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Protocol Title: A Pilot, Open-label Study of Tislelizumab in Combination With Chemotherapy in First-line treatment of Unresectable/Metastatic Non-small Cell Lung Cancer or Recurrent / Metastatic Squamous Cell Head and Neck Cancer

Study Treatment: Tislelizumab (Study Drug) + Chemotherapy (Platinum Agent, Pemetrexed, Taxane)

Key Inclusion criteria

Patients affected by histologically or cytologically documented solid tumor malignancies as described below:

Cohort 1: Unresectable Locally Advanced/Metastatic Non- Small Cell Lung Cancer

- ▶ Locally advanced or recurrent NSCLC ALK / EGFR Mutations Negative that is not eligible for curative surgery and/or definitive radiotherapy with or without chemoradiotherapy, or metastatic non squamous or squamous NSCLC.
- ▶ No prior systemic treatment for metastatic NSCLC. Patients who have received prior neoadjuvant, adjuvant chemotherapy, radiotherapy, or chemoradiotherapy with curative intent for nonmetastatic disease must have experienced a disease-free interval of ≥ 6 months from the last dose of chemotherapy and/or radiotherapy prior to signing informed consent.

Cohort 2: Recurrent/Metastatic Squamous Cell Head and Neck Cancer

- ▶ Recurrent or metastatic HNSCC that is not amenable to by local curative therapies with surgery or radiation.
- ▶ Primary tumor site of oral cavity, oropharynx, hypopharynx, or larynx.
Patients with a primary tumor site of nasopharynx are excluded. (Note: human papillomavirus (HPV) status will not be required prior to entering the study)
- ▶ No prior systemic therapy administered in recurrent or metastatic setting. Systemic therapy which is given as part of multimodal treatment for locally advanced disease is allowed.
- ▶ Tumor progression or recurrence ≥ 6 months after last dose of platinum therapy for patients who received multimodality treatment for locally advanced or locally recurrent disease

For further more information please contact

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