atezolizumab (NSC#783608) in Patients with Advanced or Metastatic Poorly Differentiated Extrapulmonary Neuroendocrine Carcinomas (NEC)

Study Design: This is a randomized, multi-center phase II/III trial in patients with advanced or metastatic poorly differentiated extrapulmonary neuroendocrine carcinomas (NEC). Patients are randomized to either 4 cycles of Platinum/Etoposide + Atezolizumab + maintenance Atezolizumab for up to 1 year; 4 cycles of Platinum/Etoposide + Atezolizumab + Observation; or 4 cycles Platinum/Etoposide + Observation. The purpose of the study is to compare the different treatment arms and overall survival across the arms.

NCT#: NCT05058651

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Key Inclusion:

- Histologically confirmed extrapulmonary poorly differentiated, neuroendocrine carcinoma (NEC)
- Disease that is unresectable or metastatic and not eligible for definitive therapy as deemed per the treating investigator
- Must have radiologically evaluable disease, measurable or non-measurable, per RECIST 1.1 criteria.
- Participants must have a Zubrod Performance Status of < 2.

Key Exclusion:

- Participants must not have symptomatic central nervous system (CNS) metastases.
- Participants must not have had prior treatment for advanced or metastatic NEC EXCEPT for one cycle of platinum (carboplatin/cisplatin) + etoposide is allowed prior to registration. Other chemotherapy regimens are not allowed.
- Participants must not have had prior treatment with an anti-PD-1, anti-PD-L1, anti-PD-L2, CD137 agonists, anti-CTLA-4 agent, or any other immune checkpoint inhibitors for any neuroendocrine neoplasm. Immune checkpoint inhibitors given for other cancer indications are allowed provided last therapy was given at least 12 months prior to study registration.
- Participants must not have received treatment with systemic immunostimulatory agents including, but not limited to, interferon and interleukin2 [IL-2] within 4 weeks or 5 half-lives of the drug (whichever is longer) prior to registration.