Cancer Research Consortium of West Michigan
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Fast Facts

ALLIANCE A091802
PHASE II RANDOMIZED TRIAL OF AVELUMAB PLUS CETUXIMAB VERSUS AVELUMAB ALONE IN ADVANCED CUTANEOUS SQUAMOUS CELL CARCINOMA OF THE SKIN (cSCC)

Pre-Registration Eligibility Criteria

1. Provide adequate tissue for PD-L1 Testing
   Fresh tissue or archival tissue can be used. Sample must be at least core needle biopsy. Fine needle aspiration is not adequate. This specimen submission is mandatory prior to registration as results will be used for stratification. See Section 6.2 for details on specimen submission.

Registration Eligibility Criteria

1. Documentation of Disease:
Histologic Documentation: Biopsy-proven advanced cutaneous squamous cell carcinoma. Advanced disease is defined as either metastatic cutaneous squamous cell carcinoma or locally advanced cutaneous squamous cell carcinoma not amenable to curative surgical resection, or the patient declines surgical resection.

2. Measurable disease as defined in Section 11.0.
The patient must have at least one lesion that is measurable disease based on RECIST 1.1.

3. Prior Treatment
• Patients who received prior treatment with cetuximab as palliative treatment for advanced cSCC are excluded. Patients that received cetuximab based chemoradiation (either definitive or adjuvant) as prior treatment for locally advanced disease are eligible as long as the last dosage was given ≥ 6 months prior to registration.
• Patients who received prior cetuximab and had a severe infusion reaction requiring discontinuation of cetuximab are excluded.
• Patients treated with prior anti-PD-1 or anti-PD-L1 mAbs are excluded.
• Patients cannot have received treatment with radiation or chemotherapy including another investigational agent within 2 weeks of registration. Other than as stated above for cetuximab there are no limits on the number of lines of other therapies given for advanced cSCC.

4. Prior Surgery
If patient received major surgery, they must have recovered adequately from the toxicity and/or complications from the intervention prior to starting therapy.

5. Not pregnant and not nursing

This study involves an investigational agent whose genotoxic, mutagenic and teratogenic effects on the developing fetus and newborn are unknown.
Therefore, for women of childbearing potential only, a negative urine or serum pregnancy test done ≤7 days prior to registration is required.

6. Age ≥ 18 years
7. ECOG Performance Status 0-2
8. Patients with a "currently active" second malignancy will be excluded with the exception of other non-melanoma skin cancers or cervical carcinoma in situ. Patients are not considered to have a "currently active" malignancy if they have completed therapy and are free of disease for 3 years.
9. If HIV positive the HIV viral load must be <200 copies/mL and CD4 count >200
   If an HIV positive patient is on HAART the patient must have been so for > 4 weeks.
10. Required Initial Laboratory Values:
    Absolute Neutrophil Count (ANC) ≥ 1,500/mm3
    Platelet Count ≥ 100,000/mm3
    Calc. Creatinine Clearance ≥ 30 mL/min
    Total Bilirubin ≤ 1.5 x upper limit of normal (ULN)
    AST / ALT ≤ 2.5 x upper limit of normal (ULN)
11. No history of the following:
    • Autoimmune disease (including inflammatory bowel disease) with the exception of patients with diabetes type I, vitiligo, psoriasis, or hypo- or hyperthyroid diseases not currently requiring immunosuppressive treatment.
    • Non-infectious pneumonitis that required steroids within 5 years.
    • Organ transplant including prior stem cell transplant.
    • Receipt of a live vaccine ≤ 4 weeks.
    • Cerebral vascular accident/stroke within 6 months of enrollment.
    • Myocardial infarction within 6 months of enrollment.
    • Active unstable angina.
    • Congestive heart failure (≥ New York Heart Association Classification Class II).
    • Serious cardiac arrhythmia requiring medication. Whether an arrhythmia is considered "serious" is at the discretion of the investigator.
12. Comorbid conditions (excluded)
    • Active infection requiring systemic treatment
    • Use of immunosuppressive medication ≤ 7 days of registration, EXCEPT for the following: a. intranasal, inhaled, topical steroids, or local steroid injection (e.g., intraarticular
    injection); b. Systemic corticosteroids at physiologic doses ≤ 10 mg/day of prednisone or equivalent; c. Steroids as premedication for hypersensitivity reactions (e.g., CT scan premedication)."
    • Other severe acute or chronic medical conditions including but not limited to immune

colitis, pulmonary fibrosis or psychiatric conditions including recent (within the past year) or active suicidal ideation or behavior; or laboratory abnormalities that may increase the risk associated with study participation or study treatment administration or may interfere with the interpretation of study results and, in the judgment of the investigator, would make the patient inappropriate for entry into this study.

Schema

1 Cycle = 28 Days