ASC0 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 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 II 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≥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. ≥ 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 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, occurrence of anti-efti -specific antibodies, safety, and quality of life. Exploratory endpoints comprise biomarkers. The study has been approved by relevant competent authorities, ethic committees and IRBs.

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