INBRX-106 in Combination With Pembrolizumab in First-line PD-L1 CPS≥20 HNSCC

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* Has histologically or cytologically confirmed diagnosis of metastatic, recurrent head and neck squamous cell carcinoma (HNSCC) that is considered incurable by local therapies. * Has tumor PD-L1 expression of CPS ≥20. Tumor tissue must be provided for PD-L1 biomarker analysis. * Has human papilloma virus (HPV) testing results for oropharyngeal cancer by p16 immunohistochemistry (IHC) testing. * Has measurable disease per RECIST 1.1 guidelines. * Has the primary tumor location of the oral cavity, oropharynx, hypopharynx, or larynx. * Has an Eastern Cooperative Oncology Group (ECOG) Performance Status of 0 or 1. * Female patients of childbearing potential must have a negative highly sensitive pregnancy test within 72 hours prior to randomization and must not be breastfeeding. * Male and female patients of childbearing potential must be willing to completely abstain from heterosexual sex or agree to use a highly effective method of contraception.

Exclusion Criteria:

* Has primary tumor site (any histology) of nasopharynx or salivary glands or occult primary site. * Has received prior systemic therapy (eg, prior chemo-, immune-, or biologic therapy) for locally advanced unresectable or metastatic HNSCC. * Prior systemic therapy completed \>6 months prior to signing informed consent is allowed if given as part of multimodal treatment for locoregionally advanced disease with curative intent, and no PD/recurrence occurred within 6 months of its completion. Prior systemic immunotherapy in the locoregionally advanced disease with curative intent, including but not limited to anti-PD-(L)1 agents, is allowed if PD/recurrence occurred ≥12 months after its completion. * Has clinically active central nervous system metastases and/or carcinomatous meningitis. * Has a diagnosis of immunodeficiency or is receiving systemic steroid therapy or any other form of immunosuppressive therapy within 7 days prior to the first dose of study treatment. * Rapidly progressing disease or with features that may confer a high risk of tumor-associated hemorrhage or uncontrolled tumor pain. * Current or history of immune-related disease that required systemic treatment in past 2 years, except for replacement therapy.

Conditions & Interventions

Interventions:
DRUG: INBRX-106, DRUG: Pembrolizumab
Conditions:
Head and Neck Squamous Cell Carcinoma (HNSCC)
Keywords:
OX40 receptor agonist, PD-L1 positive, Pembrolizumab, Immunotherapy, Chemotherapy-free, HNSCC, Head and Neck Cancer, Keytruda, Oropharyngeal cancer, Hypopharyngeal cancer, Laryngeal cancer, Oral cancer, INBRX-106

More Information

Contact(s): Study Director - Inhibrx - clinicaltrials@inhibrx.com
Principal Investigator:
Phase: PHASE2
IRB
Number:
System ID: NCT06295731
