Research Study Summary for UAB 16117

Title of Protocol:
NRG-HN003 : A Phase I and Expansion Cohort Study of Adjuvant Cisplatin, Intensity-Modulated Radiotherapy, and MK-3475 (Pembrolizumab) in High-Risk Head and Neck Squamous Cell Carcinoma CHNSCC)

Purpose/Objective of Study:
The primary objective is to determine the recommended phase II schedule for the combination of MK-34 75 (Pembrolizumab) and standard, adjuvant cisplatin-radiotherapy in patients with high-risk, HPV- negative head and neck squamous cell carcinoma CHNSCC)

Study Agent(s) and Mechanism of Drug Action/Device Description:
Cisplatin: is a platinum based alkylating agent that inhibits DNA synthesis by forming inter- and intra-strand crosslinks. It can also chelated DNA and bind to cell membranes thereby stimulating immune mechanisms
Pembrolizumab: is a humanized monoclonal antibody which inhibits programmed death receptor-1 (PD-1) activity by binding to the PD-1 receptor on T-cells to block PD-1 ligands from binding. Anti-PD-1 antibodies reverse T-cell suppression and induce antitumor responses.

Toxicities/Side Effects:
Cisplatin: Most common side effects include pancytopenia, neutropenic fever and infections, mucositis, vomiting, ototoxicity, and electrolyte wasting. Serious side effects include renal failure and there are rare reports of hemolytic uremic syndrome
Pembrolizumab: has the potential to cause serious auto-immune side effects that result from the immune system activation (auto-immune hepatitis, colitis, dermatitis, hypophysitis)

Caution:
Cisplatin+Radiotherpy: Combination of radiation and cisplatin worsens toxicities, especially mucositis and neutropenia.
Pembrolizumab: Patients should not receive live vaccines while on Pembrolizumab. As with any auto-immune condition, treatment of choice for such study agent associated auto-immune toxicities is JUDICIOUS USE OF CORTICOSTEROIDS. Prolonged steroid administration may potentially exclude patient from the study.

In cases of serious medical conditions, including study agent related toxicity, all patients should be treated as per Standard of Care guidelines

Please contact PI or study team ASAP.

PI name:……..

PI contact number:……..