A Study of Ficlatuzumab in Combination With Cetuximab in Participants With Recurrent or Metastatic (R/M) HPV Negative Head and Neck Squamous Cell Carcinoma

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* Male or female and ≥ 18 years of age * Histologically and/or cytologically confirmed primary diagnosis of R/M HNSCC * Participants with oropharyngeal cancer will be required to have proof of p16 negative status submitted on the basis of a pathology report * At least 1 measurable lesion by contrast CT or MRI scan according to RECIST v.1.1. Such lesions must not have been previously irradiated; if the measurable lesion(s) has been irradiated, clear progression must be documented * Participants must have failed prior therapy with an anti-PD-1/PD-L1 ICI and with platinum-based chemotherapy administered in combination or sequentially, in either the locally advanced or R/M setting. Failure of prior treatment may be due to progression of disease or intolerance to treatment * Patient's tumor must be considered inoperable and incurable * Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1 with a life expectancy of at least 12 weeks * For women of childbearing potential (WOCBP), documentation of negative serum pregnancy test within 30 days of randomization * For WOCBP and male participants whose sexual partners are of childbearing potential, agreement to use an effective method of contraception during the study and for at least 5 months after the last dose of study treatment. Birth control methods which may be considered highly effective include methods that achieve a failure rate of less than 1% per year when used consistently and correctly. * Ability to give written informed consent and comply with protocol requirements * Patients with feeding tubes are eligible for the study. * Archived tissue sample must be submitted to the Sponsor-designated laboratory within 60 days of randomization for c-Met analysis (if a tissue sample is not available, a fresh biopsy may be required prior to enrollment)

Exclusion Criteria:

* Participants who have received \> 2 prior lines of anticancer therapy or prior treatment with cetuximab/alternative EGFR inhibitors for the treatment of R/M HNSCC * History of severe allergic or anaphylactic reactions or hypersensitivity to recombinant proteins or excipients in the investigational agent or cetuximab * Known or suspected untreated and uncontrolled brain metastases or leptomeningeal carcinomatosis Note: Participants with locally treated brain metastases are eligible provided 2 weeks have elapsed since local therapy. Participants are allowed to continue steroid taper during the start of study treatment. * Prior treatment with any other investigational drug or biologic agent or radiation therapy before a washout has been completed (must be completed prior to randomization): 1. 2 weeks (14 days) or 5 half-lives, whichever is shorter, for chemotherapeutic agents, small molecules, and checkpoint inhibitors 2. 3 weeks (21 days) or 5 half-lives, whichever is shorter, for antibody-drug conjugates 3. 4 weeks (28 days) for cell therapies 4. 2 weeks (14 days) for radiation therapy * Any unresolved and significant toxicity (National Cancer Institute Common Terminology Criteria for Adverse Events \[NCI-CTCAE\] version 5.0) Grade \> 2 from previous anticancer therapy (including radiation therapy), other than alopecia * Significant cardiovascular disease, including: Cardiac failure New York Heart Association class III or IV; Myocardial infarction, severe or unstable angina within 6 months prior to randomization; History of serious ventricular arrhythmia (i.e., ventricular tachycardia or ventricular fibrillation) * Any other medical condition or psychiatric condition that, in the opinion of the Investigator, might interfere with the participant's involvement in the study or interfere with the interpretation of study results * History of prior malignancy within 2 years prior to randomization (except for adequately treated non-melanoma skin cancer, carcinoma in situ of the breast or cervix, superficial bladder cancer, or early-stage prostate cancer, without evidence of recurrence; participants may or may not be on maintenance therapy) * Participants who are positive for HBV or HCV with indication of acute or chronic hepatitis (as defined in protocol) * Radiographic evidence (historical or at screening) of interstitial lung disease or idiopathic pulmonary fibrosis * Female participants who are pregnant or breastfeeding A full list of inclusion and exclusion criteria can be found in the protocol.

Conditions & Interventions

Interventions:
BIOLOGICAL: Ficlatuzumab, BIOLOGICAL: Cetuximab, OTHER: Placebo
Conditions:
Metastatic Head-and-neck Squamous-cell Carcinoma, Recurrent Head and Neck Squamous Cell Carcinoma
Keywords:
Recurrent, Metastatic, HPV-negative, Head and Neck, Squamous Cell Carcinoma

More Information

Contact(s): Clinical Trials Office - clinical@aveooncology.com
Principal Investigator:
Phase: PHASE3
IRB
Number:
System ID: NCT06064877
