Testing the Addition of Anti-Cancer Drug, Cetuximab, to Standard of Care Treatment (Pembrolizumab) for Returning or Spreading Head and Neck Cancer After Previous Treatment

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* Histologically confirmed diagnosis head and neck squamous cell carcinomas (HNSCC). * Previously untreated for recurrent and/or metastatic disease incurable by local therapies. * Primary tumor location of oral cavity, oropharynx, larynx, or hypopharynx. * Note: Other primary tumor sites of HNSCC, including nasopharynx primary tumor are not eligible. Unknown primary tumors may be eligible and can be enrolled at the discretion of the treatment team with approval by the study chair. * Measurable disease. * Must have platinum-refractory disease defined as disease progression during or ≤ 6 months after completion of definitive therapy (chemoradiation therapy) or adjuvant (post-operative) therapy. * Patient must have a combined positive score PD-L1 positive (CPS \>/= 1) tumor. * Any radiation therapy must be completed \>= 10 days prior to registration. * Patients should not have received any prior treatment in the recurrent or metastatic setting. * Prior therapy with anti PD-1/PD-L1 monoclonal antibody or cetuximab in the curative setting is allowed if last treatment dose was \>= 6 months prior to registration without evidence of disease progression during that treatment period. * Patient has not received a live vaccine within 30 days prior to registration. * Patient does not have a history of any contraindication or has a severe hypersensitivity to any component of pembrolizumab or cetuximab (≥ grade 3). * Patient has not received chronic systemic steroid therapy (in dosing exceeding 10 mg daily of prednisone or equivalent) or any other form of immunosuppressive therapy within 7 days prior to registration. * Patient with oropharyngeal cancer only must have negative results from testing of human papillomavirus (HPV) status defined as p16 immunohistochemistry (IHC) and/or HPV in situ hybridization (ISH). * Note: A Clinical Laboratory Improvement Act (CLIA) certified circulating tumor HPV deoxyribonucleic acid (ctHPVDNA) assay can be used if tissue sample is not available. * Age ≥ 18 years. * Eastern Cooperative Oncology Group (ECOG) performance status ≤ 2. * Absolute neutrophil count (ANC) ≥ 1,500/mm\^3. * Platelet count ≥ 100,000/mm\^3. * Hemoglobin (Hgb) ≥ 9 g/dL (if \< 9 g/dL, then transfusions are acceptable to increase hemoglobin above 9 g/dL). * Creatinine ≤ 1.5 x upper limit of normal (ULN) OR calculated (calc.) creatinine clearance ≥ 30 mL/min using the Cockcroft-Gault formula for participant with creatinine levels \> 1.5 x institutional ULN. * Total bilirubin ≤ 1.5 x ULN OR direct bilirubin \< ULN for participant with total bilirubin \> 1.5 x institutional ULN. * Aspartate aminotransferase (AST) (serum glutamic-oxaloacetic transaminase \[SGOT\])/alanine aminotransferase (ALT) (serum glutamic-pyruvic transaminase \[SGPT\]) ≤ 3.0 x ULN unless liver metastases are present in which case \< 5.0 x ULN. * Not pregnant and not nursing, because this study involves an agent that has known genotoxic, mutagenic, and teratogenic effects. * Therefore, for women of childbearing potential only, a negative pregnancy test done ≤ 7 days prior to registration is required. * Patients with a prior or concurrent malignancy whose natural history or treatment does not have the potential to interfere with the safety or efficacy assessment of the investigational regimen should be included. * For treated/stable brain metastases: Patients with treated brain metastases are eligible if follow-up brain imaging after central nervous system (CNS)-directed therapy shows no evidence of progression. * Patients with new or progressive brain metastases (active brain metastases) or leptomeningeal disease are eligible if the treating physician determines that immediate CNS specific treatment is not required and is unlikely to be required during the first cycle of therapy. * HIV-infected patients on effective anti-retroviral therapy with undetectable viral load within 6 months prior to registration are eligible for this trial. * For patients with evidence of chronic hepatitis B virus (HBV) infection, the HBV viral load must be undetectable on suppressive therapy, if indicated. * Patients with a history of hepatitis C virus (HCV) infection must have been treated and cured. For patients with HCV infection who are currently on treatment, they are eligible if they have an undetectable HCV viral load. * Patients with known history or current symptoms of cardiac disease, or history of treatment with cardiotoxic agents, should have a clinical risk assessment of cardiac function using the New York Heart Association Functional Classification. To be eligible for this trial, patients should be class 2B or better. * Patients does not have a history of active myocarditis. * Patients does not have a history of any form of pneumonitis or diffuse idiopathic or immune mediated interstitial pulmonary disease. * Patient does not have a history of solid organ transplantation.

Conditions & Interventions

Interventions:

PROCEDURE: Biospecimen Collection, BIOLOGICAL: Cetuximab, PROCEDURE: Computed Tomography, PROCEDURE: Magnetic Resonance Imaging, BIOLOGICAL: Pembrolizumab, PROCEDURE: Positron Emission Tomography

Conditions:

Metastatic Head and Neck Squamous Cell Carcinoma, Metastatic Hypopharyngeal Squamous Cell Carcinoma, Metastatic Laryngeal Squamous Cell Carcinoma, Metastatic Oral Cavity Squamous Cell Carcinoma, Metastatic Oropharyngeal Squamous Cell Carcinoma, Recurrent Head and Neck Squamous Cell Carcinoma, Recurrent Hypopharyngeal Squamous Cell Carcinoma, Recurrent Laryngeal Squamous Cell Carcinoma, Recurrent Neck Squamous Cell Carcinoma of Unknown Primary, Recurrent Oral Cavity Squamous Cell Carcinoma, Recurrent Oropharyngeal Squamous Cell Carcinoma, Refractory Head and Neck Squamous Cell Carcinoma, Refractory Hypopharyngeal Squamous Cell Carcinoma, Refractory Laryngeal Squamous Cell Carcinoma, Refractory Oral Cavity Squamous Cell Carcinoma, Refractory Oropharyngeal Squamous Cell Carcinoma, Stage IV Head and Neck Cutaneous Squamous Cell Carcinoma AJCC v8, Stage IV Hypopharyngeal Carcinoma AJCC v8, Stage IV Laryngeal Cancer AJCC v8, Stage IV Lip and Oral Cavity Cancer AJCC v8, Stage IV Oropharyngeal (p16-Negative) Carcinoma AJCC v8

More Information

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Principal Investigator:

Phase: PHASE3

IRB Number:

System ID: NCT06589804