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

Study PI:
Dr. Alexandria Phan

Clinical Research Coordinator:
Grace Westerman
Phone: 414-805-8986

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.

Clinical Trial Name: HARPOON HPN328-4001: A Phase I/II Open-label, Multicenter, Dose Escalation and Dose Expansion Study of the Safety, Tolerability, and Pharmacokinetics of HPN328 Monotherapy and, HPN328 with Atezolizumab or Ifinatamab Deruxtecan (I-DXd) in Patients with Advanced Cancers Associated with Expression of Delta-like Canonical Notch Ligand 3 (DLL3)

Study Design: Characterize the impact of HPN328 on peripheral blood mononuclear cell (PBMC) and soluble serum cytokines, including but not limited to interferon gamma (IFNγ), interleukin (IL)-6, and tumor necrosis factor alpha (TNFα). Then assess DLL3 expression levels and associate with tumor response or treatment toxicity.

NCT#: NCT04471727

Study PI:
Dr. Jonathan Thompson

Clinical Research Coordinator:
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Phone: 414-805-8839

Key Inclusion:

- Histologically or cytologically confirmed high-grade malignancy associated with expression of DLL3. Pre-screening of tissue required and DLL3 expression demonstrated in a tumor sample in pre-screening.
- Disease that is relapsed/refractory to standard systemic therapy, Disease for which standard therapy does not exist, or Disease for which standard therapy is not considered appropriate by the Investigator.
- Inpatient admission required for study treatment.

Key Exclusion:

- Pleural effusion, pericardial effusion, or ascites requiring recurrent drainage procedures (e.g., biweekly or more frequently, or requiring indwelling catheter drain).
- Active or history of autoimmune disease or immune deficiency.
- History of arterial thrombosis (e.g., stroke or transient ischemic attack) within 6 months of the first dose of study drug.
- Patient received prior therapy with a DLL3 targeted agent.