

SITC 2022 TiP: Tacti-003

TACTI-003: A randomized Phase IIb study of eftilagimod alpha (soluble LAG-3 protein) and pembrolizumab as first-line treatment of patients with recurrent or metastatic head and neck squamous cell carcinoma

Background:

Eftilagimod alpha (efti) is a soluble LAG-3 protein targeting a subset of MHC class II molecules that mediate antigen-presenting cell (APC) and then CD8 T-cell activation. Data from a non-randomized, phase II trial of efti plus pembrolizumab (TACTI-002) showed encouraging antitumor activity and manageable safety when given as second-line treatment of patients with recurrent or metastatic head and neck squamous cell carcinoma (RM-HNSCC). TACTI-003 (NCT04811027) is a multicenter, open-label, randomized phase IIb trial to investigate efti plus pembrolizumab in the first line setting for RM-HNSCC.

Methods:

A total of 154 patients (pts) are currently being recruited into two cohorts (A+B). In cohort A, pts with tumors that are CPS \geq 1 will be randomly assigned 1:1 to receive either efti (30 mg subcutaneously Q2W for initial 6 months, thereafter Q3W) plus pembrolizumab (400 mg intravenously Q6W) for up to two years or pembrolizumab alone. Randomization will be stratified by CPS (1-19 vs. \geq 20) and ECOG PS (0 vs. 1). Pts with tumors that are CPS $<$ 1 will receive efti plus pembrolizumab (cohort B). Imaging will be performed every 9 weeks. The primary endpoint (EP) is the objective response rate (ORR) by RECIST1.1. Secondary EPs include overall survival, ORR according to iRECIST, time to and duration of response, disease control rate, progression-free survival, the occurrence of anti-efti -specific antibodies, safety, and quality of life. Exploratory endpoints comprise biomarkers.

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