Study of NKTR 255 in Combination With Cetuximab in Solid Tumors

Status: Recruiting

Eligibility Criteria

Sex: All
Age: 18 Years and over
This study is NOT accepting healthy volunteers

Key Inclusion Criteria:
- Histologically confirmed diagnosis of a locally advanced or metastatic HNSCC or CRC.
- Life expectancy > 12 weeks as determined by the Investigator.
- Eastern Cooperative Oncology Group (ECOG) performance status 0 or 1.
- Measurable disease per RECIST 1.1. HNSCC: Progression on any first or second line platinum-based chemotherapy and/or anti-PD-1 or programmed death-ligand 1 antibody. CRC: Patients must have received or were intolerant to at least 2 prior cancer therapy regimens administered for metastatic disease. CRC: Patients with microsatellite instability-high (MSI-H) or mismatched repair disease (dMMR) tumors must have been exposed to checkpoint inhibitors such as anti-PD-(L)1 or anticytotoxic T-lymphocyte-associated protein (CTLA)-4 antibody.

Key Exclusion Criteria:
- Use of an investigational agent or an investigational device within 28 days before administration of first dose of study drug(s)
- Prior surgery or radiotherapy within 14 days of initiating study drug(s)
- Evidence of clinically significant interstitial lung disease or active, noninfectious pneumonitis; active infection requiring systemic therapy within 7 days prior to dosing
- Patients who have been previously treated with IL-2 or IL-15
- Contraindication to or unable to receive cetuximab

Conditions & Interventions

Interventions:
- Drug: NKTR-255
- Drug: NKTR-255

Conditions:
- Head and Neck Squamous Cell Carcinoma (HNSCC)
- Colorectal Cancer (CRC)

Keywords:
- HNSCC
- CRC
- R/R
- NKTR-255
- Cetuximab
- Phase I Clinic

More Information

Description: This study is a Phase 1b (Dose Escalation) / 2 (Dose Expansion), open-label, multicenter dose escalation and dose expansion study in patients with relapsed or refractory (R/R) head and neck squamous cell carcinoma (HNSCC) or colorectal carcinoma (CRC). The intervention is FDA-approved cetuximab combined with an investigational drug, NKTR-255. Patients will receive a loading dose of cetuximab alone, followed 7 days later by the first combination treatment of cetuximab and NKTR-255 on Cycle 1 Day 1. Thereafter, NKTR-255 will be given in 21-day cycles in combination with weekly IV cetuximab. After determination of the recommended Phase 2 dose (RP2D) of NKTR-255 in combination with cetuximab, this dose of NKTR-255 will be further studied in patients with HNSCC (Cohort A) and CRC (Cohort B) in Phase 2 of the study. Patients will remain on treatment until meeting one of the criteria for discontinuation.

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Phase: Phase 1/Phase 2
IRB Number: STUDY00011716
System ID: NCT04616196

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